

Medical Technologies Advisory Committee (MTAC)

Thursday 16 January 2025

GID-HTE10049 Intermittent urethral catheters for long-term urinary management in adults: Late-stage assessment

This product class was selected for late-stage assessment in 2023.

Clinical and economic evidence has been submitted to NICE by the companies in RFIs, and an external assessment group report has been completed by the EAG. Alongside this, a user preference report has been produced by NICE.

This pack presents the information required for the MTAC to make draft recommendations on this topic.

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Papers included in pack:

- 00. Front sheet
- 01. Overview
- 02. External Assessment Report
- 03. EAG response to factual accuracy check comments
- 04. User Preference report
- 05. Thematic review
- 06. User survey report
- 07. Executive summary of user-centred work
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- 09. Register of interests
 - a. MTAC members
 - b. Specialist Committee members and experts

Late-stage assessment

Intermittent urethral catheters for chronic incomplete bladder emptying in adults

Assessment report overview

This is a feature-based assessment, and the decision question is, ‘does the value added by incremental innovation justify the price variation caused by distinguishing or innovative features?’

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the [final scope](#), the external assessment report, and the user experience, need and preference reports. List of abbreviations used in this overview is in appendix A.

1. Technology

The technology identified for this assessment is intermittent urethral catheters for bladder drainage. Intermittent urethral catheters can be characterised as “a smooth, flexible tube with holes, used for short term drainage of urine from the bladder and the catheter has no balloon”. Intermittent catheters can be made of different materials, are available in different sizes, have different coatings, and have different tips. The basic requirements of the sterile catheters include the following features:

- traditional lubrication (pre-lubricated or lubrication applied externally) or hydrophilic coated
- 2 to 4 drainage eyelets (drain holes or catheter eyes)
- available in a range of sizes and lengths
- Nelaton tip or other tip types
- catheter drainage funnels or connectors
- clearly labelled sizes.

This feature-based assessment included a total of 838 intermittent catheters, across 86 catheter product lines (aggregated by catheter size, male or female, tip type) from 17 manufacturers. Based on Drug Tariff Part IXA, the price per catheter ranged from £0.40 to £3.28. This indicated the maximum price difference could be up to £2.88 per catheter.

To determine whether the pricing variation is justified, this assessment considered 8 additional features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer, micro-holes, enhanced coating, specially designed catheter case, specially designed packaging) that were listed in the [final scope](#) (link to the scope corrected May 2025).

A list of features of interest and association descriptions are shown in Table 1 of the external assessment report (EAR). Further details, including descriptions of the interventions, comparator, care pathway and outcomes, are in the [final scope](#) (link to the scope corrected May 2025).

1.1 Price variation

Catheters listed on the Drug Tariff are present with multiple additional features and basic features. To estimate the average cost of individual features, a multiple regression model was used. The model assumed that the price of a single catheter was a linear function of the basic features and 8 additional features, with each feature having an independent additive impact on the cost.

The R-squared statistic suggested that approximately 78% of the variation in prices could be accounted for by the presence of basic and additional features. When compared with a reference catheter (a male catheter with a Nelaton tip, uncoated without a lubricant, which had a mean cost of £1.37), multiple basic features were found to have a statistically significant impact on price:

- an uncoated pre-lubricated catheter had a higher price (£0.15 more)
- a basic hydrophilic catheter without liquid provided had a lower price (0.12 less)

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- a unisex catheter had a higher cost (£0.18 more).

In addition, 5 additional features were also identified to have a statistically significant difference in price:

- an integrated urine bag had a higher price (£0.89 more)
- an integrated handle or marking had a higher cost (£0.10 more)
- a tip protector had a higher price (£0.28 more)
- an enhanced coating had a higher cost (£0.25 more)
- a specially designed packaging had a higher cost (£0.06 more).

The EAG also carried out one-way sensitivity analysis to determine the impact of changes in input parameters to the linear regression modelling. The results were sensitive to changes, in particular the integrated urine bag (greater than £0.80 in all analyses). However, there was no significant change to the price with the presence of micro-hole in any analysis. More information can be found in section 3.2 and Appendix F of the EAR.

2. Clinical effectiveness

The EAG performed target literature searches to identify relevant published clinical evidence. They also reviewed primary evidence included in the relevant systematic reviews and evidence provided by the companies.

The inclusion criteria were: 1) studies on catheters where the additional features were verified by the company; 2) studies where the intervention or comparator arm included a mixture of catheters with different features; 3) studies that included both healthy volunteers and users of intermittent catheter; and 4) studies from any setting.

The search strategy and study selection methods are detailed in sections 4.1.1 and 4.1.2 of the EAR.

To assess whether price variations between catheters with different features are justified by the additional features, pairwise component meta-analysis (CMA) and component network meta-analysis (CNMA) were conducted.

2.1 Overview of key studies

The clinical review included 18 comparative studies evaluating intermittent catheters with different features, coatings and lubrication methods. Across the 18 studies, there were 3 RCTs, 12 cross-over RCTs, 1 cross-sectional study, 1 prospective comparative cohort study, and 1 in vitro study. The follow-up durations varied across studies between 1 day and 1 year. There was variation in who performed the intermittent catheterisation across studies.

The included evidence covered all intermittent catheter features of interest listed in the [final scope](#). The features of the interventions and comparators varied across studies, and some studies compared more than 2 catheters. There was substantial variation in outcome definitions, measures and reporting.

For the randomised trials, sample sizes were powered in 9 studies but to detect different outcomes (UTI in 3 studies; discomfort measured using the visual analogue scale (VAS) in 1 study; residual urine volume in 1 study; and residual volume of urine at the first flow-stop in 4 studies). One study used a convenience sample for a pilot RCT, and another study did not conduct a power calculation. Power calculations were not reported in the other 5 studies.

Most studies (11/18) were company funded or included authors who were company employees. Publication years ranged from 1997 to 2024, with 8 studies published from 2020 onwards (42%). There was a difference between the feature of focus (hypothesis tested) of the study and the features present within that study. Most studies aimed to compare coated and uncoated catheters.

Table 1 shows study characteristics, including study design, country, setting, population (age and sex), indications, intervention and comparator. The included comparative studies are detailed in Table 4 and Appendix C1 of the EAR, features tested and present in the included studies are summarised in table 5 of the EAR, and the risk of bias and methodological quality of the included studies are described in section 4.2.2 and Appendix C2 of the EAR.

Table 1 Summary of 18 included comparative clinical studies

Study (year); Country	Study design (n people) [length of follow-up]	Indication for IC	Age (years) and sex	Setting (who conducts IC)	Interventions	Comparator
Athanasiadou (2023) Abstract/Poster Denmark	In vitro study; samples taken from 3 trials [Follow-up: not reported]	Healthy volunteers (n=30); Intermittent catheter users (n=29; neurogenic dysfunction: 62%, non-neurogenic dysfunction: 38%)	Age: IC users: [range 21 to 82] Healthy controls: [range 20 to 57] Male: 50%	Sample obtained in hospital setting	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging
Biering-Sørensen (1999) Denmark	Cross-over RCT (n=20) [Follow-up: 24h for each catheter]	Spinal cord lesions	Age, male: 53 [27-69] Age, female: 45 [17-48] Male: 70%	NR (assumed inpatient setting)	Hydrophilic coating (liquid not provided) with Enhanced coating	Hydrophilic coating (liquid not provided)
Bonello (2021) Brazil	Cross-over design (4 catheters qualitatively evaluated in randomised order) (n=32), [Follow-up: 1 day]	NR	Age: 54.2 [range: 32-76] Male: 84%	Community	<u>Intervention 1:</u> Uncoated (pre-lubricated) with - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging <u>Intervention 3:</u> Hydrophilic (provided with water to activate the coating) with - Insertion sleeve or grip - Enhanced coating	Uncoated catheter (Lubricant not provided)
Cardenas (2011) US, Canada	RCT (n=224) [Follow-up: maximum 6 months study period, maximum 3	Neurogenic bladder dysfunction due to traumatic spinal cord injury	Age: intervention 37.2 (14.4), comparator 35.1 (13.2) Male: intervention	Rehabilitation unit or acute care followed by community (healthcare	Hydrophilic catheter (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)

Study (year); Country	Study design (n people) [length of follow-up]	Indication for IC	Age (years) and sex	Setting (who conducts IC)	Interventions	Comparator
	months in the community]		79%, comparator 82%	professional and self-catheterisation or by caregivers)		
Cardenas (2009)	RCT (n=56) [Follow-up: 12 months]	Spinal cord injury	Age, intervention: 42.3 (10.4); comparator: 40.1 (9.3). Male, intervention: 77%, comparator: 52%.	Community (implied self- or carer-catheterisation)	Hydrophilic catheter (pre-activated) with Enhanced coating	Uncoated catheter (Lubricant not provided)
Chartier-Kastler (2011) France, Denmark	Cross-over RCT (n=36) [Follow-up: 14± 2 days in each arm]	Traumatic spinal cord lesion 66.7%; Non-traumatic spinal cord lesion 33.3%	Median age: 43.2; [range: 20 to 70] Male: 100%	Community (self-catheterisation)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging
De Ridder (2005) Spain, Belgium	RCT (n=123) [Follow-up: 12 months]	Spinal cord injury	Age: intervention 37.5 (14.6), comparator 36.7 (14.6) Male: 100%	Community Hospital and community (self or carer)	Hydrophilic catheter (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)
Domurath (2011) Germany	Cross-over RCT, non-inferiority (n=37) [Follow-up: 5 to 8 days each arm]	Spinal cord injury	Age: 40 [range 21 to 66] Male: 100%	Community (self-catheterisation)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging
Gopalakrishnan (2022) Canada	Cross-over RCT, pilot (n=20). [Follow-up: 5 to 10 days]	Spinal cord injury	Age: 45 [range 26 to 65]	Self-catheterisation, in clinic while timed by investigator in clinic or self-catheterisation while timed by investigator	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)
Gregghi (2022) Brazil	Prospective cohort (n=50), [Follow-up: 7 days]	NR	Age: 44.8 (14.1) Male: 72%	Community (self-catheterisation)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating

Study (year); Country	Study design (n people) [length of follow-up]	Indication for IC	Age (years) and sex	Setting (who conducts IC)	Interventions	Comparator
					Specially designed packaging	- Specially designed catheter case - Specially designed packaging
Koenen (2004) [Poster] Netherlands	Cross-over RCT; 3 arm study (n=72), [Follow-up: 4 weeks per catheter]	Spinal cord lesion (n=66); spina bifida (n=4); multiple sclerosis (n=2)	Male: 70.8%	Community (self-catheterisation)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Comparator 1: Hydrophilic coating (liquid not provided) with Enhanced coating Comparator 2: Hydrophilic coating (liquid not provided)
Landauro (2023a) Denmark	3 cross-over RCTs combined (n=59), [Follow-up: 3 single visits]	Healthy volunteers (n=30); Intermittent catheter users (n=29; neurogenic dysfunction: 62%, non-neurogenic dysfunction: 38%)	Age: IC users: [range 21 to 82] Healthy controls: [range 20 to 57] Male: 50%	Hospital, self-catheterisation and catheterisation by healthcare professional	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging
Landauro (2023b) Denmark	Cross-over RCT (n=42), [Follow-up: 3 visits]	Non-neurogenic bladder dysfunction (69%), neurogenic bladder dysfunction (31%)	Age: mean 68 [range 41 to 87] Male: 100%	Hospital (healthcare professional)	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed packaging
Pascoe (2001) UK	Cross-over RCT (n=27), [Follow-up: 7 days]	Multiple sclerosis, voiding dysfunction secondary to back injury, spina bifida	NR	Community	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with Enhanced coating
Sarica (2010) Turkey	Cross-over RCT; 3 arm study (n=25), [Follow-up: 6 week per catheter type]	Spinal injury	Age: mean 37.0 (11.9) Male: 100%	Inpatient setting (self-catheterisation)	<u>Intervention 1:</u> Uncoated catheter (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer	Uncoated catheter (Lubricant not provided)

Study (year); Country	Study design (n people) [length of follow-up]	Indication for IC	Age (years) and sex	Setting (who conducts IC)	Interventions	Comparator
					• Specially designed catheter case • Specially designed packaging <u>Intervention 2:</u> Hydrophilic coated catheter (liquid not provided) with • Insertion sleeve or grip • Specially designed packaging	
Thiruchelvam (2024a) Denmark, UK, France	Cross-over RCT (n=82), [Follow-up: approx. 2 weeks each arm]	Mixed (72% neurogenic lower urinary tract dysfunction)	Age: 54 [range: 24 to 78] Male: 0%	Community (healthcare professional and self-catheterisation)	Hydrophilic (pre-activated) with • Integrated handle or markings • Insertion sleeve or grip • Tip protector or introducer • Micro-hole zone technology • Enhanced coating • Specially designed catheter case • Specially designed packaging	Hydrophilic (pre-activated) with • Integrated handle or markings • Enhanced coating • Specially designed catheter case • Specially designed packaging
Thiruchelvam (2024b) Denmark, France, Germany, UK	Cross-over RCT (n=73), [Follow-up: 4 weeks in each arm]	Mixed (62% neurogenic bladder dysfunction)	Age: 64 [range: 28 to 87] Male: 100%	Community (self-catheterisation and healthcare professional for some outcomes)	Hydrophilic (pre-activated) with • Integrated handle or markings • Insertion sleeve or grip • Tip protector or introducer • Micro-hole zone technology • Enhanced coating • Specially designed catheter case • Specially designed packaging	Hydrophilic (pre-activated) with • Integrated handle or markings • Insertion sleeve or grip • Tip protector or introducer • Enhanced coating • Specially designed catheter case • Specially designed packaging
Waller (1997) Sweden	Cross-over RCT (n=14). [Follow-up: 10 days per arm]	Spinal cord injury	Age: median 30 [22 to 62] Male: 100%	Hospital (the same nurse performed all catheterisations).	Hydrophilic coating (liquid not provided) with Enhanced coating	Hydrophilic coating (liquid not provided)

Note: Age reported as mean [SD], median [Q1, Q3] unless otherwise stated

Abbreviations: IC, Intermittent catheterisation; ISC, intermittent self-catheterisation; NR, not reported; RCT, Randomised Controlled Trial. **f1**, integrated drainage bag; **f2**, integrated handle or markings; **f3**, insertion sleeve or grip; **f4**, tip protector or introducer; **f5**, micro-hole technology; **f6**, enhanced coating; **f7**, specially designed catheter case; **f8**, specially designed packaging; **HRQoL**, Health-related quality of life; **H1**, Hydrophilic coated catheter (liquid not provided); **H2**, Hydrophilic coated catheter (provided with water to activate coating); **H3**, Hydrophilic coated catheter (pre-activated); **U1**, Uncoated catheter (lubricant not provided); **U2**, Uncoated catheter (provided with lubricant); **U3**, Uncoated catheter (pre-lubricated)

2.2 Outcomes of interest

This assessment focused on 5 outcomes that were prioritised by clinical and lay experts, including UTI, haematuria, residual volume, comfort and ease of use. Due to heterogeneity in reporting, the reported results on the 5 outcomes were transformed into a common scale or format where possible to maximise the number of studies included in CNMA.

CNMA aimed to assess the effectiveness of the intervention features, and interactions between them. The results from the CNMA analyses were then used in the economic evaluation to determine whether the variation in price could be justified by the effectiveness of the features.

The feasibility and appropriateness of performing CMA and CNMA was assessed based on whether data was sufficient to inform reliable estimates and whether studies were sufficiently comparable to be included in the same analyses. If feasible and appropriate, CMA and CNMA were performed in a Bayesian framework.

Confidence in Network Meta-analysis (CINeMA) was used to assess the certainty in the results of CNMA. CINeMA consisted of 6 domains: within-study bias, reporting bias, indirectness, imprecision, heterogeneity and incoherence.

Each domain (except 'reporting bias') was judged to have no concerns, some concerns, or major concerns. 'Reporting bias' was judged as 'suspected' or 'undetected'. Judgements across the 6 domains are summarised to obtain 4 levels of confidence for each relative treatment effect: very low, low, moderate, or high. Details of CNMA and CINeMA can be found in section 4.1.4 of the EAR.

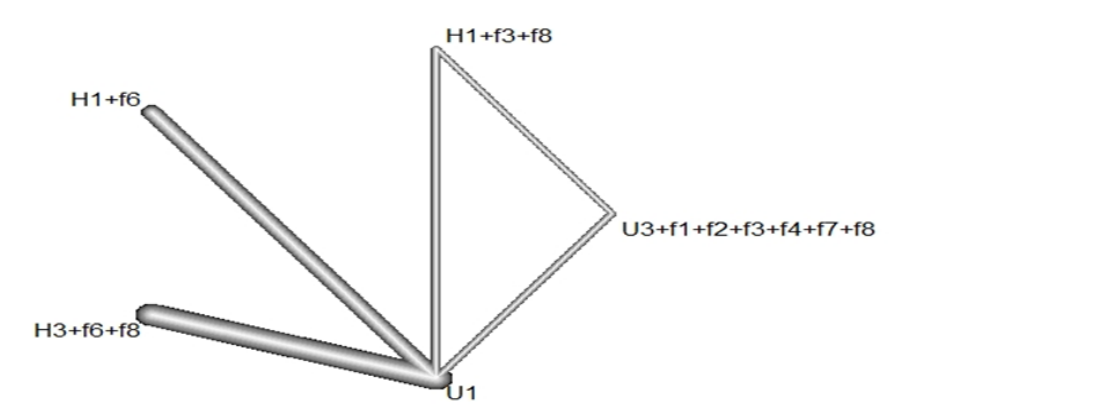
UTI

Six studies reported on UTI, and of these, 4 studies (2 RCTs and 2 cross-over RCTs) were included in the CNMA and CMA following transformation of outcomes. The EAG defined the UTI as the proportion of people experiencing a UTI within 30 days.

Figure 1 illustrates the network of intervention features and their combinations. The 4 studies covered 7 features (integrated drainage bag; integrated handle or markings; insertion sleeve or tip; tip protector; enhanced coating; specially designed catheter case, and specially designed packaging) and 3 types of lubrication or coating (uncoated catheters with no lubrication provided, hydrophilic catheters with no water provided, and hydrophilic pre-activate). No data reporting on UTI included the micro-hold-zone feature.

The lines of the network diagram were weighted by inverse variance to highlight for which feature there was more evidence, with thicker lines representing more evidence. There was only one closed loop identified, where a set of 3 or more interventions in a network diagram are connected by a polygon. In this case, the closed loop was between one uncoated catheter with no features, one uncoated with features and one hydrophilic coated catheter with features. This came from a 3-arm trial, where inconsistency was not a concern. Results were calculated using 3 types of models: pairwise model (well-fitting model), independent (additive) effects model and 2-way interaction (combination) model.

Figure 1 Network diagram for trials reporting UTI



[Key: integrated drainage bag **f1**_{drain}; integrated handle or markings **f2**_{handle}; insertion sleeve or tip **f3**_{sleeve}; tip protector **f4**_{tip}; enhanced coating **f6**_{lubric}; specially designed catheter case **f7**_{case}, specially designed packaging **f8**_{packaging}; U1 uncoated catheter (no lubricant provided); H1 hydrophilic catheters with no water provided; H3 hydrophilic pre-activated catheter; U3 uncoated (pre-lubricated)]

Table 2 shows the results of UTI risk from CNMA and CMA of the 4 studies. The pairwise model suggested that enhanced coating reduced UTI risk

compared with an uncoated catheter (relative risk [RR] 0.69, 95% CrI 0.44 to 0.96).

When the effects of enhanced coating and specially designed packaging features were considered in isolation, the independent effects model found that enhanced coating might lead to a small reduction in UTI risk compared with an uncoated catheter (RR 0.95, 95% CrI 0.56 to 1.30). This model also showed that specially designed packaging might reduce UTI risk compared with an uncoated catheter (RR 0.58, 95% CrI 0.25 to 1.02).

When enhanced coating and specially designed packaging were used together, the 2-way interaction model found that each feature might result in UTI risk reduction compared with an uncoated catheter (enhanced coating: RR 0.86, 95% CrI 0.44 to 1.27; specially designed packaging: RR 0.35, 95% CrI 0.01 to 1.15). However, the benefit of both features in combination might increase UTI risk compared with an uncoated catheter (RR 1.35, 95% CrI 0.44 to 1.84).

Overall, the results indicated that enhanced coating or specially designed packaging might be more effective in reducing the risk of UTI than a basic uncoated catheter. However, when combining these 2 features together, the benefit was less than their effectiveness in isolation. All results were rated as very low certainty.

Table 2 Summary of CNMA and CMA results for UTI risk (n=4 studies)

Type of model	Enhanced coating (f6 _{lubric}) RR (95% CrI)	Enhanced coating (f6 _{lubric}) CINeMA rating	Specially designed packaging (f8 _{packaging}) RR (95% CrI)	Specially designed packaging (f8 _{packaging}) CINeMA rating	Both features combined (f6 _{lubric} , f8 _{packaging}) RR (95% CrI)	Both features combined (f6 _{lubric} , f8 _{packaging}) CINeMA rating
<i>Pairwise model:</i> compared with uncoated catheter (U1)	0.69 (0.44 to 0.96)	Very Low ^{1,2,4}	-	-	-	-
<i>Independent (additive) effects model:</i> compared with U1	0.95 (0.56 to 1.30)	Very Low ^{1,2,3}	0.58 (0.25 to 1.02)	Very Low ^{1,2,4}	-	-
<i>2-way interaction (combination)</i>	0.86	Very Low ^{1,2,3}	0.35	Very Low ^{1,2,4}	1.35	Very Low ^{1,2,3}

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Type of model	Enhanced coating (f6 _{lubric}) RR (95% CrI)	Enhanced coating (f6 _{lubric}) CINeMA rating	Specially designed packaging (f8 _{packaging}) RR (95% CrI)	Specially designed packaging (f8 _{packaging}) CINeMA rating	Both features combined (f6 _{lubric} , f8 _{packaging}) RR (95% CrI)	Both features combined (f6 _{lubric} , f8 _{packaging}) CINeMA rating
<i>model</i> : compared with U1	(0.44 to 1.27)		(0.01 to 1.15)		(0.44 to 1.84)	

¹ Some concerns due to heterogeneity: follow up varied from 6 weeks to 12 months, ² Major concerns due to risk of bias: two trials where authors did not adjust for clustering within individuals, ³ Major concerns due to imprecision: wide 95% CrI and limited weight in the CNMA, ⁴ Some concerns due to imprecision: only one small/moderate sized trial available for this comparison

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis, CMA, Component meta-analysis; CrI, Credible interval; RR, relative risk; UTI, Urinary tract infection; U1, uncoated catheter

Haematuria

Ten studies reported on bleeding or haematuria, and of these, 6 studies (2 RCTs, 3 cross-over RCTs and one combination of 3 cross-over RCTs) were included in the CNMA analyses following transformation of outcomes. The EAG estimated haematuria as the proportion of people experiencing an episode of visible haematuria (blood visible in the urine) or haematuria detected by a urinary dipstick test (presence of blood cells in the urine) within 30 days. Of the 6 studies included in the CNMA, 4 studies reported on bleeding as identified from dipstick.

Figure 2 demonstrates 2 networks of features with the lines weighted by the inverse variance. The 6 studies covered 7 features (integrated handle or markings; insertion sleeve or tip; tip protector; micro-holes; enhanced coating; specially designed catheter case, specially designed packaging) and 2 types of lubrication or coating (uncoated catheters with no lubrication provided, and hydrophilic pre-activate).

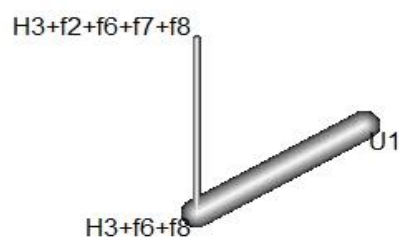
Studies that compared catheters including insertion sleeve or tip, enhanced coating, and specially designed packaging features with uncoated catheters were most common. There were several overlapping features across studies and an independent (additive) effects model was then selected for the analysis using random effects.

Figure 2 Network diagram for trials reporting haematuria

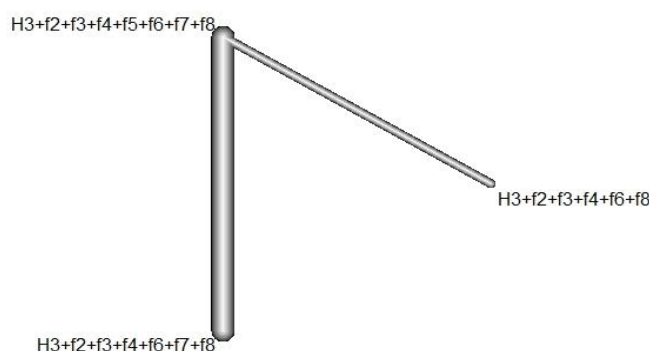
a) Subnetwork 1

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b) Subnetwork 2



[Key: integrated drainage bag **f1**_{drain}; integrated handle or markings **f2**_{handle}; insertion sleeve or tip **f3**_{sleeve}; tip protector **f4**_{tip}; micro-hole **f5**_{micro}; enhanced coating **f6**_{lubric}; specially designed catheter case **f7**_{case}; specially designed packaging **f8**_{packaging}; U1 uncoated catheter (no lubricant provided); H3 hydrophilic pre-activated catheter]

Table 3 presents the results of CNMA. When compared with a basic uncoated catheter, micro-hole technology might reduce the risk of haematuria (RR, 0.16; 95% CrI 0.01 to 2.27). However, the effect on the risk of haematuria was unclear in hydrophilic pre-activated catheter compared with an uncoated catheter (RR, 1.04; 95% CrI 0.19 to 2.36). The risk of haematuria might increase in specially designed catheter cases compared with uncoated catheters (RR, 2.05; 95% CrI 0.09 to 3.34). All 95% CrIs were very wide, indicating uncertainty about the magnitude of true effects. All results were judged as very low certainty.

Table 3 Summary of CNMA results for haematuria risk

Independent (additive) effects model: feature compared with uncoated catheter (U1)	RR (95% CrI)	CINeMA rating
Micro-hole (f5_{micro-hole})	0.16 (0.01 to 2.27)	Very Low ^{1,2,3}
Hydrophilic pre-activated catheter (H3)	1.04 (0.19 to 2.36)	Very Low ^{1,2,3}
Specially designed catheter case (f7_{case})	2.05 (0.09 to 3.34)	Very Low ^{1,2,3}

¹ Some concerns identified regarding risk of bias: most studies did not report sufficient information on allocation concealment or random sequence generation methods), ² Major imprecisions reflected in wide 95% CrIs, ³ high heterogeneity (between-study standard deviation=0.79, 95% CrI 0.09 to 3.46)

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis, CrI, credible interval; RR, relative risk

Residual volume

Four studies (3 cross-over RCTs and one combination of 3 cross-over RCTs) reported on residual volume, which was defined by the EAG as the volume of urine remaining the bladder after catheterisation done by the person, a carer, or a healthcare professional. These 4 studies used hydrophilic pre-activated catheters with additional features. Due to strong evidence of skewed data, CNMA was considered inappropriate and was therefore not performed.

Only one cross-over RCT found a statistically significant mean reduction in residual volume of 19.6 ml (95% CI 1.70 to 37.43 ml, p=0.033) in people using a catheter with micro-hole.

No statistically significant difference was found in 2 studies. One cross-over RCT (non-inferiority) reported a median difference of 2.06 ml (95% CI -1.94 to 7.72) within the pre-designed non-inferiority margin. One combination of 3 cross-over RCTs reported the mean difference by gender, with a mean difference of -4.30 ml (95% -17.0 to 8.82) for male and a mean difference of -4.09 ml (95% CI -17.60 to 9.41) for female.

One cross-over RCT reported that mean post-void residual volume was 7.7 ml in the intervention arm and 9.3 ml in the comparator arm but did not report the difference between arms.

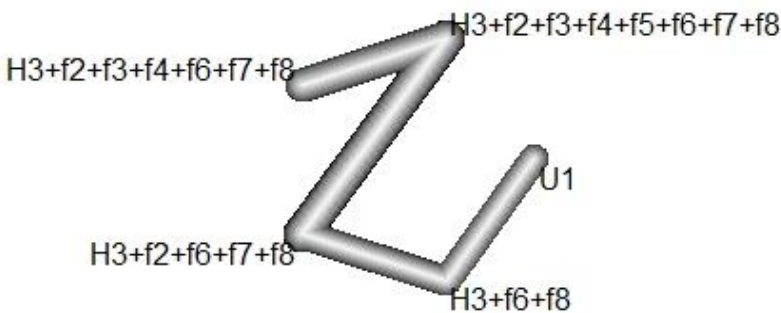
Discomfort or pain

Seven studies reported on discomfort or pain, including 1 RCT, 5 cross-over RCTs and 1 prospective cohort study.

For comfort, 5 studies were included in the CNMA analyses (1 RCT and 4 cross-over RCTs). To combine these studies, a standardised mean difference (SMD) was used. Figure 3 shows the network of features with the lines weighted by the inverse variance. The 5 studies covered 7 features (integrated handle or markings; insertion sleeve or tip; tip protector; micro-hole; enhanced coating; specially designed catheter case, and specially designed packaging) and 2 types of lubrication or coating (uncoated catheters with no lubrication provided, and hydrophilic pre-activate).

An independent (additive) effects model was selected for the analysis. The model did not fit the data well. The data was examined further, showing that almost all data was driven by 1 RCT and 1 cross-over trial.

Figure 3 Network diagram for trials reporting comfort



[Key: U1, uncoated catheter (no lubricant provided); H3, hydrophilic pre-activated catheter; **f2**_{handle}, integrated handle or markings; **f3**_{sleeve}, insertion sleeve or tip; **f4**_{tip}, tip protector; **f5**_{micro}, micro-hole; **f6**_{lubric}, enhanced coating; **f7**_{case}, specially designed catheter case, **f8**_{packaging}, specially designed packaging]

Table 4 shows the results of CNMA. When compared with a basic uncoated catheter, a small improvement in comfort was found in the use of pre-activated hydrophilic catheter (SMD: 0.26, 95% CrI -0.21 to 0.73) and a small-to-negligible decrease in comfort was reported in the use of a tip protector or

introducer feature (SMD: -0.16, 95% CrI -0.74 to 0.42). The findings for both features were judged to be very low certainty.

Table 4 Standardised mean differences for comfort

Independent (additive) effects model: feature compared with uncoated catheter (U1)	SMD (95% CrI)	CINeMA rating
Hydrophilic pre-activated catheter (H3)	0.26 (-0.21 to 0.73)	Very Low ^{1,2}
Tip protector or introducer (f4 _{tip})	-0.16 (-0.74 to 0.42)	Very Low ^{1,3}

¹Major concerns with risk of bias: one cross-over trial unadjusted for clustering within individuals

²Some concerns with imprecision: just two studies contributing to analyses, and relatively wide 95% CrI

³Major concerns with imprecision: just two studies contributing to analyses, and wide 95% CrI indicates substantial uncertainty about the magnitude of the true effect

Abbreviations: CINeMA: Confidence in Network Meta-analysis; CrI, credible interval; f4_{tip}, tip protector or introducer; H3, pre-activated hydrophilic catheter; SMD, standardised mean difference; U1, uncoated catheter (with no lubricant provided)

For discomfort, 4 studies (1 RCT, 2 cross-over RCTs and 1 prospective cohort study) reported on this outcome, but a CNMA was judged to be infeasible.

Three studies (1 RCT and 2 cross-over RCTs) reported similar levels of discomfort using VAS between intervention and comparator catheters which were all pre-activated hydrophilic catheters with additional features. One prospective cohort study found similar median levels of discomfort (unclear measurement) between pre-lubricated uncoated catheters with features and pre-activated hydrophilic catheters with features in people with urethral sensitivity.

In terms of pain, 6 studies (1 RCT and 5 cross-over RCTs) reported on this outcome, but a CNMA was judged to be infeasible. There were mixed outcomes in pinching or stinging, resistance or blocking sensation between intervention and comparator arms. There was variation in outcome measures and reporting, and in features in each arm across studies.

Ease of use

Eleven studies reported on ease of use, including 1 RCT, 8 cross-over RCTs, 1 prospective cohort study and 1 cross-sectional study. Ease of use covered a range of measures, including ease of preparation, opening, inserting, sliding use, handling, manipulation, removal, emptying, reclosing and disposal as well as increase in level of control. Given the variation in outcome definitions

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and measures and in features included in each arm across studies, a CNMA was considered impossible.

The reported outcomes for ease of use and time taken for catheterisation were mixed. When a statistically significant difference in any of these 2 outcomes was found, this mainly happened in studies comparing pre-activated hydrophilic coated catheters with additional features and uncoated catheters without additional features. The results of each study reporting on ease of use are in Table 13 of the EAR.

Other adverse events

Six studies (1 RCT and 5 cross-over RCTs) reported other device-related adverse events. The absolute number of adverse events was lower in the intervention arms than the comparators across all RCTs. Details of the results are in Appendix C4.7 of the EAR.

Details of the results for the key outcomes of interest and further explanation of model selection are in section 4.2.4 of the EAR.

3. Cost effectiveness

The EAG did target literature searches to identify suitable health economic models. They also reviewed all the economic evidence submitted by the companies and primary evidence included in the relevant systematic reviews.

Thirteen studies were identified, and they all reported the use of a Markov models to evaluate the cost-effectiveness of various intermittent catheters. An overview of these studies is shown in section 5.2 of the EAR (table 14).

Of the 13 studies, 4 were undertaken from an UK NHS perspective. Only one (Cawson et al., 2023; abstract) described an economic model which assessed an intermittent catheter feature (micro-holes). The remaining identified literature was not directly relevant to the decision problem of this LSA. Hence, formal quality assessment of economic evidence was not done.

3.1 Health economic model

The key driver in all the models in the literature was the risk of developing UTI. To assess the impact on cost-effectiveness of individual catheter features, UTI and 3 outcomes (successful drainage, ease of use, reduction in pain or discomfort specific outcomes) were incorporated into the model in terms of utilities or disabilities and costs or cost savings.

The EAG developed a Markov model in Microsoft Excel which was informed by an economic model used in NICE Clinical Guideline (CG139). The Markov model consisted of 7 key health states:

- Catheter users alive
- Symptomatic UTI
- UTI resistant to first-line antibiotics
- Multidrug resistant UTI
- Catheter-associated bacteraemia
- Urethral complications (such as strictures, false passage, urethritis, or other complications as a results of urethral trauma)
- Death.

Figure 4 illustrates the model structure which was adapted from Bermingham et al. (2013). The arrows indicate the direction of transition of people from one state to another in each model cycle. Urethral complications could occur in any state except 'death'.

Due to gaps in the evidence, changes in costs and utilities from outcomes other than UTI were primarily based on assumptions and were applied across all the health states in the model rather than focusing on one health state.

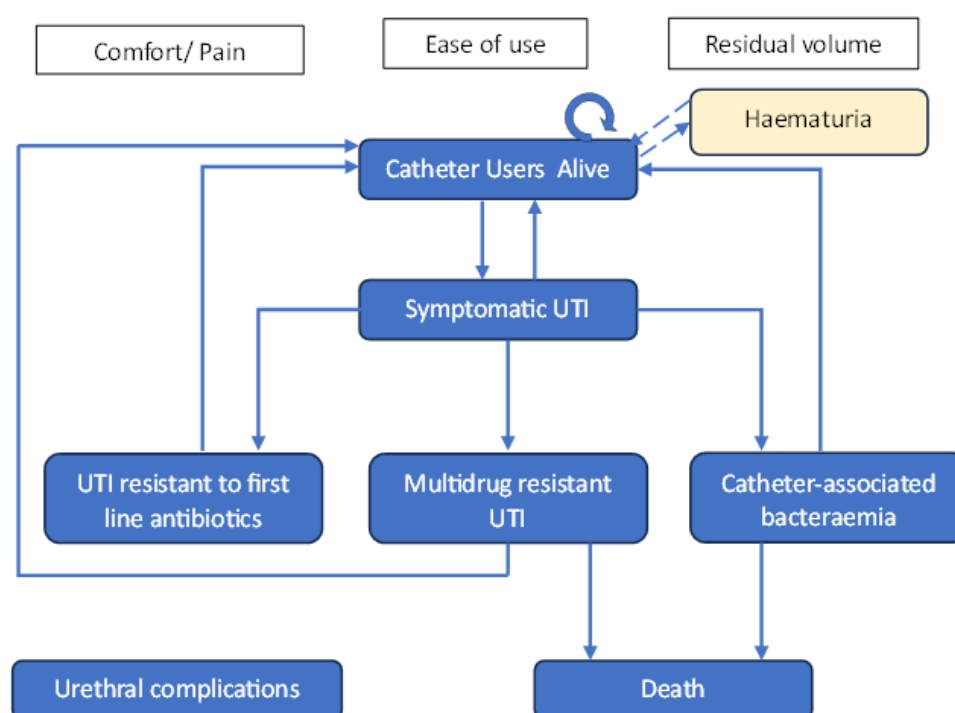
To simplify the model structure and the economic analysis, key assumptions were made:

- There would be no transitions between 'UTI resistant to first-line antibiotics', 'multidrug resistant UTI' and 'catheter-associated bacteraemia'.

- People would use the same type of catheters throughout the 2-year time horizon.
- Adherence (5 catheters used per day) would be the same across catheters.
- The antibiotic resistance would not change over time.

In the model, a time horizon of 2 years was used with 1 month cycles. A discount rate of 3.5% per year was applied for both costs and outcomes.

Figure 4 Economic model structure



Population

Based on the clinical evidence and the economic studies, the base case population was modelled to be a representative cohort of people with urinary retention requiring intermittent catheterisation. The population was assumed at a mean age of 45 and 70% of the cohort were male.

Comparator

The comparator in the economic model was an uncoated catheter (non-lubricated) with no additional features.

3.2 Model inputs

Clinical parameters

Baseline transition probabilities

The comparator treatment was an uncoated catheter with no additional features. For this comparator, the baseline transition probabilities per 1-month cycle used in the economic model are shown in table 5. Antibiotic resistance and mortality associated with antibiotic resistance was assumed to remain constant throughout a lifetime. This assumption was conservative due to the difficulty in predicting the dynamic nature of antibiotic resistance and mortality over time.

Table 5 Baseline transition probabilities

Parameter description	Mean estimate	Source
Haematuria risk	0.0509	Average estimates from Cardenas (2011) and De Ridder (2005)
Symptomatic UTI risk	0.0772	Average estimates from Cardenas (2009); Sarica (2010); De Ridder (2005)
Urethral complication risk	0.0019	Couchman et al. (2022)
First-line antibiotic resistant UTI risk	0.0073	Derived from Bermingham et al. (2013)
Multidrug resistant UTI risk	0.00603	Derived from Bermingham et al. (2013)
Multidrug resistant excess mortality	0.0022	Derived from Bermingham et al. (2013)
Bacteraemia risk	0.00305	Derived from Bermingham et al. (2013)
Bacteraemia excess mortality	0.00665	Derived from Bermingham et al. (2013)

Relative treatment effectiveness

In the model, the relative risks of symptomatic UTI and haematuria used were derived from the CNMA, including the treatment effect of enhanced coating or specially designed packaging on UTI, and the treatment effect of micro-holes or specially designed catheter case on haematuria. For other features

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(integrated drainage bag, integrated handle or marking, insertion sleeve or tip protector) or outcomes (residual volume, ease of use or discomfort), the treatment effect was set to be 1.

In addition, due to a lack of data, an assumption was made that 10% of people using a catheter with additional features that explicitly aimed at improving ease of use, discomfort or pain, or successful drainage would benefit through an improvement (HRQoL) and reduce in health resource use. More details and results can be found in section 6.1.5 of the EAR (tables 16 and 17).

Survival

Life expectancy estimates for people using intermittent catheters were generated, based on standardised mortality ratios (SMR=5.41 in Bermingham et al. 2013) and mortality data from the life tables for England and Wales 2023/24 ([ONS, 2024](#)) adjusting by age and gender to generate.

Health related quality of life

Health outcomes were measured using quality adjusted life years (QALY), which is a combination of HRQoL and life expectancy into a single index. HRQoL is calculated using utility weights related to each specific health state in the model.

Table 6 shows the baseline utility values used in the model. The utility values for 7 health states relating to UTIs, bacteraemia, urethral complication and haematuria were informed by the literature (Bermingham et al. 2013; Rognoni and Tarricone, 2017a). An assumption of 2% increase in the baseline utility was made for improvement in ease of use, discomfort or pain, or residual volume, leading to a net 0.017 increase in baseline utility for each outcome. Detailed information on the utility values at the different health states is present in section 6.1.6 of the EAR.

Table 6 Utility weights used in the base case evaluation

Health State	Mean estimate	Std. Err.	95% CI LL	95% CI UL	Distribution
No symptomatic UTI	0.831	0.01	0.809	0.852	Beta ($\alpha=969.06$, $\beta=197.08$)
Symptomatic UTI	0.782	0.01	0.764	0.799	Beta ($\alpha=1671.41$, $\beta=465.96$)
First-line resistant UTI	0.760	0.04	0.685	0.834	Beta ($\alpha=95.19$, $\beta=30.06$)
Multidrug resistant UTI	0.738	0.03	0.688	0.787	Beta ($\alpha=222.99$, $\beta=79.16$)
Bacteraemia	0.716	0.04	0.645	0.786	Beta ($\alpha=111.82$, $\beta=44.35$)
Urethral complication	0.738	0.03	0.688	0.787	Beta ($\alpha=222.99$, $\beta=79.16$)
Disutility/additional utility	Mean estimate	Std. Err.	95% CI LL	95% CI UL	Distribution
Haematuria	-0.093	-	-	-	-
Comfort/less pain	0.017	-	-	-	-
Easy to use	0.017	-	-	-	-
Improved residual volume	0.017	-	-	-	-

Abbreviations: CI, confidence interval; LL, lower limit; UL, upper limit; UTI, urinary tract infection. Disutility/additional utility values explored with 10% higher values in scenario analyses rather than assigning a distribution.

Resource use and costs

Resource use and costs in the model consisted of:

- Catheter and additional feature costs
- UTI-related healthcare consultation costs
- Symptomatic UTI, first-line and second-line antibiotic therapy costs
- Bacteraemia costs
- Haematuria and urethral complication costs
- Healthcare resource use from improvements in ease of use, discomfort or pain, or residual volume.

Intermittent catheter costs

The basic catheter cost consisted of the cost of a single-use uncoated catheter without additional lubrication or features (£1.37) and the cost of external gel lubrication (£0.19 per catheter). Based on this cost, home delivery (£9.30) and 10-minute GP consultation (£41), the total monthly cost of catheterisation for a person using basic catheters (5 per day) was estimated at £287.42.

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Costs for additional features and healthcare

The results from the regression models (table 1) were used to calculate catheter costs. The monthly costs of catheters with features and healthcare costs are detailed in section 6.1.7 (table 19) of the EAR.

3.3 Model results

Base case

Across the 8 additional features, when compared with the comparator (uncoated intermittent catheter with no lubrication provided):

- 4 features (integrated handle or markings, insertion sleeve or grip, micro-hole zone technology, and specially designed packaging) were less costly and increased QALYs. Hence, these 4 features were dominant.
- 1 feature (specially designed catheter case) was lower cost and slightly less QALYs. This feature was considered cost-effective at the £20,000 per QALY threshold, because an ICER was calculated based on a comparator that was not cost-effective (more effective but more costly) and the increased ICER was associated with the comparator. The potential ineffectiveness (increased haematuria risk) of this feature might be influenced by confounding variables. For example, people might prefer a compact or hard case when conducting catheterisation outside a home environment (such as when travelling or at work) which might influence the outcome more than the catheter feature itself. For this feature, the reduction in cost more than compensated for the reduction in QALYs. Therefore, the potential harm might be very small compared to cost savings meaning feature cost-effective at £20,000.
- 1 feature (enhanced coating) increased QALYs and was slightly costly.
- 2 features (integrated drainage bag and tip protector or introducer) slightly increased QALYs and incurred increased cost, with ICER greater than £90,000.

Table 7 Base case analysis results (Deterministic)

Feature	Total Costs (£)	Total QALYs	Inc. Costs (£)	Inc. QALYs	ICER

Comparator (U1) - <i>Reference</i>	7228	1.6355	-	-	-
Integrated drainage bag	9771	1.6389	2543	0.0034	752,525
Integrated handle or markings	6890	1.6389	-338	0.0034	Dominates U1
Insertion sleeve or grip	6526	1.6389	-703	0.0034	Dominates U1
Tip protector or introducer	7547	1.6389	318	0.0034	94,231
Micro-hole zone technology	6487	1.6462	-741	0.0107	Dominates U1
Enhanced coating	7398	1.6431	170	0.0076	22,296
Specially designed catheter case	6574	1.6298	-654	-0.0058	113,724*
Specially designed	6606	1.6431	-622	0.0076	Dominates U1

Abbreviations: ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; U1, uncoated catheter with no lubrication provided (required separately)

*ICER for U1 catheter with no features vs specially designed catheter case, U1 is not considered cost-effective at the £20,000 per QALY threshold from NICE.

Additional scenario analysis was done to include age and gender adjustments to general population utility values, using an absolute adjustment and a relative adjustment methodology. The incremental results did not change compared with the base case results. Details of the additional analysis are in Appendix H of the EAR.

Sensitivity analysis

One-way sensitivity analysis

One-way sensitivity analysis was done to evaluate the sensitivity of the base case results across various parameters. In almost all the alternative scenarios, the results of the base case analysis remained unchanged. For 4 features (integrated handle or markings, insertion sleeve or grip, micro-hole zone technology, and specially designed packaging), they still remained dominant.

In terms of the other 4 features (integrated drainage bag, tip protector or introducer, enhanced coating, and specially designed catheter case), when changes to the direction or magnitude of effect occurred, the key driver across all 4 features was the improvement in ease of use.

Longer time horizons (up to a lifetime) had little impact on the direction or magnitude of effect, because most of the costs being attributed to the catheter

and differences in QALYs were small. Scenario analyses were summarised in Table 22 of the EAR.

Based on the impact on net monetary benefit (NMB) which is the difference between the monetary value of total expected QALYs and total expected costs, the factors that significantly impacted on NMB included:

- both intervention and comparator catheter costs across all features
- relative risk of haematuria for micro-holes and specially designed catheter case
- relative risk for symptomatic UTI for specially designed packaging
- healthcare consultant costs for specially designed packaging.

Tornado diagrams are shown in Figure 9 of the EAR.

Exploratory marginal analysis

Based on the cost per catheter of £1.56 (a basic uncoated catheter with water-based lubricant), the results showed that an integrated drainage bag and the tip protector or introducer would need to provide 45% and 6%, respectively, more benefits than the comparator to be considered equal to their costs. On the contrary, the integrated handle or marking and the insertion sleeve or grip could provide 6% and 12%, respectively, less benefits and still remain equal to their costs.

Probabilistic sensitivity analysis (PSA)

The PSA results showed that micro-holes (probability 98%) and specially designed package (100%) are highly likely to be considered cost-effective. For enhanced coating, there is uncertainty for it to be cost-effective (probability 47%). Although the specially designed catheter case was less costly and less effective, its comparator was more effective and more costly. In this case, the reduction in cost of the feature more than compensated for the reduction in QALYs of the catheter with this feature. Therefore, this feature has a probability of 95% being cost-effective relative to an uncoated catheter with no additional features.

All sensitivity analysis results are detailed in section 6.2.2 of the EAR.

4. Summary of feature findings

Based on clinical evaluation and cost-utility analysis of the 8 additional features,

- possible clinical benefit was found in micro-hold zone technology (not associated with statistical difference in price) and specially designed packaging (with increased price). The base case model found that both features were dominant (less costly and increased QALYs) over a 2-year time horizon.
- uncertain clinical benefit was shown in integrated handle or marking, insertion sleeve or grip, and specially designed catheter case. However, the first 2 features (integrated handle or marking, and insertion sleeve or grip) led to reductions in costs.
- uncertain cost effectiveness was found in enhanced coating.
- unknown benefit remained in integrated drainage bag and tip protector or introducer.

The findings of intermittent catheter features from both clinical and cost evaluation are summarised in Table 8. More information can be found in table 25 of the EAR.

Table 8 Summary of findings across intermittent urethral catheter features

Intermittent catheter feature	Significant contributor to catheter price	Evidence showing effect of individual feature (from CNMA)	Economics	EAG comment
Integrated drainage bag	£0.89 increase	Not available	Base case <u>not</u> cost effective (ICER: £752,525)	Unknown benefit No evidence identified to confirm benefit; not cost effective at £20,000 WTP. Magnitude of clinical effect necessary to demonstrate cost-effectiveness may be implausible but may be possible to identify in further research.
Integrated handle or markings	£0.10 increase	Not available	Dominant in base case (even if assumed equivalent clinical effect)	Uncertain clinical benefit Not a significant contributor to cost, no evidence identified to confirm benefit, but no safety signal identified. Possible uncertainty on whether this should be aggregated with 'insertion sleeve or grip' feature; alternative groupings could be considered in future analysis.
Insertion sleeve or grip	No significant difference in price	Not available	Dominant in base case (even if assumed equivalent clinical effect)	Uncertain clinical benefit Not a significant contributor to cost, no evidence identified to confirm benefit, but no safety signal identified.
Tip protector or introducer	£0.28 increase	Not available	Base case <u>not</u> cost effective (ICER: £94,231)	Unknown benefit No evidence identified to confirm benefit; not cost effective at £20,000 WTP. The magnitude of clinical effect necessary to demonstrate cost-effectiveness is likely to be small and hence difficult (and costly) to detect.
Micro-hole zone technology	No significant difference in price	Possible reduction in haematuria	Dominant in base case, 98% probability cost-effective in PSA.	Possible clinical benefit (not associated with statistical difference in price) Not a significant contributor to cost, possible reduction in haematuria (wide CrI). [Possible mechanism of action less catheter manoeuvres, less risk of urethral damage] Additional non-prioritised outcomes showed reduction in pressure and flow stops with this feature; however Clinical Experts advised that pressure is not measure in routine clinical practice, and they were unclear of the clinical validity of flow stops as an outcome measure.
Enhanced coating	£0.25 increase	Possible reduction in UTI	Base case uncertain (ICER=£22,296), 47% probability cost-effective in PSA	Uncertain cost effectiveness Significantly increases catheter price, with potential evidence of reduction in UTI (however wide CrI leading to uncertainty). [Possible mechanism of action: less friction, less trauma, used more frequently]
Specially designed catheter case	No significant difference in price	Possible increased risk of haematuria	Less costly and less effective. ICER for comparator compared with feature: £113,724*	Uncertain clinical benefit Not a significant contributor to catheter price, however potential evidence of harm (from RR derived from CNMA). [Possible confounding by other factors: patients conducting catheterisation out with home]

Intermittent catheter feature	Significant contributor to catheter price	Evidence showing effect of individual feature (from CNMA)	Economics	EAG comment
			Hence feature is cost-effective. 95% probability cost-effective in PSA	<i>environment may choose a more discrete catheter, which is intrinsic to this feature]. Potential harm may be very small compared to cost savings meaning feature cost-effective at £20,000.</i>
Specially designed packaging	£0.06 increase	Possible reduction in UTI	Dominant in base case, 100% probability cost-effective in PSA.	Possible clinical benefit (with increased price) Not a significant contributor to cost, however potential for clinical benefit. [Possible mechanism of action: easier to hold, better drainage or used more frequently]

* all other ICERS are feature vs comparator except this one which is comparator vs feature, it shows whether the extra QALYs provided by the comparator are worth its extra cost. As the ICER is very high we can conclude that they are not and therefore compared with the comparator the feature is cost-effective. Abbreviations: CNMA, component network meta-analysis; CrI, credible interval; ICER, incremental cost-effectiveness ratio; RR, relative risk; UTI, urinary tract infections, WTP, willingness to pay

5. User preferences, needs and experiences

To understand people's needs, preferences and experiences of using intermittent catheters, 3 pieces of user-centred work were carried out, including a thematic review of the literature, a user preference assessment and an online survey.

5.1 User preference assessment

A group of 9 people (4 people with experience of using intermittent catheters for their own bladder management and 5 people with experience of prescribing intermittent catheter) participated in the user preference assessment to identify what is important to them when choosing a catheter.

They identified a total of 16 criteria, with 7 criteria relating to clinical needs and 9 criteria associated with personal preference. Table 9 illustrates the 9 criteria ranked in order of importance and definitions as well as supporting information from the survey findings. Also, the user preference assessment highlighted the importance of shared decision-making and the significance of catheters being 'comfortable to use'.

Table 9 Criteria and definitions

Criteria	Definition	Supported by the survey findings (n=69)
Comfortable to insert	Can be inserted with minimal difficulty, pain or discomfort.	One challenge people faced was 'difficult to insert or remove a catheter' 'Easy to insert' was considered important or very important by 99% of people 'Pain or discomfort' was rated as important or very important by 96% of people
Comfortable to remove	Can be removed with minimal difficulty, pain or discomfort.	
Full bladder drainage	Drains the bladder fully, as quickly as possible and without the need for repositioning the catheter.	Not reported
Risk of infection	A low risk of developing an infection.	One challenge faced by people using catheters was experiencing infections and 'infection rates' was considered

		important or very important by 87% of people
Options to suit individual needs and lifestyles	Available in various options (such as different sizes, designs or styles) that are as convenient and discreet as possible, suitable for various activities (such as travelling) and have options that create minimal mess (such as less liquid).	One challenge people faced was that it was hard with their schedule or interfered with their lifestyles
Easy to remove from packaging and prepare for use	Can be removed from the packaging and prepared for use easily (for example, with minimal spillage of lubrication [for pre-lubricated catheters], minimal handling, or a self-adhesive tab that remains stuck to a hard surface during catheter preparation).	'Ready to use or easy activation' was considered important or very important by 97% of people and 'easy to open' by 93%
Level of catheter flexibility	Appropriate flexibility for a person's individual and situational needs to enable insertion and removal with minimal pain or discomfort.	'Pain or discomfort' was rated as important or very important by 96% of people
Ease of disposal	Can be disposed of at a person's earliest convenience without leakages.	One challenge people faced was a lack of space, facilities or accessibility when doing IC and disposing the used devices outside the home environment.
Reduced environmental impact	Minimal packaging, with components that can be recycled. A catheter that can be recycled (where appropriate) that is manufactured using sustainable practices and materials, with the option for a reusable catheter.	Recyclable catheters were preferred by 2 people

5.2 Online survey

A total of 69 people were included. Only one-third were given a choice to select a suitable catheter to use when they initially started doing IC. People experienced various challenges, with the top 3 significant challenges being 'lack of appropriate space, facilities or accessibility for doing catheterisation', 'embarrassing or public stigma' and 'experience infections'.

People's preference of catheters varied, with the top 5 very important factors they considered being 'easy to insert', 'hygiene', 'easy to hold or handle', 'pain or discomfort', and 'ready to use or easy activation'. People often looked for help from 'specialised nurse/doctor' or 'they figured it out themselves' if they had any questions or concerns about IC.

In terms of people's overall experiences, there was a strong sense of positivity towards using intermittent catheters and the impact of IC on daily life.

However, the feeling of negativity was also expressed and could be impactful in some cases. People also pointed out the importance of support from others and the need for regular review of IC by healthcare professionals during their IC journey.

5.3 Thematic review

The thematic review included 19 articles, and 5 themes emerged: 'general experience of IC', 'technology and procedure', 'internal influential factors', 'external influential factors', and 'facilitation or enablement'.

The theme of 'general experience of IC' indicated that people's experience and adherence of IC varied, and that IC could have both positive and negative impacts on their daily lives.

The theme of 'technology and procedure' illustrated that technology and procedure played a crucial role in the integration of IC in their daily lives. People's preferences of the technology features differed due to personal needs, such as avoiding discomfort, pain or trauma, and improving ease of use. These features included catheter flexibility, diameter, material, size, coating, hygienic properties, packaging, quality, disclosure and discretion of IC use. Some people also took a broader view and considered factors beyond their personal needs, and instead, they were concerned about cost and environmental impact of IC devices as part of their decision making.

The themes of 'internal influential factors' and 'external influential factors' revealed that people's experience and adherence of IC were affected by internal and external factors. The former included 'age and sex', 'physical or cognitive function', 'psychological factors', and 'complications of IC', whereas the latter covered both physical and social environments.

To improve their journey of IC, this review drew attention to the theme of 'facilitation and enablement', which highlighted the need for education and regular follow up, supporting materials and tools, and enabling environment.

6. Equality considerations

The [final scope](#) and the [scoping equality impact assessment](#) describe equality considerations for this assessment. The EAG did not identify additional equality issues but drew attention to some subgroups, such as people in wheelchairs and those who are bed bound. Catheters that have an integrated bag or can be connected to an external collection bag may provide a better user experience to these people. An integrated bag or connection to an external collection bag would also reduce the need to use an additional container.

7. Committee considerations

7.1 Clinical effectiveness

Key results:

Of the 5 key outcomes, CNMA was feasible for 3 outcomes, including UTI, haematuria and comfort. When compared with a basic uncoated catheter,

- there was a possible reduction in UTI when enhanced coating or specially designed packaging was present.
- micro-hole technology might reduce the risk of haematuria, but specially designed catheter cases might increase the risk (the clinical validity of this result for specially designed catheter cases is in question). The effect on the risk of haematuria was unclear when hydrophilic pre-activated catheter was used.
- a small improvement in comfort was found in the use of pre-activated hydrophilic catheter, and a small-to-negligible decrease in comfort was shown in the use of a tip protector or introducer feature. For this outcome, the independent (additive) effects model did not fit the data well. After further examination, it was found that almost all data was driven by 1 RCT and 1 cross-over trial.

Across all CNMA outcomes, certainties were judged as 'very low'.

There was insufficient evidence to isolate the effectiveness of 4 features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer).

Key issues:

- There was a lack of consensus around the categorisation of features which might undermine the assessment.
- The number of studies included in the CNMA and CMA was restricted by heterogeneity in features and outcomes (definitions, timepoint measured, and statistical analysis reported) across studies and by poor reporting.
- Generalisability of the evidence to:
 - current NHS care and pathways remained unclear due to some outdated evidence (publication years ranged from 1997 to 2024)
 - people with indications other than those reported in the included studies was unclear.
- There was a lack of:
 - a core outcome set in long-term IC
 - clear and transparent reporting of the specific technology used across studies.

Limitations are detailed in section 4.3 of the EAR.

Questions for committee:

- What can the published studies tell us about the effectiveness of the additional features?
- What can the CNMA and CMA results (very low certainty) tell us about the effectiveness of the additional features?
- Is there sufficient evidence to demonstrate the effect of the additional features?

7.2 Cost effectiveness

Key results:

Over a two-year time horizon, the base case model found that 4 features (integrated handle or markings, insertion sleeve or grip, micro-hole zone

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technology, and specially designed packaging) were dominant (less costly and increased QALYs). The model also found that 1 feature (specially designed catheter case) was less costly and slightly less effective, but this feature was considered cost-effective at the £20,000 per QALY threshold.

In terms of the other 3 features, the cost-effectiveness of enhanced coating remained uncertain, and integrated drainage bag and tip protector were not considered cost-effective at a £20,000 willingness to pay threshold. Extensive one-way sensitivity analysis did not markedly change these findings.

Key issues:

- All modelling was restricted to people with urinary retention using IC.
- There were limitations with the modelling approach:
 - one assumption that people used the same type of catheter throughout the entire time horizon did not reflect people's experiences.
 - costs and utilities from outcomes other than UTI and haematuria were primarily based on assumptions.
- There were limitations on how the cost of a feature was estimated and whether utilities derived from Bermingham et al. (2013) reflected current people's experience of IC. Some results of sensitivity analyses were sensitive to the utility values used.
- The model focussed on one feature at a time, but catheters often contain multiple features.
- Based on one-way sensitivity analysis, the results of the regression model were sensitive to changes.

Limitations are present in section 6.3 of the EAR.

Questions for committee:

- Are the economic model structure, assumptions and clinical and cost parameters suitable to answer the decision question (see [final scope](#)) for this assessment?
- What can the model results tell us about the cost-effectiveness of the additional features?

- Can the results enable us to determine if the price variation between catheters with different features is justified?

7.3 User experiences, needs and preferences

Key results:

- People's needs, preferences and experiences of using intermittent catheters varied.
- When choosing a catheter to use, shared decision making was considered important. Choice was not always available in practice.
- When choosing a catheter to use, the most common factors that people considered important were ease and comfort of insertion, and risk of infection.
- People faced various challenges, and they were more likely to experience difficulties when doing IC outside the home environment.
- Different catheters need to be available to meet individual's lifestyles and needs across a range of situations and settings.
- Sustainability could be better incorporated in the range of available catheters. Also, where components of a catheter are recyclable, information about catheter sustainability needs to be made available and accessible.

Key issues:

- The sample sizes for the online survey (n=69) and user preference assessment (n=9) were small and did not reflect the wider population. Limitations are detailed in the user preference assessment report, the online survey report and the thematic review of the literature.

Question for committee:

- Does the committee agree with the key results from the 3 pieces of user-centred work?

Appendix A Abbreviations

CG	Clinical Guideline
CI	Confidence interval
CINeMA	Confidence In Network Meta-Analysis
CMA	Component Meta-Analysis
CNMA	Component Network Meta-Analysis
CrI	Credible interval
EAG	External assessment group
EAR	External assessment report
IC	Intermittent catheterisation
f1drain	Catheter feature: integrated drainage bag
f2handle	Catheter feature: integrated handle or markings
f3sleeve	Catheter feature: insertion sleeve or grip
f4tip	Catheter feature: tip protector or introducer
f5micro	Catheter feature: micro-hole technology
f6lubric	Catheter feature: enhanced coating
f7case	Catheter feature: specially designed catheter case
f8pack	Catheter feature: specially designed packaging
HRQoL	Health-related quality of life
H1	Hydrophilic coated catheter: liquid not provided
H2	Hydrophilic coated catheter: provided with water to activate coating
H3	Hydrophilic coated catheter: pre-activated
IC	Intermittent catheterisation
ICER	Incremental cost effectiveness ratio
ISC	Intermittent self-catheterisation
LSA	Late-stage assessment
MD	Mean Difference
NR	Not reported
OR	Odds ratio
PSA	Probabilistic sensitivity analysis
PSS	Personal social services
QALY	Quality adjusted life year
RCT	Randomised controlled trial

RR	Risk ratio
RV	Residual volume
RV1	Residual volume of urine at the first flow-stop
SD	Standard deviation
SMD	Standardised Mean Difference
SMR	Standardised mortality ratio
UL	Upper limit
UTI	Urinary tract infection
U1	Uncoated catheter: lubricant not provided
U2	Uncoated catheter: provided with lubricant
U3	Uncoated catheter: pre-lubricated
VAS	Visual analogue scale

Document cover sheet

Late-stage assessment report: GID-HTE10049 Intermittent urethral catheters for chronic incomplete bladder emptying in adults

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Late-stage assessment guidance GID-HTE10049 Intermittent urethral catheters for chronic incomplete bladder emptying in adults Late-stage assessment report

Produced by: Newcastle EAG

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Purpose of the late-stage assessment report

Late-stage assessment forms part of NICE's new lifecycle approach to technology evaluation, that ensures NICE can look at any technology at any stage across the product lifecycle. This external assessment report is part of the late-stage guidance process described in the [Late-Stage Interim Methods and Process Statement \(2024\)](#). NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Committee when it is making decisions about the late-stage assessment.

Declared interests of the authors

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE.

Any errors are the responsibility of the authors.

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Abbreviations

Term	Definition
BMI	Body mass index
CAUTI	Catheter-associated urinary tract infection
CENTRAL	Cochrane Central Register of Controlled Trials
CG	Clinical Guideline
CI	Confidence interval
CINAHL	Cumulated Index in Nursing and Allied Health Literature
CINeMA	Confidence In Network Meta-Analysis
CMA	Component Meta-Analysis
CNMA	Component Network Meta-Analysis
CrI	Credible interval
DEHP	Di(2-Ethylhexyl)Phthalate
DIC	Deviance Information Criterion
EAG	External Assessment Group
EAUN	European Association of Urological Nurses
f1drain	Catheter feature: integrated drainage bag
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f7case	Catheter feature: specially designed catheter case
f8pack	Catheter feature: specially designed packaging
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations
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HTA	Health Technology Assessment
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H2	Hydrophilic coated catheter: provided with water to activate coating
H3	Hydrophilic coated catheter: pre-activated
IC	Intermittent catheterisation
ICER	Incremental cost effectiveness ratio
ICTRP	International Clinical Trials Registry Platform
INAHTA	International Health Technology Assessment database
ISC	Intermittent self-catheterisation
ITT	Intention to treat
LL	Lower limit
LSA	Late-stage assessment
MD	Mean Difference
MEDLINE	Medical Literature, Analysis, and Retrieval System Online
NICE	National Institute for Health and Care Excellence
NR	Not reported
OR	Odds ratio
OWSA	One-way sensitivity analysis
POBE	Polyolefin-based elastomer
PP	Per protocol

Term	Definition
PSA	Probabilistic sensitivity analysis
PSS	Personal social services
PVC	Polyvinyl chloride
PVP	Polyvinyl pyrrolidone
QALY	Quality-adjusted life years
RCN	Royal College of Nursing
RCT	Randomised controlled trial
RFI	Request for information
RR	Risk ratio
RV	Residual volume
RV1	Residual volume of urine at the first flow-stop
SD	Standard deviation
SMD	Standardised Mean Difference
SMR	Standardised mortality ratio
TPE	Thermoplastic elastomer
TPO	Thermoplastic polyolefins
TPU	Thermoplastic polyurethane
UL	Upper limit
UTI	Urinary tract infection
U1	Uncoated catheter: lubricant not provided
U2	Uncoated catheter: provided with lubricant
U3	Uncoated catheter: pre-lubricated
VAS	Visual analogue scale
WHO	World Health Organization

Executive summary

Background: The focus of this late-stage assessment was single-use intermittent urethral catheters for long-term (more than 4 weeks) urinary management in adults. The population are heterogeneous in terms of age, medical conditions, employment, family responsibilities, mobility, body shape, hand control, vision, and memory abilities. This is reflected in the heterogeneity of available intermittent catheters and their features. The EAG recognises and respects diversity of bodies, genders, and identities. In reviewing the published evidence, company documentation and professional guidelines the EAG acknowledges the frequent use of “male” or “female”. The EAG has used these terms as reported in each source and otherwise uses inclusive terminology wherever possible.

Technologies: The External Assessment Group (EAG) identified 849 distinct intermittent catheters from 20 manufacturers which were prescribed in the NHS within the 2023/24 financial year. The EAG attributed the presence of 8 catheter features (integrated drainage bag, integrated handle or markings, insertion sleeve or grip, tip protector or introducer, micro-holes, enhanced coating, specially designed catheter case, specially designed packaging - as listed in the NICE Final Scope) to intermittent catheter product lines from information provided by 12 companies (who responded to NICE), company websites and published literature. Catheter design and features were generally poorly described, missing or open to interpretation; this may have resulted in cases of mis-categorisation by the EAG. There was no consensus on the definition or importance of intermittent catheter features among Clinical and Lay Experts. Features of intermittent catheters are not explicitly outlined in the product information of the NHS Drug Tariff. Additional features were identified by the EAG inductively, but none of the identified published literature addressed the clinical efficacy or effectiveness of these features directly. The EAG included a total of 838 intermittent catheters, across 86 catheter product lines (aggregated by catheter size, male or female, tip type) from 17 manufacturers within subsequent analysis.

The EAG estimated the effect of the presence of catheter features on intermittent catheter prices using multivariate regression modelling. This analysis found that the intermittent catheter price was associated with the presence of all features, except of micro-holes which were not statistically significant contributors to catheter price in

any exploratory analysis. Due to lack of consensus around features, the EAG undertook sensitivity analysis in the regression analysis to determine whether including different combination of features had an impact on intermittent catheter price. However, the EAG noted that differing definitions regarding the inclusion of various catheter features may have influenced findings.

Clinical evidence: The EAG identified 18 comparative studies (of which 15 were randomised controlled trials) evaluating intermittent catheters with different features, coatings and lubrication methods. The included evidence covered all intermittent catheter features of interest listed in the NICE Final Scope. Some of the evidence was published as early as 1997, and therefore the generalisability of the evidence to current NHS care and pathways are unclear. Standardised reporting of outcomes (definition and timepoint measured, statistical analysis reported) was poor which limited the inclusion of all studies in subsequent complex evidence synthesis (component network meta-analysis, CNMA). The EAG considered CNMA to be ideal for answering the LSA decision problem in a features-based assessment because it is designed to isolate the effect of individual features in complex multifactorial questions. All studies included in CNMA had an RCT design but the heterogeneity of most outcomes and features that were analysed limited the evidence rating to “very low” certainty.

CNMA was considered for 5 outcomes which were prioritised by Clinical and Lay Experts (UTI, haematuria, residual volume, comfort and ease of use). Analysis was only feasible for UTI, haematuria, and comfort outcomes. There was a possible reduction in UTI when either the enhanced coating or specially designed packing features were present. Separately, the micro-hole feature was found to reduce the risk of haematuria, but conversely the presence of specially designed catheter case was found to increase the risk of haematuria. However, the EAG note the low number of studies and patients included in these analyses, and the wide credible intervals mean that there are large uncertainties associated with these findings (the confidence in CNMA was rated as very low in all instances). The EAG note that 76% of intermittent catheter product lines available on NHS Drug Tariff have at least one of those features (enhanced coating, specially designed packaging, micro-hole, or specially designed catheter case); acknowledging that the micro-hole feature is only available from one manufacturer. The EAG consider that there is insufficient

evidence to isolate the effectiveness of the remaining intermittent catheter features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer).

Economic evidence: The EAG identified 13 studies using Markov models to evaluate the cost-effectiveness of various intermittent catheters; 4 of which were undertaken from an UK NHS perspective. Only one described an economic model which assessed an intermittent catheter feature (micro-holes); however, this was available as an abstract with limited details on model structure. The remaining identified literature was not directly relevant to the decision problem of this late-stage assessment, however this published evidence helped to inform the development of the economic model and to validate the modelling approach taken by the EAG.

Economic model: The EAG developed a Markov model in Microsoft Excel which was informed by an economic model used in a previous NICE Clinical Guideline (CG139). The relative effects for individual intermittent catheter features were populated using the results from the CNMA analyses, enabling the EAG to estimate both the costs and outcomes of individual features from a UK NHS perspective. Over a two-year time horizon, the base case model found that micro holes and specially designed packaging were dominant (less costly, increased QALYs), as were integrated handles and insertion sleeves or grips (less costly and increased QALYs).

One feature was less costly but slightly less effective but would still be considered cost-effective compared with the comparator (specially designed catheter case). Two features were not considered cost-effective at a £20,000 willingness to pay threshold (tip introducer ICER: £94,231; integrated drainage bag ICER: £752,525); which is in part due to the lack of clinical evidence demonstrating a benefit of those features. The cost-effectiveness of enhanced coating remains uncertain (ICER: £22,296). Extensive one-way sensitivity analysis including scenario and probabilistic sensitivity analysis (PSA) did not markedly change these findings.

Key points for decision makers:

The EAG considered that pricing variation of micro-hole and specially designed packaging features was justified by the available evidence (potential clinical benefit), there was uncertainty regarding the clinical benefit of integrated handle or marking and insertion sleeve or grip features, however these lead to reduction in costs and

therefore can be justified on that basis (as long as assumption of equivalence remains). There is uncertainty regarding the cost-effectiveness of enhanced coating feature, and potential for specially designed catheter case to have a small negative impact (increased haematuria) which may be confounded by other factors, although its lower cost still meant it was cost-effective compared with the comparator. No clinical benefit was observed in published literature for integrated drainage bag or tip protector or introducer. Therefore, any increase in intermittent catheter price associated with these features is not considered justified. Furthermore, the EAG note that an integrated catheter bag would need to provide substantial additional benefits to justify the additional cost which may not be clinically plausible. Whereas, for tip protector or introducer the additional benefits needed would be small, but consequently difficult (and costly) to identify. However, there are large uncertainties (in attributing meaningful features to intermittent catheters consistently, in conducting CNMA on a limited evidence base, and subsequently populating this data into an economic model); such that the results should be interpreted with caution.

Future research

The EAG highlight the lack of a core outcome set in intermittent catheterisation (as evidenced by the heterogeneity in results reported in the included evidence) and lack of clear and transparent reporting of the specific technology used (manufacturer and model) across the published literature. Improvements in these would enable the assessment of value of individual features to be updated when more evidence becomes available. The EAG recommend that the product information listed on the NHS Drug Tariff be revised to make clear to prescribers and commissioners the differences between intermittent catheters. This could include features present (using standardized definitions), which would enable prescribers and users to optimise catheter selection to meet individual preferences (which could include changes in lifestyle, catheterisation setting, or preferences). This approach could in part reduce catheter wastage and contribute to large cost savings in the NHS.

1 Decision problem

This late-stage assessment (LSA) will explore the evidence for single-use intermittent urethral catheters used for long-term urinary management in adults. Some intermittent urethral catheters have additional features intended to overcome

barriers to use, to ease bladder drainage or to reduce the risk of infection. This assessment will examine whether price variations between technologies are justified by these additional features, and which of these features represent value for money for the NHS.

The decision problem for this late-stage assessment on intermittent urethral catheters for long-term urinary management in adults was described in the [Final Scope](#), published 01 October 2024. The External Assessment Group (EAG) reviewed and provided comment on the decision problem as described in the [EAG protocol](#).

2 Clinical context

Intermittent urethral catheterisation is when a urinary catheter is inserted via the urethra far enough to empty the bladder and is then removed; this is repeated several times a day. Clean intermittent catheterisation is a method of emptying the bladder of urine using a thin plastic tube (catheter) when the bladder is unable to empty itself. It is a non-sterile technique that needs the area around the urethra and the hands to be cleaned before using the catheter. The tip of the catheter that enters the urethra should remain untouched on insertion and during bladder emptying. The technique can be done by a healthcare professional, a carer or the person themselves, in which case it is called clean intermittent self-catheterisation. This late-stage assessment is restricted to adult long-term intermittent urethral catheter users (NICE [Final Scope](#)). NICE defines long-term use as a person who needs to use a catheter for at least 4 weeks ([NICE CG139, 2012](#)) with no maximum duration defined.

Long-term intermittent urethral catheterisation can be indicated as treatment for patients with bladder emptying problems. This could be due to disturbances or injuries to the nervous system, non-neurogenic bladder dysfunction or intravesical obstruction with incomplete bladder emptying (Royal College of Nursing, 2021). The Royal College of Nursing (RCN) Catheter Care: RCN Guidance for Health Care Professionals (2021) states:

- *“Intermittent catheterisation is contraindicated if the patient is experiencing priapism, suspected tumours or urethral injury. False passage, stricture and*

some diseases of the penis (such as injury, tumours or infection) can contraindicate intermittent catheterisation. Caution should be displayed with patients following prostatic, bladder neck or urethral surgery, female genital mutilation and in patients with a stent or artificial prosthesis.”

- *“Before commencing a patient on intermittent catheterisation, their symptom severity profile, renal function, risk assessment, psychological and physical ability to perform intermittent catheterisation and residual urine status must be considered. Do not initiate intermittent catheterisation based solely on the residual urine status.”*
- *“Intermittent catheterisation is preferable to an indwelling urethral or suprapubic catheter with patients who have a bladder emptying dysfunction or spinal cord injury.”*

The need for long-term intermittent catheter use crosses all ages, all sectors of society, and a broad range of medical conditions. Adults who use intermittent catheterisation may work, travel, exercise or care for families, and they can find their participation in such activities impacted or limited because of bladder emptying issues. The population of interest has a wide range of body shapes, hand control, vision, and memory abilities. Reduced mobility can increase the likelihood of bladder leakage and therefore urinary incontinence, and the need for long-term intermittent catheterisation may limit mobility and thus impact life activities. The heterogeneity of the population and conditions has resulted in a wide range of needed catheter features as advised by clinicians (McClurg et al., 2015). Features prioritised by users include convenience, lubrication, ease of insertion, avoidance of trauma, independence, with risk of infection and independence being highly ranked (Kimoto et al., 2015; Pinder et al., 2015; Welk et al., 2021).

An intermittent catheterisation assessment and referral to urology can be started from a primary or secondary care setting. The referral may include spinal specialists where necessary. Selection of an appropriate product is determined by the patient and healthcare professional and is guided by local formulary in some cases. Intermittent catheterisation is typically taught by a urology or continence specialist nurse in an acute hospital setting (outpatient or inpatient appointment) where specific recommendations may be made in consideration of issues such as complex

anatomical features (Rew et al., 2018). Two Clinical Experts confirmed that commencement of intermittent catheterisation in an acute care setting was typical, however, one Clinical Expert also noted that intermittent catheterisation can be commenced by a District Nurse in the community setting if a patient cannot mobilise well enough to attend an acute care setting ([Appendix D](#)). Ongoing intermittent catheterisation support typically occurs in a community setting where the catheters are prescribed by a GP or prescribing nurse specialist and dispensed by a local chemist or delivered to patients through a Dispensing Appliance Contractor. Alternative products may be offered in community settings and a survey of prescribing nurses described significant variation in access and restriction of choice (McClurg et al., 2015). Patients may change their intermittent catheter model following experience and feedback on their catheter (Goldstine et al., 2019). Intermittent catheters are typically provided in a box of 25 to 30 however this varies by manufacturer. The minimum quantity of catheters on prescription is 1 month's supply.

Two Clinical Experts advised that annual review of patient catheterisation was good practice. One Clinical Expert stated that users are provided with direct contact information if problems arose with their catheter, and one acknowledged that annual review may not occur due to issues with staff resourcing. One Clinical Expert advised that some patients stay with the same model of intermittent catheter for years. One Clinical Expert advised that an unpublished survey of 200 intermittent catheter users indicated that 65% had been using intermittent catheterisation for more than 5 years, with approximately half (95/195) changing their catheter model since their first prescribed one. Two Clinical Experts advised that intermittent catheter users are not routinely prescribed more than one model of catheter to cover lifestyle changes (such as travel) or changes in circumstances. The EAG consider that this limited choice of catheterisation may impact costs, quality of life and potentially increase health inequalities across the UK.

Three Clinical Experts and one Lay Expert advised that several considerations are made when selecting an appropriate intermittent urinary catheter. These include: manual dexterity, whether mobility aids are needed, whether the individual can conduct self-catheterisation or whether another person is needed, whether multiple types are needed (for work or home), ease of transport, ease of opening, lubrication

type, ease of preparation, infection control, ease of manipulation, rigidity of catheter and tip on catheter insertion, or anatomical conditions such as enlarged prostate or tortuous urethras. A recent review of urinary retention in females noted how this has been under-diagnosed compared with males and the annual incidence in females is 7 per 100,000 with a male to female ratio of 13:1 (Ghonaimy et al., 2024). Three Clinical Experts advised that there is no national clinical data collection of outcomes for intermittent catheterisation within community or acute care settings in the UK.

In order to help navigate the wide range of products and features, and make an optimal choice based on needs and preferences, evidence based practical advice is available for users, families, carers and healthcare professionals from the European Association of Urological Nurses, EAUN (Vahr Lauridsen et al., 2024) and the Continence Product Advisor (Continence Product Advisor, 2019). Both resources provide product descriptions, information for users and healthcare professionals that are based on relevant research evidence. Search strategies and disclosures are stated. The [British Association of Urological Nurses](#) website provides urological guidance and training, which is accessible to members only. For patient information, they refer to relevant topics on the NHS website and to the British Association of Urological Surgeons website, the latter of which contains a section on [catheter-related procedures](#).

3 Technologies

Intermittent urethral catheters can be characterised as “a smooth, flexible tube with holes, used for short term drainage of urine from the bladder and the catheter has no balloon” ([NICE Final Scope](#)). The external catheter diameter is measured in mm and described using the French Charrière scale (Ch) where 1Ch=1/3 mm and is selected based on the diameter of the urethra. The catheter size range available on the NHS Drug Tariff is between 6 and 20 Ch.

Intermittent catheters can be made of different materials, have different coatings, and have different tips to assist with easy catheter insertion and removal. Before an intermittent catheter can be inserted it needs lubrication, which helps to reduce the surface friction of the device and makes insertion and removal less likely to damage the lining of the urethra. This can be externally applied, such as using water, saline, gel, or supplied as a separate lubricant within the catheter packaging or incorporated

onto the catheter device (pre-lubricated). The latter being ready to use straight from the packaging without additional preparation. Alternatively, catheters can have a hydrophilic polymer coating, usually made of polyvinyl pyrrolidone (PVP). The hydrophilic coating is applied during the manufacturing process and is dried or cured with the use of heat or ultraviolet light onto the catheter surface. The hydrophilic coating is then reactivated with water (sterile or tap water depending on catheter) which can be supplied separately or integrated in the catheter packaging. Some catheters are described as hydrophilic pre-lubricated which means they have been pre-activated and are ready to use straight from the packaging without requiring additional preparation. For the remainder of this report the EAG will refer to “uncoated” to mean lacking hydrophilic polymer coating.

Intermittent catheters can have different shaped tips to ease insertion into the urethra. For example, Nelaton is a straight catheter tip, and Tiemann is a curved tip considered in patients with an enlarged prostate and for patients with urethral strictures. Intermittent catheters can also have additional features designed to support catheterisation. An initial list of features of interest was described in the [NICE Final Scope](#). The EAG have included a description and the claimed intended benefit (as reported by manufacturers) for each of these described features in Table 1.

Table 1: Summary of features of intermittent catheters, as listed in the NICE Final Scope and their intended benefits (as reported by manufacturers)

Feature	Description	Intended benefit (as reported by manufacturers)
Integrated drainage bag	A urinary drainage bag which can be attached to, or combined with, an intermittent catheter. The EAG note that catheters supplied with drainage bags are often referred to as kits or sets (however these are not always explicitly stated within the product name) and the composition of these may vary and include other accessories (for example gloves, wipes etc) across manufacturers.	Intended to be useful for wheelchair users and those patients who catheterise from a seated or prone position, useful in restricted or confined spaces or in settings where access to toilet facilities could be limited and could be given to patients during learning intermittent catheterisation techniques.
Integrated handle or markings	Integrated handle attached to the catheter or coloured markings on the catheter tube	Intended to aid with correct orientation and positioning, and support individuals with limited dexterity.
Insertion sleeve or grip	Catheter cover guiding insertion into the urethra without the catheter being touched.	Intended to introduce the catheter without handling, to support a hygienic, no-touch aseptic routine to reduce chance of UTI.

Feature	Description	Intended benefit (as reported by manufacturers)
Tip protector or introducer	Sterile tip or introducer covers the catheter tip from the colonised portion of the urethra.	Intended to help shield the catheter from bacteria located within the initial distal portion of the urethra and avoid pushing bacteria into the urinary tract.
Micro-hole zone technology	A larger number of holes with smaller diameter (<1mm) are placed in the drainage zone when compared with traditional larger 2-4 eyelets.	Intended to reduce mucosal suction, increased speed of urine drainage therefore help improve complete bladder emptying, reduce the risk of UTI and can reduce the number of times a patient catheterises and may potentially improve adherence. This feature may be unsuitable in patients with visible particles in urine as these may block the micro-holes.
Enhanced coating	A hydrophilic coating which differs from the traditional PVP which can also include: • Pre-activated coatings which do not need an additional 'wetting' step (typically needed for hydrophilic coated catheters), • hydrophilic catheters with a non-PVP hydrophilic coating, • hydrophilic coating which has high-osmolality (hydrophilic coatings that corresponds to osmolality levels normally present in urine) or contain a hydrophilic integrated amphiphilic surfactant.	Intended to overcome challenges such as dry spots on catheter and short dry-out times, less friction, less trauma, easier and less painful to insert and remove. Definition of coating components was largely poorly reported and difficult to determine from documentation provided by companies. The EAG note that some manufacturers have claimed that repeated use with PVP coated catheters may result in microplastic residue in the urethra, and reduced sperm mobility.
Specially designed catheter case	Catheter provided with case or pouch which is compact, resealable or hard, in order to store the catheter if unable to dispose of directly after use.	Intended to be transported easily, compactly and discreetly which may improve convenience, confidence and adherence outside of a home environment or in restricted spaces.
Specially designed packaging	Thumb holes or ring pulls, flip top, hanger.	Intended to aid ease of opening, reduce need for support during catheterisation and potentially quicker catheterisation, facilitate use for people with partly reduced manual dexterity.

Abbreviations: PVP, polyvinylpyrrolidone; UTI, urinary tract infection

The EAG note the description of 'handle' or 'sleeve' differs between manufacturers, and that the description of coating (including coating material) between manufacturers is open to interpretation. This resulted in difficulty for the EAG when attempting to distinguish these features across intermittent catheters.

3.1 Intermittent catheters used in the NHS

To capture all the intermittent catheters currently available to the NHS, the EAG extracted all 62,682 items listed in the NHS Drug Tariff Part IXA ([NHS Business](#)

[Authority](#)) on 29 September 2024. The EAG then excluded the following (multiple reasons for exclusion may apply):

- 60,984 non-catheter items (for example: ampoule, applicator, bag, bandage, bottle, capsule, device, dose, dressing, enema, glove, gram, lancet, lozenge, m, ml, needle, pack, pad, pastille, patch, pessary, plaster, pre-filled disposable injection, sachet, stocking, strip, suture, swab, syringe, tablet, truss, unit dose, vial)
- 46 dilatation catheters,
- 397 Foley or indwelling catheters,
- 48 suprapubic catheters,
- 182 paediatric catheters (scope of this late-stage assessment is restricted to adults),
- 4 reusable catheters (scope of this late-stage assessment is restricted to single-use),
- 46 which stated “generic (unspecified)” manufacturer,
- 5 MobiStom catheters, which the company (Teleflex) confirmed is not indicated for use in Intermittent urethral catheterisation.

A total of 941 different catheters from 20 manufacturers remained. The EAG then merged in activity information from the Prescription Cost Analysis for the 2023/24 financial year ([NHS Business Authority](#)), using the SNOMED data field which was unique to each catheter that was common across the data sets, Table 2. A total of 95,437,405 intermittent catheters were prescribed in 2023/24. To put this number into context, this would equate to approximately 52,300 patients assuming patients use 5 intermittent catheters a day (as advised by clinical input, Appendix D; question 9) for a year.

Table 2: Intermittent catheters available on Drug Tariff including total number prescribed by manufacturer

Manufacturer	No. of different catheter products	Total Quantity prescribed in 2023/24	Percentage of total intermittent catheter prescriptions
B.Braun Medical Ltd	84	5,592,720	5.9%
Bard Ltd	34	1,537,560	1.6%
Charles S. Bullen Stomacare Ltd	55	677,720	0.7%
CliniMed Ltd	21	960,480	1.0%
CliniSupplies Ltd	24	575,010	0.6%
Coloplast Ltd	83	44,563,865	46.7%
Convatec Ltd	46	560,700	0.6%
Flexicare Medical Ltd	51	665,370	0.7%
GTA (UK) Ltd	30	40	0.0%
Hollister Ltd	85	14,127,100	14.8%
Hunter Urology Ltd	49	354,330	0.4%
Manfred Sauer UK Ltd	33	1,849,350	1.9%
Mediwatch UK Ltd	32	180	0.0%
Peak Medical Ltd	34	325,760	0.3%
Pennine Healthcare Ltd	6	314,660	0.3%
Pioneer Medical Europe Ltd	13	200	0.0%
Spirit Healthcare Ltd	11	360	0.0%
Teleflex	127	3,922,810	4.1%
Vesica Urology Ltd	31	534,090	0.6%
Wellspect HealthCare	92	18,875,100	19.8%
Total	941	95,437,405	100%

The EAG aggregated catheter size (in Ch; as all catheters are available in a range of sizes as defined by the NHS Supply Chain bladder and bowel framework, as described in the NICE Final Scope), male or female, and tips (as described in the NICE Final Scope, these were not considered additional features) to create 96 catheter product lines. The EAG undertook an inductive approach to categorising and evaluating the feature components of the intermittent catheters which are routinely prescribed in the NHS; also referred to as Intervention Components Analysis. The EAG identified the presence of additional features for each catheter model from company websites which were sent to the companies for verification (via NICE) [Appendix A](#). Follow-up questions were sent by the EAG for clarification (via NICE). The EAG noted that 8 out of 20 manufacturers did not respond, and therefore information for those devices was obtained from publicly available information only, where available, and is unverified by the manufacturer (Flexicare Medical Ltd, Hunter

Urology Ltd, Malvern Medical, Manfred Sauer UK Ltd, Mediwatch UK Ltd, Pioneer Medical Europe Ltd, Spirit Healthcare Ltd and Vesica Urology Ltd). When identifying catheter features from company websites, the EAG identified that Mediwatch UK Ltd has since been acquired by [Cattaneo](#); as these catheters were listed on the Drug Tariff at the time of data extraction, the EAG has assumed that these catheters are still available to the NHS. The EAG note that multiple manufacturers stated that newer catheters were going to be made available, however, as these were not listed in the NHS Drug Tariff at the time of review, and therefore did not have cost data available, they were excluded from the current analysis.

Regarding assignment of features the EAG note that terminology differs between manufacturers. Some manufacturers refer to their product as a kit or set if it includes a drainage bag, and two Clinical Experts advised that the product name listed in NHS Drug Tariff may not include the word 'kit' or 'set' ([Appendix D](#)), thus making it difficult to attribute this feature with confidence. The EAG also note that the components of kits or sets vary by manufacturer - including drainage bag, gloves, drapes, swabs or wipes – which may contribute additional variation in costs. The EAG also noted mixed terminology between description of technical of 'integrated handle' and 'sleeve' meaning potential overlap of these features. The EAG therefore assigned features based on claimed benefit (fixed handles based on orientation, moveable sleeves or grippers based on ease of use and handling). Subsequent to the EAG categorisation, one Clinical Expert stated that main difference in terminology was between male and female catheter lengths; sleeves and grippers being designed primarily to prevent direct handling of the catheter but may also aid insertion of typically male length catheters, whereas integrated handles are usually within female length catheters and designed to primarily to aid insertion but may also help avoid direct handling of the catheter ([Appendix D](#)). The EAG that these features may there be confounded by other factors. Another Clinical Expert stated that there was no difference between handle, sleeve or gripper. The EAG note that there was no consensus among experts on the feature of "enhanced coating", and that the companies claimed that hydrophilic coatings were "multi-action technology" or "low osmolality"; however, the EAG was unable to identify a strict definition of these. Additionally, the EAG note that enhanced coating, specially designed catheter case, and specially designed catheter packaging are composite features which are open to interpretation and described differently across manufacturers; this is a potential

source of variation and may introduce uncertainty when incorporated in subsequent analysis. The EAG were unable to identify the presence of features for all intermittent catheters (no company website found, no information provided to NICE), therefore a total of 838 catheter products across 86 catheter product lines from 17 manufacturers were included in clinical and economic analysis:

- 18 had an integrated drainage bag,
- 30 had integrated handle or markings,
- 50 had insertion sleeve or grip,
- 21 had tip protector or introducer,
- 1 had micro-hole zone technology,
- 31 had enhanced coating,
- 27 had specially designed catheter case,
- 61 had specially designed packaging.

The EAG noted that 14 catheter product lines had 0 additional features, 10 had 1 additional feature, 18 had 2 features, 8 had 3 features, 22 had 4 features, 14 had 5 or more features.

Data for basic product features was extracted from the product names including:

- Catheter sex (male, female, or unisex). The EAG note that if 'male' or 'female' was not stated in the product name as listed on the NHS Drug Tariff that 'unisex' was assigned by the EAG. Of the 838 catheters, 61.1% were categorised as male, 37.2% as female, and 1.7% as unisex.
- Type of catheter tip. The EAG note that this was not explicitly stated in the product name for all catheters, so where missing, the EAG assumed a standard Nelaton tip. Of the 838 catheters, 81.7% were categorised as Nelaton tip, 15.6% as Tiemann, 1.6% as Ergothan, and 1.1% as Coude.

Catheter material was not consistently reported in the product name on NHS Drug Tariff (missing in a number of cases). The intermittent catheter materials, and how

these were described by companies varied, and included: latex, polyvinyl chloride (PVC), polyolefin-based elastomer (POBE), polyurethane, silicone, thermoplastic elastomer (TPE), thermoplastic polyolefins (TPO), thermoplastic polyurethane (TPU), or material undefined but reported to not contain Di(2-Ethylhexyl)Phthalate (DEHP).

The EAG analysed the quantity of prescribed intermittent catheters within the 2023/24 financial year across the included catheters:

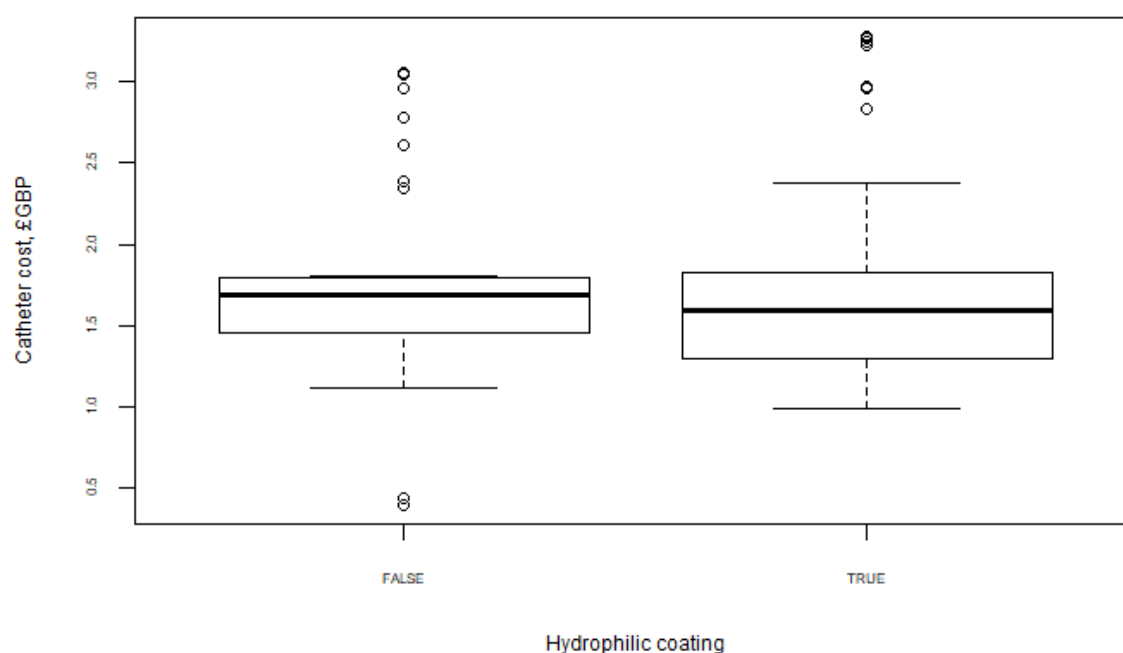
- 10.3% of prescribed intermittent catheters were uncoated (2.5% provided without lubrication, 0.6% with lubrication provided separately, 7.2% pre-lubricated).
- 89.7% of prescribed intermittent catheters had a hydrophilic coating (4.3% needed wetting to activate the coating where the water was not provided with the catheter, 22.7% had water integrated into the packaging, 62.7% were pre-activated).

3.2 Variation in price of intermittent catheters

To illustrate the variation in price of intermittent catheters, the EAG has plotted the distribution of price per single catheter as derived from the NHS Drug Tariff 2023/24 for the 838 included intermittent catheters by coating (uncoated or hydrophilic coating categories Figure 1). The price range per catheter was between £0.40 to £3.28. Therefore, the maximum price difference could be up to £2.88 per catheter which is equivalent to £14.40 per day per patient (assuming 5 catheters used per day), or £5,256 per year per patient. For illustration of the impact of this on the NHS, and assuming the prevalence of 50,000 adult intermittent catheter users in the UK (estimated from NICE Final Scope), this could equate to a maximum saving of £263 million per year, although the impact is likely to be much less. As Figure 1 shows most catheters have an approximate cost per intermittent catheter of between £1.25 and £1.75. Equivalently, the NHS would save £9.13 million per year for each 10p (£0.10) reduction in the average price paid per catheter.

Figure 1: Distribution of price per intermittent catheter, as derived from NHS Drug Tariff 2023/24 across 838 included catheters separated by uncoated (n=272 catheters) and hydrophilic coated (n=566 catheters)

[Note: circles indicate values which are 1.5 times the interquartile range above the 75th percentile, or below the 25th percentile]



As the aim of late-stage assessments is to evaluate evidence to determine whether the pricing variation is justified, the EAG aimed to assess the impact that the additional features have on the unit price per catheter for those catheters currently used for intermittent self-catheterisation by the NHS.

Data extracted from the Drug Tariff Part IXA was used to estimate the price of each *additional feature* (NHS Business Service Authority, 2024) for the 86 catheter product lines included for the analysis in Section 3. Moreover, as catheter product lines in the Drug Tariff are offered with multiple additional features plus basic features outside the scope, a regression analysis was deemed as the most suitable approach to estimate the average price of each feature (additional or basic) for a specific catheter product line. This methodology was based on the cost analysis presented in the late-stage assessment on one-piece closed bags for adults with a colostomy ([PenTAG GID-HTE10045, 2024](#)).

The EAG constructed a multiple regression model (built in R statistical programming language) to estimate the effect of each feature (as attributed in [Appendix A](#)) on the price of a catheter (R Core Team, 2019). The model assumes that the price of a single intermittent catheter is a linear function of the catheter's *basic product features* (sex, type of tip, type of coating and method of lubrication), and 8 *additional features* (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer, micro-holes, enhanced coating, specially designed catheter case, specially designed packaging). Each feature is considered to have an independent additive impact on the cost of an individual catheter. Only main effects were considered, no interaction terms between covariates were considered in the modelling. By controlling for the effect of *basic product features* the analysis reduces the risk of confounding factors in the estimation of the price of catheters with *additional features*.

The data on the 86 eligible catheter product lines described in Section 3.1 were used to assess the price of each feature. The presence of features (both *additional* or *basic product features* as defined above) were coded as independent predictor variables, with the cost per catheter as the dependent variable. The EAG was unable to categorise catheter material as this was not always listed on product name in the NHS Drug Tariff; was not provided by the company in all cases and was not available on company websites for all catheters.

Results from the regression analysis on the price of 838 intermittent catheters are reported in Table 3, and shown in Figure 2. The R-squared statistic (as a measure of goodness of fit) suggested that approximately 78% of the variation in intermittent catheter prices can be accounted for by the presence of basic and additional features. Multiple *basic product features* were found to have a statistically significant impact on price at the 95% confidence level when compared with a reference catheter (taken to be a male catheter with a Nelaton tip, uncoated without a lubricant, which had a mean cost of £1.37 standard error: 0.02).

Coating type and lubrication methods were found to statistically contribute to catheter price compared with the reference catheter. Uncoated pre-lubricated catheters were most costly than the reference (£0.15 more) and basic hydrophilic intermittent catheters with no liquid provided to the user (which would need wetting under a tap) were found to have a lower catheter price than the reference (£0.12

less). The EAG noted that catheters not listed specifically as “male” or “female” in the NHS Drug tariff (branded as “Unisex” by the EAG) were statistically higher cost (£0.18 more).

Additional features from the NICE Scope with a statistically significant difference in price included: having an integrated urine bag (£0.89 more per catheter), integrated handle or markings (£0.10 more), tip protector (£0.28 more), enhanced coating (£0.25 more) and specially designed packaging (£0.06 more). The EAG note that uncoated intermittent catheters also need additional lubricant which costs approximately £0.19 per administration, (see section 6.1.6), and therefore the additional and reduced costs per feature should be considered in context of this. The EAG also note that at the time of the review only Luja intermittent catheters (manufactured by Coloplast Ltd) offered micro-hole zone technology for the UK NHS; the entry of more catheter products with this feature in the future could introduce more variation associated with the price associated with this specific feature.

Table 3: Results from regression modelling (including 838 catheters)

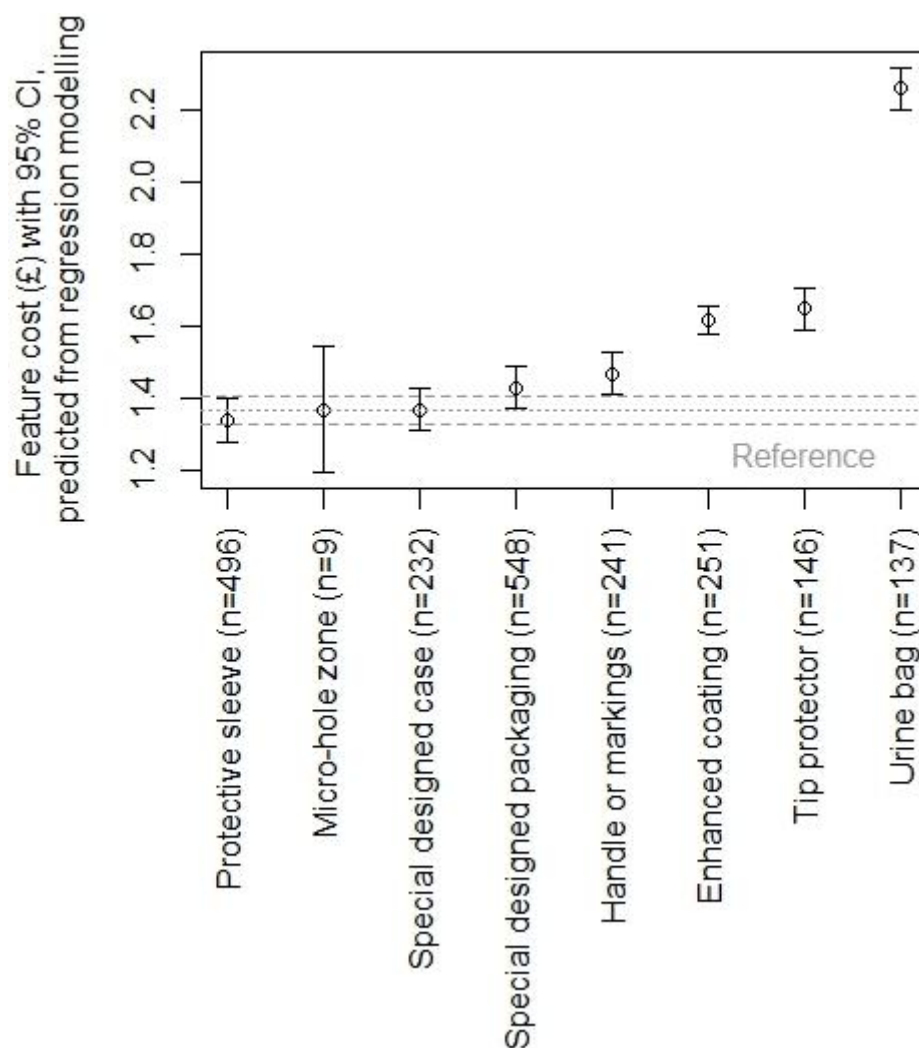
[Note that features statistically significantly associated with the catheter price are presented in bold]

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features “Ref”)	1.37	0.02	-
Male	<i>Ref</i>	-	-
Female	-0.01	0.02	0.46
Unisex	0.18	0.08	0.04*
Standard Nelaton tip	<i>Ref</i>	-	-
Tiemann tip	-0.01	0.03	0.71
Other tip (Coude, Ergothan)	0.06	0.05	0.23
Uncoated: no lubricant provided	<i>Ref</i>	-	-
Uncoated: lubricant provided	0.11	0.07	0.13
Uncoated: pre-lubricated	0.15	0.04	0.0007***
Hydrophilic: no liquid provided	-0.12	0.03	0.0004***
Hydrophilic: liquid provided	-0.03	0.03	0.45
Hydrophilic: pre-activated	0.02	0.04	0.69
No additional features	<i>Ref</i>	-	-
Urine bag	0.89	0.03	<0.0001***
Handle or markings	0.10	0.03	0.0008***
Protective sleeve	-0.03	0.03	0.32
Tip protector	0.28	0.03	<0.0001***
Micro-hole zone	-0.00	0.09	0.97
Enhanced coating	0.25	0.02	<0.0001***

Feature	Price (£)	Std. Err.	p-value
Special designed case	0.00	0.03	0.75
Special designed packaging	0.06	0.03	0.03*

Key: * p-value<0.05, ** p-value< 0.01, *** p-value<0.001

Figure 2: visual representation of results from regression modelling (additional features only)



Due to lack of consensus regarding features of intermittent catheters, and lack of consensus regarding whether coating was an ‘innovative’ feature, the EAG undertook additional exploratory analysis ([Appendix F](#)) to determine the impact of univariate changes in input parameters to the linear regression modelling, including:

- Dichotomising coating: uncoated or hydrophilic.

- Removal of method of lubrication basic product features (uncoated or uncoated, without lubrication, with lubrication, pre-lubricated) included in the model.
- Removal of method of lubrication categories (basic product features) and enhanced coating (additional feature).
- Aggregating integrated handle or markings and insertion sleeve or grip into one feature.
- Dichotomisation of tips (Nelaton/other).
- Including catheters only from manufacturers who responded to NICE or EAG queries as the EAG had higher confidence in features assigned to these catheters.

The EAG noted that the regression was sensitive to changes, however throughout all analyses the integrated urine bag significantly increased catheter price by the largest amount (greater than £0.80 in all analyses). The EAG note that the presence of micro-hole did not significantly increase nor decrease the price in any analysis.

3.3 Shelf-life

The shelf-life of intermittent catheters is around 2 to 3 years, however Clinical Experts advised that most individuals performing intermittent catheterisation would have a new supply each month. Therefore, differences in shelf-life between intermittent catheters was not considered a major concern.

3.4 Training

Intermittent urethral catheterisation needs training (of the user, carer, clinical professional); which will vary by device and by user group. Multiple manufacturers advised that they offer training to healthcare professionals. Multiple manufacturers provide educational materials for patients including videos, anatomy posters, booklets and user guides, with some training materials available online or over the phone. Multiple manufacturers stated that they provide catheters free of charge to clinics to support training. One Clinical Expert advised that teaching intermittent catheterisation is usually done in a hospital setting, or by an outreach hospital team going to community centres; requiring staff resource. Two Clinical Experts advised that there is little variation in training needed between catheter products.

The EAG notes that effective training may have an influence on outcomes. A recent study involving 84 patients with spinal cord injury found that those receiving nurse-led interactive health education (n=44) for 30 days had significantly better urinary management scores, compliance with hydration and bladder training, lower urinary tract infection rates, and higher satisfaction compared with those who only received informational materials (n=40) (Luo et al., 2024). Timing of training did not affect adherence or complication rates in 100 first-time users, but adherence to prescribed catheterisation frequency was linked to a lower infection risk (De Palma et al., 2023). A recent observational study showed that among first-time intermittent catheter users, 75.5% felt capable of performing intermittent catheterisation independently, despite the various settings in which catheterisation was performed (Biscotto et al., 2021). Those results indicate the benefits of tailored, interactive training could potentially improve the outcomes of intermittent catheterisation in bladder emptying.

3.5 Regulatory

The EAG assumed that all devices available on the NHS Drug Tariff have valid and appropriate regulatory documentation in place, therefore the regulatory certification for all 946 devices was not checked. However, the EAG note most devices are classified as Class I sterile, with some catheters being Class IIa (for example: Curan Advantage by CliniMed Ltd). Of two Clinical Experts consulted, both advised that they could not identify patient groups that would be prescribed a higher regulatory class (Class IIa) device.

3.6 Equality considerations

From the 'Instructions for Use' supplied by companies to NICE as part of this late-stage assessment, specific contraindications varied across intermittent catheters and included: high intravesical pressure, poor manual dexterity, poor visual capability, absence of trained caregivers, acute urethritis, acute prostatitis, acute epididymitis, allergies or hypersensitivity to catheter materials and lubricants, urinary stone disease, used in conjunction with irrigation or instillation, acute urinary tract bleeding or injury, patients experiencing difficulty in inserting through urethra. The EAG note that some catheters have design features to overcome some of these issues.

In addition, the EAG noted the following equality considerations:

- Some patient groups that have latex or PVC allergy and may need a catheter made of different materials (such as silicone or polyurethane material), which may limit additional available features.
- Some catheters include features designed to aid catheterisation handling (for example: handles, grippers) which are intended to support people across a range of dexterities, disabilities and impairments; thereby reducing inequalities across intermittent catheter users.
- Catheters that have an integrated bag or can be connected to an external collection bag may provide a better user experience to some patient populations such as those in wheelchairs and those who are bed bound. An integrated bag or connection to an external collection bag would also reduce the need to use an additional container.

Age, gender reassignment, sex and disability are protected characteristics under the [Equality Act \(2010\)](#).

One Clinical Expert emphasised that intermittent catheterisation is the first choice for management of bladder emptying problems, and therefore all potential users should be given the opportunity to try intermittent catheterisation if they wish. One Clinical Expert advised that there may be a lack of access to people who can train the user or carer on how to perform intermittent catheterisation, particularly in rural locations. The EAG consider that this would be applicable across all intermittent catheters.

3.7 Sustainability

None of the evidence included by the EAG reported explicitly on catheter features and their impact on sustainability outcomes. The EAG requested information regarding recyclability of the catheter from the companies (see [Appendix A](#)). Of the 86 catheter product lines available on NHS Drug Tariff: 4 stated that all the product components were recyclable. Additionally, some reported that individual components were recyclable: 5 had a recyclable film pack, 3 had a recyclable case, 1 reported recyclable bottom half of the case, 1 recyclable handle, 7 recyclable tip protector, 7 stated a recyclable product box. It is unclear to the EAG whether the recyclable components of all intermittent catheters are explicitly marked to users. One company provided a carbon footprint for one intermittent catheter product line.

Most catheters used for clean intermittent catheterisation are single-use and made from non-biodegradable, non-recyclable plastics, contributing to long-lasting waste in landfills in the UK. The EAG identified the study by Sun et al. which estimated the environmental impact of single-use intermittent catheters in the US across neurogenic bladder diagnoses (multiple sclerosis, spina bifida and spinal cord injury) assuming 5 catheters used each day (Sun et al., 2018). This study reported that single-use intermittent catheters generated an equivalent of 206 million litres of waste annually in the US (more than 26,000 cars). This study acknowledged the different catheter materials (PVC, polyurethane, latex, silicone, polyolefin-based elastomer) and the different lengths of time it took each to degrade. However, it is unclear whether these estimates accounted for packaging, drainage bags, and other materials used for intermittent catheterisation. Other environmental factors to consider which may differ between intermittent catheters are raw material extraction, manufacturing processes, and resources needed for the management of catheter-associated infections.

3.8 Protocol deviations

Within the published protocol the EAG stated that presence of intermittent catheter features would be obtained directly from companies and would not be verified by the EAG. The EAG initially identified the presence of features (as listed in the NICE Final Scope) across all catheter product lines using information provided by companies (which included completed requests for information, instructions for use, patient brochures) and then asked companies to confirm the features attributed by the EAG. Responses obtained from companies identified that the catheter features, as listed in the NICE Final Scope, were open to interpretation and applied inconsistently across manufacturers. Two reviewers (EB, KK) subsequently went back through instructions for use and information on company websites for each catheter product line in order to ensure that assignment of features were applied consistently.

3.9 Summary

The EAG identified 849 intermittent catheters from 20 manufacturers which were prescribed in the NHS within the 2023/24 financial year. Product information (including presence of features) is lacking from NHS Drug Tariff. The EAG identified the presence of catheter features (which were listed in the NICE final scope) across intermittent catheter product lines from information provided by the company (responses gained from 12 manufacturers during the assessment), company

websites and published literature. However, the catheter design and features across each intermittent catheter product line was generally poorly described and open to interpretation which may have resulted in mis-categorisation by the EAG. Due to missing information, a total of 838 intermittent catheter products, across 86 catheter product lines from 17 manufacturers was included in the EAG analysis.

The EAG explored intermittent catheter price variation through multivariate regression modelling, where it found that the price was associated with the presence of all features, except for micro-holes which were not statistically associated with catheter price across any exploratory analysis. The EAG also acknowledge that the regression model may be affected by clustering if price depends on the manufacturer and because some manufacturers have more catheter product lines; whereby they contribute more to the analysis than others.

This analysis presented by the EAG centred on publicly available sources and represents the intermittent catheterisation products that were available for the NHS at the time of review; thus representing contemporaneous NHS practice. Moreover, the number of catheter products assessed was large enough to allow for a regression analysis that generated informative evidence on the impact of catheter features (including those considered additional features as listed within the scope) in the price of a representative sample of catheter products in the UK.

One Specialist Committee Member and members of the University of Southampton Bladder and Bowel management research group shared with the EAG two days before final report submission their independent categorisation of features for all intermittent catheters available on the Prescription Cost Analysis, which was based on information available on company website and physical review of sample catheters (where provided by manufacturers). This work is ongoing has been shared with and utilised by the modernising section IX of the Drug Tariff project. While there was no time to include this within the EAG report, the independent and clinically informed intermittent catheter feature categorisation led by the Specialist Committee Member and their team could be considered in future analysis to determine the impact on regression analysis, CNMA and economic analysis.

4 Clinical evidence

This late-stage assessment (LSA) evaluates the evidence for single-use intermittent urethral catheters in long-term urinary management for adults, focusing on whether the additional features justify price variations and which features offer value for money for the NHS.

4.1 *Methods*

4.1.1 Search methods

The search methods used were those outlined in the published [protocol](#). Briefly, we searched for:

- Systematic reviews of controlled comparative studies published since the relevant Cochrane review (Prieto et al., 2021), found during preliminary scoping, in MEDLINE, Embase, Cumulated Index in Nursing and Allied Health Literature (CINAHL). The Cochrane Database of Systematic Reviews, the Trip Database and the International Health Technology Assessment database (INAHTA) had already been searched during preliminary scoping work. The search for relevant systematic reviews was primarily aimed at identification of relevant primary studies within them sooner than searching for the primary studies directly. These prioritised records could then move through to data extraction while the second set of searches was performed.
- Controlled comparative studies published since the date of last search for the Prieto 2021 Cochrane review (1 January 2021 to the most recently available record in each database at the time of the search) in MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL and INAHTA. Due to Clinical Experts advising that some features were introduced as early as the year 2000, the EAG also searched for controlled comparative studies published between 1 January 2000 to 31 December 2020 in MEDLINE, Embase, CENTRAL, CINAHL and INAHTA.

For full details of the searches along with the search strategies please see [Appendix B](#).

Studies were also sought from the following additional sources:

- The EAG also reviewed primary evidence contributing to systematic reviews comparing intermittent catheters to determine whether any of the included catheters had any additional features (as listed in Table 1).
- Relevant evidence provided by the Companies.

The EAG prioritised published peer-reviewed comparative publications; and while ongoing studies were identified by the EAG, these were not sifted within the timescales provided.

4.1.2 Study selection

The EAG only included evidence on catheters where the additional features were verified by the company (questions sent to companies from NICE). Any evidence where the comparator catheters were not explicitly named or were not currently available on the Drug Tariff available to the NHS (and therefore unable to verify device features with the company) were excluded. The EAG considered evidence where the intervention or comparator arm included a mixture of catheters with different features. For those studies which did not report outcomes separately for each catheter, the EAG attributed outcomes to the catheter which was used in most of cases. Studies were excluded if multiple catheters were used in the same arm, and the proportion of each was not reported (as this prevented the EAG assigning catheter features). As the decision problem is focused on single-use intermittent catheters, the EAG did not consider evidence comparing single-use and multi-use intermittent catheters. The EAG considered that catheters without any additional features ([Appendix A](#)) were basic technology catheters and therefore all evidence comparing basic intermittent catheters against each other was excluded from analysis. The EAG excluded any evidence undertaken exclusively in healthy volunteers (individuals who would not routinely be prescribed intermittent catheters). However, due to the limited evidence base the EAG included evidence where the population included a mix of both healthy volunteers and intermittent catheter users.

Due to a general lack of detail in the published studies, the EAG did not exclude evidence from any study setting (inpatient, outpatient, community and so on). The individual performing the catheterisation (self, carer or healthcare professional) was extracted where available, due to its potential to influence outcomes.

The EAG excluded any comparative studies including fewer than 10 patients, single arm studies (including case reports, case series), bench tests, animal studies, narrative reviews, letters, editorials and any studies where the full paper was not available in the English language. The EAG only extracted adverse event data which were considered by the reporting authors as attributable to the catheter; the EAG acknowledge that this approach may introduce bias as these may be selectively or inconsistently reported.

Critical appraisal of included studies was undertaken by the EAG using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials (Higgins et al., 2011), and the Critical Appraisal Checklist for Cohort Studies (Joanna Briggs Institute, 2017) by a single reviewer (sample reviewed by a second reviewer), [Appendix C2](#). For a consistency check, the EAG broadly compared their risk of bias assessment with those reported by other systematic reviews that included the same primary evidence (Health Quality Ontario, 2019; Prieto et al., 2021; Rognoni & Tarricone, 2017b; Shamout et al., 2017). The EAG also provided a narrative summary of the quality of evidence.

4.1.3 Data extraction

Study characteristics

Data was extracted from included studies reporting clinical outcomes into a bespoke table to enable descriptive statistics, including study design, setting, eligibility criteria, population characteristics, intervention characteristics (see below for further details) and list of outcomes where results are reported. Data was extracted from included studies reporting on economic outcomes into a bespoke table to enable descriptive statistics, including model design, setting, time horizon, intervention and comparator characteristics, and key findings.

Results were extracted from included clinical studies for each outcome listed in the Final Scope. Complex evidence synthesis (component network meta-analysis, CNMA) was considered for the top two prioritised outcomes outlined by Clinical and Lay Experts (see [Appendix D](#), question 6). For cross-over trials, estimates from regression analyses adjusting for patients receiving both intervention and comparator were preferred over unadjusted analyses.

Coding of standard and additional features

The EAG categorised each catheter by coating and lubrication method, and also considered the catheter features which were listed in the NICE Final Scope (Table 1), which were then developed into a matrix. The EAG's features matrix was iteratively updated during the data extraction, based on evidence from included studies. Intervention components analysis (Sutcliffe et al., 2015), a pragmatic method for inductively categorising intervention features, was applied during the data extraction stage to identify any new additional features not currently included in the EAG's matrix (features based on those listed in the scope, and input from Clinical and Lay Experts). Where possible, the EAG searched company websites, and requested information from companies, to identify the specific features associated with relevant intermittent catheters. One reviewer coded intermittent catheter features based on free-text descriptions of interventions using this matrix; a second reviewer checked a 10% sample of papers. Where specific products were explicitly named, the EAG were guided by this product information when coding intervention features. For example, where not all features of the intermittent catheter were comprehensively described in the paper, the EAG assumed features based on known product information. As catheter choice should be a joint decision made between clinician and patient, the EAG shared the compiled list of features with Clinical and Lay Experts to determine whether each feature listed would be likely to be considered in decision making when selecting an intermittent catheter ([Appendix D](#)).

4.1.4 Component network meta-analysis (CNMA)

Standard meta-analysis and network meta-analysis have become a foundational aspect of health technology assessment. These analyses help estimate the effectiveness of specific products or interventions in comparison with standard care. However, there are limitations in the application of these methods to complex interventions with multiple, potentially interacting, features. A component network meta-analysis (CNMA) (Freeman et al., 2018; Welton et al., 2009) approach extends the principles of meta-analysis and network meta-analysis to identification of “active ingredients” or effective features shared by complex interventions. Since this late-stage assessment (LSA) aims to identify effective features, rather than the effectiveness of specific products or interventions, the EAG considered CNMA a

potentially appropriate statistical technique to assess whether price variations between technologies are justified by these additional features.

4.1.4.1 Feasibility

The EAG assessed the feasibility and appropriateness of conducting CNMA, based on whether there were sufficient data across outcomes to inform reliable estimates and whether studies were sufficiently comparable to be included in the same analyses. The EAG considered CNMA for outcomes listed in the Final Scope which were prioritised by Clinical and Lay Experts (UTI, haematuria, residual volume, discomfort or pain, ease of use). The EAG assessed how each included study reported on these outcomes, and whether they were sufficiently comparable to combine in the CNMAs. Where possible the EAG standardised data onto common metrics to make best use of data. The EAG also assessed comparability of population characteristics for included studies available for each outcome including setting, and who undertook the catheterisation.

Second, the EAG assessed whether it was possible to assemble a connected network of features for each relevant outcome. In the case of a connected network, the EAG assessed whether there was sufficient data for each feature and combination of features (using a rule of thumb of five studies assessing a feature or combination of features).

These judgments were informed by visual assessment of the distribution of intervention features and population characteristics of included studies based on data extraction tables for each outcome.

4.1.4.2 Statistical analyses

Where further analysis was deemed feasible, CNMA was performed in a Bayesian framework with a random-effects model using WinBUGS/OpenBUGS (MRC Biostatistics Unit, Cambridge, UK) considering the correlation between multi-arm trials when appropriate, [Appendix E](#). However, where data were insufficient to reliably estimate between-study heterogeneity, we compared the goodness of fit of fixed-effect and random-effects models and selected the better-fitting model (based on total residual deviance and deviance information criterion). If both models fitted equally well, we selected the simpler model. The EAG analyses were based on

adaptations of published WinBUGS code for conducting CNMA (Freeman et al., 2018).

A binomial likelihood was used for dichotomous data and a normal likelihood for continuous data and treatment differences (that is, standardised mean differences or log-odds ratios). We assumed a common between-study heterogeneity variance of the relative treatment effects across all treatment comparisons. We used vague prior distributions for trial baselines, heterogeneity (where applicable) and relative treatment effects. Network geometry was illustrated using network diagrams and convergence of two chains was assessed through visual inspection of history, Brooks–Gelman–Rubin and autocorrelation plots.

Intervention effects were estimated along with 95% credible intervals (CrIs). Continuous outcomes were pooled mean differences (MDs) on natural units where possible. Otherwise, we used standardised mean differences (SMDs). For dichotomous data, we reported relative risks (RR) with 95% CrIs for ease of interpretation.

4.1.4.3 Confidence in Network Meta-analysis (CINeMA)

The EAG used the CNMA (CINeMA) approach to assess the certainty in the results from the component network meta-analysis (Salanti et al., 2014); (Nikolakopoulou et al., 2020). CINeMA is based on the GRADE framework for assessing the certainty of the body of evidence and involves assessing the following six domains: within-study bias (the impact of risk of bias of the included trials); reporting bias (the impact of missing studies, outcomes and results); indirectness; imprecision; heterogeneity; and incoherence. Each domain (except 'reporting bias') is judged to have no concerns, some concerns, or major concerns. 'Reporting bias' is judged as 'suspected' or 'undetected'. Judgements across the six domains are summarised to obtain four levels of confidence for each relative treatment effect: very low, low, moderate, or high.

CINeMA allows for semi-automated judgments based on frequentist methods, however the EAG checked the validity of these judgments with their Bayesian analyses. Given that frequentist and Bayesian approaches (with vague priors) are usually in agreement, the EAG considered the use of CINeMA to assess the certainty of evidence to be appropriate.

4.1.5 Protocol deviations

In the published [protocol](#) the EAG stated that they would search for ongoing studies in ClinicalTrials.gov and World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and would prioritise studies undertaken in a UK setting if there were more than 10 ongoing studies identified that were relevant to the decision problem. These searches were undertaken but not screened as the focus of this late-stage assessment (LSA) was on completed studies (using published results to inform subsequent evidence synthesis and economic impact of applying those results) rather than identification of ongoing studies. For completeness we present details of the searches of ongoing studies and the number of records identified in [Appendix B3](#). Given the limited data available for all outcomes, the EAG did not restrict analysis to features which had a minimum of five studies (original intention) but instead commented on any issues with imprecision in the text and used the Confidence In Network Meta-Analysis (CINeMA) ratings (see 4.1.4.3 for further details).

The EAG also planned to compare the goodness of fit of several models (based on the categories proposed by (Welton et al., 2009) and (Freeman et al., 2018)) including:

- Independent effects model (additive) where each feature is assumed to have an independent impact on outcome compared with standard features alone.
- Interaction model (combined) to assess the effectiveness of a priori combinations of features based on expert opinion from clinicians and patients.

Both types of models were fitted, where possible. However, due to limited data, CNMA could not be used for some outcomes (for example, ease of use). For other outcomes, only independent effects models were reported, as interaction models were not feasible (for example analyses of haematuria, and comfort). The EAG took a pragmatic approach of assessing the effectiveness of either individual features, or combinations of features separately for each outcome. This was guided by the data based on available in the included studies and reference to Table 1, which outlines the intended benefits of each of the features in question.

Where sufficient data were available, the EAG planned to assess the impact of including additional covariates to adjust for potential confounding (for example individual performing self-catheterisation, setting, the patient having a neurogenic or

non-neurogenic indication). However, there was very limited data for most outcomes, therefore these analyses were not possible to conduct. The EAG noted that total duration of intermittent catheterisation was inconsistently reported and therefore the evidence may include short-term and long-term intermittent catheter users. The EAG had also intended on conducting subgroup analysis (by gender, by groups requiring life-long catheterisation, people with UTIs or being significantly vulnerable to UTIs, people with mobility or cognitive impairment, and where intermittent catheterisation was undertaken by carers and others rather than patients themselves); however due to limited evidence, which was further restricted when conducting CNMA, the EAG felt that subgroup analysis was not feasible.

4.2 Results

A total of 396 systematic reviews of controlled comparative studies were identified, 263 remained following removal of duplicates ([Appendix B1a](#)). A single reviewer (KB) reviewed the title and abstract of 263 records (minimum 10% sample was reviewed by a second reviewer, KK). Of the 262 studies 8 were included for full paper retrieval. Following review of the studies included across those 8 systematic reviews, the EAG subsequently included a total of 8 studies as primary evidence as relevant to the decision problem of this late-stage assessment ([Appendix B4](#)).

A total of 1500 controlled comparative studies published on or after 01 January 2021 were identified, 1128 remained following removal of duplicates ([Appendix B1b](#)). A single reviewer (KK) reviewed the title and abstract of 1128 records (minimum 10% sample was reviewed by a second reviewer, KB), of which 29 were included for full paper retrieval. Following full paper review by two reviewers (KK, PL), a total of 6 studies were subsequently included ([Appendix B4](#)). A total of 4070 comparative studies were published between 01 January 2000 and 31 December 2020 ([Appendix B1c](#)). Of the 4,070 records, the EAG prioritised screening of 1,401 records which mentioned “intermittent catheter” in the title or abstract (with catheter* being any word starting with the stem catheter - allowing for plurals as well as different spellings of catheterization or catheterisation) first and screened the remaining 2,669 after this. This approach enabled parallel data extraction of eligible studies. A single reviewer (RO) reviewed the title and abstract of 4070 records (minimum 10% sample was reviewed by a second reviewer, KB), of which 80 were included for full paper

retrieval. Following full paper review (KK) a total of 10 studies were subsequently included ([Appendix B4](#)).

A total of 144 pieces of evidence (excluding clear marketing or technical/clinical guidelines) were submitted by companies; of which 6 were duplicates from more than one company. The resulting 138 items included company reports, academic-in-confidence and commercial-in-confidence papers, conference abstracts and posters, published papers, and items lacking clarity in the title requiring further evaluation. All 138 items were reviewed by a single reviewer (PL), of which 116 were excluded (animal, in vitro or bench studies; marketing material in graphical form lacking data; clinical guidelines; narrative reviews; single-arm user evaluation reports which were not submitted to peer-reviewed journals; and items lacking detail to enable retrieval of the full work). A total of 13 comparative and 9 economic studies submitted by the companies were considered relevant to the decision problem ([Appendix B4](#)).

Following its review of clinical evidence, the EAG included a total of 18 unique comparative studies (19 were considered duplicates across the different sources; ([Appendix B4](#))). The EAG reviewed and excluded a total of 264 studies, [Appendix C5](#).

4.2.1 Included studies

Across the 18 included studies, **Table 4**, the features of the interventions and comparators varied across studies, and some studies compared more than 2 catheters. The EAG note that many catheters have multiple features, therefore, the aims outlined in each paper may not represent all differences between catheters.

Table 4: Summary of included comparative clinical studies (n=18)

[Note age reported in years and BMI in kg/m2, both reported as mean (SD), median [Q1,Q3] unless otherwise stated; blue columns refer to coating and method of lubrication; green columns refer to catheter features for each intervention (I) and comparator (C) which were numbered consecutively in cases where multiple interventions or comparators were included in the study; bold text indicates short hand used to summarise the coating and lubrication method, and features which will be used in later analyses]

#	Study (year); Country	Study design (n patients) [length of follow-up]	Indication for intermittent catheterisation	Demographic summary	Setting (who conducts catheterisation)	Intermittent catheterisation (IC) summary (patient history)	Interventions (I)	Comparator (C)	Uncoated (Lubricant not provided) (U1)	Uncoated (provided with a lubricant source) (U2)	Uncoated (pre-lubricated) (U3)	Hydrophilic coating (liquid not provided) (H1)	Hydrophilic (provided with water to activate the coating) (H2)	Hydrophilic (pre-activated) (H3)	Integrated drainage bag (f1)	Integrated handle or markings (f2)	Insertion sleeve or grip (f3)	Tip protector or introducer (f4)	Micro-hole zone technology (f5)	Enhanced coating (f6)	Specially designed catheter case (f7)	Specially designed packaging (f8)
1.	Athanasiaou (Nephrology Dialysis Transplantation, 2023; i250); Abstract/Poster Denmark	In vitro study; samples taken from 3 trials (Landauro et al. 2023) [Follow-up not reported]	Healthy volunteers (n=30); Intermittent catheter users (n=29; neurogenic dysfunction: 62%, non-neurogenic dysfunction: 38%)	Age: IC users: [range 21 to 82] Healthy controls: [range 20 to 57] Male:50%	Sample obtained in hospital setting	NR (minimum 3 months as per study eligibility criteria)	Micro-hole zone catheters (2 prototypes of Luja)	SpeediCath Male/Female	-	-	-	-	-	I,C	-	I	I	I	I	I,C (pre-activated)	I	I,C
2.	Biering-Sørensen (Spinal Cord, 1999; 299-300); Denmark	Cross-over RCT (n=20) [Follow-up: 24h for each catheter]	Spinal cord lesions	Age, male: 53 [27-69] Age, female: 45 [17-48] Male: 70%	NR (assumed inpatient setting)	IC performed average 5 times per day [range: 4 to 10] Median IC duration, male: 4 months [1 month to 7 years] after spinal cord lesion; female: 8 months [2 to 16 months] after spinal cord lesion.	LoFric	EasiCath	-	-	-	C,I	-	-	-	-	-	-	-	I (low osmolality)	-	-
3.	Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321); Brazil	Cross-over design (4 catheters qualitatively evaluated in randomised order) (n=32), [Follow-up: 1 day]	NR	Age: 54.2 [range: 32-76] Male: 84%	Community	IC duration: 6.28 (5.46) [0 to 25.6] years Catheters per day: - four (21.9%) - five (31.2%) - six (34.4%) - seven (6.2%) - eight (6.2%)	Actreen Lite (I1) SpeediCath Standard (I2) LoFric Primo (I3)	Conventional uncoated PVC catheter	C	-	I1	-	I3	I2	-	I1	I1,I3	-	-	I2 (pre-activated), I3 (low osmolality)	I1	I1,I2
4.	Cardenas (PM&R, 2011; 408-417); US, Canada	RCT (n=224) [Follow-up: maximum 6 months study period,	Neurogenic bladder dysfunction due to traumatic spinal cord injury	Age: intervention 37.2 (14.4), comparator 35.1 (13.2) Male: intervention 79%, comparator 82%	Rehabilitation unit or acute care followed by community (healthcare professional and self-	Median IC duration: intervention 5 [2,7] days, comparator [2,8] days	SpeediCath	Conveen (assumed the same as EasiCath; uncoated with no features)	C	-	-	-	-	I	-	-	-	-	-	I (pre-activated)	-	I

#	Study (year); Country	Study design (n patients) [length of follow-up]	Indication for intermittent catheterisation	Demographic summary	Setting (who conducts catheterisation)	Intermittent catheterisation (IC) summary (patient history)	Interventions (I)	Comparator (C)	Uncoated (Lubricant not provided) (U1)	Uncoated (provided with a lubricant source) (U2)	Uncoated (pre-lubricated) (U3)	Hydrophilic coating (liquid not provided) (H1)	Hydrophilic (provided with water to activate the coating) (H2)	Hydrophilic (pre-activated) (H3)	Integrated drainage bag (f1)	Integrated handle or markings (f2)	Insertion sleeve or grip (f3)	Tip protector or introducer (f4)	Micro-hole zone technology (f5)	Enhanced coating (f6)	Specially designed catheter case (f7)	Specially designed packaging (f8)
		maximum 3 months in the community]		Paraplegic: intervention 57%, comparator 56% Tetraplegic: intervention 43%, comparator 44%	catheterisation or by caregivers)																	
5.	Cardenas (Arch Phys Med Rehab, 2009; 1668-1671)	RCT (n=56) [Follow-up: 12 months]	Spinal cord injury	Age, intervention: 42.3 (10.4); comparator: 40.1 (9.3). Male, intervention: 77%, comparator: 52%.	Community (implied self- or carer-catheterisation)	NR	LoFric	Uncoated standard	C	-	-	-	-	I	-	-	-	-	-	I (low osmolality)	-	-
6.	Chartier-Kastler (Spinal Cord, 2011; 844-850) France, Denmark	Cross-over RCT (n=36) [Follow-up: 14± 2 days in each arm]	Traumatic spinal cord lesion 66.7%; Non-traumatic spinal cord lesion 33.3%	Median age: 43.2; [range: 20 to 70] Male: 100% BMI: NR Mobility: - 16.7% walking - 33.3% walking with aids - 50.0% wheelchair	Community (self-catheterisation)	Median IC duration, 39 months [range: 1 to 219] Median catheters per day 6.0 [range: 4 to 10]	SpeediCath Compact Male	SpeediCath Male	-	-	-	-	-	I,C	-	I	-	-	-	I,C (pre-activated)	I	I,C
7.	De Ridder (Eur Urol, 2005; 991-995); Spain, Belgium	RCT (n=123) [Follow-up: 12 months]	Spinal cord injury	Age: intervention 37.5 (14.6), comparator 36.7 (14.6) Male: 100%	Community Hospital and community (self or carer) (NR)	IC was method of bladder management in 33% of intervention arm, and 27% in comparator arm Mean catheters per day: intervention 3.4, comparator 3.6	SpeediCath	Conveen (assumed the same as EasiCath; uncoated with no features)	C	-	-	-	-	I	-	-	-	-	-	I (pre-activated)	-	I
8.	Domurath (Spinal Cord, 2011; 817-821); Germany	Cross-over RCT, non-inferiority (n=37) [Follow-up: 5 to 8 days each arm]	Spinal cord injury	Age: 40 [range 21 to 66] Male: 100% All users had paraplegia (none had tetraplegia)	Community (self-catheterisation)	IC duration: 88.7 [range 2 to 264] months Mean catheters per day: 5.3 [range 4 to 10]	SpeediCath Compact Male	SpeediCath Male	-	-	-	-	-	I,C	-	I	-	-	-	I,C (pre-activated)	I	I,C
9.	Gopalakrishnan (Continence Reports, 2022; 100010); Canada	Cross-over RCT, pilot (n=20). [Follow-up: 5 to 10 days]	Spinal cord injury	Age: 45 [range 26 to 65] 55% paraplegic	Self-catheterisation, in clinic while timed by investigator in clinic or self-catheterisation	NR	SpeediCath	Self-Cath with lubrication jelly	C	-	-	-	-	I	-	-	-	-	-	I (pre-activated)	-	I

#	Study (year); Country	Study design (n patients) [length of follow-up]	Indication for intermittent catheterisation	Demographic summary	Setting (who conducts catheterisation)	Intermittent catheterisation (IC) summary (patient history)	Interventions (I)	Comparator (C)	Uncoated (Lubricant not provided) (U1)	Uncoated (provided with a lubricant source) (U2)	Uncoated (pre-lubricated) (U3)	Hydrophilic coating (liquid not provided) (H1)	Hydrophilic (provided with water to activate the coating) (H2)	Hydrophilic (pre-activated) (H3)	Integrated drainage bag (f1)	Integrated handle or markings (f2)	Insertion sleeve or grip (f3)	Tip protector or introducer (f4)	Micro-hole zone technology (f5)	Enhanced coating (f6)	Specially designed catheter case (f7)	Specially designed packaging (f8)
					n while timed by investigator																	
10.	Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50), [Follow-up: 7 days]	NR	Age: 44.8 (14.1) Male: 72%	Community (self-catheterisation)	IC duration: 10.3 (7.3) years	Actreen Glys	SpeediCath Compact	-	-	I	-	-	C	I,C	I,C	I	-	-	C (pre-activated)	C,I	C
11.	Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]; the Netherlands	Cross-over RCT; 3 arm study (n=72), [Follow-up: 4 weeks per catheter]	Spinal cord lesion (n=66); spina bifida (n=4); multiple sclerosis (n=2)	Male: 70.8% Hand function: • 90.3% good • 4.2% fairly • 1.4% decreased • 4.2% strongly decreased	Community (self-catheterisation)	NR	SpeediCath	LoFric (C1), EasiCath (C2)	-	-	-	C1,C2	-	I	-	-	-	-	-	C1 (low osmolality), I (pre-activated)	-	I
12.	Landauro (J Wound Ostomy Continence, 2023; 504-511), Denmark	3 cross-over RCTs combined (n=59), [Follow-up: 3 single visits]	Healthy volunteers (n=30); intermittent catheter users (n=29; neurogenic dysfunction: 62%, non-neurogenic dysfunction: 38%)	Age: IC users: [range 21 to 82] Healthy controls: [range 20 to 57] Male: 50%	Hospital, self-catheterisation and catheterisation by healthcare professional	NR (minimum 3 months as per study eligibility criteria)	Micro-hole zone catheter	SpeediCath Flex SpeediCath Standard	-	-	-	-	-	I,C	-	I,C	I,C	I,C	I	I,C (pre-activated)	I,C	I,C
13.	Landauro (J Clin Med, 2023; 5266); Denmark	Cross-over RCT (n=42), [Follow-up: 3 visits]	Non-neurogenic bladder dysfunction (69%), neurogenic bladder dysfunction (31%)	Age: mean 68 [range 41 to 87] Male: 100%	Hospital (healthcare professional)	NR	Micro-hole zone catheter	VaPro	-	-	-	-	-	I,C	-	I,C	I,C	I,C	I	I (multiactivation; pre-activated), C (Proprietary process of coating; pre-activated)	I	I,C
14.	Pascoe (Br J Nurs, 2001; 325-329); UK	Cross-over RCT (n=27), [Follow-up: 7 days]	Multiple sclerosis, voiding dysfunction secondary to back injury, spina bifida	Dexterity: 91.7% (22/24) had full use of both hands	Community	IC duration: [range 1 to 5 years] Mean catheters per day: 3.8 [range 2 to 9]	SpeediCath	LoFric	-	-	-	C	-	I	-	-	-	-	-	I (multiactivation; pre-activated), C (low osmolality)	-	I

#	Study (year); Country	Study design (n patients) [length of follow-up]	Indication for intermittent catheterisation	Demographic summary	Setting (who conducts catheterisation)	Intermittent catheterisation (IC) summary (patient history)	Interventions (I)	Comparator (C)	Uncoated (Lubricant not provided) (U1)	Uncoated (provided with a lubricant source) (U2)	Uncoated (pre-lubricated) (U3)	Hydrophilic coating (liquid not provided) (H1)	Hydrophilic (provided with water to activate the coating) (H2)	Hydrophilic (pre-activated) (H3)	Integrated drainage bag (f1)	Integrated handle or markings (f2)	Insertion sleeve or grip (f3)	Tip protector or introducer (f4)	Micro-hole zone technology (f5)	Enhanced coating (f6)	Specially designed catheter case (f7)	Specially designed packaging (f8)
15.	Sarica (Eur J Phys Rehab Med, 2010; 473-480); Turkey	Cross-over RCT; 3 arm study (n=25), [Follow-up: 6 week per catheter type]	Spinal injury	Age: mean 37.0 (11.9) Male: 100% Paraplegia/paraparesis: 84% Tetraplegia: 16%	Inpatient setting (self-catheterisation)	NR (spinal injury within 6 months)	Flocath Intro-Gel (I1), Flocath Hydro Gel (I2)	Standard PVC (with water soluble lubricant)	C	-	I1	I2	-	-	I1	I1	I1, I2	I1	-	-	I1	I1,I2
16.	Thiruchelvam (Br J Nursing, 2024; 834-843); Denmark, UK, France	Cross-over RCT (n=82), [Follow-up: approx. 2 weeks each arm]	Mixed (72% neurogenic lower urinary tract dysfunction)	Age: 54 [range: 24 to 78] Male: 0% BMI: 27.5 (8.2) Mobility: • 69.1% walking • 23.5% walking with difficulty/aids • 7.4% use of a wheelchair	Community (healthcare professional and self-catheterisation)	NR (at least 1 month from study eligibility criteria)	Micro-hole catheter	Conventional eyelet catheter (undefined; assumed SpeediCath Compact Eve)	-	-	-	-	-	I,C	-	I,C	I	I	I	I,C (multiactivation; pre-activated)	I,C	I,C
17.	Thiruchelvam (Neurourology Urodynamics, 2024; 464-478); Denmark, France, Germany, UK	Cross-over RCT (n=73), [Follow-up: 4 weeks in each arm]	Mixed (62% neurogenic bladder dysfunction)	Age: 64 [range: 28 to 87] Male: 100% Urethral sensation: • Normal: 79% • Impaired 19% • Hypersensitive 1%	Community (self-catheterisation and healthcare professional for some outcomes)	NR (minimum 2 months self catheterising from study eligibility)	Micro-hole catheter	95% SpeediCath Flex, 5% VaPro (assumed features from SpeediCath)	-	-	-	-	-	I,C	-	I,C	I,C	I,C	I	I,C (multiactivation; pre-activated)	I,C	I,C
18.	Waller (Spinal Cord, 1997; 229-233) Sweden	Cross-over RCT (n=14). [Follow-up: 10 days per arm]	Spinal cord injury	Age: median 30 [22 to 62] Male: 100% Paraplegia: 36% Tetraplegia: 57% Spinal paralysis: 7%	Hospital (the same nurse performed all catheterisations).	NR (post-injury time spanned from 5 days to 5 months).	LoFric	EasiCath	-	-	-	C,I	-	-	-	-	-	-	-	I (low osmolality)	-	-

Abbreviations: BMI, body mass index; C, Comparator; I, Intervention; IC, Intermittent catheterisation; ISC, intermittent self-catheterisation; NR, not reported; PVC, Polyvinyl chloride; RCT, Randomised Controlled Trial.

4.2.2 Quality appraisal of clinical evidence

Across the 18 comparative studies, the following study designs were used:

- 12 cross-over RCTs (Biering-Sørensen et al., 1999; Chartier-Kastler et al., 2011; Domurath et al., 2011; Gopalakrishnan et al., 2022; Koenen & Van Kuppevelt, 2004; Landauro et al., 2023a; Landauro et al., 2023b; Pascoe & Clovis, 2001; Sarica et al., 2010; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b; Waller et al., 1997) of which 1 was a combination of 3 trials (Landauro et al., 2023b) and 1 was a pilot (Gopalakrishnan et al., 2022).
- 3 RCTs (Cardenas & Hoffman, 2009; Cardenas et al., 2011; De Ridder et al., 2005);
- 1 cross-sectional study which randomised the order of 4 catheters to a cohort of patients and qualitatively evaluated them (Bonello et al., 2021);
- 1 prospective comparative cohort describing the use of one catheter and then another after (Gregghi et al., 2022);
- 1 in vitro study of drained samples obtained from 3 clinical trials (Athanasiadou et al., 2023) assuming same patient population as reported in Landauro (Landauro et al., 2023b). This study was evaluating drainage of sediment through micro-holes and therefore the EAG considered this study relevant to the decision problem as may lead to increased adverse events (see intended benefit listed in Table 1).

Two studies were available in abstract or poster form only (Athanasiadou et al., 2023; Koenen & Van Kuppevelt, 2004).

The EAG note that the maximum sample size was 224 participants, minimum 14; with 9 studies (50%) including less than 50 participants.

The EAG note that the intermittent catheter feature of focus varied across the included studies, Table 5:

- Hydrophilic coating compared with uncoated or gel-lubricated in 6 studies (Cardenas & Hoffman, 2009; Cardenas et al., 2011; De Ridder et al., 2005; Gopalakrishnan et al., 2022; Gregghi et al., 2022; Sarica et al., 2010);

- Type of hydrophilic coating in 1 study (Waller et al., 1997);
- Micro-hole zone technology in 5 studies (Athanasiadou et al., 2023; Landauro et al., 2023a; Landauro et al., 2023b; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b);
- Compact catheter case in 2 studies (Chartier-Kastler et al., 2011; Domurath et al., 2011);
- Ready to use, that is a catheter which does not need additional preparation and consider ready for insertion straight from the packaging, in 2 studies (Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001);
- Multiple catheter features were investigated across multiple catheters, including easy to open packaging (Bonello et al., 2021);
- No specific intermittent catheter feature was reported in 1 study (Biering-Sørensen et al., 1999).

The EAG note a difference between the feature of focus (hypothesis tested) of the study and the features present within that study, Table 5. The aim of the majority of studies was to compare coated and uncoated catheters.

The comparator varied across studies, including basic technology catheters with no additional features and those with a mixture of features, Table 4. Follow-up varied across included studies between 1 day and 1 year. Critical appraisal identified a high risk of bias in at least one domain across all RCTs. Most RCTs were open-label or unblinded to the person conducting the catheterisation (Cardenas & Hoffman, 2009; Cardenas et al., 2011; Chartier-Kastler et al., 2011; De Ridder et al., 2005; Domurath et al., 2011; Gopalakrishnan et al., 2022; Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b; Waller et al., 1997) which have been considered at high risk of bias. However, the EAG acknowledges that it is difficult to blind users to the method of lubrication and features of some catheters. Although this is an important risk of bias, it is a bias shared across studies and therefore does not favour any product or feature over others. For the randomised trials, sample sizes were powered to detect differences

in: urinary tract infection (UTI; (Cardenas & Hoffman, 2009; Cardenas et al., 2011; De Ridder et al., 2005)), discomfort measured using the Visual Analogue Scale (VAS; (Chartier-Kastler et al., 2011)), residual urine volume (non-inferiority; (Domurath et al., 2011)) and residual volume of urine at the first flow-stop (Landauro et al., 2023a; Landauro et al., 2023b; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b). Furthermore, one study used a convenience sample for a pilot RCT (Gopalakrishnan et al., 2022), and another one study reported not conducting a power calculation prior to the start of the study (Sarica et al., 2010). Power calculations were not explicitly reported in 5 studies (Biering-Sørensen et al., 1999; Bonello et al., 2021; Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001; Waller et al., 1997).

Population characteristics varied across studies:

- 9 studies included only patients with spinal cord injury (Biering-Sørensen et al., 1999; Cardenas & Hoffman, 2009; Cardenas et al., 2011; Chartier-Kastler et al., 2011; De Ridder et al., 2005; Domurath et al., 2011; Gopalakrishnan et al., 2022; Sarica et al., 2010; Waller et al., 1997);
- 2 studies included patients with neurogenic bladder dysfunction exclusively (Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001);
- 2 studies included a mixture of patients with neurogenic or non-neurogenic bladder dysfunction (Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b);
- 2 studies included a mix of healthy volunteers and intermittent catheter users (50% of each; some outcomes were reported separately for each subgroup) (Athanasiadou et al., 2023);(Landauro et al., 2023b).
- 3 studies did not report the indication for catheterisation (Bonello et al., 2021; Gregghi et al., 2022; Landauro et al., 2023a).

When considering the generalisability of evidence generated with exclusively neurogenic or non-neurogenic patients, one Clinical Expert advised that differences in haematuria, discomfort and ease of use outcomes would be expected between neurogenic and non-neurogenic patient groups, however, they considered that little

difference in UTI and residual volume outcomes would be expected between those patient groups ([Appendix D](#)).

One Clinical Expert advised that outcomes may differ depending on who conducts the intermittent catheterisation. The EAG noted variation in who undertook the catheterisation across the included studies:

- 8 studies were either exclusively undertaken in patient groups conducting self-catheterisation (Chartier-Kastler et al., 2011; Gregghi et al., 2022), or this was implied from the study eligibility criteria (Bonello et al., 2021; Domurath et al., 2011; Gopalakrishnan et al., 2022; Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001; Sarica et al., 2010);
- 3 studies included carers conducting catheterisation (Cardenas & Hoffman, 2009; Cardenas et al., 2011) assumed because authors state that all but 1 subject had adequate hand function to routinely conduct self-catheterisation; (De Ridder et al., 2005);
- 2 studies had catheterisation undertaken exclusively by healthcare professionals (Landauro et al., 2023a; Waller et al., 1997);
- 5 studies included a combination of self- and healthcare professional-led catheterisation (Biering-Sørensen et al., 1999; Cardenas et al., 2011; Landauro et al., 2023b; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b).

The EAG note that some studies reported residual volume as measured by bladder ultrasound, and some studies compared outcomes between healthcare professional and self-catheterisation; therefore, catheterisation by a healthcare professional was considered appropriate in some cases.

Seven studies were undertaken exclusively in males (Chartier-Kastler et al., 2011; De Ridder et al., 2005; Domurath et al., 2011; Landauro et al., 2023a; Sarica et al., 2010; Thiruchelvam et al., 2024b; Waller et al., 1997). One study was undertaken exclusively in females (Thiruchelvam et al., 2024a). The remaining studies included both male and female intermittent catheter users (median 70%, mean 68% male) or did not report the patient demographics of participants. Across the studies which

reported age, the median was 44.8 years, mean 46.7 (acknowledging that the range of participants within studies was between 17 and 87 years).

The EAG noted a large amount of heterogeneity in outcomes reported and their definition. For example, definition of UTI varied among studies (clinical symptomatic, bacteriuria $\geq 10^2$ colony-forming unit (CFU)/ml, prescription of antibiotics, antibiotic episodes, positive dipstick, median number of UTIs per 1000 catheter days, occurrence of leukocyturia or bacteriuria, number of leucocytes, pyuria score). The EAG also note that the questions and format of responses varied across all studies reporting on satisfaction and catheter preference, broadly lacking the use of a validated scales, making categorisation and tabulation of results difficult. Furthermore, multiple questions were posed to catheter users to cover different aspects of their experience of the intermittent catheter used, however some of these results lacked numerical values and few studies had adjusted their results for multiple statistical tests applied.

Nine studies were exclusively undertaken in a community or primary care setting (Bonello et al., 2021; Cardenas & Hoffman, 2009; Chartier-Kastler et al., 2011; De Ridder et al., 2005; Domurath et al., 2011; Greggi et al., 2022; Koenen & Van Kuppevelt, 2004; Pascoe & Clovis, 2001; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b). One study was explicitly reported as being undertaken in an inpatient setting (Sarica et al., 2010), the EAG assumed another two studies were also undertaken in an inpatient setting (Biering-Sørensen et al., 1999; Waller et al., 1997), one study recorded time to catheterise during an assessment visit (Gopalakrishnan et al., 2022) and two reported measurement of residual void volume in a hospital setting (Landauro et al., 2023a; Landauro et al., 2023b). A mixed hospital and community setting was reported in 2 studies (Athanasiadou et al., 2023);(Cardenas et al., 2011). One Clinical Expert advised that the amount of time for teaching and follow-up availability would likely differ between acute and community setting. An additional Clinical Expert advised that very few inpatients use intermittent catheterisation.

In terms of the country of setting:

- 1 study was undertaken in a UK setting (Pascoe & Clovis, 2001);

- 2 in Brazil (Bonello et al., 2021; Gregghi et al., 2022);
- 1 in Canada (Gopalakrishnan et al., 2022);
- 4 in Denmark (Athanasiadou et al., 2023); (Biering-Sørensen et al., 1999); (Landauro et al., 2023a); (Landauro et al., 2023b);
- 1 in Germany (Domurath et al., 2011);
- 1 in the Netherlands (Koenen & Van Kuppevelt, 2004);
- 2 in the US (Cardenas & Hoffman, 2009; Cardenas et al., 2011);
- 1 in Sweden (Waller et al., 1997);
- 1 in Turkey (Sarica et al., 2010);
- 4 studies were undertaken in multiple countries (Chartier-Kastler et al., 2011; De Ridder et al., 2005; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b).

Two Clinical Experts advise that patient pathways may differ across countries but felt that results from other regions may be generalisable to the UK. One Clinical Expert stated that the UK may have a broader choice of catheters than other countries.

Most included studies (11/18) were company funded or included authors who were company employees (funding and declaration of interests are reported in [Appendix C1](#) for each included study). Eight studies were published from 2020 onwards (42%), the oldest evidence was published in 1997. The EAG note that older evidence may not reflect current NHS care.

Table 5: Summary of features tested and present in included clinical evidence

Feature of intermittent catheter	No. of studies focusing on testing a specific feature (references)	No. of studies where the catheter (intervention or comparator) had that feature (references)
Integrated drainage bag	0	2 (Greghi et al. 2022; Sarica et al. 2010)
Integrated handle or markings	0	10 (Athansiadou et al. 2023; Bonello et al. 2021; Chartier-Kastler et al. 2011; Domurath et al. 2011; Greghi et al. 2022; Landauro et al. 2023a; Landauro et al. 2023b; Sarica et al. 2010; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)
Insertion sleeve or grip	0	8 (Athansiadou et al. 2023; Bonello et al. 2021; Greghi et al. 2022; Landauro et al. 2023; Landauro et al. 2023b; Sarica et al. 2010; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)
Tip protector or introducer	0	6 (Athansiadou et al. 2023; Landauro et al. 2023; Landauro et al. 2023b; Sarica et al. 2010; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)
Micro-hole zone technology	5 studies (Athansiadou et al. 2023; Landauro et al. 2023; Landauro et al. 2023b; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)	5 (Athansiadou et al. 2023; Landauro et al. 2023; Landauro et al. 2023b; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)
Enhanced coating	1 (Waller et al. 1997)	17 (Athansiadou et al. 2023; Biering-Sørensen et al. 1999; Bonello et al. 2021; Cardenas et al. 2011; Cardenas et al. 2009; Chartier-Kastler et al. 2011; De Ridder et al. 2005; Domurath et al. 2011; Gopalakrishnan et al. 2022; Greghi et al. 2022; Koenen et al. 2004; Landauro et al. 2023; Landauro et al. 2023b; Pascoe et al. 2001; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b; Waller et al. 1997)
Specially designed catheter case	2 (Chartier-Kastler et al. 2011; Domurath et al. 2011)	10 (Athansiadou et al. 2023; Bonello et al. 2021; Chartier-Kastler et al. 2011; Domurath et al. 2011; Greghi et al. 2022; Landauro et al. 2023; Landauro et al. 2023b; Sarica et al. 2010; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)
Specially designed packaging	1 (Bonello et al. 2021)	15 (Athansiadou et al. 2023; Bonello et al. 2021; Cardenas et al. 2011; Chartier-Kastler et al. 2011; De Ridder et al. 2005; Domurath et al. 2011; Gopalakrishnan et al. 2022; Greghi et al. 2022; Koenen et al. 2004; Landauro et al. 2023; Landauro et al. 2023b; Pascoe et al. 2001; Sarica et al. 2010; Thiruchelvam et al. 2024a; Thiruchelvam et al. 2024b)

4.2.3 Technology features

For each included study, the list of features (as described in the NICE Final Scope) present across the catheters used and outcomes reported have been summarised by the EAG in Table 4:

- Integrated drainage bag (described using the following shorthand, **f1_{drain}**, when summarising technologies across studies and in subsequent evidence synthesis, see Section 4.2.4) in 2 studies.
- Integrated handle or markings (**f2_{handle}**) in 10 studies,
- Insertion sleeve or grip (**f3_{sleeve}**) in 8 studies,
- Tip protector or introducer (**f4_{tip}**) in 6 studies,
- Micro-hole technology (**f5_{micro-hole}**) in 5 studies.
- Enhanced coating technology (**f6_{lubric}**) was included in 17 studies; 14 used an intermittent catheter with pre-activated coat, 6 studies used a catheter where the coating was defined as low osmolality (some studies included both),
- Specially designed catheter case (**f7_{case}**) in 10 studies,
- Specially designed packaging (**f8_{packaging}**) in 15 studies.

The EAG identified 13 additional features from information provided by the companies, these included:

- Unique shaped handle: with claimed benefit of improved ergonomics to make the catheter easier to hold, insert and withdraw.
- Flexibility of the tip: with claimed benefit of reduced trauma and pain.
- Polished eyelets: with claimed benefit of reduced urethral trauma.
- Rigidity of tube: with claimed benefit of easy to handle, rigid enough to insert, but compliant enough to conform to the body's anatomy,
- Hangers on the outer packaging: with claimed benefit of easing preparation.

- Transparent catheter: with claimed benefit to enable easy viewing of urine.
- Ready-to-use: with claimed benefit of immediate use straight from packaging with no additional water solution or lubrication needed. This reduces preparation time (including the need for support from others to help with preparation), quicker catheterisation, and able to use without access to hand washing facilities.

The EAG asked the Clinical and Lay Experts to comment on whether these identified features would be considered innovative ([Appendix D](#); Question 3). The responses received from 4 Experts were heterogenous; none of the above features were categorised as innovative by all 4 Experts. The EAG note that none of the published comparative evidence, specifically tested the efficacy of these features. Due to this, the EAG focused on the features listed in the Final Scope within its analyses.

4.2.4 Key primary evidence

The EAG extracted the primary data for all outcomes listed in the scope ([Appendix C4](#)):

- Residual volume (5 studies),
- UTI (6 studies),
- Urethral trauma (10 studies),
- Other device-related adverse events (6 studies),
- Adherence (3 studies),
- Comfort or pain (7 studies),
- Ease of use (11 studies)
- General satisfaction (7 studies)
- Overall preference (5 studies)
- Health related quality of life (1 study).

None of the included comparative studies reported on frequency of use, sepsis, bladder or kidney stones or hospitalisation outcomes. The EAG asked Clinical and

Lay Experts to individually rank the 13 outcomes listed in the NICE Final scope in order of importance. There was a lack of consensus across the four Clinical Experts who responded ([Appendix D](#)). The bottom two outcomes considered to have lowest importance varied by Expert included: bladder or kidney stones, other device-related adverse events (for example retained fragment), frequency of use per day, hospitalisation, sepsis, and UTIs or recurrent UTIs.

Additional outcomes were reported in the literature, including:

- Flow stops (3 studies). One Clinical Expert advised that the clinical validity of this outcome was unclear.
- Intra-catheter pressure as a proxy for minimising mucosal suction (2 studies). Two Clinical Experts advised that this is not measured in routine clinical practice, and that the meaning and interpretation of this specific outcome remains unclear.
- Ability to drain sediment (2 studies).
- Discretion (4 studies).
- Hygiene (2 studies).
- Storing or carrying (1 study).
- Disposal (3 studies).
- Learning curve (1 study).

The EAG focused their review on 5 outcomes which were prioritised by Clinical and Lay Experts (top two outcomes considered to have the most importance: UTI, haematuria, residual volume, comfort and ease of use). To account for heterogeneity in reporting across the included studies, and to maximise the number of studies which could be incorporated into subsequent CNMA, the EAG undertook transformation of the reported results for those prioritised outcomes onto a common scale or format where possible. Due to the potential skew in the data, results

reported as median were excluded from CNMA. Additional rules were also applied depending on the outcome being measured.

4.2.4.1 UTI

Six studies reported UTI (raw data provided in [Appendix C4.5](#)). While the follow-up duration of studies reporting UTI varied (between 10 days and 12 months), the EAG standardized the definition of the UTI as the proportion of patients experiencing a UTI within 30 days. Results without a follow-up duration were excluded. Results reporting the number of UTI symptoms, number of leucocytes, or p-value without any additional detail were also excluded. For the 4 remaining studies included, the number of patients experiencing a clinical UTI (defined as patient-reported symptoms or antibiotic treatment) were converted into the proportion of patients experiencing a UTI per 30 days (UTI/30 days) (Cardenas & Hoffman, 2009; De Ridder et al., 2005; Sarica et al., 2010; Waller et al., 1997). This calculation used the longest available follow-up duration. If clinical UTI data was not reported in the study, other definitions of UTI were included. For example, focus on bacteria counts or dipstick results, rather than patient symptoms. All 4 studies were undertaken in spinal cord injury populations.

Included studies

Following transformation of outcomes, 4 trials reporting on UTI risk were included in the analyses, Table 6 (Cardenas & Hoffman, 2009; De Ridder et al., 2005; Sarica et al., 2010; Waller et al., 1997).

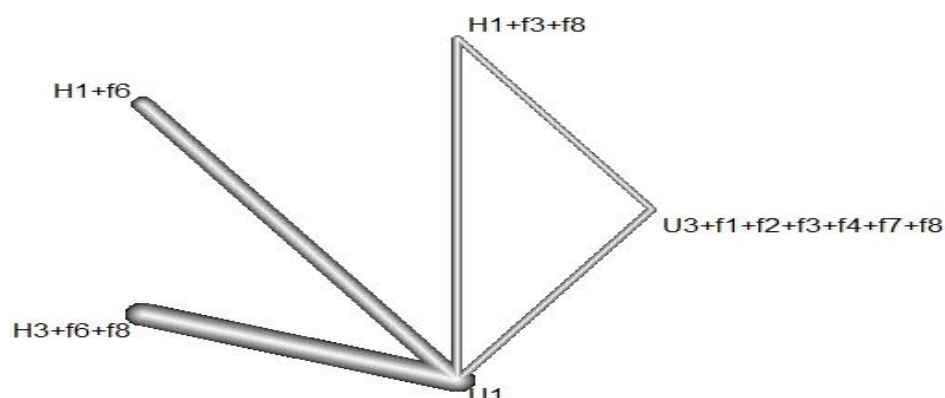
These provided data across 7 features (integrated drainage bag **f1_{drain}**; integrated handle or markings **f2_{handle}**; insertion sleeve or tip **f3_{sleeve}**; tip protector **f4_{tip}**; enhanced coating **f6_{lubric}**; specially designed catheter case **f7_{case}**, specially designed packaging **f8_{packaging}**) and across 3 types of lubrication or coating (uncoated catheters with no lubrication provided U1, hydrophilic catheters with no water provided H1, and hydrophilic pre-activate H3; as defined in Table 4). The EAG note that no included study reporting on this outcome included the micro-hole catheter feature.

Figure 3 illustrates the network of intervention features, and their combinations. Assessment of the effectiveness of intervention features was challenging due to the wide variety of intervention features used, and the limited number of included

studies. The EAG noted that closed loops in network meta-analysis help verify that the indirect evidence used agrees with the direct evidence, enabling assessment of the transitivity assumption and ensuring the validity of the results. However, for this analysis only one closed loop was identified (between one uncoated catheter with no features, one uncoated with features and one hydrophilic coated catheter with features), however this came from a three-arm trial, where inconsistency was not a concern (all data was from a single source).

Figure 3: Network diagram illustrating features assessed in included studies (lines weighted by inverse variance – highlighting for which features there is more evidence)

[Key: integrated drainage bag $f1_{\text{drain}}$; integrated handle or markings $f2_{\text{handle}}$; insertion sleeve or tip $f3_{\text{sleeve}}$; tip protector $f4_{\text{tip}}$; enhanced coating $f6_{\text{lubric}}$; specially designed catheter case $f7_{\text{case}}$; specially designed packaging $f8_{\text{packaging}}$; U1 uncoated catheter (no lubricant provided); H1 hydrophilic catheters with no water provided; H3 hydrophilic pre-activated catheter; U3



The EAG adopted a pragmatic approach to model selection, which considered: the magnitude of data available, goodness of fit; the plausibility of effects and 95% credible interval (CrI) estimates. Results were provided for three types of models: pairwise (where one feature was compared with U1 the most basic feature), independent (additive) models whereby features were analysed separately; and combined (interaction) models whereby features were analysed in combination.

Table 6: Studies reporting UTI/30 days (outcomes transformed into common scale for illustrative purposes) (n=4 studies)

Study	Study design	Intervention features (refer to Table 4)	Comparator features (refer to Table 4)	Intervention: UTI/30 days	Comparator: UTI/30 days
De Ridder (Eur Urol, 2005; 991-995)	RCT	Hydrophilic catheter (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	≥1 UTIs: 39/61 (64%) in 12 months CALCULATED: proportion of patients experiencing UTI/30 days: 0.0525	≥1 UTIs: 51/62 (82%) in 12 months CALCULATED: proportion of patients experiencing UTI/30 days: 0.0676
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	<u>Intervention 1:</u> Uncoated catheter (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic coated catheter (liquid not provided) with - Insertion sleeve or grip - Specially designed packaging	Uncoated catheter (Lubricant not provided)	<u>Intervention 1:</u> 1/25 in 6 weeks; CALCULATED proportion of patients experiencing UTI/30 days: 0.0286 <u>Intervention 2:</u> 1/25 in 6 weeks CALCULATED proportion of patients experiencing UTI/30 days: 0.0286	4/25 in 6 weeks CALCULATED: proportion of patients experiencing UTI/30 days: 0.114
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	Hydrophilic coated catheter (pre-activated) with Enhanced coating	Uncoated catheter (Lubricant not provided)	12/22 (54%) in 12 months CALCULATED: proportion of patients experiencing UTI/30 days: 0.0448	14/23 (61%) in 12 months CALCULATED: proportion of patients experiencing UTI/30 days: 0.0500
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	Hydrophilic coating (liquid not provided) with Enhanced coating	Hydrophilic coating (liquid not provided)	2/14 patients within 10 days CALCULATED proportion experiencing UTI within 30 days: 0.429	3/14 patients within 10 days CALCULATED proportion experiencing UTI within 30 days: 0.643

Abbreviations: RCT, randomised controlled trials; UTI, urinary tract infection

Pairwise, independent (additive) and combined (interaction) feature models: model selection

All models were run for an initial burn-in of 50,000 iterations and then discarded after reaching convergence. The model was then run for an additional 50,000 iterations. The initial independent effects model included all catheter features captured within the included studies. However, due to the small number of included trials, the 95% credible intervals (CrIs) were wide and implausible for all features except for enhanced coating (f6_{lubric}). To address this, we simplified the model by focusing only on the catheter features which had the most data available for the outcome of interest. In all models, plausible estimates were consistently available for the enhanced coating feature because it was the most studied catheter feature which was compared against uncoated catheters (U1). When focusing on this feature, the component network meta-analysis (CNMA) simplified into a pairwise component meta-analysis (CMA). Along with the pairwise CMA, the goodness of fit of two CNMA models were assessed:

- an independent effects model that compared the effectiveness of enhanced coating (f6_{lubric}), and specially designed packaging (f8_{packaging}) features in isolation versus a basic uncoated catheter (U1)
- a combination effects model that assessed the effectiveness of f6_{lubric} and f8_{packaging} features, and in combination, versus U1 (see Table 7).

DIC was similar for all three models (conventionally a difference between 3-5 points or more is considered a substantial difference. The pairwise model is the simplest, had a total residual deviance closest to the number of datapoints (suggestive of a well-fitting model), and is therefore the preferred model:

- Pairwise model: total residual deviance=9.07 (from 9 datapoints) and lower Deviance Information Criterion (DIC)=41.97
- Independent effects model: total residual deviance=6.82 (from 9 datapoints), DIC=40.76
- Combination effects model: total residual deviance=7.58 (from 9 datapoints), DIC=42.41

Results

The pairwise model found that enhanced coating may reduce UTI risk by 31% (RR 0.69, 95% CrI 0.44 to 0.96) compared with an uncoated catheter, where the baseline UTI risk was estimated to be 58% for intermittent catheter users receiving an uncoated catheter.

A smaller benefit (RR 0.95, 95% CrI 0.56 to 1.30) was found for enhanced coating in the independent effects model (where the benefits of enhanced coating and specially designed packaging catheter features were considered independently). In addition, specially designed packaging may be associated with a 42% UTI risk (RR 0.58, 95% CrI 0.25 to 1.02) compared with an uncoated catheter.

Similarly, in a combination effects model (assessing whether enhanced coating and specially designed packaging catheter features used together led to greater or less reduction in UTI risk than predicted by their effectiveness in isolation), enhanced coating may be associated with 18% reduction in UTI risk compared with an uncoated catheter (RR 0.86, 95% CrI 0.44 to 1.27). The impact was potentially even higher for specially designed packaging (RR 0.35, 95% CrI 0.01 to 1.15). However, when enhanced coating and specially designed packaging were used together, benefits were less than would be expected based on their effectiveness in isolation (RR 1.35, 95% CrI 0.44 to 1.84).

Summary of findings

In summary, enhanced coating ($f_{6\text{lubric}}$) and specially designed packaging ($f_{8\text{packaging}}$) may be more effective than an uncoated catheter. However, it should be noted that all evidence was rated as very low certainty. Therefore, although there is potentially promising evidence for these features, the evidence base is limited as the population is, restricted to spinal cord injury patients. From Clinical Expert feedback, it is unclear whether results can be generalised to other populations ([Appendix D](#)) and are therefore uncertain.

Table 7: Summary of CNMA and CMA results for UTI risk (pairwise, independent, and combination of two features) (n=4 studies)

Type of model	Enhanced coating (f6 _{lubric}) RR (95% CrI)	Enhanced coating (f6 _{lubric}) CINeMA rating	Specially designed packaging (f8 _{packaging}) RR (95% CrI)	Specially designed packaging (f8 _{packaging}) CINeMA rating	Both features combined (f6 _{lubric} , f8 _{packaging}) RR (95% CrI)	Both features combined (f6 _{lubric} , f8 _{packaging}) CINeMA rating
<i>Pairwise model</i> : compared with uncoated catheter (U1)	0.69 (0.44 to 0.96)	Very Low ^{1,2,4}	-	-	-	-
<i>Independent (additive) effects model</i> : compared with U1	0.95 (0.56 to 1.30)	Very Low ^{1,2,3}	0.58 (0.25 to 1.02)	Very Low ^{1,2,4}	-	-
<i>2-way interaction (combination) model</i> : compared with U1	0.86 (0.44 to 1.27)	Very Low ^{1,2,3}	0.35 (0.01 to 1.15)	Very Low ^{1,2,4}	1.35 (0.44 to 1.84)	Very Low ^{1,2,3}

Key: ¹ Some concerns due to heterogeneity: follow up varied from 6 weeks to 12 months, ² Major concerns due to risk of bias: two trials where authors did not adjust for clustering within individuals, ³ Major concerns due to imprecision: wide 95% CrI and limited weight in the CNMA, ⁴ Some concerns due to imprecision: only one small/moderate sized trial available for this comparison

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis, CMA, Component meta-analysis; CrI, Credible interval; RR, relative risk; UTI, Urinary tract infection; U1, uncoated catheter

4.2.4.2 Haematuria

Ten studies reported on bleeding or haematuria (raw data provided in [Appendix C4.6](#)). For haematuria, as with the UTI outcome, the follow-up duration across studies varied (between immediately post-catheterisation and 12 months), however the period of duration was not always reported. Proportions of participants with UTI at follow up were included in the CNMA.

However, for illustrative purposes, the EAG also estimated standardised haematuria estimates as the proportion of participants experiencing an episode of either visible haematuria (blood visible in the urine) or haematuria detected by a urinary dipstick test (presence of blood cells in the urine) within 30 days. In addition, the variability in follow up duration between studies was noted in the CINeMA assessments.

Studies that only reported p-values without reporting additional numerical values of events were excluded. One inpatient study reported 0% haematuria cases in both comparator and intervention arms. To avoid outcome bias, the EAG excluded this study, as the results were deemed unrepresentative of outcomes in the community setting (based on similar published evidence). In one study the number of cases of bleeding was reported, however it was unclear if multiple cases were experienced by one patient or single cases across multiple patients, or a combination of both; due to lack of denominator in this study (Cardenas et al., 2011) the EAG used the results from erythrocyte dipstick.

Included studies and network of features

Following transformation of outcomes, 6 studies were included which reported on haematuria, Table 8 (Cardenas et al., 2011; Chartier-Kastler et al., 2011; De Ridder et al., 2005; Landauro et al., 2023a; Landauro et al., 2023b; Thiruchelvam et al., 2024b). These provided data across 7 features (integrated handle or markings **f2_{handle}**; insertion sleeve or tip **f3_{sleeve}**; tip protector **f4_{tip}**; micro-holes **f5_{micro}**; enhanced coating **f6_{lubric}**; specially designed catheter case **f7_{case}**, specially designed packaging **f8_{packaging}**) and across 2 types of lubrication or coating (uncoated catheters with no lubrication provided U1, and hydrophilic pre-activate H3). The EAG note that no included study reporting on this outcome included the integrated drainage bag feature; however, the intended benefit of that feature did not include reduction in haematuria (see Table 1). Three of the studies were exclusively in spinal cord injury (Cardenas et al., 2011; Chartier-Kastler et al., 2011; De Ridder et al.,

2005), the remaining three studies were in mixed populations (neurogenic and non-neurogenic dysfunction) (Landauro et al., 2023a; Landauro et al., 2023b; Thiruchelvam et al., 2024b).

Three studies (Landauro et al., 2023a; Landauro et al., 2023b; Thiruchelvam et al., 2024b) primarily aimed to evaluate the effectiveness of the micro-hole feature compared against catheters with the same coating and lubrication method (where largely the only difference between arms was the presence or absence of micro-holes). Two further studies assessed the effectiveness of the enhanced coating compared with an uncoated catheter (Cardenas et al., 2011; De Ridder et al., 2005). One study compared the effectiveness of the integrated handle and specially designed catheter case, against catheters of the same coating and lubrication method (Chartier-Kastler et al., 2011). Four of the six studies reported on bleeding as identified from dipstick; one Clinical Expert advised that only macroscopic or visible bleeding would have clinical importance.

Table 8: Studies reporting haematuria over 30 days (outcomes transformed into common scale) (n=6 studies)

Study	Study design	Intervention features (refer to Table 4)	Comparator features (refer to Table 4)	Outcome	Outcome in intervention arm: haematuria over 30 days	Outcome in comparator arm: haematuria over 30 days	Treatment differences (reported when included in CNMA)
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Incidents of haematuria (dipstick)	9.6% across undefined period (assumed immediately post-catheterisation)	17.2% across undefined period (assumed immediately post-catheterisation)	OR 0.50 (95% CI 0.19 to 1.32) in intermittent catheter users only (inverted to reflect similar effect direction to other studies in analyses)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Probability of positive haematuria (dipstick)	17% (14% to 19%) over 4 weeks	19% (17% to 22%) over 4 weeks	OR 0.83 (95% CI 0.65 to 1.04) (inverted to reflect similar effect direction to other studies in analyses)
Landauro (J Clin Med, 2023; 5266)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed packaging	Probability of a positive haematuria (dipstick)	10% (3% to 24%) across undefined period	29% (17% to 45%) across undefined period	OR 0.26 (95 % CI 0.07 to 0.96)
Cardenas (PM&R, 2011; 408-417)	RCT	Hydrophilic catheter (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Microhaematuria (erythrocyte dipstick)	23% when measured daily during weeks 3 and 4.	34% when measured daily during weeks 3 and 4.	-
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Visible bleeding	5.6% (2/36) over 2 weeks CALCULATION: (2/36)x2=11.1% over 4 weeks	0% (0/36) over 2 weeks CALCULATION: N/A	-
De Ridder (Eur Urol, 2005; 991-995)	RCT	Hydrophilic catheter (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Visible bleeding	69% (38/55) over 12 months CALCULATION: (38/55)/12 = 5.8% over 4 weeks	54% (32/59) over 12 months CALCULATION: (32/59)/12 = 4.5% over 4 weeks	-

Abbreviations: RCT, Randomised Controlled Trial.

Figure 4 shows that there were two subnetworks of features targeted by included studies. The links are weighted by the inverse variance (in other words, thicker lines generally reflect there are more data for these comparisons). Studies that compared catheters including H3+f6+f8 features with U1 catheters were most common. As observed above, there are two main sets of trials reporting haematuria data. These different sets of trials focused on:

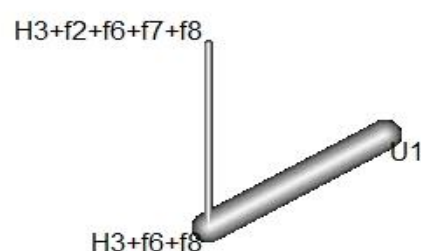
- the effectiveness of micro-hole zone technology when added to a catheter with other features (subnetwork 2) or
- a smaller number of features compared with an uncoated catheter with no additional features (subnetwork 1).

However, as can be seen in Figure 4, there are several overlapping features across these studies, therefore the EAG undertook component network meta-analyses (CNMA) on individual features and explored alternative model approaches.

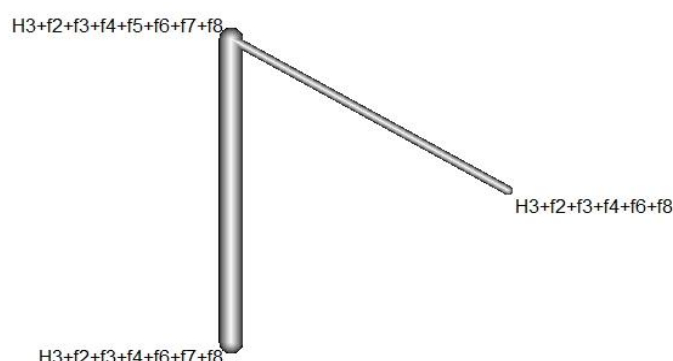
Figure 4: Network diagram for trials reporting haematuria outcomes

[Key: integrated drainage bag **f1_{drain}**; integrated handle or markings **f2_{handle}**; insertion sleeve or tip **f3_{sleeve}**; tip protector **f4_{tip}**; micro-hole **f5_{micro}**; enhanced coating **f6_{lubric}**; specially designed catheter case **f7_{case}**, specially designed packaging **f8_{packaging}**; U1 uncoated catheter (no lubricant provided); H3 hydrophilic pre-activated catheter]

a) Subnetwork 1



b) Subnetwork 2



Independent (additive) and combined (2-way interaction) feature models: model selection

All models were run for an initial burn-in of 50,000 iterations and then discarded after reaching convergence. The model was then run for an additional 50,000 iterations. The initial independent effects model included catheter coating and lubrication method and additional features, see Table 9. However, due to the small number of included trials, the 95% credible intervals (CrIs) were wide and implausible for most features. We therefore simplified the model by focusing only on features with the most data and most precise 95% CrIs (preactivated hydrophilic catheters with micro-holes or specially designed catheter case). There was insufficient data to explore the impact of combining these features (that is including interaction terms), as adding these terms to the model led to unstable estimates of 95% CrIs for most features.

Given the slightly larger number of included studies on haematuria, we compared fixed-effect and random effects models. Goodness-of-fit was poor for the fixed effect model (DIC=15.76, total residual deviance=13.69 from 6 data points), suggesting there is substantial variability between studies not accounted for in these analyses. Although the DIC was only 2 points less than for the fixed-effect model, total residual deviance suggested an acceptable fit (DIC=13.74, total residual deviance=6.28 from 6 data points). The EAG therefore selected the random effects model.

Independent (additive) and combined (2-way interaction) feature models: results

Evidence was judged to be of very low certainty for all features included in the CNMA. Micro-hole (f5_{micro-hole}) features may be associated with an 84% reduced risk of haematuria (RR 0.16, 95% CrI 0.01 to 2.27). The estimated risk of haematuria was 34% for patients receiving U1 (a basic uncoated catheter). It is unclear if H3 is more or less effective (RR 1.04, 95% CrI 0.19 to 2.36) than U1. Specially designed catheter cases may not be effective at reducing risk of haematuria (RR 2.05, 95% CrI 0.09 to 3.34). However, for all effect estimates, 95% CrIs were very wide suggesting substantial uncertainty about the true nature of feature effectiveness.

Table 9 Summary of CNMA results for haematuria risk (independent effects model)

Independent (additive) effects model: feature compared with uncoated catheter (U1)	RR (95% CrI)	CINeMA rating
Micro-hole (f5 _{micro-hole})	0.16 (0.01 to 2.27)	Very Low ^{1,2,3}
Hydrophilic pre-activated catheter (H3)	1.04 (0.19 to 2.36)	Very Low ^{1,2,3}
Specially designed catheter case (f7 _{case})	2.05 (0.09 to 3.34)	Very Low ^{1,2,3}

¹ Some concerns identified regarding risk of bias: most studies did not report sufficient information on allocation concealment or random sequence generation methods), ² Major imprecisions reflected in wide 95% CrIs, ³high heterogeneity (between-study standard deviation=0.79, 95% CrI 0.09 to 3.46)

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis, CrI, credible interval; RR, relative risk;

Summary of findings

In summary, micro-hole technology (f5_{micro-hole}) was the only feature with evidence to support reduced risk of haematuria. Specially designed catheter case (f7_{case}) features may not be effective in reducing the risk of haematuria; with the relative risk showing an increase in events with this feature when accounting for the presence of other features. This result may be influenced by confounding; for example, users may prefer a compact or hard case when conducting catheterisation outside a home environment (for example when travelling or at work) which may influence the outcome more than the catheter feature itself. However, the 95% CrIs are very wide (indicating uncertainty about the magnitude of true effects) and the certainty of the evidence was judged to be very low for all features.

4.2.4.3 Residual volume

The EAG defined residual volume as the volume of urine remaining in the bladder after catheterisation, regardless of whether the catheterisation was performed by the individual, a carer, or a healthcare professional. When available, post-void residual volumes measured after catheterisation, where the catheterisation was performed by the user or carer, were extracted and prioritised over those post-residual volumes

measured after catheterisation where the catheterisation was undertaken by healthcare professionals, based on published literature. Using this definition, 4 studies reporting on residual volume were included, Table 10 (raw data available in [Appendix C4.1](#)). All reported use of hydrophilic preactivated catheters with additional features. However, the EAG determined that it was inappropriate to perform a component network meta-analysis (CNMA) for this outcome due to strong evidence of skewed data. Based on Altman and Bland's rule of thumb for aggregate data (Altman & Bland, 1996):

- Three studies (Domurath et al., 2011; Landauro et al., 2023a; Thiruchelvam et al., 2024a) showed strong evidence of skewed distributions (where the mean and standard deviation (SD) ratio were less than 1).
- One study (Thiruchelvam et al., 2024b) suggested evidence of skew (where the mean SD ratio was less than 2).

None of the studies reported log-transformed data, which would have reduced the effects of the skewed data. Therefore, to avoid potential risk of bias from combining untransformed skewed data, the EAG summarised data from these studies narratively, rather than through CNMA. One Clinical Expert also advised that measurement of this outcome is prone with significant error (estimated to be approximately 20%), stating that a between-group difference less than 50 ml was not considered clinically significant.

Domurath et al. (2011) undertook a non-inferiority study comparing two catheters in male patients where the difference between catheters was the presence of an integrated handle and specially designed catheter case (Domurath et al., 2011), Table 10. No significant difference was found between arms in residual volume (median: 2.06 (95%CI -1.94 to 7.72) ml), within the pre-defined non-inferiority margin. Two studies reported a mean difference between catheters investigating the impact of f5_{micro-hole} (Landauro et al., 2023b; Thiruchelvam et al., 2024b).

Thiruchelvam et al. (2024) reported a statistically significant mean reduction in residual volume of 19.6 (95%CI 1.70 to 37.43) ml in patients using a catheter with micro-holes; p=0.033. Whereas Landauro et al. (2023) reported no statistical difference in mean post residual volume in male (mean difference: -4.30 (95%CI -17.0 to 8.82) ml; p=0.551) or female patients (mean difference: -4.09 (-17.60 to 9.41)

ml; $p=0.519$). The remaining study reported mean (SD) post void residual volume but did not report the difference between arms (Thiruchelvam et al., 2024a).

Summary of findings

Across all the included studies reporting on post-void residual volume, there was no statistical difference observed. However, the EAG noted that for residual volume to be measured (most likely with portable ultrasound), the user would be needed to attend a healthcare setting. Therefore, their behaviour may change and not reflect results if the intermittent catheterisation was undertaken in user's usual setting. The additional noted skewed distributions in this outcome make drawing conclusions uncertain.

Table 10: Studies reporting residual volume (outcomes transformed into common scale)

Study	Study design	Intervention features (refer to Table 4)	Comparator Features (refer to Table 4)	Outcome measure [individual conducting catheterisation]	Outcome intervention arm, mean (SD) or (95%CI)	Outcome in comparator arm	Difference (intervention-comparator)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Residual volume [self]	12.44 (15.66) ml	9.35 (11.43) ml	Median: 2.06 (95%CI -1.94 to 7.72) Non-inferiority met
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Post-void residual volume [self]	7.7 (13.9) ml	9.3 (20.5) ml	NR
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Residual urine post-catheterisation [self]	12.1 (-1.8 to 25.9) ml	31.6 (17.8 to 45.5) ml	19.6 (1.70 to 37.43) ml; p=0.033
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Post-void residual volume [healthcare professional and self]	Male: 25 (51) ml Female: 8 (45) ml	Male: 21 (36) ml Female: 4 (10) ml	Male: -4.30 (-17.0 to 8.82); p=0.551 Female: -4.09 (-17.60 to 9.41); p=0.519

Abbreviations: CI, Confidence Interval; NR, not reported; RCT, Randomised Controlled Trial; SD, Standard Deviation

4.2.4.4 Discomfort or pain

A total of 7 studies reported on discomfort or pain, Table 11 (raw data in [Appendix C4.9](#)). Although with a similar broad aim, there were differences in how outcomes were defined and measured; the EAG attempted to order the rows of Table 10 to group similar outcomes together. Additional reporting issues were identified such as a mix of means, medians, and count data without dispersion measures were reported, which further limited the analysis. The EAG therefore provided a narrative summary for this outcome to outline common themes, where possible. Many studies reported multiple discomfort or pain outcomes, using slightly different scales or definitions, so the EAG considered there to be no additional benefit to combine them in the same analyses. The feasibility of component network meta-analysis (CNMA) was considered separately for discomfort, comfort, and pain outcomes.

Table 11: Studies reporting comfort or pain

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Discomfort (VAS)	10.1 (16.65) mm	6.8 (9.77) mm	p=0.30
Gregghi (ESTIMA, 2022; e2522);	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Discomfort during the procedure with the catheter [scale unclear]: in those with urethral sensitivity	Median: 1	Median 1	p=0.083
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Discomfort (VAS)	mean (SD): 1.59 (2.24)	mean (SD): 1.94 (2.28)	-0.35 (95% CI -1.49 to 0.80; ITT) Non-inferiority met -0.9 (95% CI -1.66 to 0.14; PP)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Discomfort (VAS) on insertion	Mean (SD): 0.3 (0.8)	Mean (SD): 1.1 (2.3)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Discomfort (VAS) during emptying	Mean (SD): 0.2 (0.7)	Mean (SD): 0.9 (1.8)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Discomfort (VAS) by completion	Mean (SD): 0.3 (0.7)	Mean (SD): 1.2 (2.3)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Discomfort (VAS) at withdrawal	Mean (SD): 0.4 (1.2)	Mean (SD): 1.3 (2.4)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Gentle to empty	• 55 strongly agree • 16 agree • 3 neither • 1 disagree • 0 strongly disagree	• 32 strongly agree • 30 agree • 3 neither • 6 disagree • 4 strongly disagree	Better in intervention arm, OR: 3.85 (1.87 to 7.96); p<0.001

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
		- Specially designed packaging			• 0 don't know	• 0 don't know	
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Pain during insertion	Severe: 2/36 Mild/moderate: 1/36 No: 33/36	Severe: 0/36 Mild/moderate: 2/36 No: 34/36	p=0.4375
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Comfort during insertion (0-10 scale)	Mean (SD): 9.3 (1.2)	Mean (SD): 8.9 (1.4)	NR; no statistical difference reported
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Gentle to insert	• 51 strongly agree • 19 agree • 1 neither • 2 disagree • 2 strongly disagree • 0 don't know	• 29 strongly agree • 32 agree • 3 neither • 5 disagree • 5 strongly disagree • 0 don't know	Better in intervention arm, OR 3.30 (1.64 to 6.64); p=0.001
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	No pain	80.0% (24/36)	73.3% (22/36)	p=0.6675
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Stinging during insertion	Severe: 0/36 Mild/moderate: 5/36 No: 31/36	Severe: 0/36 Mild/moderate: 3/36 No: 33/36	p=0.5000
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Pinching or stinging	• 1 strongly agree • 3 agree • 2 neither • 27 disagree • 42 strongly disagree • 0 don't know	• 7 strongly agree • 11 agree • 5 neither • 24 disagree • 26 strongly disagree • 0 don't know	OR 3.01 (1.60 to 5.67); odds of disagreeing with statement; p<0.001
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	No stinging	80% (24/36)	76.6% (23/36)	p=0.6831
Thiruchelvam (Neurourology Urodynamics, 2024b; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Blocking sensation	• 0% strongly agree • 6% agree • 15% neither • 29% disagree • 50% strongly disagree	• 4% strongly agree • 12% agree • 21% neither • 40% disagree • 24% strongly disagree	OR 3.15 (95%CI 1.65 to 6.01), p<0.001
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Resistance during insertion	Severe: 3/36 Mild/moderate: 11/36 No: 22/36	Severe: 2/36 Mild/moderate: 15/36 No: 19/36	p=0.8604

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	No resistance	53.3% (16/36)	30% (9/36)	OR 2.69 (95%CI 1.12 to 6.49); p=0.0273
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Comfort during withdrawal	9.4 (1.1)	9.0 (1.5)	NR; no statistical difference reported
Thiruchelvam (Br J Nursing, 2024a; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Gentle to withdraw	• 54 strongly agree • 18 agree • 1 neither • 3 disagree • 0 strongly disagree • 0 don't know	• 26 strongly agree • 28 agree • 5 neither • 7 disagree • 7 strongly disagree • 0 don't know	Better in intervention arm, OR 3.21 (1.62 to 6.37); p=0.001
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Did not feel burning (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [3, 5]	p=0.043; not significant after adjustment for multiple comparisons
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Did not feel pain (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [4, 5]	4 [3, 5]	p=0.173
Gregghi (ESTIMA, 2022; e2522);	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Feeling while using the catheter [scale unclear]	Median: 3	Median 3	p=0.272

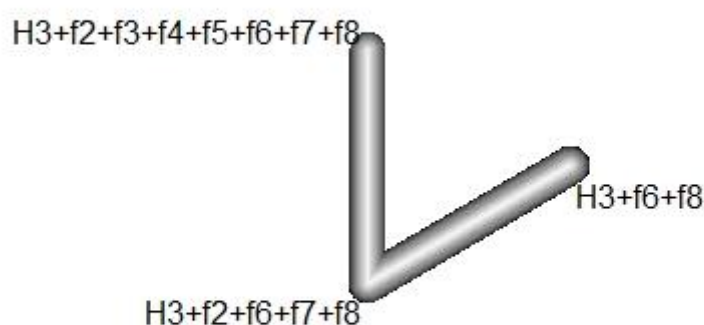
Abbreviations: NR, not reported; OR, odds ratio; RCT, randomised controlled trial; SD, standard deviation;

Discomfort

When assessing patient reported discomfort the EAG attempted to conduct a CNMA (see Figure 5 for a network diagram). However, it was judged to be infeasible. The EAG tried several different models which either failed to converge or led to estimates with implausibly wide 95% credible intervals (Cris).

Figure 5: Network diagram for trials reporting discomfort on the Visual Analogue Scale (VAS)

[Key: integrated handle or markings $f2_{\text{handle}}$; insertion sleeve or tip $f3_{\text{sleeve}}$; tip protector $f4_{\text{tip}}$; micro-hole $f5_{\text{micro}}$; enhanced coating $f6_{\text{lubric}}$; specially designed catheter case $f7_{\text{case}}$; specially designed packaging $f8_{\text{packaging}}$; H3 hydrophilic pre-activated catheter]



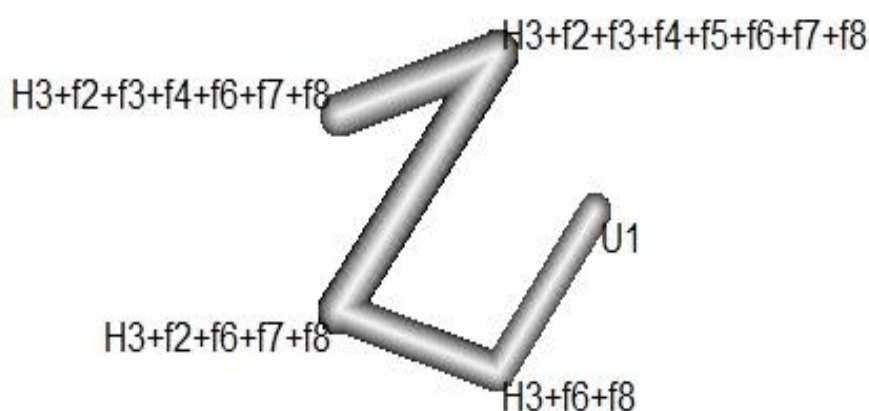
Four studies reported similar levels of discomfort between catheters. Three studies (Chartier-Kastler et al., 2011; Domurath et al., 2011; Thiruchelvam et al., 2024a) used the Visual Analogue Scale (VAS) to assess discomfort. Results showed similar discomfort levels between intervention and comparator catheters which were all pre-activated hydrophilic catheters with additional features, Table 11. Another study (Gregghi et al., 2022) reported similar median discomfort levels while using the catheter between pre-lubricated uncoated catheters with features and pre-activated hydrophilic catheters with features in users with urethral sensitivity; however the scale on how this was measured was not defined (Gregghi et al., 2022).

Comfort

Comfort was assessed in varying ways, with reporting of this outcome included difference in means and binary data. The EAG attempted to combine five studies that reported outcomes related to comfort (Cardenas et al., 2011; Chartier-Kastler et al., 2011; Domurath et al., 2011; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b), Figure 6. To combine the studies, a standardised mean difference (SMD) was used.

Figure 6: Network diagram for trials reporting comfort based on standardised mean difference

[Key: U1, uncoated catheter (no lubricant provided); H3, hydrophilic pre-activated catheter; **f2**_{handle}, integrated handle or markings; **f3**_{sleeve}, insertion sleeve or tip; **f4**_{tip}, tip protector; **f5**_{micro}, micro-hole; **f6**_{lubric}, enhanced coating; **f7**_{case}, specially designed catheter case, **f8**_{packaging}, specially designed packaging]



Model selection

Including all features in the CNMA, not unsurprisingly, led to either poor convergence or implausibly wide 95% CrIs. Therefore, the EAG fitted a simplified model including just uncoated catheters (U1 as a comparator), pre-activated hydrophilic catheters (H3), and tip protector and introducer (**f4**_{tip}) feature. This model converged after 100,000 iterations which were discarded as burn-in. After 100,000 further iterations, Late-stage assessment report: GID-HTE10049 Intermittent catheters for chronic incomplete bladder emptying in adults
Date: January 2025

the EAG compared the effectiveness of these features with the comparator. Total residual deviance (3.23 from 5 datapoints) indicated that the model did not fit the data well. Further examination of the data identified that almost all data were driven by two trials (Cardenas et al., 2011; Thiruchelvam et al., 2024b).

Results

The use of pre-activated hydrophilic catheters was potentially associated with a small improvement in comfort compared with an uncoated catheter (standardised mean difference, SMD: 0.26, 95% CrI -0.21 to 0.73). The presence of a tip protector or introducer feature was associated with a small-to-negligible decrease in comfort (SMD: 0.16, 95% CrI -0.74 to 0.42). However, data for both features were judged to be at very low certainty.

Table 12 Standardised mean differences for comfort

Independent (additive) effects model: feature compared with uncoated catheter (U1)	SMD (95% CrI)	CINeMA rating
Hydrophilic pre-activated catheter (H3)	0.26 (-0.21 to 0.73)	Very Low ^{1,2}
Tip protector or introducer (f4_{tip})	-0.16 (-0.74 to 0.42)	Very Low ^{1,3}

¹Major concerns with risk of bias: one cross-over trial unadjusted for clustering within individuals

²Some concerns with imprecision: just two studies contributing to analyses, and relatively wide 95% CrI

³Major concerns with imprecision: just two studies contributing to analyses, and wide 95% CrI indicates substantial uncertainty about the magnitude of the true effect

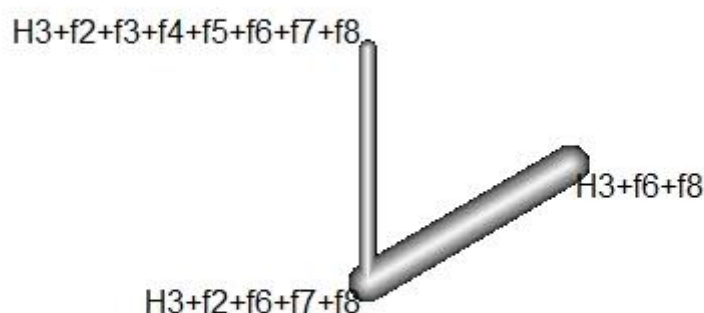
Abbreviations: CINeMA: Confidence in Network Meta-analysis; CrI, credible interval; f4_{tip}, tip protector or introducer; H3, pre-activated hydrophilic catheter; SMD, standardised mean difference; U1, uncoated catheter (with no lubricant provided)

Pain

The EAG fitted several CNMA models for outcomes regarding pain or stinging. These were combined into a single data point for each study (n=3). Unfortunately, none of these models converged, and therefore we could not undertake this analysis. The network diagram can be observed in Figure 7. None of the studies compared an arm to the uncoated catheter and were all variations of the hydrophilic pre-activated catheter.

Figure 7: Network diagram for trials reporting pain/stinging

[Key: integrated handle or markings $f2_{\text{handle}}$; insertion sleeve or tip $f3_{\text{sleeve}}$; tip protector $f4_{\text{tip}}$; micro-hole $f5_{\text{micro}}$; enhanced coating $f6_{\text{lubric}}$; specially designed catheter case $f7_{\text{case}}$; specially designed packaging $f8_{\text{packaging}}$; H3 hydrophilic pre-activated catheter]



Two studies (Chartier-Kastler et al., 2011; Domurath et al., 2011) reported no statistically significant difference in pain or stinging between pre-activated hydrophilic catheters where integrated handle and specially designed catheter case features were present. However, another study (Thiruchelvam et al., 2024a) reported a lower likelihood of pinching or stinging between pre-activated hydrophilic coated catheters. The authors found that a catheter with micro-holes, compared with a catheter with all other features being the same (that is presence of handle, packaging), led to participants reporting less pinching and stinging. Variability in trends continued in three studies which also reported resistance or blocking sensation, with one study reporting no statistical difference in resistance between arms (Domurath et al., 2011) and two studies reporting a statistical difference (Chartier-Kastler et al., 2011; Thiruchelvam et al., 2024b). One study reported no difference in feeling of pain or burning between an uncoated catheter with no additional features, and a pre-activated hydrophilic coated catheter with enhanced coating and specially designed package (Gopalakrishnan et al., 2022).

Summary of findings

Overall, the evidence suggests a similar level of discomfort between catheters across the included evidence. However, there is potential benefit across tip introducer and introduction sleeve where studies have reported statistical differences in pain and comfort outcomes where these features are present. These findings need further validation.

4.2.4.5 Ease of use

A total of 11 studies were included which reported on ease of use, [Appendix C4.10](#). However, the EAG considered it was not possible to conduct a CNMA due to heterogeneity between the outcome definitions and measures. Additionally, there were issues in reporting, with means, medians, and count data provided. In some instances, no dispersion data was available to transform. A narrative is therefore presented below.

General ease of use

Two studies consistently reported statistically significant improved odds for ease of use across an array of measures (ease of opening, inserting, use, handling, emptying, reclosing) between pre-activated hydrophilic coated catheters when insertion sleeve, tip protector and micro-holes features were present (Chartier-Kastler et al., 2011; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b), Table 13. However, all these measures were reported as subjective questions which were open to interpretation, with agreement or disagreement noted.

One study reported greater ease of manipulation and sliding into the urethra for a pre-lubricated uncoated catheter (with features), hydrophilic coated catheter (with liquid supplied and features) and a pre-activated hydrophilic catheter (with features) when compared with an uncoated catheter (Bonello et al., 2021). However, two studies reported no statistical difference in ease of sliding into the urethra between pre-lubricated uncoated catheter with features and pre-activated hydrophilic coated catheter with features (Bonello et al., 2021; Gregghi et al., 2022). The scale used in one of these studies was not explicitly reported, and data is only available as a median and p-value (no dispersion) (Gregghi et al., 2022). This study also reported no difference in ease of removal or ease of opening the packaging between uncoated

catheters with a sleeve compared with a pre-activated hydrophilic catheter with enhanced coating and specially designed catheter case.

Two studies reported an increased level of control between pre-activated hydrophilic coated catheters when an integrated handle and specially designed catheter case was present (Chartier-Kastler et al., 2011; Domurath et al., 2011). One of these studies also reported that the catheter with those additional features was rated higher for inserting (a term which is not defined by the authors) (Chartier-Kastler et al., 2011). However, two additional studies reported no statistically significant difference in ease of use (across ease of preparation, handling, insertion, manipulation, removal) between an uncoated catheter with no additional features and a pre-activated hydrophilic coated catheter with additional features (Cardenas et al., 2011; Gopalakrishnan et al., 2022). One study reported a statistically significant difference in ease of withdrawal in favour of 3 catheters which each had additional features when compared with an uncoated catheter with no features; however, the method of lubrication differed across all 3 catheters (Bonello et al., 2021). This study did report that the pre-activated hydrophilic coated catheter with specially designed packaging was easier to open compared with 3 other catheters with varying features. One study reported no difference in ease of use of disposal between an uncoated catheter with no additional features, and a pre-activated hydrophilic coated catheter with a specially designed packaging and enhanced coating (Gopalakrishnan et al., 2022). Another reported no statistical difference when specially designed packaging feature was present in difficulty opening or handling the catheter packaging (Pascoe & Clovis, 2001).

Time related ease of use

One study reported a statistically significant reduction in time for catheterisation using a pre-activated hydrophilic coated catheter with specially designed packaging and enhanced coating when compared with a hydrophilic coated catheter with enhanced coating (Pascoe & Clovis, 2001). However, the EAG noted that only the p-value was available for this study. Another study similarly reported reduction in total catheterisation time with enhanced coating feature, however the p-value was not reported (Waller et al., 1997).

Speed of emptying the bladder was reported in one study which compared pre-activated hydrophilic coated catheters where additional insertion sleeve, tip protector and micro-holes were present (Thiruchelvam et al., 2024a). However, this measure was subjective, with patients being asked how much they agree with the statement of speed of emptying the bladder. In another study, when users were asked to pick their preferred hydrophilic coated catheter when considering speed of catheterisation, most users (76%) selected a catheter which had a specially designed package feature present (Pascoe & Clovis, 2001).

One study reported the overall time taken to undertake catheterisation was statistically significantly lower in those using a pre-activate hydrophilic catheter with enhanced coating and specially designed package when compared with an uncoated catheter with no additional features (Gopalakrishnan et al., 2022), Table 13. There were also non-statistically significant decreases in time for subgroups of patients with tetraplegia (n=9) and paraplegia (n=11), however the EAG note the small sample sizes in these analyses. No statistical difference was noted to undertake intermittent catheterisation between pre-activated hydrophilic catheter with additional features including enhanced coating and specially designed catheter case when compared with an uncoated catheter with additional insertion sleeve feature (Gregghi et al., 2022).

Overall, there is evidence of similarities between the catheters. There are some instances of differences in time taken and ease of use, however these largely occur in studies comparing pre-activated hydrophilic coated catheters with additional features and uncoated catheters without additional features. There is limited data available on many of the catheters and further data is needed to establish preferences.

Table 13: Studies reporting ease of use

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Controlling	-	-	OR 13.30 (2.51 to 70.60); p=0.0024
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Need to touch the coated part of the catheter	-	-	OR 0.09 (0.02 to 0.035)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Control during insertion	• very easy or easy 32 • not easy nor difficult 2 • difficult or very difficult 2	• very easy or easy 18 • not easy nor difficult 10 • difficult or very difficult 8	p<0.0001
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters qualitatively evaluated in randomised order)	<u>Intervention 1:</u> Uncoated (pre-lubricated) with - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging <u>Intervention 3:</u> Hydrophilic (provided with water to activate the coating) with - Insertion sleeve or grip - Enhanced coating	Uncoated catheter (Lubricant not provided)	Ease of opening (01 very easy to 05 very difficult)	I1: 2.4; I2: 1.8; I3: 2.6	2.8	Pair-wise comparisons reported; SpeediCath lower than all other 3 catheters (p<0.05), also difference between Actreen Lite and PVC (p<0.05)
Gregghi (ESTIMA, 2022; e2522)	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of package opening [scale unclear]	Median: 4	Median 4	p=0.796
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Difficult in opening the packaging	12%	4%	NR
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Handling of packaging (preference)	46%	54%	p=0.839
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Time taken to undertake catheterisation	-	-	p=0.015 (shorter than normal in 68% using the intervention catheter)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case	Ease of use of catheter	• 57 strongly agree • 17 agree • 1 neither • 3 disagree	• 38 strongly agree • 21 agree • 7 neither • 11 disagree	OR 3.11 (95%CI 1.54 to 6.29); p=0.002

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
		- Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	- Specially designed packaging		• 0 strongly disagree • 0 don't know	• 0 strongly disagree • 0 don't know	
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of opening the catheter	• 46 strongly agree • 23 agree • 7 neither • 2 disagree • 0 strongly disagree • 0 don't know	• 25 strongly agree • 26 agree • 8 neither • 15 disagree • 3 strongly disagree • 0 don't know	OR 3.84 (2.01 to 7.34); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of emptying the bladder	• 51 strongly agree • 19 agree • 5 neither • 3 disagree • 0 strongly disagree • 0 don't know	• 28 strongly agree • 35 agree • 10 neither • 2 disagree • 2 strongly disagree • 0 don't know	OR 2.96 (1.56 to 5.60); p=0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of re-closing the catheter	• 27 strongly agree • 34 agree • 6 neither • 6 disagree • 2 strongly disagree • 3 don't know	• 25 strongly agree • 16 agree • 9 neither • 15 disagree • 10 strongly disagree • 2 don't know	OR 2.03 (1.11 to 3.72); p=0.022
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Speed of emptying bladder using catheter	• 34 strongly agree • 22 agree • 15 neither • 5 disagree • 2 strongly disagree • 0 don't know	• 17 strongly agree • 30 agree • 18 neither • 6 disagree • 5 strongly disagree • 1 don't know	OR 2.06 (1.14 to 3.73); p=0.017
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Confidence that catheter empties bladder completely	• 43 strongly agree • 24 agree • 4 neither • 6 disagree • 0 strongly disagree • 1 don't know	• 22 strongly agree • 29 agree • 12 neither • 11 disagree • 3 strongly disagree • 0 don't know	OR 3.27 (1.74 to 6.14); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case	Lack of worry about urine left in bladder	• 47 strongly agree • 15 agree • 9 neither	• 24 strongly agree • 30 agree • 8 neither	OR 2.68 (1.45 to 4.95); p=0.002

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
		- Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	- Specially designed packaging		• 5 disagree • 2 strongly disagree • 0 don't know	• 11 disagree • 4 strongly disagree • 0 don't know	
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Overall confidence in catheter	• 57 strongly agree • 13 agree • 3 neither • 4 disagree • 1 strongly disagree • 0 don't know	• 35 strongly agree • 26 agree • 7 neither • 5 disagree • 4 strongly disagree • 0 don't know	OR 3.06 (1.57 to 5.93); p=0.001
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in randomised order)	<u>Intervention 1:</u> Uncoated (pre-lubricated) with - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging <u>Intervention 3:</u> Hydrophilic (provided with water to activate the coating) with - Insertion sleeve or grip - Enhanced coating	Uncoated catheter (Lubricant not provided)	Ease of manipulation (01 very easy to 05 very difficult)	Actreen Lite: 2.7; SpeediCath : 1.9; LoFric Primo: 2.6	PVC: 3.3	Pair-wise comparisons reported; SpeediCath lower than all other 3 catheters (p<0.05), also difference between LoFric Primo and PVC (p<0.05)
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in randomised order)	<u>Intervention 1:</u> Uncoated (pre-lubricated) with - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging <u>Intervention 3:</u> Hydrophilic (provided with water to activate the coating) with - Insertion sleeve or grip - Enhanced coating	Uncoated catheter (Lubricant not provided)	Ease of sliding on the urethra (01 very easy to 05 very difficult)	Actreen Lite: 2.4; SpeediCath : 1.6; LoFric Primo: 2.3	PVC: 3.3	Pair-wise comparisons reported; all statistically significant with the exception of comparison of Actreen Lite and LoFric Primo.
Gregghi (ESTIMA, 2022; e2522)	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of sliding into the urethra [scale unclear]	Median: 3.5	Median 3	p=0.643

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Need rotation to empty	• 3% strongly agree • 6% agree • 11% neither • 41% disagree • 39% strongly disagree	• 6% strongly agree • 16% agree • 16% neither • 35% disagree • 27% strongly disagree	OR 1.98 (1.16 to 3.39), p=0.013
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Need slow withdrawal to empty	• 6% strongly agree • 12% agree • 15% neither • 38% disagree • 29% strongly disagree	• 18% strongly agree • 32% agree • 18% neither • 24% disagree • 9% strongly disagree	OR 4.32 (2.31 to 8.06), p<0.001
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Need withdraw in small steps to empty	• 9% strongly agree • 18% agree • 12% neither • 35% disagree • 26% strongly disagree	• 22% strongly agree • 44% agree • 4% neither • 25% disagree • 4% strongly disagree	OR 4.42 (2.24 to 8.72), p<0.001
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Confident bladder is empty when flow stops	• 46% strongly agree • 41% agree • 6% neither • 6% disagree • 2% strongly disagree	• 28% strongly agree • 34% agree • 24% neither • 12% disagree • 3% strongly disagree	OR 2.85 (0.47 to 5.53), p=0.003 <i>[likely error in reporting of results]</i>
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Confident catheter empties completely	• 49% strongly agree • 38% agree • 9% neither • 2% disagree • 3% strongly disagree	• 28% strongly agree • 44% agree • 19% neither • 6% disagree • 3% strongly disagree	OR 2.50 (1.32 to 4.71), p=0.005
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Enhanced coating - Specially designed catheter case - Specially designed packaging	Easy to empty the bladder	• 70% very easy • 23% easy • 6% neither • 2% difficult • 0% very difficult	• 43% very easy • 47% easy • 7% neither • 2% difficult • 0% very difficult	OR 2.73 (1.40 to 5.35), p=0.004.

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
		- Specially designed packaging					
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Speed (preference)	76%	25%	p=0.015
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Convenience (preference)	88%	12%	p=0.000
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to undertake IC (Median [Q1,Q3])	283 [242, 342] seconds	373 [249, 441] seconds	p=0.01
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to undertake IC (Median [Q1,Q3]) Tetraplegia (n=9)	300 [249, 352] seconds	421 [398, 515] seconds	p-value NR; reported as no statistically significant difference
Gregghi (ESTIMA, 2022; e2522)	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Time taken to undertake IC [scale unclear]	Median: 2	Median 2	p=0.592
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to undertake IC (Median [Q1,Q3]) Paraplegia (n=11)	272 [210, 353] seconds	296 [225, 443] seconds	p-value NR; reported as no statistical significant difference
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to prepare catheter (Median [Q1,Q3]) All individuals (n=20)	15 [10, 20] seconds	41 [20, 69] seconds	p=0.02
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to prepare catheter (Median [Q1,Q3]) Tetraplegia (n=9)	16 [11, 20] seconds	67 [46, 81] seconds	p=0.038; not significant following adjustment for multiple comparisons
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Overall time taken to prepare catheter (Median [Q1,Q3]) Paraplegia (n=11)	15 [9, 24] seconds	21 [14, 25] seconds	p=0.023; not significant following adjustment for multiple comparisons
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Easy to handle before insertion (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [2, 5]	4 [2, 5]	p=0.806
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Inserting	-	-	OR 4.09 (95%CI 1.35 to 12.36); p=0.0127
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating	Ease of handling the catheter during insertion	45 strongly agree 24 agree 5 neither	31 strongly agree 22 agree 15 neither 8 disagree	OR 2.32 (1.35 to 3.99); p=0.003

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
		- Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	- Specially designed catheter case - Specially designed packaging		• 3 disagree • 1 strongly disagree • 0 don't know	• 1 strongly disagree • 0 don't know	
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Introduction of catheter to urethra and bladder (preference)	62%	38%	p=0.383
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Hydrophilic (pre-activated) with - Integrated handle or markings - Insertion sleeve or grip - Tip protector or introducer - Micro-hole zone technology - Enhanced coating - Specially designed catheter case - Specially designed packaging	Hydrophilic (pre-activated) with - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of inserting catheter	• 52 strongly agree • 18 agree • 5 neither • 2 disagree • 1 strongly disagree • 0 don't know	• 33 strongly agree • 29 agree • 7 neither • 7 disagree • 1 strongly disagree • 0 don't know	OR 2.61 (1.42 to 4.79); p=0.002
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Easy to insert (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [2, 5]	4 [2, 4]	p=0.748
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Ease of insertion [0-10 very difficult to very easy] (catheterisation conducted by individual or caregiver)	9.2 (1.6)	8.6 (1.6)	NR; reported as not statistically significant.
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Able to drain bladder (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.756
Gopalakrishna n (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Uncoated catheter (Lubricant not provided)	Easy to remove (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.984
Gregghi (ESTIMA, 2022; e2522)	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Ease of removal of catheter from urethra [scale unclear]	Median: 34	Median 4	p=0.561
Gregghi (ESTIMA, 2022; e2522)	Prospective cohort (n=50)	Uncoated (pre-lubricated) with - Integrated drainage bag - Integrated handle or markings - Insertion sleeve or grip - Specially designed catheter case	Hydrophilic (pre-activated) with - Integrated drainage bag - Integrated handle or markings - Enhanced coating - Specially designed catheter case - Specially designed packaging	Difficult catheter removal [scale unclear]	Median: 5	Median 2	p=0.317
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging	Hydrophilic coating (liquid not provided) with - Enhanced coating	Withdrawal of catheter from urethra and bladder (preference)	60%	40%	p=0.503
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in	<i>Intervention 1:</i> Uncoated (pre-lubricated) with - Integrated handle or markings - Insertion sleeve or grip	Uncoated catheter (Lubricant not provided)	Ease of withdrawal (01 very easy to 05 very difficult)	Actreen Lite: 2.2; SpeediCath : 1.7; LoFric Primo: 2.0	PVC: 3.0	Pair-wise comparisons reported; all statistically significant with the exception of comparison of

Study	Study design	Intervention (refer to Table 4)	Comparator (refer to Table 4)	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
	randomised order)	- Specially designed catheter case - Specially designed packaging <u>Intervention 2:</u> Hydrophilic (pre-activated) with - Enhanced coating - Specially designed packaging <u>Intervention 3:</u> Hydrophilic (provided with water to activate the coating) with - Insertion sleeve or grip - Enhanced coating					Actreen Lite and SpeediCath, and SpeediCath compared with LoFric Primo.
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Easy to dispose (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.553
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Easy to prepare (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [(4, 5)]	4 [(2, 4)]	p=0.047; not significant after adjustment for multiple comparisons p=0.047
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Preparation of catheter in usual surroundings [0-10 very difficult to very easy]	8.9 (1.4)	8.5 (1.8)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Catheterisation procedure in usual surroundings [0-10 very difficult to very easy]	9.3 (1.1)	8.8 (1.5)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Preparation of catheter outside usual surroundings [0-10 very difficult to very easy]	7.6 (2.8)	6.8 (2.7)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	Hydrophilic (pre-activated) with	Uncoated catheter (Lubricant not provided)	Catheterisation procedure outside of usual surroundings [0-10 very difficult to very easy]	7.7 (2.7)	6.8 (2.7)	NR; reported as not statistically significant.
Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]	Crossover RCT	Hydrophilic (pre-activated) with	<u>Comparator 1:</u> Hydrophilic coating (liquid not provided) with Enhanced coating <u>Comparator 2:</u> Hydrophilic coating (liquid not provided)	Use of friendliness (numerical scale, 1-10)	7.8 (1.8)	LoFric: 6.9 (1.6); EasiCath: 6.7 (1.7)	p=0.32
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	Hydrophilic coating (liquid not provided) with	Hydrophilic coating (liquid not provided)	Number of cases of catheter 'sticking'	5 cases in 2 patients	42 cases in 9 patients	-
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	Hydrophilic coating (liquid not provided) with	Hydrophilic coating (liquid not provided)	Catheterisation time	Mean: 4.3 (range: 3.5 to 8.2) minutes	Mean: 4.4 (range: 3.3 to 9.6) minutes	-

Key: Abbreviation: NR, not reported; RCT, randomised controlled trial;

4.2.5 Other adverse events

The EAG extracted other device-related adverse events from the included evidence (N=6 studies), [Appendix C4.7](#). Adverse events included epididymitis and stenosis (among others). The absolute number of adverse events was lower in the intervention arm than the comparator arm in all RCTs, however the EAG notes the small sample size across studies, and other study designs, including real-world observational studies, may be better suited in detecting device related complications.

4.3 Summary, strengths and limitations

From literature searching and information provided by the Companies and Experts, the EAG included 18 comparative studies (of which 15 were RCTs) which compared intermittent catheters with different features but also different coating or lubrication methods. The included evidence covered all intermittent catheter features of interest listed in the NICE Final Scope. Some of the evidence was published as early as 1997, and therefore the generalisability of the evidence to current NHS care and pathways remains unclear. There was a general lack of standardised reporting of outcomes (definition and timepoint measured, statistical analysis reported) across included studies, which limited the ability to include all studies in subsequent complex evidence synthesis (component network meta-analysis). The generalisability of results from studies reporting on specific catheterisation indications (for example studies exclusively in patients with spinal cord injury) to other populations is unclear.

Transforming results onto a common scale across outcomes, further restricted use of the included evidence. The relative effect of enhanced coating or specially designed packing features could be estimated for UTI outcome, and separately the relative effect of micro-hole or specially designed catheter case features could be estimated for haematuria outcome. The EAG note that 76% (65/86) of intermittent catheter product lines have at least one of those features (enhanced coating, specially designed package, micro-hole, specially designed catheter case). The EAG consider that there is insufficient evidence to determine the effectiveness of the remaining intermittent catheter features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer). CNMA identified potential increased risk of haematuria with specially designed catheter case, however the EAG note the wide CrI and 'very low' certainty rating across all CNMA analyses. The EAG has not identified a safety signal associated with remaining catheter features

across the included evidence; however, acknowledges that larger cohort studies may be better suited to detect complications.

The approach of using CNMA applied by the EAG to isolate the effect of individual catheter features was considered ideal for answering the late-stage assessment (LSA) decision problem in a features-based assessment, as this method is designed specifically for such research questions. CNMA enables a greater depth of exploration of the comparative effectiveness of individual features and various combinations of these features than possible from narrative summaries of the evidence or traditional pair-wise meta-analyses. This may explain the differences in results between the EAG report and previously published systematic reviews which compared uncoated and hydrophilic coated intermittent catheters (Prieto et al., 2021). Network diagrams graphically illustrated the current evidence base for intervention features, thus showing the evidence gaps in answering the decision problem. Nevertheless, the lack of consistent reporting of outcomes, presence of multiple intermittent catheter features and multiple coating or lubrication methods resulted in sparse networks. Most of our CNMAs included between 4-6 studies, limiting the potential to explore the effectiveness of all intermittent catheter features, and combinations of features. One feature (micro-hole) was only available from one catheter manufacturer. All studies included in CNMA had an RCT design, however there were multiple limitations to these data including risk of bias (for example not adjusting for paired-data in cross-over trials, unclear reporting of allocation concealment or sequence generation method); heterogeneity; and extremely wide 95% CrIs (imprecision). Therefore, for most outcomes and features, where evidence was analysed, were rated as very low certainty.

The EAG would like to highlight that the most frequent application of CNMA has been in the evaluation of behaviour change techniques. In that topic area, extensive taxonomies have been developed to aid consistency and comprehensiveness in extracting intervention features. Such taxonomies are not available for intermittent catheters, which potentially limits the reproducibility of our data extraction and therefore CNMAs. The EAG sought to minimise potential biases related to consistency and comprehensiveness when extracting catheter features from information provided by companies (reviewing company websites, and EAG requesting clarifications from companies via NICE) and published literature (seeking

advice from clinical and patient experts). To better understand the clinical relevance, the EAG asked the Clinical and Lay Experts to rank the importance of identified features (listed in the Final Scope) and the importance of outcomes (also listed in the Final Scope). The EAG noted that the ranking proposed by 4 Experts differed significantly ([Appendix D](#)); which may indicate the impact of different perspectives. While additional features were identified by the EAG inductively, none of the published literature sought to determine the clinical efficacy or effectiveness of these features directly. Furthermore, there was lack of consensus from the Experts on the relevance of these additionally identified features. As such the CNMA was restricted to those features listed in the Final Scope only, which had gone through stakeholder consultation. The EAG also noted that the features included in the Final Scope included classes of features. For example, specially designed catheter cases included hard cases, compact cases, and resealable cases which may mask treatment effects. Taking a pragmatic approach, and due to the limited published evidence available, the EAG assumed these features as comparable. However, it is acknowledged that effect estimates are likely to be impacted by these decisions. Aggregating integrated handle and insertion sleeve or grip would have limited impact on these findings.

5 Economic evidence

5.1 Methods

5.1.1 Searches for economic evidence

The full search methods were described in the published [protocol](#). In brief the following searches were undertaken:

- A search of NHS Economic Evaluation Database (NHS EED) for any economic evaluation or systematic review of economic evaluations (covering from 1968, the earliest record in NHS EED to 31 December 2014, inclusive, when updating of NHS EED ceased).
- A search for systematic reviews of economic evaluations or modelling covering from when NHS EED ceased to be updated to the most recent record available (1 January 2015 onwards) in MEDLINE and Embase.

- In case no relevant systematic reviews were found a search was undertaken to identify economic evaluations and models published from 1 January 2015 onwards (when NHS EED ceased to be updated) in MEDLINE and Embase.

For efficiency of sifting the NHS EED search results and search results for systematic reviews of economic evaluations or models (1 and 2 above) were deduplicated as a batch, sifted and reported together. As per the clinical evidence, the EAG reviewed all the economic evidence submitted by the Companies, and all the primary evidence from systematic reviews for relevance to the decision problem.

5.1.2 Study selection

The study selection of economics was broader than that of the clinical, to enable the EAG to review economic modelling methodologies used in the published literature which compared intermittent catheters. This included any economic evaluations of single-use intermittent catheters, including comparison of basic technology catheters with no additional features, such that the EAG could review the economic model structure, model parameters used, and model assumptions. This information was used to support EAG model development. The EAG provided a narrative summary of those studies undertaken from an UK NHS perspective.

5.1.3 Protocol deviations

The search and study selection of economic evidence was undertaken in accordance with the protocol; no deviations were identified. The intention, as stated in the published protocol, was for the EAG to formally critically appraise evidence which included an evaluation of additional intermittent catheter features of interest. Only one study reported economic evaluation of features (Cawson et al. 2023 which evaluated the impact of micro-holes compared with conventional eyelet catheters); however, this was available as a poster only (Cawson et al., 2023). Due to the limited reporting of model design and assumptions in this published abstract, the EAG did not conduct formal critical appraisal.

5.2 Results

A total of 251 economic systematic reviews were identified, 209 remained following removal of duplicates ([Appendix B2a](#)). A single reviewer (KK) reviewed the title and abstract of 209 records (minimum 10% reviewed by a second reviewer, KB), of

which 24 were included for full paper retrieval. Seven systematic reviews were considered relevant to the decision problem, on review of the primary evidence contributing to each systematic review, the EAG subsequently included a total of 7 studies ([Appendix B5](#)).

A total of 2042 economic evaluations published on or after 01 January 2021 were identified, 1741 remained following removal of duplicates ([Appendix B2b](#)). A single reviewer (KK) reviewed the title and abstract of 1741 records (minimum 10% reviewed by a second reviewer, KB), of which 52 were included for full paper retrieval. Following full paper review by two reviewers (KK, PL), a total of 19 studies were subsequently included.

A total of 10 economic studies were identified from information provided by the Companies; all were identified by the EAG literature searching.

Across all sources, after removal of duplicates, a total of 22 relevant economic studies were identified. This included 13 studies which included a description of an economic model, Table 14.

One economic evaluation assessed catheters with the additional features listed in the initial NICE scope; this compared micro-hole catheters with conventional eyelet catheters (Cawson et al., 2023). All the economic evaluations reviewed (apart from 3 abstract only publications, where details could not be assessed) used the Markov model structures developed by Bermingham et al. (2013) or Clark et al. (2016) and their subsequent adaptations (Bermingham et al., 2013; Clark et al., 2016). UTI and its short or long-term sequelae were the key drivers of these models. The model parameters were mainly informed by literature and Clinical Expert opinion, and assumptions were made where evidence was not available. All models appear to be based on people with chronic urinary retention and spinal cord injury, except one study (Baker et al., 2023) which included people with multiple sclerosis along with spinal cord injury. However, Bermingham et al. (2013) undertook a scenario analysis in people with chronic urinary retention but with no spinal cord injury (Bermingham et al., 2013). All models were evaluated over the lifetime of the patient, except one study (Health Quality Ontario, 2019) which used a 5-year time horizon. Four of these studies were undertaken from a UK NHS perspective:

- [illegible]

incremental cost per QALY, in 2011 GBP of £6,100 (£8,171 when inflated to 2023 price), £3,300 per life-year gained, and £79 per UTI avoided compared with uncoated catheters.

- Baker et al. (2023) undertook a cost-utility analysis, using a Markov model over a lifetime horizon, and from the UK NHS and Personal Social Services (PSS) perspective, to compare single-use conventional uncoated intermittent catheter with hydrophilic coated intermittent catheters in people with spinal cord injury or multiple sclerosis (Baker et al., 2023). Their model structure varied slightly to that initially developed by Bermingham et al. (2013); here, a two-state model (Alive and Dead) was used. In this model, the occurrence of catheter-associated urinary tract infections (CAUTI) was stratified into 6 different categories according to their severity and were incorporated into the 'Alive' health state with a treatment effect applied to the hydrophilic coated intermittent catheters (Bermingham et al., 2013). The rate of CAUTIs in the model used in Baker et al. (2023) was informed by weighted average of estimates from four RCTs, whereas the relative risks of CAUTIs for the hydrophilic catheters were sourced from a network meta-analysis (Baker et al., 2023). Several parameters (for example, utility decrement and duration for each UTI event and incidence of simple UTI treated in primary care) were based on clinical opinion. The study findings show that hydrophilic coated intermittent catheters had an incremental cost per QALY in 2020/2021 GBP of £5,775 (£6,340 when inflated to 2023 prices) compared with uncoated intermittent catheters. This result was driven by substantial reductions in the number of CAUTIs.
- Cawson et al. (2023), undertook a cost-effectiveness analysis, using a Markov model over the lifetime horizon and from the UK NHS perspective, to compare single-use Micro-hole Zone Technology (MHZT) catheters with single-use conventional eyelet catheters in people with spinal cord injury (Clark et al., 2016). The detailed model structure and price year was not reported as this was an abstract-only publication. The model was largely informed by efficacy parameters collected from literature, a user survey and Clinical/Expert opinion. The analysis showed that MHZT catheters had an incremental cost per QALY gained of £19,913 with an incremental cost per patient of £13,342, an incremental QALY of 0.67, and a reduction of 6.5 CAUTIs over a lifetime

compared with conventional eyelets. The cost-effectiveness of MHZT was primarily driven by the reduction in the number of CAUTI events.

During the economic evidence search, the EAG also identified:

- 4 cost analyses:
 - Angermund et al. (2021) was a descriptive study with a retrospective, longitudinal cohort design which utilised a research database from the German statutory health insurance claims data system to evaluate the standard of care and burden of illness in German individuals using intermittent catheters (exact model undefined) (Angermund et al., 2021). Their findings suggest that healthcare utilisation post the use of intermittent catheters was lower than prior to its use.
 - Berendsen et al. (2021) was an observational retrospective study which explored the use of clean intermittent catheterisation by neurogenic and non-neurogenic bladder patients, using the data from the drug information system of the National Health Care Institute in the Netherlands (Berendsen et al., 2021). The study found that the use and costs of disposable catheters in the Netherlands increased substantially between 1997 and 2018.
 - Buchter et al. (2023) undertook a descriptive observational nationwide study based on retrospective data from Danish national registers, explored the total and complication-specific burden (in terms of resource utilisation) of urinary retention caused by benign prostatic hyperplasia or other non-neurogenic causes among people using intermittent catheters in Denmark (Buchter et al., 2023). The total healthcare utilisation in people using intermittent catheters were driven mainly by hospitalisations arising from UTIs.
 - Healy and Dyer (2023) described up-to-date techniques used for difficult urethral catheterisation and their costs in the UK (Healy & Dyer, 2023). The authors listed a breakdown of items and equipment costs sourced from the NHS supply chain and stocklist of a local NHS hospital. A summary of the costs of catheterisation techniques ranging from simple urethral techniques to complex and percutaneous techniques was presented as the results.

The cost analysis studies identified were not full economic evaluations of intermittent catheters and they were not considered helpful in informing the EAG economic model. All studies except Healy & Dyer (2023) were undertaken in a non-UK population setting (Healy & Dyer, 2023). This study only provided the total costs of techniques that could be used for difficult catheterisation undertaken by clinicians, which is out of scope of this late-stage assessment (LSA) which focuses on intermittent self-catheterisation by the users.

- 3 time-trade off analyses:
 - Averbeck et al. (2018) investigated the impact on health state utilities associated with four different aspects of urinary catheters: steps needed for intermittent catheterisation, time needed for the intermittent catheterisation process, pain related to intermittent catheterisation, and frequency of UTIs (Averbeck et al., 2018). Health state utilities were elicited through an internet-based time trade-off survey in adult volunteers representing the general population in Canada and the UK. The study findings show an incrementally higher utility gain associated with one-time use catheters (less steps and time needed; UK: +0.021), ready-to-use catheters (less steps and time needed and less pain; +0.017), and with a reduction of 1 UTI per year (+0.011).
 - Krassioukov et al. (2018) used a time trade-off survey in a sample of adults' representative of UK general population to estimate the disutilities associated with three different catheter products: access to patient support services, the use of catheters that do not contain phthalates, and the use of catheters that are of a compact design (Krassioukov et al., 2018). The study findings show an incremental utility value of 0.031, 0.009 and 0.037 respectively for catheters with compact design, availability of support services and catheters not containing phthalates.
 - Looby et al. (2023) used a time trade-off online survey in separate and combined samples of adults' representative of the UK general population and those with spinal cord injury (SCI), to calculate utility decrements for three attributes (mild, moderate and severe) associated

with catheterisation for individuals with a spinal cord injury: the process of catheterisation, the physical impact of UTIs, and worry associated with hospitalisation (Looby et al., 2023). This study reported that in the general population both the moderate and severe health states corresponded to a utility decrement of 0.019 and 0.028 respectively when compared with the mild health state. The average utility decrement difference between those with uncoated catheters (process: severe) and hydrophilic catheters, which need repositioning (process: moderate) was 0.009. In the sample with spinal cord injury, the moderate and severe levels of process attribute had utility decrements of 0.030 and 0.042 respectively when compared with the mild level. The average utility decrement difference between the uncoated and hydrophilic catheters which need repositioning was 0.012. However, the utility decrements in the SCI population were not significantly different from the results observed in the general population.

The utility decrement in the general population for the moderate level of physical attribute (involved treatment in hospital as a day case patient) and severe level (involved treatment in hospital as inpatient) was 0.07 ($p=0.237$, no evidence of a significant difference) and 0.031 ($P<0.001$) respectively when compared with mild level, with a utility decrement difference of 0.024 between moderate and severe levels of physical attribute. In the SCI population, the utility decrement was 0.012 ($p=0.450$, no evidence of significant difference) and 0.069 ($p<0.001$) for moderate and severe levels respectively when compared with mild level of physical attribute.

The utility decrement for the general population for a moderate and severe level of worry of hospitalisation was 0.023 and 0.082 respectively when compared with the mild level. The utility decrement difference between moderate and severe worry was 0.0059. In the SCI population, the utility decrement for the moderate and severe level of worry was 0.022 ($p=0.156$, no evidence of significant difference) and 0.090 ($p<0.001$) respectively when compared with the mild level.

Based upon the review of preference elicitation studies, where a catheter feature claims to result in ease/comfort to use and improved drainage, a utility increment of

2% of the catheter users' utility was assumed (Averbeck et al., 2018). Further details from all the studies extracted are reported in Table 14 below.

Table 14: Summary of included economic studies

#	Study (year); Country	Design [Time horizon]; Perspective; Economic evaluation model	Population	Interventions	Comparator	Key findings	EAG comment on methodology
1.	Baker (Curr Med Res Opin, 2023; 319-328); UK	Cost utility [lifetime]; UK NHS PSS; Markov model	Spinal cord injury and multiple sclerosis	Single-use hydrophilic-coated intermittent catheter	Single-use Uncoated intermittent catheter	Hydrophilic coated intermittent catheters were cost effective (ICER: £5,755 per additional QALY gained) and could prevent seven UTIs per patient over their lifetime compared with uncoated intermittent catheters.	Their model was closely similar to the one developed by Birmingham et al. 2013, however it differed in how the UTIs were modelled. A two-state model (Alive and Dead) where the occurrence CAUTIs, stratified into 6 different categories according to their severity, were incorporated into the alive cohort with a treatment effect applied to the hydrophilic coated intermittent catheters. The evidence on CAUTIs was sourced as weighted average of estimates from four randomized controlled trials and a network meta-analysis.
2.	Bermingham (BMJ, 2013; e8639); UK	Cost utility [lifetime]; UK NHS; Markov model	Neurogenic bladder condition due to spinal cord injury, Non-spinal cord injury population modelled in scenario analysis	Single-use hydrophilic catheters; Single-use gel reservoir catheters, Single-use uncoated	Clean uncoated catheters used multiple times	Clean uncoated catheters (1 per week) were cost effective at a £20 000 threshold. Excluding clean uncoated catheters, single-use gel reservoir catheters were cost-effective compared with hydrophilic-coated catheters (ICER: £3071 per QALY gained)	Systematic literature reviews and meta-analysis (of randomized controlled trials and randomized crossover trials of long-term intermittent self-catheterisation in the primary settings) informed the treatment effect.
3.	Cawson (Value in Health, 2023; S165); UK [Abstract]	Cost-effectiveness [lifetime]; UK NHS; Markov model	Spinal cord injury	Micro-hole zone technology catheters	Standard hydrophilic coated catheters; single-use conventional eyelet catheters	Micro-hole zone catheters were found cost-effective (Incremental cost: £13,342, incremental QALYs:0.67), and reduced 6.5 intermittent UTIs per patient lifetime compared with conventional eyelet catheters.	Limited detail published as abstract online (EAG unable to find full publication).
4.	Clark (Spinal Cord, 2016; 73-77); UK	Cost-effectiveness [lifetime]; UK NHS; Markov model	Spinal cord injury and chronic urinary retention	Sterile uncoated catheters	Single-use hydrophilic intermittent catheters	Hydrophilic-coated catheters were cost-effective with an ICER of £6100 per QALY gained, £3300 per life-year gained, and £79 per UTI event avoided	Treatment effect primarily derived from uncontrolled observational studies accessed without a systematic review. The study has considered the long-term sequelae of UTI by including three renal states (no renal impairment, major renal impairment, renal failure), however the monthly event rates of major renal impairment and renal failure used in the model were 0.020% and 0.004%, which is quite low and do not appear to have significant impact on the ICER. Instead, UTI events were the key driver of the cost-effectiveness results.
5.	Couchman (Continence, 2022; 100513); Australia	Cost utility [lifetime]; Australian healthcare; Societal perspective undertaken in scenario analysis; Markov model	Neurogenic bladder from traumatic spinal cord injury	Hydrophilic coated catheters	Uncoated catheters	Hydrophilic coated catheters were cost-effective with an ICER of AUD \$48,542 per QALY gained. The number of non-severe UTI decreased by 4 and severe UTI or sepsis events were reduced by 0.02 per patient lifetime with the use of hydrophilic coated catheters.	The model used in this study was an adaptation of the model used in Clark et al. 2016 and considered long-term sequelae from UTIs and renal impairment. The model also considered additional scenario analysis from the societal perspective by incorporating the adverse impact of UTIs on productivity. The clinical evidence informing their model was taken largely from the literature (which included meta-analyses) and expert panel.
6.	Hakansson (2016; 233-242); US	Cost-effectiveness [lifetime]; US healthcare system; Markov model	Spinal cord injury and chronic urinary retention	Hydrophilic coated catheters	Uncoated catheters	Single-use hydrophilic-coated catheters reduced long-term healthcare costs. Hydrophilic-coated catheters were more cost effective than uncoated catheters, saving \$10,184, gaining 0.55 QALY, and avoiding 16 UTIs per person on average	The model, an adaptation of the model developed in Bermingham et al. 2013, also used short term UTI sequela, however included health states for epididymitis, strictures, and bladder stones. The costs of different catheter types were same, except for additional cost of \$0.13 per uncoated catheters to account for costs of additional lubricant.
7.	Neovius (Value Health, 2016; A310); US [Abstract]	Cost-effectiveness analysis [lifetime]; US healthcare; Markov model	40 year old intermittent catheter users	Hydrophilic catheter	Uncoated catheter	Hydrophilic coated catheters avoided on average per person 16 symptomatic UTIs, 0.6 events of bacteraemia, 0.7 events of epididymitis and 0.7 events of strictures, translating it to \$9,714 per patient savings when compared with patients using uncoated catheters.	Limited detail published as abstract online (EAG unable to find full publication). The model was informed by US specific parameters sourced from the literature.
8.	Neovius (Value Health, 2016; A860-A861); Japan [Abstract]	Cost-effectiveness analysis [1 year]; Japanese healthcare system Markov model	40 year old intermittent catheter users	Hydrophilic catheter	Uncoated catheter	Reduced treatment costs for complications of ¥74,522 per patient, fewer events of UTI (1.8 vs 2.2/patient), sepsis (0.07 vs 0.08/patient), epididymitis (0.002 vs 0.020/patient) and strictures (0.002 vs 0.020/patient).	Limited detail, published as abstract online (EAG unable to find full publication). The model was informed by Japan specific parameters sourced from the literature.
9.	Health	Cost-utility [5	Inpatients and	Single-use	Single-use	ICER for single-use	The model was adapted from that

#	Study (year); Country	Design [Time horizon]; Perspective; Economic evaluation model	Population	Interventions	Comparator	Key findings	EAG comment on methodology
	Quality Ontario (HTA, 2019); Canada	years]; Canadian public payer; Markov model	outpatients with chronic urinary retention due to spinal cord injury	hydrophilic catheters; Multiple use uncoated catheters (out of scope)	uncoated intermittent catheters	hydrophilic-coated vs repeated use uncoated (1/wk) catheters: approximately \$3.7 million per QALY gained. ICER for single-use hydrophilic-coated vs single-use uncoated catheters: about \$3.1 million per QALY gained	developed by Bermingham et al. 2013 and used short term UTI sequelae as model states, however unlike the Bermingham et al., it also considered risks of haematuria and bladder stones. The model was largely informed by parameters derived from the literature. The study found the multiple use (1 per week) uncoated catheters was the most cost-effective catheter when compared with multiple use (1 per day) uncoated, single-use uncoated and single-use hydrophilic catheters.
10	Rognoni (BMJ Open, 2017; e012360); Italy	Cost-effectiveness [lifetime]; Italian healthcare service; Markov model	Spinal cord injury, using intermittent catheterisation in a community setting	Hydrophilic coated catheters	Uncoated catheters	Single-use hydrophilic-coated catheters were cost effective compared with uncoated catheters (ICER: €24,405 per QALY gained and €20,761 euros per life-year gained)	The model was adapted from the one developed by Bermingham et al. 2013 and examined short term consequences of UTIs and its sequelae. However, in addition to the parameters included in the Bermingham et al., the model also included events of other infections and inflammations relevant to intermittent catheterisation including epididymitis/orchitis, urethritis, prostatitis, strictures, false passage and bladder stones (though these events were not distinguished between hydrophilic and uncoated catheters). The model was informed by healthcare resource utilisation parameters collected using an electronic survey of 25 urologists and neuro-urologists.
11	Truzzi (Int Braz J Urol, 2018); Brazil	Cost-effectiveness [lifetime]; Brazilian public healthcare system; Markov model	Inpatients and outpatients with spinal cord injury	Hydrophilic coated catheters	Uncoated polyvinylchloride (PVC) catheters	Single-use hydrophilic-coated catheters were cost effective in comparison to uncoated catheters with an ICER of R\$57,432 per life-year gained and R\$122,300 per QALY gained. When accounting for only UTIs, hydrophilic-coated catheters reduced UTI risk by 6% for an additional cost of R\$31,240	The model was adapted from the one used in Clark et al. 2016 and considered long-term sequelae of UTI (impairment of renal functions and renal failure), however different to the Clark et al model, it also considered additional health states of first- and second-line antibiotics resistance. The evidence on UTI risks were largely taken from the literature. Their model was run for two different scenarios: the first including all possible adverse events (that is UTIs, bladder stones, kidney stones, urethral injury, and urosepsis) and the second including only UTIs.
12	Watanabe (LUTS, 2017; 142-150); Japan	Cost-effectiveness [lifetime]; Japanese payer; Markov model	Inpatients with spinal cord injury and chronic urinary retention	Hydrophilic coated catheters	Uncoated catheters	Hydrophilic-coated catheters were cost-effective compared with uncoated catheters with an ICER of ¥3,826,351 (US \$31,623) per QALY gained and ¥1,639,562 (US \$13,550) per life-year gained	The model used was an adaptation of the model used in Clark et al, however was adjusted largely with Japanese data taken from clinician surveys, published literature and national statistics. The model considered long-term sequelae of UTIs (impairment of renal functions and renal failure).
13	Welk (J Med Econ, 2018; 639-648); Canada	Cost-effectiveness [lifetime]; Canadian public payer; Societal perspective as a scenario analysis	Neurogenic bladder dysfunction due to spinal cord injury	Hydrophilic-coated intermittent catheters	Uncoated catheters	Hydrophilic-coated catheters were cost-effective compared with uncoated catheters (ICER: \$66,634 per QALY gained)	Societal perspective accounting for productivity lost was taken as a scenario analysis. The model used was an adaptation of the model used in Clark et al. 2016 and considered the long-term sequelae of UTIs (renal impairment and failure). The parameters were informed by literature (including meta-analyses), national and provincial data including statistics Canada.

Abbreviations: CAUTI, catheter-associated urinary tract infections; ICER, incremental cost effectiveness; ratio PSS, personal social services; QALY, Quality-adjusted life years; UTI, urinary tract infection.

5.3 Summary, strengths and limitations

The economic evidence review identified 13 studies using Markov models to evaluate the cost-effectiveness of various intermittent catheters; 4 undertaken from an UK NHS perspective. Only one economic evaluation model (Cawson et al., 2023) assessed an intermittent catheter feature (micro-holes) listed in the initial NICE scope however this was available as an abstract only and provided limited details on model structure. None of the remaining identified studies were directly relevant to the decision problem of this late-stage assessment. Nevertheless, the identified published economic evaluations informed the development of the economic model developed by the EAG, including model structure, key health states and model parameters. The review also added to the validity of the modelling approach and model structure used by the EAG.

6 Economic model

6.1 *Methods*

As summarised in Table 14 (Section 5.2), previous economic evaluations comparing catheter types used Markov models adapted from the model structures originally presented by Bermingham et al. (2013) or Clark et al. (2016) (Bermingham et al., 2013; Clark et al., 2016). The risk of the patient developing a UTI was the key driver in all the models reviewed. However, unlike the previous models, the EAG model focused on assessing the impact on cost-effectiveness of individual catheter features. Therefore, in addition to UTI events, other specific outcomes include those prioritised by Clinical and Lay Experts (haematuria, successful drainage, reduced discomfort or pain, and ease of use, see Section 4.2.4). These were also informed by the CNMA and were incorporated into the model in terms of utilities or disutilities and costs or cost savings (using available evidence, Clinical Expert opinion or assumptions) for these outcomes.

6.1.1 Model structure

The EAG constructed a Markov model in Microsoft Excel (Figure 8), adapted from the economic model structure initially developed by Bermingham et al. (2013) informing NICE Clinical Guideline 139 ([NICE CG139](#), 2012), to estimate costs and health-related quality of life (HRQoL) for each comparator (Bermingham et al., 2013).

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The Bermingham et al. (2013) model structure was validated by clinical experts and has been used in multiple economic evaluations since its publication (Bermingham et al., 2013; Håkansson et al., 2015; Rognoni & Tarricone, 2017a).

The EAG were not aware of any significant changes in the clinical pathway of UTIs associated with intermittent catheterisation that would need changes to the decision model structure after the publication of Bermingham et al. (Bermingham et al., 2013). The model consisted of 7 key health states: Catheter users alive, Symptomatic UTI, UTI resistant to first-line antibiotics, Multidrug resistant UTI, Catheter-associated bacteraemia, Urethral complications (such as strictures, false passage, urethritis, or other complications as a results of urethral trauma) and Death. The arrows in

Figure 8 indicate the direction of transition of people from one state to another in each model cycle.

The cohort of patients start in the “Catheter users alive” state, and for each model cycle patients can either remain in this state, or move to the “Symptomatic UTI” state, or to the “Haematuria” state, or to the “Death” state. All alive patients in the cohort are at risk of moving to the “Urethral complications” state unless the patient is within the “Death” state (

Figure 8).

Patients moving to the “Symptomatic UTI” state can either return to the “Catheter users alive” state, or move to the “Urethral complications” state, or progress to any of the following states: “UTI resistant to first-line antibiotics”, “Multidrug-resistant UTI”, or “Catheter-associated bacteraemia”.

Patients progressing to the “UTI resistant to first-line antibiotics”, “Multidrug-resistant UTI”, or “Catheter-associated bacteraemia” states receive a health-state related monetary and HRQoL cost related to treatment, and either return to “Catheter users alive” or progress to the “Death” state. As illustrated in

Figure 8, patients in the “Multidrug-resistant UTI”, or “Catheter-associated bacteraemia” states have a higher background mortality risk compared with the rest of the population.

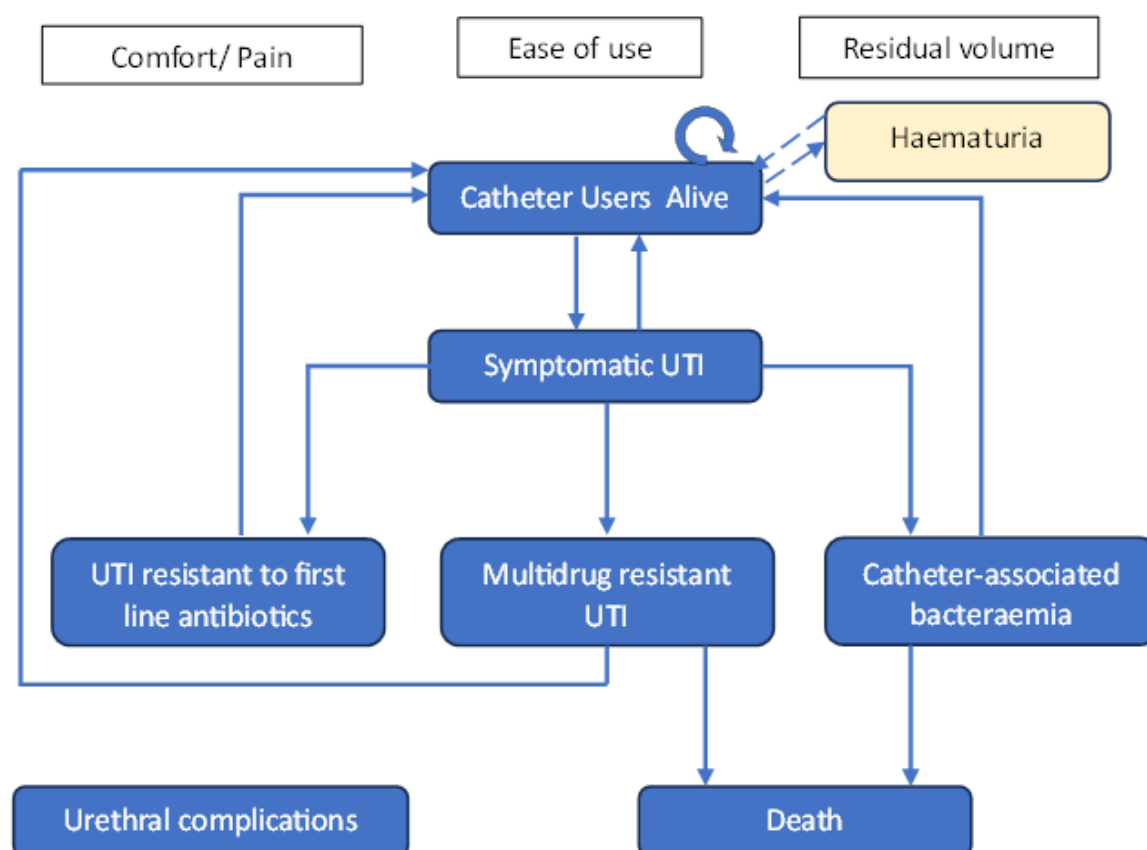
Patients moving to the “Haematuria” state return to the “Catheter users alive” state or progress to the “Death” state. As noted above, patients could also move to this state from any alive state. “Urethral complications” was an umbrella term that included: strictures, false passage, urethritis, or any other complications that could arise from urethral trauma. Patients can move to this health-state and either progress to the “Death” state or return to their previous health state.

All patients at any health-state have an all-cause mortality risk to move to the “Death” state (not indicated in Figure 8), however people with “Multidrug resistant UTI” and “Catheter associated bacteraemia” could have a higher level of mortality by virtue of their severe disease state. Death is the absorbing state in the model.

In addition to UTI rates, the decision model includes the direct impact of three of the primary outcomes in the CNMA: successful drainage, ease of use, reduction in pain or discomfort. Due to gaps in the evidence, changes in costs and utilities from these three outcomes were primarily based on assumptions and were applied across all the health states in the model rather than focusing on one health-state.

Figure 8: Economic model structure

[Note: Model structure adapted from Bermingham et al. 2013. Additionally urethral complications can occur in any state except “death” therefore to simplify the diagram no arrows are marked]



Key assumptions in the model were made to simplify the model structure and the economic analysis:

- There are no transitions between the three states: UTI resistant to first-line antibiotics, multidrug resistant UTI and catheter-associated bacteraemia.
- People continuously use the same type of catheter and do not switch between catheters throughout the 2-year time horizon.

- Adherence (assuming 5 catheters used each day) is assumed to be the same across catheters. However, utilities for ease of use, comfort, successful drainage may indirectly reflect adherence; that is patients may adhere to their prescribed frequency of use of intermittent catheterisations each day when their catheter is easier to use and more comfortable. Capturing the impact of ease of use, comfort, and successful drainage on cost and utilities is not straight forward as the EAG is not aware of any relevant cost or utility data. Rather than omitting impacts on cost and utility, the EAG have assumed that they would result in a saving per cycle for each outcome equivalent to 10% of the cost of one GP surgery consultation (cost of GP surgery consultation £41). A 10% proportion of the cohort was assumed to find the feature very easy to use, very comfortable or to strongly agreed that the catheter reduced residual volume, where the catheter feature claimed to have these outcomes. As these cost savings and proportions are essentially arbitrary, in scenario analysis the EAG varied the percentage cost savings attributed to the ease of use, comfort and improved residual volume to 50% of the cost of a GP surgery consultation. The EAG varied the proportions assumed to find the features that were very easy to use, very comfortable or had strongly agreed that the catheter reduced residual volume between 25%, 50% and 75%.
- The antibiotic resistance does not change over time. However, 2-years used as the base case analysis time horizon may be too short a duration to mark any significant changes in the antibiotic resistance.

6.1.2 Time horizon and discounting

A cycle length of 1-month was used in the economic model. For the base case analysis, a 2-year time horizon was considered the most appropriate approach by the EAG since it reflects the short-term nature of the clinical effectiveness evidence available, while more research is needed on how some benefits would translate to longer-term outcomes (for example survival differences between catheter features). The 2-year time horizon also reflected a healthcare review cycle where intermittent catheters may change.

All the relevant costs and health outcomes of patients having long-term intermittent catheterisation were discounted at a rate of 3.5% per year. Longer time horizons of 5 years and 10 years were also explored in the sensitivity analysis.

6.1.3 Perspective

An NHS and Personal Social Services (PSS) perspective was taken in line with the NICE reference case ([NICE PMG36, 2022](#)). All costs were presented in 2023 pounds sterling (£ GBP).

6.1.4 Population

Based on the clinical evidence and the economic studies available for our economic model, the base case population was modelled to be a representative cohort of patients with urine retention due to neurogenic (for example spinal-cord injury, multiple sclerosis) or non-neurogenic urine retention requiring intermittent catheterisation. The EAG assumed a cohort population with average age 45, of which 70% of the cohort were male; as derived from the included clinical evidence. Due to sparsity of the data, which were used in the CNMA, the EAG did not conduct a sensitivity analysis by indication; however, results from future analysis could be used to populate the economic model when further evidence becomes available.

6.1.5 Clinical effectiveness

Baseline risk parameters for the comparator

The baseline transition probabilities per 1-month model cycle for the comparator treatment (an uncoated catheter with no additional features present) are reported in Table 15.

Table 15. Baseline transition probabilities for comparator (U1) used in the economic model

Parameter description	Mean estimate	Source
Haematuria risk	0.0509	Average estimates from Cardenas, 2011 and De Ridder, 2005 (see Table 8)
Symptomatic UTI risk	0.0772	Average estimates from Cardenas, 2009; Sarica, 2010; De Ridder, 2005 (see Table 6)
Urethral complication risk	0.0019	(Couchman et al., 2022)
First-line antibiotic resistant UTI risk	0.0073	Derived from Bermingham et al. 2013
Multidrug resistant UTI risk	0.00603	Derived from Bermingham et al. 2013
Multidrug resistant excess mortality	0.0022	Derived from Bermingham et al. 2013
Bacteraemia risk	0.00305	Derived from Bermingham et al. 2013
Bacteraemia excess mortality	0.00665	Derived from Bermingham et al. 2013

Antibiotic resistance and mortality associated with antibiotic resistance was assumed to remain constant throughout the lifetime of the patients. This is a conservative assumption; however, it was difficult to predict the dynamic nature of antibiotic resistance and mortality over time.

Relative treatment effectiveness across features

Relative risk of symptomatic UTI and haematuria

Table 16 summarises the relative treatment effect used in the economic model, using results from the CNMA. The EAG notes that no treatment effect was isolated for integrated drainage bag, integrated handle or marking, insertion sleeve or tip protector features in the CNMA, therefore for this late-stage assessment the relative treatment effect was set to 1 (that is no difference to the comparator). The EAG acknowledge that from the CNMA, only enhanced coating or specially designed packaging had a treatment effect on UTI, and only micro-holes or specially designed catheter case had a treatment effect on haematuria. The EAG note that a CNMA was not possible for residual volume, ease of use or discomfort, and therefore the relative treatment effect was set to 1 for those outcomes also. However, the economic model includes functionality to include treatment effects for these features when further evidence is generated.

Table 16: Relative risk used in the economic model all derived from the CNMA

Feature	Deterministic UTI (compared with U1)	Sigma (Lognormal distribution)	Distribution	95% CrI LL	95% CrI UL
Integrated drainage bag	1	-	-	-	-
Integrated handle or markings	1	-	-	-	-
Insertion sleeve or grip	1	-	-	-	-
Tip protector or introducer	1	-	-	-	-
Micro-hole zone technology	1	-	-	-	-
Enhanced coating	0.86	0.27	Lognormal	0.44	1.27
Specially designed catheter case	1	-	-	-	-
Specially designed packaging	0.35	1.21	Lognormal	0.01	1.15
Feature	Deterministic Haematuria (compared with U1)	Sigma (Lognormal distribution)	Distribution	95% CrI LL	95% CrI UL
Integrated drainage bag	1	-	-	-	-
Integrated handle or markings	1	-	-	-	-
Insertion sleeve or grip	1	-	-	-	-
Tip protector or introducer	1	-	-	-	-
Micro-hole zone technology	0.16	1.38	Lognormal	0.01	2.27
Enhanced coating	1	-	-	-	-
Specially designed catheter case	2.05	0.92	Lognormal	0.09	3.34
Specially designed packaging	1	-	-	-	-

Abbreviations: CrI: credible interval; LL, lower limit; UL, upper limit; UTI, urinary tract infection.

Ease of use, discomfort or pain, or successful drainage:

Since there was a gap in the evidence between the CNMA results for: ease of use, discomfort or pain, or successful drainage, and quality adjusted life-years (QALYs) for economic evaluations or healthcare resource use; the EAG has assumed that 10% of the patient cohort utilising a catheter with additional features that explicitly aimed at improving either: ease of use, discomfort or pain, or successful drainage would benefit through an improvement (HRQoL, see Section 6.1.6, Table 18) and reduction in health resource use (see Section 6.1.7, Table 19).

Features that aim to offer an improvement on these three key primary outcomes were sourced from the information gathered in Table 1. The EAG advises caution in the interpretation of these values as they are arbitrary; uncertainty was further explored in the sensitivity analysis (Section 6.1.8). The features assumed to offer an improvement in ease of use, discomfort or pain, or successful drainage are reported below in Table 17.

Table 17 Features assumed to offer an improvement in ease of use, discomfort or pain, successful drainage grouped by key outcome

Feature	% of the cohort to benefit	Source
Improved ease of use	-	-
Integrated drainage bag	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Integrated handle or markings	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Insertion sleeve or grip	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Tip protector or introducer	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Enhanced coating	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Specially designed catheter case	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Specially designed packaging	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Less discomfort/less pain	-	-

Feature	% of the cohort to benefit	Source
Enhanced coating	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)
Improved residual volume	-	-
Micro-hole technology	10%	Assumed based on claimed benefits for intermittent catheter features stated in Table 1 (for other features not listed here, the assumption was zero)

Survival

Standardised mortality ratios (SMR=5.41) used in Bermingham et al. (2013) that informed NICE CG139 were used alongside mortality data from the life tables for England and Wales 2023/24 ([ONS, 2024](#)) adjusting by age (median age 45 years) and gender (70% male; 30% female) to generate life expectancy estimates for people using intermittent catheters (median values derived from included clinical evidence).

6.1.6 Health related quality of life

In line with the NICE reference case ([NICE PMG36, 2022](#)); health outcomes were measured using Quality Adjusted Life Years (QALYs). The QALY is a combination of HRQoL and life expectancy into a single index. HRQoL is calculated using utility weights related to each specific health state in the model.

Baseline utility weights

Utility values in the economic model were informed by the economic evaluation of intermittent catheters in [NICE CG139 \(2012\)](#) and the economic model of Bermingham et al. (2013), which were informed by a systematic review of HRQoL studies related to UTI and UTI-related bacteraemia (Bermingham et al., 2013), see Table 18. In addition, results from the literature search of economic evaluations were used to parametrise the impact of bacteraemia on HRQoL, which was extracted from Rognoni, C., and Tarricone, R. (2017) (Rognoni & Tarricone, 2017a).

Health-related quality of life from improvements in ease of use, discomfort or pain, or residual volume

Due to the sparse and heterogeneous evidence across features and outcomes, the EAG was unable to quantify the impact from improvements in ease of use, discomfort or pain, or residual volume into the utility values that would fit into a QALY calculation (see Sections 4.2.4, 4.2.3, and 5.2). Instead, the approach taken by the EAG was to assume a 2% increase in the baseline utility of a catheter user that uses a catheter product with additional features explicitly aimed at improving any of ease of use, discomfort or pain, or residual volume, based on Averbeck et al. (2018) (Averbeck et al., 2018). The 2% increase in utility was assumed to be the same across all three outcomes, leading to a net 0.017 increase in baseline utility, see Table 18.

Table 18. Utility weights used in the base case evaluation

Health State	Mean estimate	Std. Err.	95% CI LL	95% CI UL	Distribution	Source
No symptomatic UTI	0.831	0.01	0.809	0.852	Beta ($\alpha=969.06$, $\beta=197.08$)	(Bermingham et al., 2013)
Symptomatic UTI	0.782	0.01	0.764	0.799	Beta ($\alpha=1671.41$, $\beta=465.96$)	(Bermingham et al., 2013)
First-line resistant UTI	0.760	0.04	0.685	0.834	Beta ($\alpha=95.19$, $\beta=30.06$)	(Bermingham et al., 2013)
Multidrug resistant UTI	0.738	0.03	0.688	0.787	Beta ($\alpha=222.99$, $\beta=79.16$)	(Bermingham et al., 2013)
Bacteraemia	0.716	0.04	0.645	0.786	Beta ($\alpha=111.82$, $\beta=44.35$)	(Bermingham et al., 2013) (Bermingham et al., 2013)
Urethral complication	0.738	0.03	0.688	0.787	Beta ($\alpha=222.99$, $\beta=79.16$)	(Bermingham et al., 2013)
Disutility/additional utility	Mean estimate	Std. Err.	95% CI LL	95% CI UL	Distribution	Source
Haematuria	-0.093	-	-	-	-	(Rognoni & Tarricone, 2017a)
Comfort/less pain	0.017	-	-	-	-	No evidence identified. Assumed 2% increase in catheter user utility, based on (Averbeck et al., 2018)
Easy to use	0.017	-	-	-	-	Assumed same as comfort/less pain

Health State	Mean estimate	Std. Err.	95% CI LL	95% CI UL	Distribution	Source
Improved residual volume	0.017	-	-	-	-	Assumed same as comfort/less pain

Abbreviations: CI, confidence interval; LL, lower limit; UL, upper limit; UTI, urinary tract infection. Disutility/additional utility values explored with 10% higher values in scenario analyses rather than assigning a distribution.

6.1.7 Resource use and cost

Catheter and additional feature costs

Results from the regression analysis in Section 3.2 on the price paid by the NHS for catheters with or without additional features (Table 3, Figure 2) were used to inform the decision-analytic model where effectiveness evidence was available, and it was feasible to implement. The basic cost of an individual single-use uncoated catheter without additional lubrication or features was assumed to be £1.37. The cost of external gel lubrication was added to the basic price as £0.19 per individual uncoated catheter without lubrication used. Gel lubrication costs were extracted from [NICE CG139 \(2012, updated 2017\)](#) and validated against the 2024 NHS Drug Tariff (NHS Business Service Authority, 2024).

Based on Bermingham et al. (2013) the economic model assumed that 5 individual catheters were used per day (Bermingham et al., 2013), with the sensitivity analysis varying the daily use from 3 to 7 catheters per day (Section 6.1.8). In addition, the cost to the NHS for the home delivery of intermittent catheters for a monthly supply of self-catheterisation products from the NHS Drugs Tariff at £9.30 were included in the EAG analysis. These costs were attributable to all intermittent catheters prescribed, regardless of features present.

Based on the care pathway in Pickard et al. (2018) the economic model assumes that patients under catheterisation attend on average 10.05 GP surgery consultations a year Pickard et al. (2018). Since the cost of a 10-minute GP consultation including qualifications was £49 (Jones et al., 2024), the monthly costs of GP consultations were on average £41, see Table 19. The EAG acknowledges this is a strong assumption based on a clinical study, whereas in practice the amount of GP consultations may be significantly lower.

This meant that the total monthly cost of catheterisation for a patient using uncoated catheters without additional lubrication and without additional features was estimated at £287.42 (Table 19). The cost of catheters with varying basic and additional features was based on the results of the regression analysis in Section 3.2 (Table 3, Figure 2), and only included price variations that were statistically significant in the base case analysis (Table 19).

UTI-related healthcare consultation cost

Health state resource use and costs in the model were informed by the economic analysis in [NICE CG139 \(2012, updated 2017\)](#). The cost of a healthcare consultation was constructed as a weighted average of the cost of a GP consultation (80% of cases), the cost of a specialist community nurse (10% of cases), and the cost of a hospital emergency visit (10% of cases). The cost of a 10-minute GP consultation including qualifications (£49, the difference with the GP consultation cost without qualifications and excluding direct costs of £38 was used to derive a standard error of £2.81) used and the cost of 1 hour with a specialist nurse (Band 6, £64, the difference with the cost of a hospital-based nurse used to derive a standard error of £1.53) were sourced from Unit Costs of Health and Social Care (Jones et al., 2024) while the average unit cost of emergency care from the national schedule of NHS costs 2022/23 (£263, the unit costs of emergency care codes VB01Z to VB11Z were used to generate a standard error of £189.55) (NHS England National Cost Collection, 2024). The average cost of a UTI consultation was assumed at £71.90 and a gamma distribution with a standard error of £60 to account for the probability of a high-cost emergency admission.

Symptomatic UTI, first-line, and second-line antibiotic therapy costs

The antibiotic medicines for first-line and second-line therapy were extracted from the economic analysis in [NICE CG139 \(2012, updated 2017\)](#), and were further validated with Clinical Experts (see Appendix D). The cost of first-line antibiotic therapy to treat catheter-associated UTIs (CAUTIs) was built as a simple average of the following antibiotic therapy costs: trimethoprim, nitrofurantoin, cefalexin, and pivmecillinam. Treatment duration was assumed to be 7 days, except for pivmecillinam which was assumed to be 3 days based on treatment schedule information on each antibiotic from the BNF (British National Formulary (BNF), 2024). Second-line antibiotic therapy was a simple average of the following antibiotic therapy costs: ciprofloxacin, cefaclor, cefixime, ofloxacin, pivmecillinam. Second-line

treatment duration was assumed to be 7 days in the base case except for ofloxacin which was 10 days and pivmecillinam (3 days) based on the BNF (British National Formulary (BNF), 2024). It was further assumed that patients are fully compliant for both first- and second-line antibiotic therapy. Drug prices were initially sourced from the drugs and pharmaceutical electronic market information tool (eMIT) (Drugs and pharmaceutical electronic market information tool (eMIT), 2024) and when not available from the BNF (British National Formulary (BNF), 2024). Dipstick analysis equipment costs (£0.66) were taken from the Drugs Tariff (NHS Business Service Authority, 2024). Fees per prescription to Dispensing Appliance Contractor in the NHS Drug Tariff (£1.27) (NHS Business Service Authority, 2024) were used to estimate antibiotic prescription costs.

Patients with first-line resistant UTI are assumed to have a healthcare consultation as defined in the first paragraph, and a urine analysis based on the national schedule of NHS costs for a microbiology assessment (£9, code DAPS07), while patients with multi-drug resistant UTI are assumed to have a healthcare consultation, the average cost from an “urethral disorder with or without intervention” (£2,287.75 code LB57C-D) (NHS England National Cost Collection, 2024).

Bacteraemia costs

The cost of a hospital admission to treat bacteraemia was generated from the average cost of “kidney or urinary tract infections with or without interventions” from the national schedule of NHS costs (£2,360.78, codes LA04H-S) (NHS England National Cost Collection, 2024). In addition, the cost of a blood test was added from the schedule of NHS costs for a phlebotomy assessment (£7, code DAPS08) (NHS England National Cost Collection, 2024).

Haematuria and urethral complication costs

The cost of haematuria treatment was assumed equivalent to the routine GP surgery consultation cost of £41 (derived from 10.5 annual visits from Pickard et al. 2018) (Pickard et al., 2018). The EAG also undertook a scenario analysis by changing the cost of haematuria from a routine GP appointment to a hospital admission to treat haematuria. This cost was generated as the weighted average of cost of “unspecified haematuria with or without interventions” from the national schedule of NHS costs (£1,764.58 codes LB38C-H) (NHS England National Cost Collection, 2024).

Hospital costs to treat further urethral complications were computed as a weighted average of the costs of “urethral disorders with and without intervention” in the national schedule of NHS costs (£2,287.75 codes LB57C-D) (NHS England National Cost Collection, 2024). The EAG identified no evidence of a difference in the proportion of urethral complications between features, therefore, the costs of urethral complications is nullified between the model arms and does not affect the conclusions drawn. However, the EAG economic model does include this complication as a health state such that it can be populated to facilitate further analysis should more data become available.

Healthcare resource use from improvements in ease of use, discomfort or pain, or residual volume

No direct evidence was found in the literature directly linking the key clinical outcomes of ease of use, discomfort or pain, or residual volume with healthcare resource use. Instead, the EAG explored directly including the health resource use implications from improvements in ease of use, discomfort or pain, and residual volume, by assuming 10% reduction in the routine GP surgery consultation costs extracted from Pickard et al. 2018 (Pickard et al., 2018). The parametric uncertainty around this assumption was assessed in the scenario analysis assuming a 50% reduction in routine GP surgery consultation costs.

The cost parameters included in the economic model were reported in Table 19.

Table 19. Healthcare costs included in the economic model

Catheter costs (Monthly)	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Uncoated (no lubricant provided)	£287.42	£6.55	£273.82	£299.50	Gamma ($\alpha=1924.93$, $\beta=0.15$)	[Based on unit costs of catheter (informed by regression analysis) + unit cost of lubricant sachet]] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Integrated drainage bag	£393.82	£10.82	£372.62	£415.02	Gamma ($\alpha=1325.67$, $\beta=0.30$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Integrated handle or markings	£273.74	£10.82	£252.54	£294.94	Gamma ($\alpha=640.50$, $\beta=0.43$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Insertion sleeve or grip	£258.54	£6.16	£246.46	£270.62	Gamma ($\alpha=715.87$, $\beta=0.35$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Tip protector or introducer	£301.10	£10.82	£279.90	£322.30	Gamma ($\alpha=774.93$, $\beta=0.39$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Micro-hole zone technology	£258.54	£6.16	£246.46	£270.62	Gamma ($\alpha=1759.68$, $\beta=0.15$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Enhanced coating	£296.54	£9.26	£278.38	£314.70	Gamma ($\alpha=1024.35$, $\beta=0.29$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Specially designed catheter case	£258.54	£6.16	£246.46	£270.62	Gamma ($\alpha=1759.68$, $\beta=0.15$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Specially designed packaging	£267.66	£10.82	£246.46	£288.86	Gamma ($\alpha=1759.68$, $\beta=0.15$)	[Based on unit costs of catheter (informed by regression analysis)] times 152 catheters in a month + one GP surgery consultation cost (£41)+ delivery charge (£9.30).
Symptomatic UTI	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Healthcare consultation	£71.90	60	£4.72	£228.01	Gamma ($\alpha=1.59$, $\beta=45.13$)	See UTI-related healthcare consultation cost (Jones et al., 2024); (NHS England National Cost Collection, 2024)
Dipstick analysis	£0.06	0.01	£0.05	£0.08	Gamma ($\alpha=61.47$, $\beta=0.001$)	(NHS Business Service Authority, 2024)
First-line antibiotic treatment	£6.40	0.58	£5.31	£7.60	Gamma ($\alpha=120.02$, $\beta=0.05$)	(British National Formulary (BNF), 2024)
Dispensing fee for antibiotics	£1.27	-	-	-	-	(NHS Business Service Authority, 2024)
Delivery fee for catheters	£9.30	-	-	-	-	(NHS Business Service Authority, 2024); added to the costs of additional catheters, and a scenario analysis is conducted with £0 costs.
Additional catheters	12	-	-	-	-	Assumption NICE CG139, 2012 ; costed with unit costs of comparator and intervention catheters for each arm respectively + £9.30 delivery charge
First-line antibiotic resistant UTI	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Healthcare consultation	£71.90	60	£4.72	£228.01	Gamma ($\alpha=1.59$, $\beta=45.13$)	See UTI-related healthcare consultation cost (Jones et al., 2024; NHS England National Cost Collection, 2024)
Urine analysis	£8.89	0.89	£7.23	£10.72	Gamma ($\alpha=99.71$, $\beta=0.09$)	Code DAPS07 (Birmingham et al., 2013; NHS England National Cost Collection, 2024)
Second-line antibiotic	£5.84	2.80	£1.71	£12.48	Gamma ($\alpha=4.52$, $\beta=1.29$)	(Drugs and pharmaceutical electronic market information tool (eMIT), 2024); (British National Formulary (BNF), 2024)
Dispensing fee for antibiotics	£1.27	-	-	-	-	(NHS Business Service Authority, 2024)
Delivery fee for catheters	£9.30	-	-	-	-	(NHS Business Service Authority, 2024); added to the costs of additional catheters, and a scenario analysis is conducted with £0 costs.
Additional catheters	12	-	-	-	-	Assumption NICE CG139, 2012 ; same as Symptomatic UTI above
Multi-drug resistant UTI	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Healthcare consultation	£71.90	60	£4.72	£228.01	Gamma ($\alpha=1.59$, $\beta=45.13$)	See UTI-related healthcare consultation cost (Jones et al., 2024); (NHS England National Cost Collection, 2024)
Urine analysis	£8.89	0.89	£7.23	£10.72	Gamma ($\alpha=99.71$, $\beta=0.09$)	Code DAPS07 (Birmingham et al., 2013; NHS England National Cost Collection, 2024)
Nonelective admission	£2,287.75	967.53	£802.29	£4,537.71	Gamma ($\alpha=5.76$, $\beta=396.92$)	Average cost LB57C-D (NHS England National Cost Collection, 2024)
Catheter associated Bacteraemia	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Healthcare consultation	£71.90	60	£4.72	£228.01	Gamma ($\alpha=1.59$, $\beta=45.13$)	Assumed same as UTI-related healthcare consultation cost (Jones et al., 2024); (NHS England National Cost Collection, 2024)
Urine analysis	£8.89	0.89	£7.23	£10.72	Gamma ($\alpha=99.71$, $\beta=0.09$)	Code DAPS07 (Birmingham et al., 2013; NHS England National Cost Collection, 2024)
Blood test	£6.63	0.66	£5.39	£7.99	Gamma ($\alpha=99.92$, $\beta=0.07$)	Code DAPS08 (Birmingham et al., 2013; NHS England National Cost Collection, 2024)

Non-elective admission	£2,360.78	2066.47	£124.49	£7,784.80	Gamma ($\alpha=1.46$, $\beta=1617.58$)	Average cost LA04H-S (NHS England National Cost Collection, 2024)
Other complications	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
Urethral complications	£2,287.75	967.53	£802.29	£4,537.71	Gamma ($\alpha=5.77$, $\beta=396.87$)	Weighted average cost LB57C-D (NHS England National Cost Collection, 2024)
Haematuria	£41	2.86	35	47	Gamma ($\alpha=179.38$, $\beta=0.23$)	Assumed as a cost of GP surgery consultation in a month (derived using 10.05 GP consultations in a year (Pickard et al., 2018) and £49 per GP consultation lasting 10 mins, sourced from (Jones et al., 2024). £1,764.58 explored in scenario analysis (weighted average cost LB38C-H (NHS England National Cost Collection, 2024). Taken as a proxy for the cost of managing this symptom)
Other costs	Mean	Std. Err.	95% CI LL	95%CI UL	Distribution	Source
GP surgery consultation	£41	2.86	35	47	Gamma ($\alpha=179.38$, $\beta=0.02$)	Derived using 10.05 GP surgery consultations in a year (Pickard et al., 2018) and £49 per GP consultation lasting 10 mins, sourced from Jones et al 2024. Assumed and added as costs of monthly healthcare utilisation to both arms.
Ease of use	£4.10	0.70	3.50	4.70	Gamma ($\alpha=179.38$, $\beta=0.02$)	Assumed ease of use would avoid 10% of GP surgery consultation cost per month (derived using 10.05 GP consultations in a year (Pickard et al., 2018) and £49 per GP consultation lasting 10 mins, sourced from (Jones et al., 2024)
Comfort/pain	£4.10	0.70	£3.50	£4.70	Gamma ($\alpha=179.38$, $\beta=0.02$)	Assumed as above for more comfort or less pain
Residual volume	£4.10	0.70	£3.50	£4.70	Gamma ($\alpha=179.38$, $\beta=0.02$)	Assumed as above for improved drainage
Unit cost of lubricant sachet	£0.19	-	£0.18	£0.19	-	Combined with the total monthly costs of catheter, not considered separately

Abbreviations: CI, confidence interval; LL lower limit; UL, upper limit; UTI, urinary tract infection.

6.1.8 Sensitivity analysis

One-way deterministic sensitivity analyses (OWSA) were undertaken to evaluate the sensitivity of the base case results across the following parameters: Age of the cohort; proportion of males; baseline UTI risks; baseline haematuria risks; intermittent catheter products used per day; proportion of benefiting from improvements in ease of use, discomfort or pain, successful drainage; no catheter delivery costs; healthcare resource use reduction from improvements in ease of use, discomfort or pain, successful drainage; time horizon of the economic analysis; HRQoL improvement from improvements in ease of use, discomfort or pain, successful drainage.

The analyses undertaken are summarised in Table 20: Model parameters varied in sensitivity analysis

Table 20: Model parameters varied in sensitivity analysis

Parameter	Value(s)	EAG comment
Population age	25 years 65 years	Intermittent catheterisation is used in a variety of patient groups (different indications), therefore applied a number of sensitivity analyses to broadly cover the age range noted in the included clinical evidence. It is important to note that changes in age impacts only the mortality outcome which comes from SMR.
Proportion male sex	0.60 0.80	Same as above.
Baseline risk of UTI/30 days in comparator arm	0.05 0.114	The aim of this is to attempt to model different indications for intermittent catheterisation, using the range identified in clinical evidence (Table 6)
Baseline risk of haematuria/30 days in comparator arm	0.045 0.19	The aim of this is to attempt to model different indications for intermittent catheterisation, using the range identified in clinical evidence where the time point was reported (Table 6)
Catheters per day	3 7	To model the impact if more or fewer catheters are used per day.
Baseline proportion finding comfortable, easy to use, successful drainage	0.25 0.50 0.75	Baseline was based on 0.10 assumption, due to limited data and poor reporting of this outcome.
Cost of haematuria	£1764.58	Baseline was assumed as a cost of one GP surgery consultation; the scenario tested here was weighted average of LB38C-H (NHS England National Cost Collection, 2024)
Cost of catheter delivery	£0.00	No difference in delivery costs is expected between arms.
Costs avoided due to ease of use, comfort, and improved drainage (as a percentage of GP healthcare consultation)	50%	Base case 10%; due to limited data.
Time horizon	5 years 10 years Lifetime	Extrapolation of results to longer time horizon.
Disutility/additional utility (10% higher than the base case)	Haematuria: -0.1023 Comfort: 0.0187 Ease of use: 0.0187 Improved residual volume: 0.0187	Explore uncertainty in these estimates

Abbreviations: EAG, External Assessment Group; SMR, standardised mortality ratio;

Uncertainty surrounding model input parameters were explored with a probabilistic sensitivity analysis (PSA; distributions described in Table 16, Table 19, Table 19). PSA included a total number of 10,000 simulations for each run.

6.1.9 Model validation

The internal validity of the economic model was checked independently by another health economist within the EAG and was undertaken by varying model input parameters and assessing whether the model results are sensitive and logical. Each model parameter was checked against its source to ensure that it has been incorporated within the economic model appropriately. Validation efforts were documented using the Assessment of the Validation Status of Health-Economic decision models (AdViSHE) tool ([Vemer et al. 2015](#)), [Appendix G](#).

6.2 Results

6.2.1 Base case

The results from the base case considering 8 intermittent catheter features are shown in Table 21.

- Five features were less costly than the comparator (uncoated intermittent catheter, U1): integrated handle or markings; insertion sleeve or grip; micro-hole zone technology; specially designed catheter case and specially designed packaging. Of these, micro-holes and specially designed packaging provided more QALYs (using relative risks derived from the included evidence and subsequently undertaken CNMA); hence as they were also lower cost a catheter with these features would be dominant in a direct head-to-head comparison with the comparator catheter (uncoated catheter with no additional features). Integrated handle and insertion sleeve or grip were also considered dominant based on lower costs and slight increase in QALYs. The EAG note that as it could not isolate an effect from the CNMA for those features, a small utility increase was applied to incorporate the potential ease of use associated with these features. Assuming they are as effective as the comparator, these features could also be selected from the impact on cost alone. The fifth feature, specially designed catheter case, had lower total cost but also provided slightly less QALYs compared with the comparator. In this case an

ICER is calculated but the ICER is for the comparison of the more effective but more costly comparator compared with the feature. In this case the ICER indicates that the comparator is not cost-effective and therefore the feature is cost-effective.

- One feature, enhanced coating, was associated with slightly more QALYs for slightly increased costs. The incremental cost per QALY was £22,296; which is close to the willingness to pay threshold. The EAG again highlight the uncertainty regarding the relative effect of this feature on reduction of UTI; sensitivity analysis was undertaken to explore this.
- For two features, integrated drainage bag and tip protector, the QALYs were slightly increased (as the EAG applied a small utility gain associated with ease of use for these features), however both incurred increased cost. The incremental cost per QALY associated with these features were greater an £90,000 (significantly so for integrated drainage bags) and therefore the price associated with features was not considered justified.

After the factual accuracy check, NICE requested the economic model to include age and gender adjustments to general population utility values. The EAG presented in Appendix H the additional scenario analysis, where the utility values were adjusted, which had an equivalent impact on the interventions and the comparator; therefore the relative incremental results did not change (See Appendix H).

Table 21. Base case analysis results (Deterministic)

Feature	Total Costs (£)	Total QALYs	Inc. Costs (£)	Inc. QALYs	ICER
Comparator (U1) - Reference	7228	1.6355	-	-	-
Integrated drainage bag	9771	1.6389	2543	0.0034	752,525
Integrated handle or markings	6890	1.6389	-338	0.0034	Dominates U1
Insertion sleeve or grip	6526	1.6389	-703	0.0034	Dominates U1
Tip protector or introducer	7547	1.6389	318	0.0034	94,231
Micro-hole zone technology	6487	1.6462	-741	0.0107	Dominates U1
Enhanced coating	7398	1.6431	170	0.0076	22,296
Specially designed catheter case	6574	1.6298	-654	-0.0058	113,724*
Specially designed packaging	6606	1.6431	-622	0.0076	Dominates U1

Abbreviations: ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; U1, uncoated catheter with no lubrication provided (required separately)
*ICER for U1 catheter with no features vs specially designed catheter case, U1 is not considered cost-effective at the £20,000 per QALY threshold from NICE

6.2.2 Sensitivity analysis

One-way sensitivity analysis (OWSA)

The results of one-way sensitivity analysis are presented in Table 22. In almost all cases the results of the base case analysis remain unchanged. The EAG note that even in the scenario where it is assumed that 75% of patients find an intermittent catheter with an integrated bag easier to use, it remains not cost-effective; the EAG consider that larger utility gains would be needed to justify the cost increase associated with that feature. Extending the time horizon of the economic model up to a lifetime has little impact on the direction or magnitude of effect; this is due to most of the costs being attributed to the catheter and differences in QALYs are small. For the enhanced coating feature, uncertainty remains. However, referring to the difference in monthly costs between intermittent catheters with an enhanced coating compared with an uncoated comparator (enhanced coating incurring an additional £9.12 per month; Table 19). To place this value into context, the EAG note a patient would need to avoid 2.2 GP appointments (£109.44/£49) for every 12 months that catheter with an enhanced coating is prescribed to compensate for the additional cost incurred for this feature. Through additional threshold analysis undertaken by the EAG, a RR of UTI of 0.805 or lower for enhanced coating would result in this feature having an ICER lower than the £20,000 WTP threshold. Similarly for integrated drainage bags, the equivalent of 26.0 GP appointments (£1,276.80/£49) per patient per year would need to be avoided to offset the additional costs incurred. The EAG considered that reductions in care equivalent to this is not clinically plausible.

Sensitivity analysis is further illustrated in the Tornado diagrams on the impact on net monetary benefitTable 22: Summary of scenario analyses

Intermittent catheter feature	Scenario	Inc. Cost (£)	Inc. QALY	ICER
Integrated drainage bag	Base-case	£2,543	0.0034	£752,525
	Time horizon: 5 years	£5,780	0.0077	£752,571
	Time horizon: 10 years	£10,151	0.0135	£752,587

	Time horizon: Lifetime	£18,063	0.0240	£752,603
	Discount rate: 0%	£2,631	0.0035	£752,528
	Discount rate: 5%	£2,507	0.0033	£752,524
	Age of cohort: 25 years	£2,568	0.0034	£752,522
	Age of cohort: 65 years	£2,410	0.0032	£752,539
	Male proportion: 60%	£2,544	0.0034	£752,525
	Male proportion: 80%	£2,541	0.0034	£752,525
	Catheters per day: 3	£1,524	0.0034	£451,113
	Catheters per day: 7	£3,561	0.0034	£1,053,937
	Proportion finding easy to use: 0.25	£2,528	0.0084	£299,274
	Proportion finding easy to use: 0.50	£2,504	0.0169	£148,190
	Proportion finding easy to use: 0.75	£2,479	0.0253	£97,828
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£2,504	0.0034	£740,949
	Ease of use utility increment 10% higher	£2,543	0.0037	£684,114
Integrated handle or markings	Base-case	-£338	0.0034	Dominant
	Time horizon: 5 years	-£768	0.0077	Dominant
	Time horizon: 10 years	-£1,349	0.0135	Dominant
	Time horizon: Lifetime	-£2,401	0.0240	Dominant
	Discount rate: 0%	-£350	0.0035	Dominant
	Discount rate: 5%	-£333	0.0033	Dominant
	Age of cohort: 25 years	-£341	0.0034	Dominant
	Age of cohort: 65 years	-£320	0.0032	Dominant
	Male proportion: 60%	-£338	0.0034	Dominant
	Male proportion: 80%	-£338	0.0034	Dominant
	Catheters per day: 3	-£207	0.0034	Dominant
	Catheters per day: 7	-£469	0.0034	Dominant
	Proportion finding easy to use: 0.25	-£353	0.0084	Dominant
	Proportion finding easy to use: 0.50	-£377	0.0169	Dominant
	Proportion finding easy to use: 0.75	-£402	0.0253	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£377	0.0034	Dominant
	Ease of use utility increment 10% higher	-£338	0.0037	Dominant
Insertion sleeve or grip	Base-case	-£703	0.0034	Dominant
	Time horizon: 5 years	-£1,597	0.0077	Dominant
	Time horizon: 10 years	-£2,805	0.0135	Dominant
	Time horizon: Lifetime	-£4,991	0.0240	Dominant
	Discount rate: 0%	-£727	0.0035	Dominant
	Discount rate: 5%	-£693	0.0033	Dominant
	Age of cohort: 25 years	-£710	0.0034	Dominant
	Age of cohort: 65 years	-£666	0.0032	Dominant
	Male proportion: 60%	-£703	0.0034	Dominant
	Male proportion: 80%	-£702	0.0034	Dominant
	Catheters per day: 3	-£426	0.0034	Dominant
	Catheters per day: 7	-£979	0.0034	Dominant
	Proportion finding easy to use: 0.25	-£717	0.0084	Dominant
	Proportion finding easy to use: 0.50	-£742	0.0169	Dominant
	Proportion finding easy to use: 0.75	-£766	0.0253	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£742	0.0034	Dominant
	Ease of use utility increment 10% higher	-£703	0.0037	Dominant
Tip protector or introducer	Base-case	£318	0.0034	£94,231
	Time horizon: 5 years	£724	0.0077	£94,237
	Time horizon: 10 years	£1,271	0.0135	£94,239
	Time horizon: Lifetime	£2,262	0.0240	£94,241
	Discount rate: 0%	£329	0.0035	£94,232
	Discount rate: 5%	£314	0.0033	£94,231
	Age of cohort: 25 years	£322	0.0034	£94,231
	Age of cohort: 65 years	£302	0.0032	£94,233
	Male proportion: 60%	£319	0.0034	£94,231
	Male proportion: 80%	£318	0.0034	£94,231

	Catheters per day: 3	£187	0.0034	£55,478
	Catheters per day: 7	£449	0.0034	£132,984
	Proportion finding easy to use: 0.25	£304	0.0084	£35,956
	Proportion finding easy to use: 0.50	£279	0.0169	£16,531
	Proportion finding easy to use: 0.75	£255	0.0253	£10,056
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£279	0.0034	£82,655
	Ease of use utility increment 10% higher	£318	0.0037	£85,665
Micro-hole zone technology	Base-case	-£741	0.0107	Dominant
	Time horizon: 5 years	-£1,685	0.0243	Dominant
	Time horizon: 10 years	-£2,959	0.0426	Dominant
	Time horizon: Lifetime	-£5,265	0.0758	Dominant
	Discount rate: 0%	-£767	0.0111	Dominant
	Discount rate: 5%	-£731	0.0105	Dominant
	Age of cohort: 25 years	-£749	0.0108	Dominant
	Age of cohort: 65 years	-£703	0.0101	Dominant
	Male proportion: 60%	-£742	0.0107	Dominant
	Male proportion: 80%	-£741	0.0107	Dominant
	Comparator Haematuria probability: 0.045	-£737	0.0098	Dominant
	Comparator Haematuria probability: 0.19	-£847	0.0307	Dominant
	Catheters per day: 3	-£465	0.0107	Dominant
	Catheters per day: 7	-£1,018	0.0107	Dominant
	Proportion finding improved residual volume: 0.25	-£756	0.0158	Dominant
	Proportion finding improved residual volume: 0.50	-£780	0.0242	Dominant
	Proportion finding improved residual volume: 0.75	-£805	0.0327	Dominant
	Cost of Haematuria: £1764.58	-£2,366	0.0107	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£780	0.0107	Dominant
	Haematuria: disutility 10% higher	-£741	0.0114	Dominant
	Improved residual volume utility increment 10% higher	-£741	0.0110	Dominant
Enhanced coating	Base-case	£170	0.0076	£22,296
	Time horizon: 5 years	£386	0.0174	£22,203
	Time horizon: 10 years	£677	0.0306	£22,146
	Time horizon: Lifetime	£1,205	0.0547	£22,037
	Discount rate: 0%	£176	0.0079	£22,291
	Discount rate: 5%	£168	0.0075	£22,298
	Age of cohort: 25 years	£172	0.0077	£22,300
	Age of cohort: 65 years	£161	0.0072	£22,276
	Male proportion: 60%	£170	0.0076	£22,296
	Male proportion: 80%	£170	0.0076	£22,296
	Comparator UTI probability: 0.05	£180	0.0073	£24,501
	Comparator UTI probability: 0.114	£160	0.0079	£20,234
	Catheters per day: 3	£83	0.0076	£10,848
	Catheters per day: 7	£257	0.0076	£33,744
	Proportion finding easy to use: 0.25	£155	0.0127	£12,239
	Proportion finding easy to use: 0.50	£131	0.0211	£6,192
	Proportion finding easy to use: 0.75	£106	0.0296	£3,598
	Proportion finding comfort: 0.25	£155	0.0127	£12,239
	Proportion finding comfort: 0.50	£131	0.0211	£6,192
	Proportion finding comfort: 0.75	£106	0.0296	£3,598
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£92	0.0076	£12,038
	Zero cost of catheter delivery	£172	0.0076	£22,576
	Comfort utility increment 10% higher	£170	0.0080	£21,350
	Ease of use utility increment 10% higher	£170	0.0080	£21,350
Specially designed catheter case	Base-case	-£654	-0.0058	£113,724*
	Time horizon: 5 years	-£1,488	-0.0131	£113,896*
	Time horizon: 10 years	-£2,612	-0.0229	£113,958*
	Time horizon: Lifetime	-£4,648	-0.0408	£114,016*
	Discount rate: 0%	-£677	-0.0060	£113,735*
	Discount rate: 5%	-£645	-0.0057	£113,720*

	Age of cohort: 25 years	-£661	-0.0058	£113,715*
	Age of cohort: 65 years	-£620	-0.0055	£113,777*
	Male proportion: 60%	-£655	-0.0058	£113,724*
	Male proportion: 80%	-£654	-0.0058	£113,725*
	Comparator Haematuria probability: 0.045	-£660	-0.0047	£140,559*
	Comparator Haematuria probability: 0.19	-£522	-0.0307	£17,006*
	Catheters per day: 3	-£378	-0.0058	£65,676*
	Catheters per day: 7	-£931	-0.0058	£161,773*
	Proportion finding easy to use: 0.25	-£669	-0.0007	£976,725*
	Proportion finding easy to use: 0.50	-£693	0.0078	Dominant
	Proportion finding easy to use: 0.75	-£718	0.0162	Dominant
	Cost of Haematuria: £1764.58	£1,377	-0.0058	Dominated
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£693	-0.0058	£120,523*
	Haematuria: disutility 10% higher	-£654	-0.0067	£98,146*
	Ease of use utility increment 10% higher	-£654	-0.0054	£120,820*
Specially designed packaging	Base-case	-£622	0.0076	Dominant
	Time horizon: 5 years	-£1,418	0.0174	Dominant
	Time horizon: 10 years	-£2,492	0.0309	Dominant
	Time horizon: Lifetime	-£4,434	0.0563	Dominant
	Discount rate: 0%	-£644	0.0078	Dominant
	Discount rate: 5%	-£613	0.0075	Dominant
	Age of cohort: 25 years	-£628	0.0076	Dominant
	Age of cohort: 65 years	-£590	0.0072	Dominant
	Male proportion: 60%	-£622	0.0076	Dominant
	Male proportion: 80%	-£622	0.0076	Dominant
	Comparator UTI probability: 0.05	-£573	0.0061	Dominant
	Comparator UTI probability: 0.114	-£674	0.0091	Dominant
	Catheters per day: 3	-£433	0.0076	Dominant
	Catheters per day: 7	-£811	0.0076	Dominant
	Proportion finding easy to use: 0.25	-£637	0.0126	Dominant
	Proportion finding easy to use: 0.50	-£661	0.0211	Dominant
	Proportion finding easy to use: 0.75	-£686	0.0295	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£661	0.0076	Dominant
	Zero cost of catheter delivery	-£612	0.0076	Dominant
	Ease of use utility increment 10% higher	-£622	0.0079	Dominant

Abbreviations: EAG, External Assessment Group; ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; UTI, urinary tract infection;

Figure 9. This approach was used because some changes result in a negative ICER which is hard to interpret.

Table 22: Summary of scenario analyses

Intermittent catheter feature	Scenario	Inc. Cost (£)	Inc. QALY	ICER
Integrated drainage bag	Base-case	£2,543	0.0034	£752,525
	Time horizon: 5 years	£5,780	0.0077	£752,571
	Time horizon: 10 years	£10,151	0.0135	£752,587
	Time horizon: Lifetime	£18,063	0.0240	£752,603
	Discount rate: 0%	£2,631	0.0035	£752,528
	Discount rate: 5%	£2,507	0.0033	£752,524
	Age of cohort: 25 years	£2,568	0.0034	£752,522
	Age of cohort: 65 years	£2,410	0.0032	£752,539
	Male proportion: 60%	£2,544	0.0034	£752,525
	Male proportion: 80%	£2,541	0.0034	£752,525
	Catheters per day: 3	£1,524	0.0034	£451,113
	Catheters per day: 7	£3,561	0.0034	£1,053,937
	Proportion finding easy to use: 0.25	£2,528	0.0084	£299,274
	Proportion finding easy to use: 0.50	£2,504	0.0169	£148,190
	Proportion finding easy to use: 0.75	£2,479	0.0253	£97,828
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£2,504	0.0034	£740,949
	Ease of use utility increment 10% higher	£2,543	0.0037	£684,114
Integrated handle or markings	Base-case	-£338	0.0034	Dominant
	Time horizon: 5 years	-£768	0.0077	Dominant
	Time horizon: 10 years	-£1,349	0.0135	Dominant
	Time horizon: Lifetime	-£2,401	0.0240	Dominant
	Discount rate: 0%	-£350	0.0035	Dominant
	Discount rate: 5%	-£333	0.0033	Dominant
	Age of cohort: 25 years	-£341	0.0034	Dominant
	Age of cohort: 65 years	-£320	0.0032	Dominant
	Male proportion: 60%	-£338	0.0034	Dominant
	Male proportion: 80%	-£338	0.0034	Dominant
	Catheters per day: 3	-£207	0.0034	Dominant
	Catheters per day: 7	-£469	0.0034	Dominant
	Proportion finding easy to use: 0.25	-£353	0.0084	Dominant
	Proportion finding easy to use: 0.50	-£377	0.0169	Dominant
	Proportion finding easy to use: 0.75	-£402	0.0253	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£377	0.0034	Dominant
	Ease of use utility increment 10% higher	-£338	0.0037	Dominant
Insertion sleeve or grip	Base-case	-£703	0.0034	Dominant
	Time horizon: 5 years	-£1,597	0.0077	Dominant
	Time horizon: 10 years	-£2,805	0.0135	Dominant
	Time horizon: Lifetime	-£4,991	0.0240	Dominant
	Discount rate: 0%	-£727	0.0035	Dominant
	Discount rate: 5%	-£693	0.0033	Dominant
	Age of cohort: 25 years	-£710	0.0034	Dominant
	Age of cohort: 65 years	-£666	0.0032	Dominant
	Male proportion: 60%	-£703	0.0034	Dominant
	Male proportion: 80%	-£702	0.0034	Dominant
	Catheters per day: 3	-£426	0.0034	Dominant
	Catheters per day: 7	-£979	0.0034	Dominant
	Proportion finding easy to use: 0.25	-£717	0.0084	Dominant
	Proportion finding easy to use: 0.50	-£742	0.0169	Dominant
	Proportion finding easy to use: 0.75	-£766	0.0253	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£742	0.0034	Dominant
	Ease of use utility increment 10% higher	-£703	0.0037	Dominant
Tip protector or introducer	Base-case	£318	0.0034	£94,231
	Time horizon: 5 years	£724	0.0077	£94,237
	Time horizon: 10 years	£1,271	0.0135	£94,239
	Time horizon: Lifetime	£2,262	0.0240	£94,241
	Discount rate: 0%	£329	0.0035	£94,232

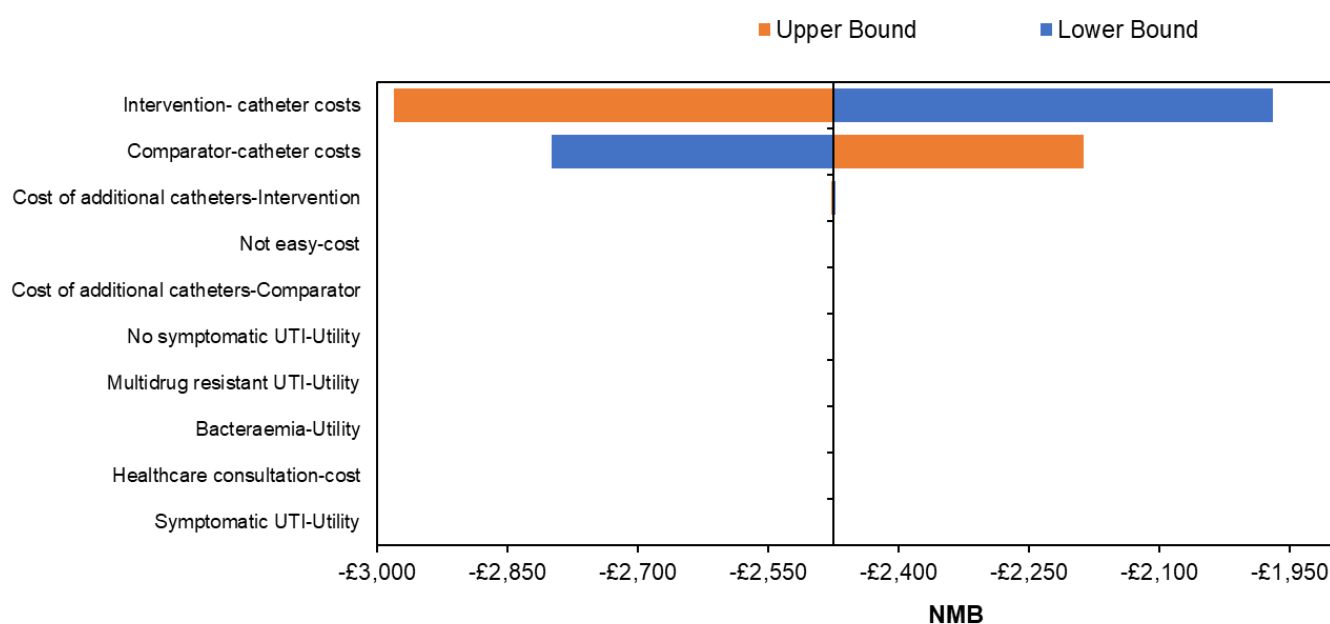
	Discount rate: 5%	£314	0.0033	£94,231
	Age of cohort: 25 years	£322	0.0034	£94,231
	Age of cohort: 65 years	£302	0.0032	£94,233
	Male proportion: 60%	£319	0.0034	£94,231
	Male proportion: 80%	£318	0.0034	£94,231
	Catheters per day: 3	£187	0.0034	£55,478
	Catheters per day: 7	£449	0.0034	£132,984
	Proportion finding easy to use: 0.25	£304	0.0084	£35,956
	Proportion finding easy to use: 0.50	£279	0.0169	£16,531
	Proportion finding easy to use: 0.75	£255	0.0253	£10,056
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£279	0.0034	£82,655
	Ease of use utility increment 10% higher	£318	0.0037	£85,665
Micro-hole zone technology	Base-case	-£741	0.0107	Dominant
	Time horizon: 5 years	-£1,685	0.0243	Dominant
	Time horizon: 10 years	-£2,959	0.0426	Dominant
	Time horizon: Lifetime	-£5,265	0.0758	Dominant
	Discount rate: 0%	-£767	0.0111	Dominant
	Discount rate: 5%	-£731	0.0105	Dominant
	Age of cohort: 25 years	-£749	0.0108	Dominant
	Age of cohort: 65 years	-£703	0.0101	Dominant
	Male proportion: 60%	-£742	0.0107	Dominant
	Male proportion: 80%	-£741	0.0107	Dominant
	Comparator Haematuria probability: 0.045	-£737	0.0098	Dominant
	Comparator Haematuria probability: 0.19	-£847	0.0307	Dominant
	Catheters per day: 3	-£465	0.0107	Dominant
	Catheters per day: 7	-£1,018	0.0107	Dominant
	Proportion finding improved residual volume: 0.25	-£756	0.0158	Dominant
	Proportion finding improved residual volume: 0.50	-£780	0.0242	Dominant
	Proportion finding improved residual volume: 0.75	-£805	0.0327	Dominant
	Cost of Haematuria: £1764.58	-£2,366	0.0107	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£780	0.0107	Dominant
	Haematuria: disutility 10% higher	-£741	0.0114	Dominant
	Improved residual volume utility increment 10% higher	-£741	0.0110	Dominant
Enhanced coating	Base-case	£170	0.0076	£22,296
	Time horizon: 5 years	£386	0.0174	£22,203
	Time horizon: 10 years	£677	0.0306	£22,146
	Time horizon: Lifetime	£1,205	0.0547	£22,037
	Discount rate: 0%	£176	0.0079	£22,291
	Discount rate: 5%	£168	0.0075	£22,298
	Age of cohort: 25 years	£172	0.0077	£22,300
	Age of cohort: 65 years	£161	0.0072	£22,276
	Male proportion: 60%	£170	0.0076	£22,296
	Male proportion: 80%	£170	0.0076	£22,296
	Comparator UTI probability: 0.05	£180	0.0073	£24,501
	Comparator UTI probability: 0.114	£160	0.0079	£20,234
	Catheters per day: 3	£83	0.0076	£10,848
	Catheters per day: 7	£257	0.0076	£33,744
	Proportion finding easy to use: 0.25	£155	0.0127	£12,239
	Proportion finding easy to use: 0.50	£131	0.0211	£6,192
	Proportion finding easy to use: 0.75	£106	0.0296	£3,598
	Proportion finding comfort: 0.25	£155	0.0127	£12,239
	Proportion finding comfort: 0.50	£131	0.0211	£6,192
	Proportion finding comfort: 0.75	£106	0.0296	£3,598
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	£92	0.0076	£12,038
	Zero cost of catheter delivery	£172	0.0076	£22,576
	Comfort utility increment 10% higher	£170	0.0080	£21,350
	Ease of use utility increment 10% higher	£170	0.0080	£21,350
Specially designed catheter case	Base-case	-£654	-0.0058	£113,724*

	Time horizon: 5 years	-£1,488	-0.0131	£113,896*
	Time horizon: 10 years	-£2,612	-0.0229	£113,958*
	Time horizon: Lifetime	-£4,648	-0.0408	£114,016*
	Discount rate: 0%	-£677	-0.0060	£113,735*
	Discount rate: 5%	-£645	-0.0057	£113,720*
	Age of cohort: 25 years	-£661	-0.0058	£113,715*
	Age of cohort: 65 years	-£620	-0.0055	£113,777*
	Male proportion: 60%	-£655	-0.0058	£113,724*
	Male proportion: 80%	-£654	-0.0058	£113,725*
	Comparator Haematuria probability: 0.045	-£660	-0.0047	£140,559*
	Comparator Haematuria probability: 0.19	-£522	-0.0307	£17,006*
	Catheters per day: 3	-£378	-0.0058	£65,676*
	Catheters per day: 7	-£931	-0.0058	£161,773*
	Proportion finding easy to use: 0.25	-£669	-0.0007	£976,725*
	Proportion finding easy to use: 0.50	-£693	0.0078	Dominant
	Proportion finding easy to use: 0.75	-£718	0.0162	Dominant
	Cost of Haematuria: £1764.58	£1,377	-0.0058	Dominated
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£693	-0.0058	£120,523*
	Haematuria: disutility 10% higher	-£654	-0.0067	£98,146*
	Ease of use utility increment 10% higher	-£654	-0.0054	£120,820*
Specially designed packaging	Base-case	-£622	0.0076	Dominant
	Time horizon: 5 years	-£1,418	0.0174	Dominant
	Time horizon: 10 years	-£2,492	0.0309	Dominant
	Time horizon: Lifetime	-£4,434	0.0563	Dominant
	Discount rate: 0%	-£644	0.0078	Dominant
	Discount rate: 5%	-£613	0.0075	Dominant
	Age of cohort: 25 years	-£628	0.0076	Dominant
	Age of cohort: 65 years	-£590	0.0072	Dominant
	Male proportion: 60%	-£622	0.0076	Dominant
	Male proportion: 80%	-£622	0.0076	Dominant
	Comparator UTI probability: 0.05	-£573	0.0061	Dominant
	Comparator UTI probability: 0.114	-£674	0.0091	Dominant
	Catheters per day: 3	-£433	0.0076	Dominant
	Catheters per day: 7	-£811	0.0076	Dominant
	Proportion finding easy to use: 0.25	-£637	0.0126	Dominant
	Proportion finding easy to use: 0.50	-£661	0.0211	Dominant
	Proportion finding easy to use: 0.75	-£686	0.0295	Dominant
	Costs attributed to ease of use, comfort and improved drainage: 50% of GP surgery consultation costs	-£661	0.0076	Dominant
	Zero cost of catheter delivery	-£612	0.0076	Dominant
	Ease of use utility increment 10% higher	-£622	0.0079	Dominant

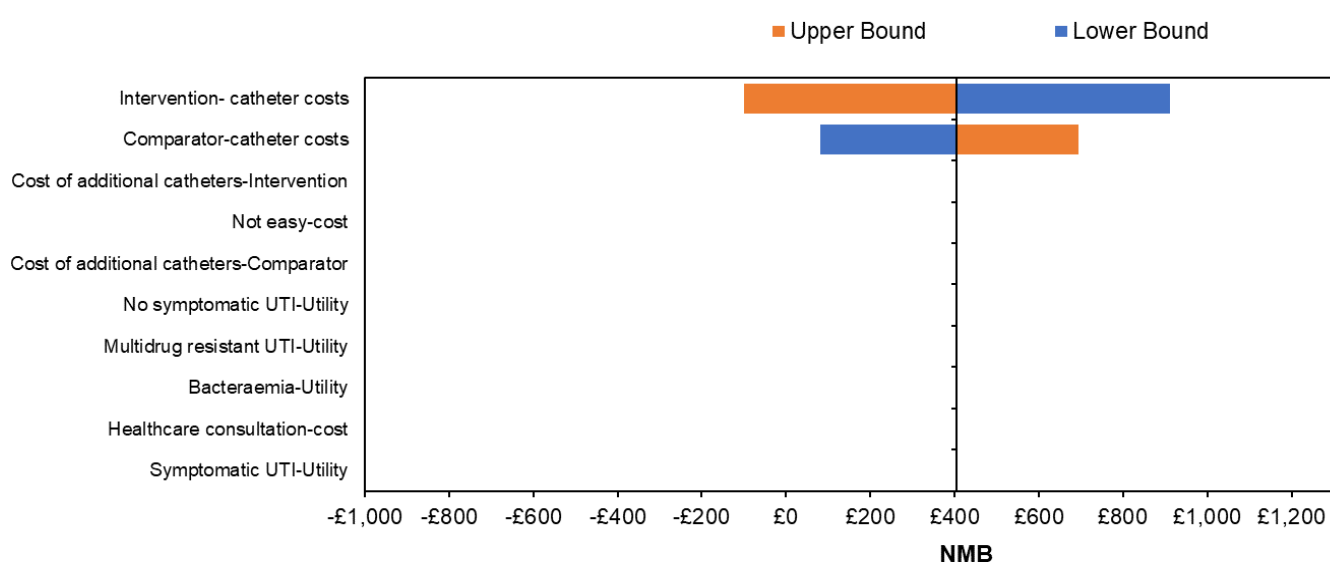
Abbreviations: EAG, External Assessment Group; ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; UTI, urinary tract infection;

Figure 9: Summary of net monetary benefit (NMB) for 8 intermittent catheter features:
a) integrated drainage bag, b) integrated handle or markings, c) insertion sleeve or grip, d) tip protector or introducer, e) micro-holes, f) enhanced coating, g) specially designed catheter case, h) specially designed packaging.

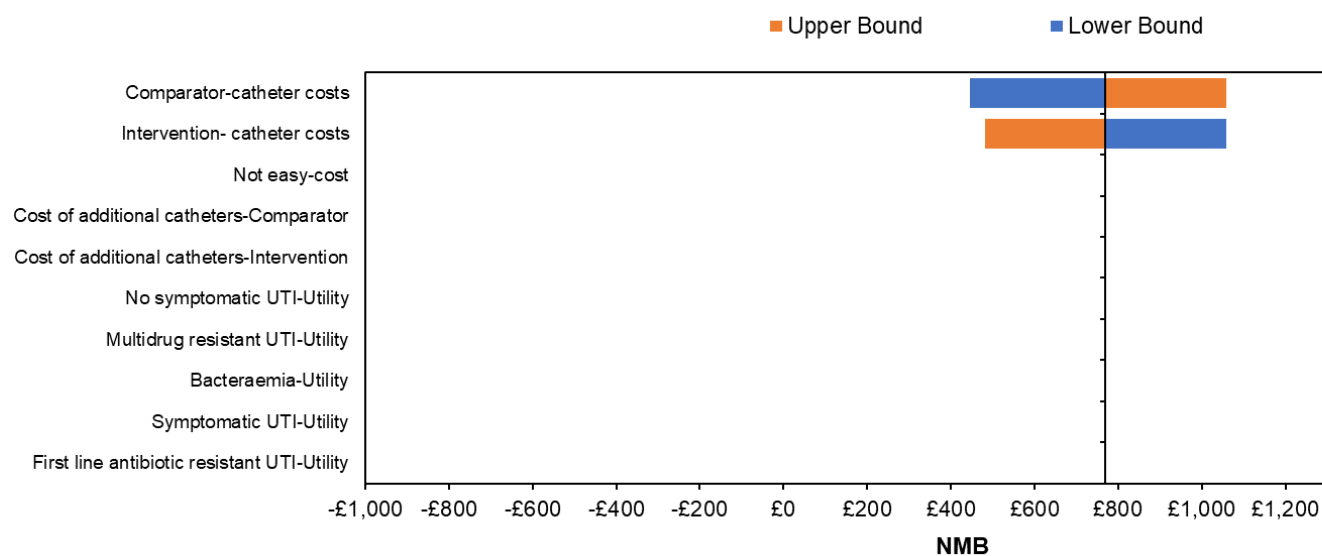
a) Integrated drainage bag



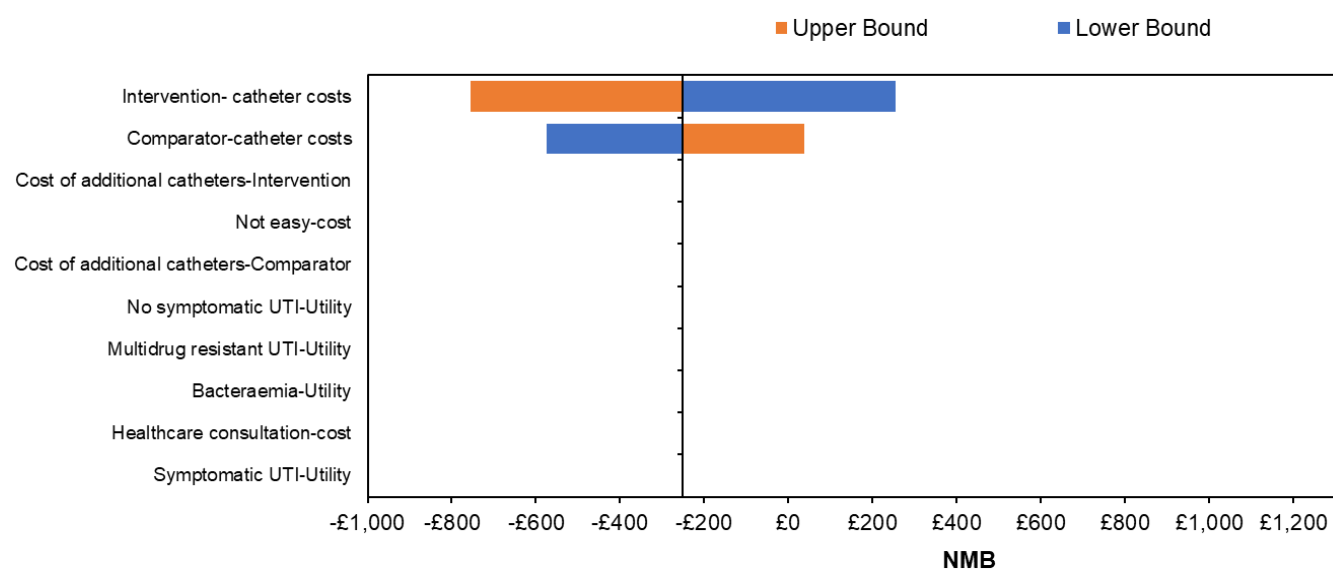
b) Integrated handle or markings



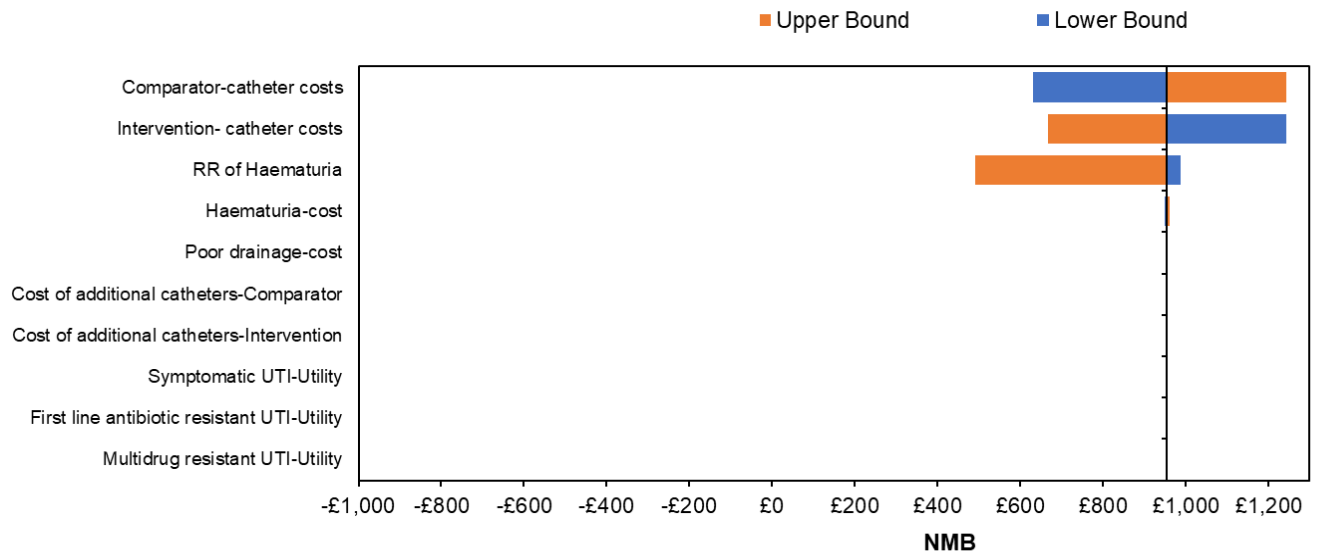
c) Insertion sleeve or grip



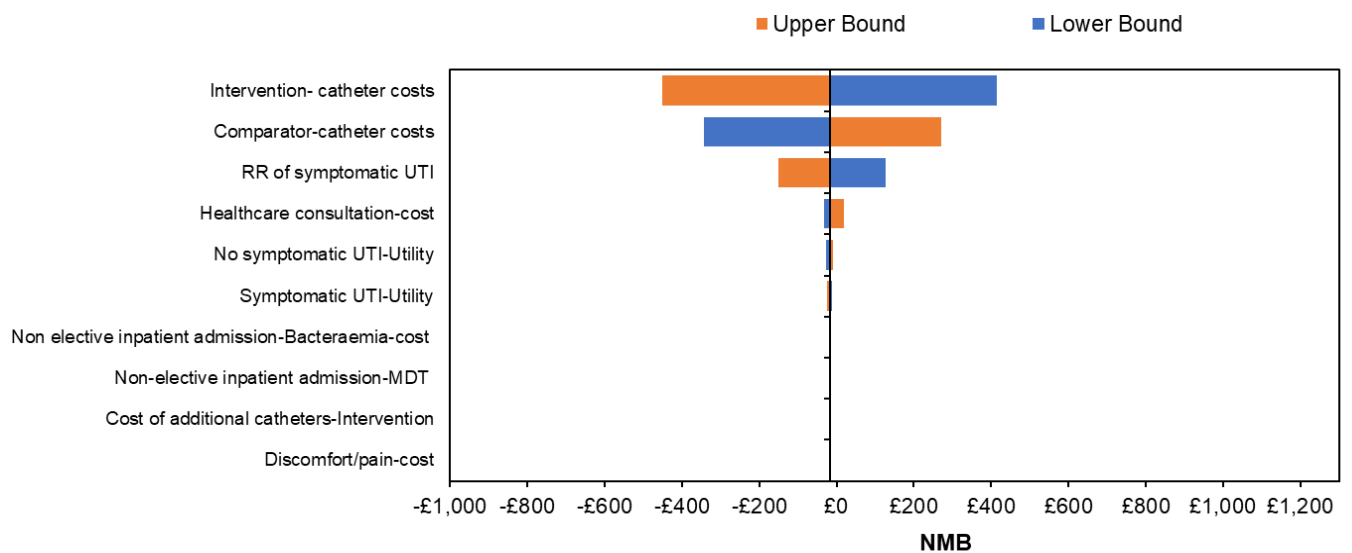
d) Tip protector or introducer



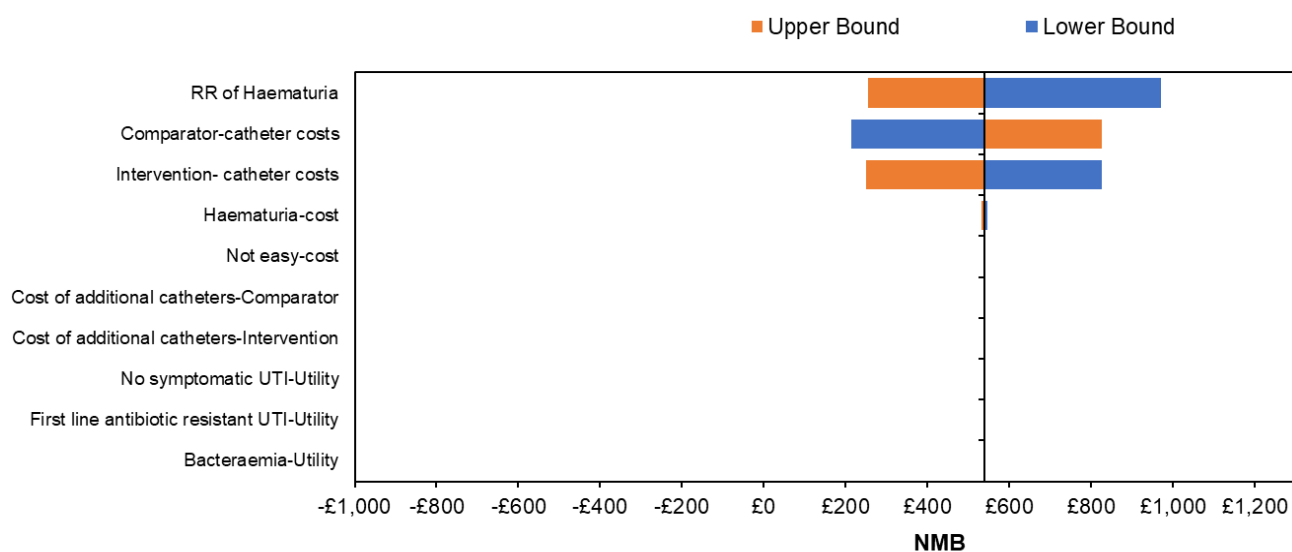
e) Micro-hole zone



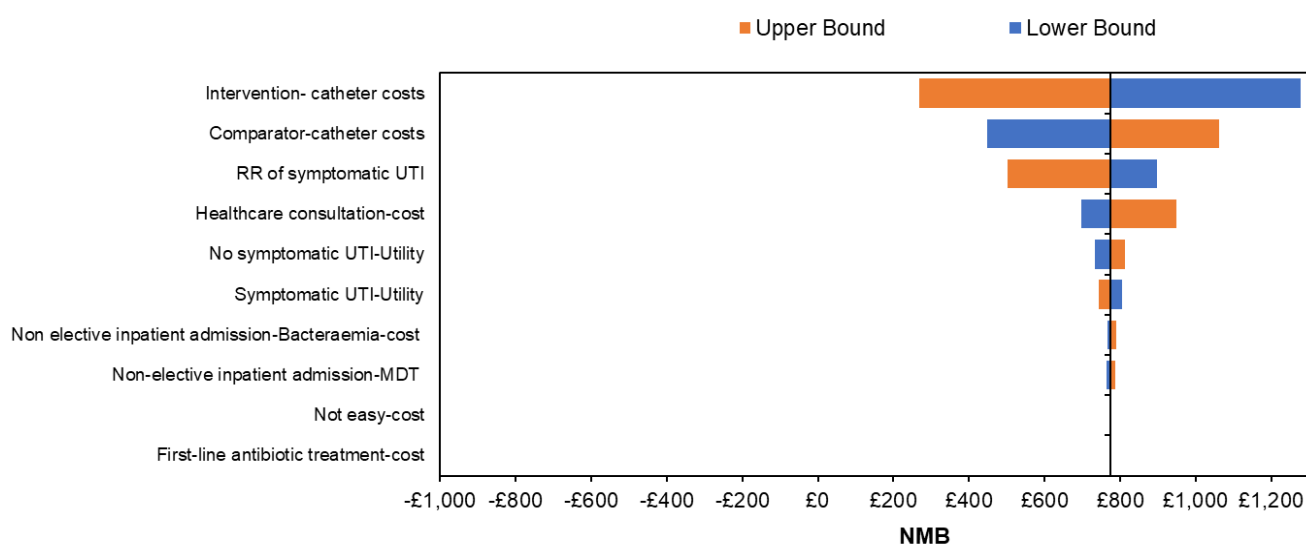
f) Enhanced coating



g) Specially designed catheter case



h) Specially designed packaging



Intervention and comparator catheter costs had the largest impact on net monetary benefit (NMB) across all features (Figure 9: Summary of net monetary benefit (NMB) for 8 intermittent catheter features: a) integrated drainage bag, b) integrated handle or markings, c) insertion sleeve or grip, d) tip protector or introducer, e) micro-holes, f) enhanced coating, g) specially designed catheter case, h) specially designed packaging. Figure 9). Additional significant factors were relative risk of haematuria (for micro-holes, specially designed catheter case), relative risk for symptomatic UTI (for specially designed packaging) and healthcare consultant costs (for specially designed packaging). The NMB spanned from positive to negative values for tip

introducer and enhanced coating features, which reiterates uncertainty associated with these features. Whereas a negative NMB was observed at upper and lower limits for integrated drainage bag, demonstrating a lack of value associated with that feature.

Exploratory Marginal analysis

Table 22 reports an exploratory analysis to help inform decision making. In this analysis the cost per catheter is considered where the comparator catheter includes the unit cost of additional water-based lubricant (£0.19) (the intervention catheter features do not incur these costs).

If NHS resources are used in an allocatively efficient manner then the ratio of marginal costs to marginal benefits for all interventions is equal. Therefore, the ratio of marginal costs is equal to the ratio of marginal benefits. This means by looking at the ratio of costs it is possible to see proportionally how much more/less benefits the feature would provide compared with the comparator. As this simplified analysis shows, an integrated drainage bag would need to provide 45% more benefits than the comparator to be allocatively efficient. The tip protector or introducer feature would only need to provide 6% more benefits than the comparator. Whereas the integrated handle or marking and the insertion sleeve or grip could provide 6% and 12% less benefits and still be allocatively efficient.

This analysis does not consider cost savings/increases that would be associated with the effects that would generate benefits, so the implied value of additional benefits is a maximum needed. The question for a decision-maker is whether additional benefits of the magnitude could occur in practice. It is less likely that these could occur for integrated drainage bag feature. Likewise, it is implausible that the comparator could provide 12% more benefits than the insertion sleeve feature. For the other features relatively small differences in benefits would be needed and the EAG note that differences of this magnitude are likely to be difficult (and very costly) to detect in practice.

Table 23. Exploratory marginal analysis

Catheter	Unit price	Ratio (Intervention/Comparator)
Comparator U1 (<i>reference</i>)	£1.56	-

Catheter	Unit price	Ratio (Intervention/Comparator)
Integrated drainage bag	£2.26	1.45
Integrated handle or markings	£1.47	0.94
Insertion sleeve or grip	£1.37	0.88
Tip protector or introducer	£1.65	1.06
Micro-hole zone technology	£1.37	0.88
Enhanced lubrication or coating	£1.62	1.04
Specially designed catheter case	£1.37	0.88
Specially designed packaging	£1.43	0.92

Probabilistic sensitivity analysis (PSA)

Results from PSA for features where relative effects were estimated from CNMA are shown in Table 24. As this analysis shows, micro-holes and specially designed packaging are highly likely (probability 98% and 100%, respectively) to be considered cost-effective. However, there is uncertainty associated with enhanced coating being cost-effective (probability 47%). The specially designed catheter case was less costly and slightly less effective than the comparator. As described above the ICER in this situation is for the more effective but more costly comparator(uncoated with no additional features). In this case the reduction in cost of the feature more than compensated for the reduction in QALYs of the catheter with this feature feature and, hence, this feature has a 95% probability of being cost-effective relative to an uncoated catheter with no additional features.

Table 24. Results from probabilistic sensitivity analysis (PSA)

Catheter	Total Costs	Total QALYs	Inc. Costs	Inc. QALYs	ICER	Prob. CE at WTP £20k
Comparator (U1)	£7,231	1.6354	-	-	-	-
Integrated drainage bag	£9,770	1.6387	£2,539	0.0034	£751,403	0%
Comparator (U1)	£7,229	1.6355	-	-	-	-
Integrated handle or markings	£6,890	1.6389	£-339	0.0034	Dominates U1	91%
Comparator (U1)	£7,229	1.6356	-	-	-	-
Insertion sleeve or grip	£6,523	1.6390	£-706	0.0034	Dominates U1	100%
Comparator (U1)	£7,228	1.6357	-	-	-	-
Tip protector or introducer	£7,545	1.6390	£317	0.0034	£93,678	21%
Comparator (U1)	£7,227	1.6352	-	-	-	-
Micro-hole zone technology	£6,506	1.6422	£-721	0.0069	Dominates U1	98%
Comparator (U1)	£7,228	1.6355	-	-	-	-
Enhanced coating	£7,401	1.6430	£173	0.0075	£23,014	47%
Comparator (U1)	£7,229	1.6353	-	-	-	-
Specially designed catheter case	£6,584	1.6281	£-645	-0.0072	£89,693*	95%
Comparator (U1)	£7,230	1.6358	-	-	-	-

Specially designed packaging	£6,628	1.6427	-£602	0.0069	Dominates U1	100%

Abbreviations: CE, cost effective; ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; U1, uncoated catheter. Note: the comparator total costs and total QALYs are slightly different in each PSA run because of random seed

*ICER for U1 catheter with no features vs specially designed catheter case, U1 is not considered cost-effective at the £20,000 per QALY threshold from NICE

The PSA results summarised in Table 24 are presented as cost and QALY plots for comparisons against the comparator for: integrated drainage bag, integrated handle or markings, insertion sleeve or grip, tip protector or introducer, micro-holes, enhanced coating, specially designed catheter case, specially designed packaging (shown in Figure 10). As these figures show the range over which incremental QALYs varies is quite narrow, between -0.05 to +0.02 in all cost and QALY plots. The variation in incremental cost was over a range of -£1500 to £3000 for all comparators, although whether this represented an extra cost or a saving varied between features. The EAG note that the magnitude of this incremental differences is constrained by the 2-year time of the base case. The cost-effectiveness acceptability curves for all the eight additional features are shown in Figure 11 and graphically show how the probability that each feature would be considered cost-effective compared with the comparator at different threshold values for the willingness to pay for a QALY.

Figure 10: Cost-effectiveness plots for 8 features: a) integrated drainage bag, b) integrated handle or markings, c) insertion sleeve or grip, d) tip protector or introducer, e) micro-holes, f) enhanced coating, g) specially designed catheter case, h) specially designed packaging.

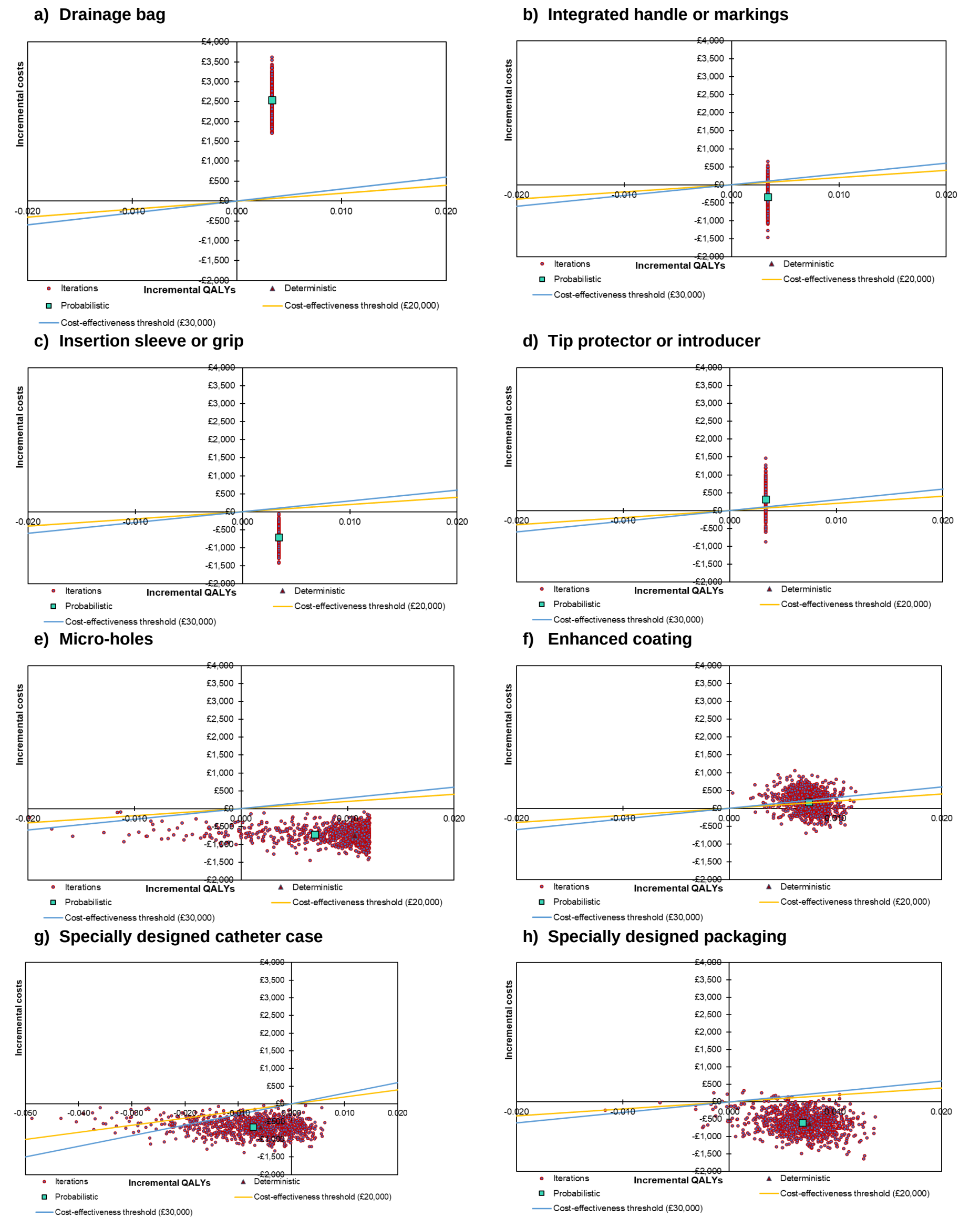
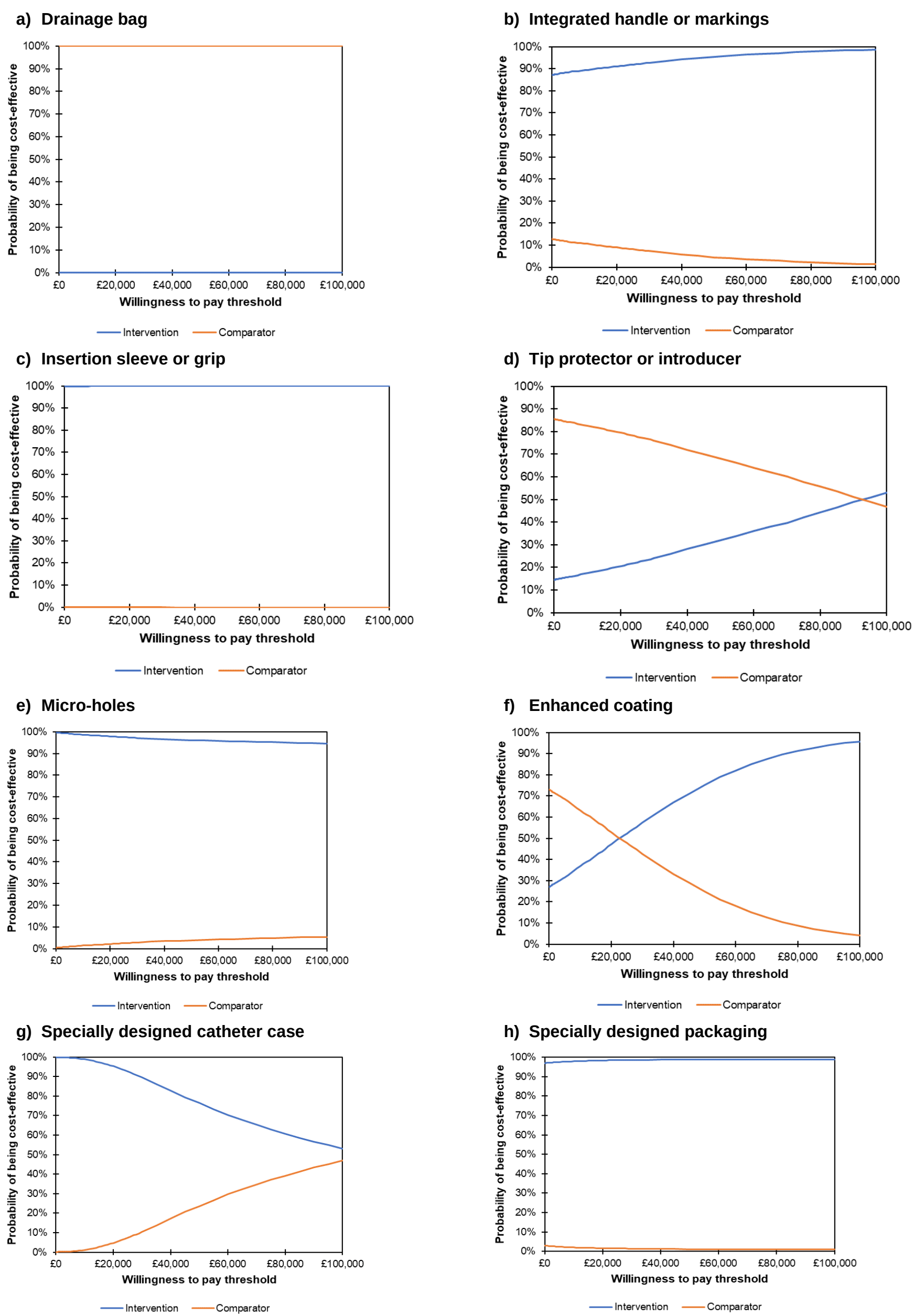


Figure 11: Cost effectiveness acceptability curves for 8 intermittent catheter features: a) integrated drainage bag, b) integrated handle or markings, c) insertion sleeve or grip, d) tip protector or introducer, e) micro-holes, f) enhanced coating, g) specially designed catheter case, h) specially designed packaging.



6.3 Summary, strengths and limitations

The EAG developed an economic model which was informed by previously published economic evaluations of intermittent catheters, which ensured its structural validity. The relative effects for individual intermittent catheter features were populated using the results from the CNMA analyses, enabling the EAG to estimate both the costs and outcomes of individual features, from a UK NHS perspective. However, issues previously identified (limited evidence, wide credible intervals from CNMA) propagate through into the economic analyses and therefore should be interpreted with caution.

A key limitation of the economic evaluation model relates to the limited availability of data. This includes lack of data for specific subgroups of patients where the indication for catheterisation differed, and where population differences (for example, age, gender, UTI risk) are expected. As a consequence, all modelling is restricted to a generic cohort using long-term intermittent catheterisation. Lack of data also relates to the clinical evidence as data were limited demonstrating the impact of features across outcomes which were deemed clinically important to Lay Experts and Clinical Experts. Consequently, the economic evaluation assumes comparative efficacy in some features. In this case the cost-effectiveness results are driven by differences in the cost of the feature. Furthermore, the lack of data meant that there were no differences in outcomes that could affect longer term estimates of costs and QALYs.

The implication of there being no outcomes that have differential long-term effects is that the model was able to adopt a short time horizon as opposed to a lifetime horizon as would be more commonly seen in technology assessments. However, should evidence arise that the incidence of events with persisting effects (some urological complications like strictures or kidney injury or differences in mortality) become available then the analysis could be updated.

In addition to the limitations caused by the sparse data there were also limitations with the modelling approach adopted although many of these were not material given the data available. For example, the economic model also does not enable simultaneous comparison of all features, instead each individual feature is modelled in isolation and compared with the comparator. Thus, the model does not allow a full

incremental analysis of the features. Rather it focuses on whether there is value on introducing each feature compared with a basic comparator which does not have any of the additional features. Of more material importance was the assumption that patients continued to use the same catheter type throughout the entire time horizon. In practice, patients may switch between catheters or may be prescribed multiple catheters to enable intermittent catheterisation across change in patient needs, lifestyle or preferences. Given the lack of data this would be hard to model but the modelling approach adopted still allows consideration as to whether a given feature could be cost-effective.

Similarly, the full impact of some of the catheter features were not readily captured in the cost per QALY metric. The impact on costs and QALYs of improvements in the outcomes: ease of use, reduced discomfort or pain, and improved drainage were wholly based upon assumptions which could be questioned. While these assumptions were explored in the sensitivity analysis there is an evidence gap around the value of these outcomes.

The cost and utility data available for the analysis was sourced from attributable sources and the catheter cost data is representative of current NHS practice but as described earlier there may be limitations with how the cost of a feature has been estimated. Utilities were derived from Bermingham et al. (2013) which ensured consistency with NICE CG139, and are derived from the EQ-5D, but may not reflect contemporary patient experience with intermittent catheterisation. This is important as our sensitivity analyses have found that some of our results are sensitive to the utility values used.

7 Discussion

Through an inductive process the EAG identified 838 intermittent catheters offered in 86 product lines from 17 manufacturers, which were prescribed in the NHS in the 2023/24 financial year. In the UK there are approximately 50,000 people who use intermittent catheters, each of whom uses approximately 5 catheters per day, with long-term users using intermittent catheters for more than 28 days (up to a lifetime). The price per intermittent catheter ranged from £0.40 to £3.28; due to the high volume of usage, each reduction in the average catheter price of ten pence (£0.10)

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would reduce the financial burden of intermittent catheter provision on the NHS by approximately £9.1 million per year.

From multivariate linear regression the EAG estimated the effect on price of each individual feature of intermittent catheters. Price was found to be significantly associated with the presence of all features defined in the NICE Final Scope except for micro-holes which did not contribute to catheter price across any exploratory regression analyses. However, the analysis was sensitive to attribution of features, which is limited by inconsistent usage of feature nomenclature.

The EAG undertook CNMA analysis across 5 prioritised outcomes (UTI, haematuria, residual volume, comfort and ease of use; as advised by Clinical and Lay Experts) to isolate the relative treatment effect of features. Due to quality, completeness and consistency of reporting in the published literature it was only possible to isolate the following possible effects, however all had low certainty:

- a possible reduction in UTI with enhanced coating, and
- a possible reduction in UTI with specially designed packaging, and
- a possible reduction in haematuria with micro-hole zone technology, and
- a possible increase in haematuria with specially designed catheter case (however the clinical validity of this result is in question).

The EAG outlined possible mechanisms of action for these results in The EAG make the above conclusions regarding justification of price with caution. All analyses rely on the EAG's assignment of features, which were only partially corroborated by companies, and Clinical Experts did not achieve consensus. This is in part due to imprecise definition of features which were open to interpretation. Any changes to these features attributed to each catheter product line would need exploring to determine the overall impact on results. That being said, the EAG has not identified any published evidence of efficacy in UTI, haematuria, residual volume, pain/discomfort or ease of use outcome, which could directly attribute an effect to the following features: integrated drainage bag, integrated handle or sleeve, tip protector or introducer; therefore, a different group of features will not change that.

The EAG highlight the lack of a core outcome set in long-term intermittent urethral catheterisation (as evidenced by the heterogeneity in results reported in the included evidence) and lack of clear and transparent reporting of the specific technology used (manufacturer and model) across the published literature. Improvements in these would enable the assessment of value of individual features to be updated when more evidence becomes available. Additionally, the EAG would recommend that the product information listed on the NHS Drug Tariff be revised to make clear to prescribers and commissioners the differences between intermittent catheters. This could include features present (using standardised definitions) which would enable prescribers and users to optimise catheter selection to meet individual preferences (which could include changes in lifestyle, catheterisation setting, or preferences) and could in part reduce catheter wastage and contribute to large cost savings in the NHS.

Table 25; however, would stress that Clinical and Lay Experts would be best suited to commenting on the plausibility of these mechanisms outlined. The EAG note that results from the CNMA will be influenced by the definition of UTI/haematuria (which differed between studies; transformed onto a single scale where possible), and that patient dropout within the included studies will contribute to bias. Across all CNMA there were wide credible intervals, and the confidence was rated very low, and results may be confounded by other factors (specific patient groups or settings favouring catheter feature selection). Therefore, the EAG would consider large uncertainty in CNMA results. The EAG note that there is a lack of evidence reporting the effectiveness of the integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer features. Aggregating integrated handle and insertion sleeve or grip would have limited impact on these findings.

- Finally, the EAG considered the value of each feature as a separate decision problem in which the price for a feature was informed by the multivariate price regression model and the relative treatment effects were derived from CNMA, in a Markov model built by the EAG in Microsoft Excel. For features associated with increased price and greater benefits, the EAG considered whether the price increase was justified using a willingness to pay threshold. There is an unknown benefit associated with **integrated drainage bag** and **tip protector or introducer** (both increase costs with no evidence demonstrating clinical benefit). The magnitude of the benefit needed to make integrated drainage bag cost-effective is comparatively large, while the magnitude of the benefit needed to make tip protector or introducer cost-effective is small and hence likely to be difficult (and costly) to detect in a clinical trial.

The EAG make the above conclusions regarding justification of price with caution. All analyses rely on the EAG's assignment of features, which were only partially corroborated by companies, and Clinical Experts did not achieve consensus. This is in part due to imprecise definition of features which were open to interpretation. Any changes to these features attributed to each catheter product line would need exploring to determine the overall impact on results. That being said, the EAG has not identified any published evidence of efficacy in UTI, haematuria, residual volume, pain/discomfort or ease of use outcome, which could directly attribute an effect to the

following features: integrated drainage bag, integrated handle or sleeve, tip protector or introducer; therefore, a different group of features will not change that.

The EAG highlight the lack of a core outcome set in long-term intermittent urethral catheterisation (as evidenced by the heterogeneity in results reported in the included evidence) and lack of clear and transparent reporting of the specific technology used (manufacturer and model) across the published literature. Improvements in these would enable the assessment of value of individual features to be updated when more evidence becomes available. Additionally, the EAG would recommend that the product information listed on the NHS Drug Tariff be revised to make clear to prescribers and commissioners the differences between intermittent catheters. This could include features present (using standardised definitions) which would enable prescribers and users to optimise catheter selection to meet individual preferences (which could include changes in lifestyle, catheterisation setting, or preferences) and could in part reduce catheter wastage and contribute to large cost savings in the NHS.

Table 25. For features associated with increased price, but whose benefits were uncertain, the EAG estimated the increased benefits (or associated reduction in costs) that would be needed to justify the price increment. The EAG considered:

- There is some evidence to justify the use of **micro-hole** and **specially designed packaging** intermittent catheter features compared with a catheter without any of these features.
- There was uncertainty regarding the clinical benefit of **integrated handle or markings** and **insertion sleeve or grip**, if clinical equivalence is assumed to the comparator, these features correspond with a reduction in catheter prices and can therefore be justified on that basis.
- There may be some evidence to suggest a clinical benefit associated with **enhanced coating** however it is unclear whether this is cost effective (close to the willingness to pay threshold, 47% probability of being cost-effective in the PSA).
- There may be some evidence to suggest that **specially designed catheter case** may increase the risk of haematuria (increased harm), however the EAG considered these results may be confounded by other factors (for example users catheterising outside of their home environment may use compact or discrete cases which is intrinsic to this feature). Furthermore, the estimated reduction in QALYs was small compared with the reduction in cost. Hence there was a 95% probability of being cost-effective in the PSA.
- There is an unknown benefit associated with **integrated drainage bag** and **tip protector or introducer** (both increase costs with no evidence demonstrating clinical benefit). The magnitude of the benefit needed to make integrated drainage bag cost-effective is comparatively large, while the magnitude of the benefit needed to make tip protector or introducer cost-effective is small and hence likely to be difficult (and costly) to detect in a clinical trial.

The EAG make the above conclusions regarding justification of price with caution. All analyses rely on the EAG's assignment of features, which were only partially corroborated by companies, and Clinical Experts did not achieve consensus. This is

in part due to imprecise definition of features which were open to interpretation. Any changes to these features attributed to each catheter product line would need exploring to determine the overall impact on results. That being said, the EAG has not identified any published evidence of efficacy in UTI, haematuria, residual volume, pain/discomfort or ease of use outcome, which could directly attribute an effect to the following features: integrated drainage bag, integrated handle or sleeve, tip protector or introducer; therefore, a different group of features will not change that.

The EAG highlight the lack of a core outcome set in long-term intermittent urethral catheterisation (as evidenced by the heterogeneity in results reported in the included evidence) and lack of clear and transparent reporting of the specific technology used (manufacturer and model) across the published literature. Improvements in these would enable the assessment of value of individual features to be updated when more evidence becomes available. Additionally, the EAG would recommend that the product information listed on the NHS Drug Tariff be revised to make clear to prescribers and commissioners the differences between intermittent catheters. This could include features present (using standardised definitions) which would enable prescribers and users to optimise catheter selection to meet individual preferences (which could include changes in lifestyle, catheterisation setting, or preferences) and could in part reduce catheter wastage and contribute to large cost savings in the NHS.

Table 25: Summary of findings across intermittent urethral catheter features

Intermittent catheter feature	Claimed benefits	Proportion of catheter product lines available on NHS Drug Tariff with that feature (out of 86 product lines)	Proportion of catheters prescribed with that feature from Prescription Costs Analysis (out of 93,587,475 prescribed catheters)	Significant contributor to catheter price (from multivariable regression analysis)	Evidence demonstrating effect of individual feature (from CNMA)	Economics	EAG comment
Integrated drainage bag	Ease of use	13.9%	10.0%	£0.89 increase	Not available	Base case <u>not</u> cost effective (ICER: £752,525)	Unknown benefit No evidence identified to confirm benefit; not cost effective at £20,000 WTP. Magnitude of clinical effect necessary to demonstrate cost-effectiveness may be implausible but may be possible to identify in further research.
Integrated handle or markings	Ease of use	30.4%	52.4%	£0.10 increase	Not available	Dominant in base case (even if assumed equivalent clinical effect)	Uncertain clinical benefit Not a significant contributor to cost, no evidence identified to confirm benefit, but no safety signal identified. Possible uncertainty on whether this should be aggregated with 'insertion sleeve or grip' feature; alternative groupings could be considered in future analysis.
Insertion sleeve or grip	Ease of use, reduction in UTI	58.2%	45.5%	No significant difference in price	Not available	Dominant in base case (even if assumed equivalent clinical effect)	Uncertain clinical benefit Not a significant contributor to cost, no evidence identified to confirm benefit, but no safety signal identified.
Tip protector or introducer	Reduction in UTI	25.3%	21.7%	£0.28 increase	Not available	Base case <u>not</u> cost effective (ICER: £94,231)	Unknown benefit No evidence identified to confirm benefit; not cost effective at £20,000 WTP. The magnitude of clinical effect necessary to demonstrate cost-effectiveness is likely to be small and hence difficult (and costly) to detect.
Micro-hole zone technology	Improved drainage, ease of use, reduction in UTI	1.3%	0.2%	No significant difference in price	Possible reduction in haematuria	Dominant in base case, 98% probability cost-effective in PSA.	Possible clinical benefit (not associated with statistical difference in price) Not a significant contributor to cost, possible reduction in haematuria (wide CrI). <i>[Possible mechanism of action less catheter manoeuvres, less risk of urethral damage]</i> Additional non-prioritised outcomes showed reduction in pressure and flow stops with this feature; however Clinical Experts advised that pressure is not measure in routine clinical practice, and they were unclear of the clinical validity of flow stops as an outcome measure.
Enhanced coating	Ease of use	35.4%	81.9%	£0.25 increase	Possible reduction in UTI	Base case uncertain (ICER=£22,296 close to WTP threshold), 47% probability cost-effective in PSA	Uncertain cost effectiveness Significantly increases catheter price, with potential evidence of reduction in UTI (however wide CrI leading to uncertainty). <i>[Possible mechanism of action: less friction, less trauma, used more frequently]</i>
Specially designed catheter case	Ease of use	27.8%	57.6%	No significant difference in price	Possible increased risk of haematuria (RR 2.05 from CNMA independent effects model when taking into the effects of the other features such as pre-activated hydrophilic coating and micro-holes; but with wide CrI so uncertain of effect)	Less costly and less effective. ICER for comparator compared with feature: £113,724* Hence feature is cost-effective. 95% probability cost-effective in PSA	Uncertain clinical benefit Not a significant contributor to catheter price, however potential evidence of harm (from RR derived from CNMA). <i>[Possible confounding by other factors: patients conducting catheterisation out with home environment may choose a more discrete catheter, which is intrinsic to this feature]. Potential harm may be very small compared to cost savings meaning feature cost-effective at £20,000.</i>
Specially designed packaging	Ease of use	70.9%	83.0%	£0.06 increased	Possible reduction in UTI	Dominant in base case, 100% probability cost-effective in PSA.	Possible clinical benefit (with increased price) Not a significant contributor to cost, however potential for clinical benefit. <i>[Possible mechanism of action: easier to hold, better drainage or used more frequently]</i>

Key: * all other ICERS are feature vs comparator except this one which is comparator vs feature, it shows whether the extra QALYs provided by the comparator are worth its extra cost. As the ICER is very high we can conclude that they are not and therefore compared with the comparator the feature is cost-effective. Abbreviations: CNMA, component network meta-analysis; CrI, credible interval; ICER, incremental cost-effectiveness ratio; RR, relative risk; UTI, urinary tract infections, WTP, willingness to pay

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Appendices

Appendix A: Intermittent catheter features by manufacturer and model (N=78)

[Note: *information obtained from public domain]

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specialty designed packaging	Recyclable components
B. Braun Medical Ltd*																			
Actreen Glyc Set	448,740 (0.5%)	2004	PVC	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No
Actreen Glyc luer lock	6,630 (0.0%)	2004	PVC	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	No	Yes	No
Actreen Lite	293,040 (0.3%)	2009	PVC	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes, Film pack
Actreen Mini	1,791,030 (1.9%)	2010	TPO	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes, Film pack
Actreen Mini Set	1,026,930 (1.1%)	2010	TPO	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes, Film pack
Actreen Hi-Lite	1,763,580 (1.8%)	2012	TPO	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes, Film pack
Actreen Hi-Lite Set	262,770 (0.3%)	2012	TPO	Prelubricated glycerine and water gel	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes, Film pack
Bard Ltd																			
HydroSil discreet	23,790 (0.0%)	2004	Silicone	NR	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No
HydroSil Silicone	215,850 (0.2%)	2004	Silicone	NR	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No
HydroSil Gripper	846,420 (0.9%)	2011	Silicone	NR	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	No	Yes	No
HydroSil rose	118,920 (0.1%)	2013	Silicone	NR	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No
BD Ready-To-Use	332,580 (0.3%)	2021	Polyurethane	NR	No	No	No	No	No	Yes	No	Yes	Yes	No	No	Yes (pre-activated)	No	No	No
Charles S. Bullen Stomacare Ltd																			
Hi-Slip	6,930 (0.0%)	NR	PVC	PVP	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No
Hi-Slip Kit	320 (0.0%)	NR	PVC	PVP	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No
Hi-Slip Plus	670,470 (0.7%)	NR	PVC	PVP and NaCl	No	No	No	No	Yes (sachet)	No	No	No	Yes	No	No	No	No	Yes	All packaging and shipping boxes are recyclable
CliniMed Ltd																			

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specialty designed packaging	Recyclable components
Curan Lady	671,310 (0.7%)	2013	PVC	Hydrogel	No	No	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes.	The materials used in all the products components are recyclable
Curan Man	137,700 (0.1%)	2017	PVC	Hydrogel	No	No	Yes	No	No	No	No	No	Yes	No	No	No	Yes	Yes.	The materials used in all the products components are recyclable
Curan Advantage	151,470 (0.2%)	2018	PVC	ComfortCoat	No	No	No	No	Yes (sachet)	No	No	Yes	Yes	No	No	No	Yes	Yes	The materials used in all the products components are recyclable
CliniSupplies Ltd																			
SensaCath Aqua	157,620 (0.2%)	NR	PVC	PVP	No	No	No	No	Yes (sachet)	No	No	No	Yes	No	No	No	No	Yes	No
SensaCath	417,390 (0.4%)	NR	PVC	PVP	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	Yes	No
Coloplast Ltd																			
EasiCath	1,116,725 (1.2%)	1993	PVC	PVP	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	Retail box only
SpeediCath	10,016,010 (10.5%)	2000	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	No	No	No	No	Yes (triple action; pre-activated)	No	Yes	Retail box only
SpeediCath Compact	13,656,240 (14.3%)	2004	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes (triple action; pre-activated)	Yes	Yes	Retail box only
SpeediCath Compact Set	2,803,320 (2.9%)	2013	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes (triple action; pre-activated)	Yes	Yes	Retail box only
Self-Cath	564,390 (0.6%)	Brand acquired 2006	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Retail box only
SpeediCath Compact Plus	4,599,900 (4.8%)	2009	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes (triple action; pre-activated)	Yes	Yes	Retail box only
SpeediCath Control	200,370 (0.2%)	2009	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	No	No	No	No	Yes (triple action; pre-activated)	No	Yes	Retail box only
SpeediCath Compact Eve	3,756,960 (3.9%)	2015	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes (triple action; pre-activated)	Yes	Yes	The bottom half of the case can be recycled (polypropylene) and the retail box
SpeediCath Flex	7,074,660 (7.4%)	2016	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	Yes (triple action; pre-activated)	Yes	Yes	Retail box only
SpeediCath Flex Set	545,220 (0.6%)	2022	Polyurethane	PVP, PEG water	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes (triple action; pre-activated)	Yes	Yes	Retail box only
Luja	230,070 (0.2%)	2023	TPU	PVP, PEG water	No	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes (triple action; pre-activated)	Yes	Yes	Retail box only

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specialty designed packaging	Recyclable components
Convatec Ltd																			
GentleCath Glide	407,790 (0.4%)	2014	-	Non PVP ("FeelClean" technology)	No	No	No	No	Yes (Sachet)	No	No	No	Yes	No	No	Yes (integrated amphiphilic surfactant)	No	Yes	No
GentleCath Air	152,910 (0.2%)	2022	-	Non PVP ("FeelClean" technology)	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes (integrated amphiphilic surfactant)	Yes	Yes	Case
Cure Ultra	0 (0%)	2024	-	Gel	No	No	Yes	No	No	No	No	Yes (control stripe)	Yes	No	No	No	Yes	Yes	No
Flexicare Medical Ltd*																			
WyCath	113,010 (0.1%)	NR	-	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
WyCath H2O	552,360 (0.6%)	NR	-	-	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No
GTA (UK) Ltd*																			
Idrocath	40 (0.0%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Idrocath Kit	0 (0%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hollister Ltd																			
InstantCath	252,950 (0.3%)	1998	PVC	Gel	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Product box
Advance	390,800 (0.4%)	2002	No DEHP	Gel	No	Yes	No	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Product box
Advance Plus	158,650 (0.2%)	2002	No DEHP	Gel	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Product box
VaPro	248,850 (0.3%)	2012	No DEHP	PVP ("HydraBalance" technology)	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
VaPro Plus	620,250 (0.6%)	2015	No DEHP	PVP ("HydraBalance" technology)	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
VaPro Pocket	4,591,620 (4.8%)	2016	No DEHP	PVP ("HydraBalance" technology)	No	No	No	No	No	Yes	No	No	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
VaPro Plus Pocket	2,169,090 (2.3%)	2016	No DEHP	PVP ("HydraBalance" technology)	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
Infyna	306,750 (0.3%)	2017	TPE	"vaporphilic" technology	No	No	No	No	No	Yes	No	No	No	No	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specially designed packaging	Recyclable components
Infyna Plus	709,950 (0.7%)	2017	NR	“vaporphilic” technology	No	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box
VaPro F-Style	149,670 (0.2%)	2017	No DEHP	PVP (“HydraBalance” technology)	No	No	No	No	No	Yes	No	No	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
VaPro Plus F-Style	26,970 (0.0%)	2017	No DEHP	PVP (“HydraBalance” technology)	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
Infyna Chic	1,747,710 (1.8%)	2019	TPE	“vaporphilic” technology	No	No	No	No	No	Yes	No	No	No	No	No	Yes (Proprietary process of coating; pre-activated)	Yes	Yes	Product box, catheter case
VaPro No Touch	2,752,560 (2.9%)	2024	No DEHP	PVP (“HydraBalance” technology)	No	No	No	No	No	Yes	No	No	Yes	Yes	No	Yes (Proprietary process of coating; pre-activated)	No	Yes	Product box, Tip protector
InstantCath Protect*	1,550 (0.0%)	NR	PVC	Gel	No	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	Product box
Hunter Urology Ltd*																			
Aloe Hydro	14,040 (0.0%)	NR	PVC	PVP, aloe vera	No	No	No	No	Yes (Sachet)	No	No	No	No	No	No	No	No	Yes	No
Aloe Hydro Plus	57,120 (0.1%)	NR	PVC	PVP, aloe vera	No	No	No	No	Yes (Sachet)	No	No	No	Yes	No	No	No	No	Yes	No
Aloe Original	33,120 (0.0%)	NR	PVC	PVP, aloe vera	No	No	No	No	Yes (Sachet)	No	No	No	No	No	No	No	No	Yes	No
Aloe Original Plus	150 (0.0%)	NR	PVC	PVP, aloe vera	No	No	No	No	Yes (Sachet)	No	No	No	No	No	No	No	No	Yes	No
HunterCath	207,990 (0.2%)	NR	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Smooth Nelaton	41,910 (0.0%)	NR	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Malvern Medical*																			
Catheter (unnamed)	-	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Manfred Sauer UK Ltd*																			
iQ Cath	1,133,160 (1.2%)	NR	NR	NR	No	No	No	Yes	No	No	NR	NR	NR	NR	NR	NR	NR	NR	NR
iQ Cath Gel+	710,160 (0.7%)	NR	NR	NR	No	No	Yes	No	No	No	NR	NR	NR	NR	NR	NR	NR	NR	NR
iQ Cath Original	5,940 (0.0%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
iQ Cath Solo	90 (0.0%)	NR	NR	NR	Yes	No	No	No	No	No	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mediwatch UK Ltd																			

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specially designed packaging	Recyclable components
UCath H2O	0 (0%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
UCath	180 (0.0%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Peak Medical Ltd																			
UltraSmooth Aqua	214,590 (0.2%)	NR	PVC	PVP	No	No	No	No	Yes (Sachet)	No	No	No	Yes	No	No	No	No	Yes	Yes
UltraSmooth Plus	31,850 (0.0%)	NR	PVC	PVP	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	Yes	Yes
UltraSmooth MCath4	79,320 (0.1%)	NR	PVC	PVP	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes
Pennine Healthcare Ltd																			
Nelaton catheter (unnamed)	314,660 (0.3%)	NR	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Pioneer Medical Europe Ltd*																			
mtg Cath-lean	25 (0.0%)	NR	-	-	No	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No
mtg EZ-Advancer	175 (0.0%)	NR	-	-	No	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No
mtg EZ-Gripper	0	NR	-	-	No	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No
Spirit Healthcare Ltd*																			
SpiritCare	360 (0.0%)	NR	PVC	PVP	No	No	No	No	Yes (Sachet)	No	No	No	Yes	No	No	No	No	Yes	No
Teleflex																			
MobiLoc	0	1996	-	Gel	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	Parts of the packaging and box can be recycled
Riplex	7,115 (0.0%)	1998	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Parts of the packaging and box can be recycled
Riplex Jaques	485,590 (0.5%)	1998	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Parts of the packaging and box can be recycled
Flocath Hydro Gel	12,930 (0.0%)	2003	PVC	PVP	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	Yes	Parts of the packaging and box can be recycled
Flocath Intro Gel	360 (0.0%)	2003	PVC	Gel	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Parts of the packaging and box can be recycled
Liquick Base	1,889,580 (2.0%)	2007	PVC	PVP	No	No	No	No	Yes (sachet)	No	No	No	Yes	No	No	No	No	Yes	Parts of the packaging and box can be recycled

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specially designed packaging	Recyclable components
Flocath Quick	329,520 (0.3%)	2012	PVC	PVP	No	No	No	No	Yes (sachet)	No	No	No	Yes	No	No	No	No	Yes	Parts of the packaging and box can be recycled
Liquick Pure	24,330 (0.0%)	2013	PVC	PVP	No	No	No	No	Yes (sachet)	No	No	No	Yes	No	No	No	Yes	Yes	Parts of the packaging and box can be recycled
Liquick Xtreme	951,360 (1.0%)	2017	PVC	PVP	No	No	No	No	No	Yes	No	No	Yes	Yes	No	Yes (preactivated)	Yes	Yes	Parts of the packaging and box can be recycled
Safety Cat Active	97,020 (0.1%)	2017	PVC	Gel	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No	Yes	Yes	Parts of the packaging and box can be recycled
Liquick Xtreme Plus	73,020 (0.1%)	2021	PVC	PVP	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes (preactivated)	Yes	Yes	Parts of the packaging and box can be recycled
Jaques*	2,575 (0.0%)	NR	Latex	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Parts of the packaging and box can be recycled
Liquick Plus	360 (0.0%)	-	-	-	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	-
Safety Cat*	49,050 (0.1%)	NR	PVC	-	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Parts of the packaging and box can be recycled
Vesica Urology Ltd*																			
OptiSmooth	95,430 (0.1%)	NR	PVC	-	No	No	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No
OptiSmooth Mitro	438,660 (0.5%)	NR	PVC	-	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Wellspect HealthCare																			
LoFric	2,773,170 (2.9%)	NR	POBE	PVP	No	No	No	Yes	No	No	No	No	No	No	No	Yes (high osmolality)	No	No	No
LoFric Elle	745,500 (0.8%)	NR	POBE	PVP	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes (high osmolality; pre-activated)	Yes	Yes	Case/Handle
LoFric Insti-Cath	16,080 (0.0%)	NR	POBE	PVP, NaCl	No	No	No	No	Yes	No	No	No	No	No	No	Yes (high osmolality)	No	No	No
LoFric Origo	6,785,130 (7.1%)	NR	POBE	PVP	No	No	No	No	Yes (sachet NaCl, water)	No	No	No	Yes	No	No	Yes (high osmolality)	Yes	Yes	No
LoFric Primo	3,949,110 (4.1%)	NR	POBE	PVP	No	No	No	No	Yes (sachet NaCl, water)	No	No	No	Yes	No	No	Yes (high osmolality)	No	No	No
LoFric Hydro Kit	464,790 (0.5%)	NR	POBE	PVP	No	No	No	No	Yes (sachet NaCl, water)	No	Yes	No	Yes	No	No	Yes (high osmolality)	No	No	No

Device manufacturer and model as listed on Drug Tariff Part IXA	Activity in 2023/24 as derived from Prescription Cost Analysis; n (%)	Year of product launch	Catheter material	Lubrication or coating material	Uncoated (non-lubricated)	Uncoated (self-lubricated)	Uncoated (pre-lubricated)	Hydrophilic coating (needs activation; water not provided)	Hydrophilic coating (needs activation; water integrated into packaging)	Hydrophilic coating (pre-activated)	Integrated drainage bag	Integrated handle or markings	Insertion sleeve or grip	Tip protector or introducer	Micro-holes	Enhanced coating	Specialty designed catheter case	Specially designed packaging	Recyclable components
LoFric Sense	4,141,320 (4.3%)	NR	POBE	PVP	No	No	No	No	Yes (sachet NaCl, water)	No	No	Yes	No	No	No	Yes (high osmolality)	Yes	No	No

Abbreviations: DEHP, Di(2-Ethylhexyl)Phthalate; NaCl, Sodium Chloride; NR, not reported; PEG, polyethylene glycol; POBE, polyolefin-based elastomer; PVC Polyvinyl chloride; PVP, Polyvinylpyrrolidone TPE, Thermoplastic Elastomer, TPO, Thermoplastic Polyolefins.

Additional notes:

- Bard stated that Hydrosil is the brand name used in the UK, whereas Magic 3 is used globally (Magic 3 is equivalent to Hydrosil).
- [REDACTED]
- [REDACTED]
- [REDACTED]
- Convatec stated GentleCath Glide and GentleCath Air may be referred to as GC Glide and GC Air respectively.
- [REDACTED]

Appendix B: Literature searches

Appendix B1: Search for clinical evidence

Appendix B1a: Search for systematic reviews of controlled comparative studies published since 1 January 2021 to most recent available record

Name of the Database	No of hits
MEDLINE – Ovid	126
Embase – Ovid	236
CINAHL	34
Total number of records before deduplication	396
Total number of duplicates removed	133
Total number of studies to screen	263

Searches were undertaken on 9 October 2024

Database(s): **Ovid MEDLINE(R) ALL** 1946 to October 04, 2024. Date of search: 9 October 2024

Search Strategy:

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15246
2	Urinary Catheters/	1530
3	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	18254
4	in out catheter*.tw,kf.	10
5	(self adj5 catheter*).tw,kf.	2258
6	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	5518
7	1 or 2 or 3 or 4 or 5 or 6	30581
8	(systematic review or meta-analysis).pt.	363920
9	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	406558
10	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	383651
11	((quantitative adj3 (review* or overview* or syntheses*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	18307
12	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	44128
13	(data syntheses* or data extraction* or data abstraction*).ti,ab,kf.	47476
14	(handsearch* or hand search*).ti,ab,kf.	11776

#	Searches	Results
15	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	39593
16	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13468
17	(meta regression* or metaregression*).ti,ab,kf.	17191
18	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).ti,ab,kf.	495231
19	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,kf.	396500
20	(cochrane or (health adj2 technology assessment) or evidence report).ti,ab,kf.	166046
21	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	19793
22	(outcomes research or relative effectiveness).ti,ab,kf.	11988
23	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4780
24	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	317
25	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*).ti,ab,kf.	183
26	umbrella review*.ti,ab,kf.	2278
27	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	15
28	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
29	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	13
30	or/8-29	780619
31	7 and 30	816
32	(Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Clinical Study or Adaptive Clinical Trial or Equivalence Trial).pt.	721890
33	(Clinical Trial or Clinical Trial, Phase I or Clinical Trial, Phase II or Clinical Trial, Phase III or Clinical Trial, Phase IV or Clinical Trial Protocol).pt.	622052
34	Multicenter Study.pt.	355996
35	Clinical Studies as Topic/	846
36	exp clinical trial/	1006187
37	multicenter study/	355996
38	Random allocation/	107712
39	Double-Blind Method/	180766
40	single-blind method/	34087
41	Placebos/	36006
42	Control Groups/	2132
43	cross-over studies/	57617
44	Interrupted time series analysis/	2216
45	(random* or sham or placebo*).tw,kf.	1727800

Late-stage assessment report: GID-HTE10049 Intermittent catheters for chronic incomplete bladder emptying in adults

Date: January 2025

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#	Searches	Results
46	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	207259
47	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	1931
48	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1332500
49	(clinical adj3 (study or studies or trial*)).tw,kf.	851722
50	Interrupted time series.tw,kf.	6855
51	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	58788
52	(phase adj6 (study or studies or trial*)).tw,kf.	198834
53	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	55219
54	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	172451
55	allocated.tw,kf.	91542
56	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	49317
57	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	13315
58	(pragmatic study or pragmatic studies).tw,kf.	676
59	((pragmatic or practical) adj3 trial*).tw,kf.	6919
60	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	14468
61	trial.tw,kf.	843894
62	or/32-61	3931051
63	31 and 62	405
64	exp animals/ not humans/	5265712
65	63 not 64	399
66	limit 65 to yr="2021 -Current"	126

The search filter used to identify systematic reviews is that developed by CDA-AMC (formerly CADTH) (lines 8-31) (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cda-amc.ca/link/33> Accessed 2024-09-17. The search filter used to identify controlled comparative studies is that developed by CDA-AMC (formerly CADTH) (lines 32-63) All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filters were originally multifile searches which have been adapted for use in MEDLINE. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not

designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters in order to make the size of the search more manageable. (Terms tested but not used as they increased the screening burden without identification of potentially relevant studies were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that very poorly reported studies may be missed.

Database(s): **Embase** (on Ovid) 1974 to 2024 October 08. Date of search: 9 October 2024

Search Strategy:

#	Searches	Results
1	urinary catheter/ or urological catheter/ or antimicrobial urinary catheter/ or coude catheter/ or straight catheter/	10206
2	urethral catheter/	4541
3	urethral drainage catheter/	50
4	bladder catheterization/ or urethral catheterization/	11220
5	intermittent catheterization/	5084
6	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	29080
7	("in out catheter*" or "in/out catheter*" or "in and out catheter*" or "In-and-out catheter*").tw,kf.	85
8	(self adj5 catheter*).tw,kf.	3621
9	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	9100
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	47437
11	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	711594
12	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	464089
13	((quantitative adj3 (review* or overview* or syntheses*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	21014
14	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	61904
15	(data syntheses* or data extraction* or data abstraction*).ti,ab,kf.	57682
16	(handsearch* or hand search*).ti,ab,kf.	14371

#	Searches	Results
17	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	52325
18	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	22772
19	(meta regression* or metaregression*).ti,ab,kf.	20971
20	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).ti,ab,kf.	617110
21	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,kf.	496460
22	(cochrane or (health adj2 technology assessment) or evidence report).ti,ab,kf.	210426
23	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	28955
24	(outcomes research or relative effectiveness).ti,ab,kf.	17287
25	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	8358
26	(meta-analysis or systematic review).ti,ab,kf.	561052
27	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	455
28	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	265
29	umbrella review*.ti,ab,kf.	2400
30	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	36
31	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	22
32	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	31
33	or/11-32	1108187
34	Clinical Studies as Topic/	167879
35	exp Clinical Trial/ or exp Clinical Trials as Topic/ or Clinical Trial Protocol/ or Clinical Trial Protocols as Topic/ or exp "Clinical Trial (topic)"/	2400398
36	Multicenter Study/ or Multicenter Studies as Topic/ or "Multicenter Study (topic)"/	448786
37	Randomization/	100152
38	Double Blind Procedure/	224649
39	Single Blind Procedure/	56611
40	Placebo/	418928
41	Control Group/	110811
42	Crossover Procedure/	79930
43	(random* or sham or placebo*).ti,ab,kf.	2364108
44	((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf.	294788
45	((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf.	2434
46	(control* adj3 (study or studies or trial* or group*)).ti,ab,kf.	1856970

#	Searches	Results
47	(clinical adj3 (study or studies or trial*)).ti,ab,kf.	1220582
48	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).ti,ab,kf.	75974
49	(phase adj6 (study or studies or trial*)).ti,ab,kf.	380844
50	((crossover or cross-over) adj3 (study or studies or trial*)).ti,ab,kf.	73124
51	((multicent* or multi-cent*) adj3 (study or studies or trial*)).ti,ab,kf.	285132
52	allocated.ti,ab,kf.	118284
53	((open label or open-label) adj5 (study or studies or trial*)).ti,ab,kf.	95284
54	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).ti,ab,kf.	19761
55	(pragmatic study or pragmatic studies).ti,ab,kf.	1056
56	((pragmatic or practical) adj3 trial*).ti,ab,kf.	9007
57	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).ti,ab,kf.	17659
58	trial.ti,ab,kf.	1235657
59	or/34-58	5808852
60	10 and 33 and 59	837
61	exp animals/ not humans/	11836543
62	60 not 61	581
63	limit 62 to yr="2021 -Current"	236

The search filter used to identify systematic reviews is that developed by CDA-AMC (formerly CADTH) (lines 8-31) (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cda-amc.ca/link/33> Accessed 2024-09-17. The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filters were originally multifile searches which were adapted for use in Embase. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters to make the size of the search more manageable. (Terms tested but not used were as they

increased the screening burden without identification of potentially relevant studies: urinary catheter/ or urological catheter/ or antimicrobial urinary catheter/ or coude catheter/ or straight catheter/; urethral catheter/; urethral drainage catheter/; bladder catheterization/ or urethral catheterization/intermittent catheterization/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; ("in out catheter*" or "in/out catheter*" or "in and out catheter*" or "In-and-out catheter*").tw,kf.; (self adj5 catheter*).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.)This could mean that very poorly reported studies may be missed.

CINAHL on EBSCOhost. Covering from inception to the most recent record available. Date of search: 9 October 2024
Search strategy:

#	Query	Limiters/Expanders	Results
S16	S13 AND S14 AND S15	Limiters - Publication Date: 20210101-20241031 Expanders - Apply equivalent subjects Search modes - Proximity	34
S15	(MH "meta analysis" OR MH "systematic review" OR MH "Technology, Medical/EV" OR PT "systematic review" OR PT "meta analysis" OR (((TI systematic* OR AB systematic*) N3 ((TI review* OR AB review*) OR (TI overview* OR AB overview*))) OR ((TI methodologic* OR AB methodologic*) N3 ((TI review* OR AB review*) OR (TI overview* OR AB overview*)))) OR (((TI quantitative OR AB quantitative) N3 ((TI review* OR AB review*) OR (TI overview* OR AB overview*) OR (TI synthes* OR AB synthes*))) OR ((TI research OR AB research) N3 ((TI integrati* OR AB integrati*) OR (TI overview* OR AB overview*))) OR (((TI integrative OR AB integrative) N3 ((TI review* OR AB review*) OR (TI overview* OR AB overview*))) OR ((TI collaborative OR AB collaborative) N3 ((TI review* OR AB review*) OR (TI overview* OR AB overview*))) OR ((TI pool* OR AB pool*) N3 (TI analy* OR AB analy*)) OR ((TI "data synthes*" OR AB "data synthes*") OR (TI "data extraction*" OR AB "data extraction*") OR (TI "data abstraction*" OR AB "data abstraction*")) OR ((TI handsearch* OR AB handsearch*) OR (TI "hand search*" OR AB "hand search*")) OR ((TI "mantel haenszel" OR AB "mantel haenszel") OR (TI peto OR	Expanders - Apply equivalent subjects Search modes - Proximity	350,270

#	Query	Limiters/Expanders	Results
	AB peto) OR (TI "der simonian" OR AB "der simonian") OR (TI dersimonian OR AB dersimonian) OR (TI "fixed effect*" OR AB "fixed effect*") OR (TI "latin square*" OR AB "latin square*") OR ((TI "met analy*" OR AB "met analy*") OR (TI metanaly* OR AB metanaly*) OR (TI "technology assessment*" OR AB "technology assessment*") OR (TI HTA OR AB HTA) OR (TI HTAs OR AB HTAs) OR (TI "technology overview*" OR AB "technology overview*") OR (TI "technology appraisal*" OR AB "technology appraisal*")) OR ((TI "meta regression*" OR AB "meta regression*") OR (TI metaregression* OR AB metaregression*)) OR (TI meta-analy* OR TI metaanaly* OR TI "systematic review*" OR TI "biomedical technology assessment*" OR TI "bio-medical technology assessment*" OR AB meta-analy* OR AB metaanaly* OR AB "systematic review*" OR AB "biomedical technology assessment*" OR AB "bio-medical technology assessment*" OR MW meta-analy* OR MW metaanaly* OR MW "systematic review*" OR MW "biomedical technology assessment*" OR MW "bio-medical technology assessment*") OR ((TI medline OR AB medline OR MW medline) OR (TI cochrane OR AB cochrane OR MW cochrane) OR (TI pubmed OR AB pubmed OR MW pubmed) OR (TI medlars OR AB medlars OR MW medlars) OR (TI embase OR AB embase OR MW embase) OR (TI cinahl OR AB cinahl OR MW cinahl)) OR (SO Cochrane OR SO health technology assessment OR SO evidence report) OR ((TI comparative OR AB comparative) N3 ((TI efficacy OR AB efficacy) OR (TI effectiveness OR AB effectiveness))) OR ((TI "outcomes research" OR AB "outcomes research") OR (TI "relative effectiveness" OR AB "relative effectiveness")) OR (((TI indirect OR AB indirect) OR (TI "indirect treatment" OR AB "indirect treatment") OR (TI mixed-treatment OR AB mixed-treatment) OR (TI bayesian OR AB bayesian)) N3 (TI comparison* OR AB comparison*)) OR ((TI multi* OR AB multi*) N3 (TI treatment OR AB treatment) N3 (TI comparison* OR AB comparison*)) OR ((TI mixed OR AB mixed) N3 (TI treatment OR AB treatment) N3 ((TI meta-analy* OR AB meta-analy*) OR (TI metaanaly* OR AB metaanaly*))) OR (TI "umbrella review*" OR AB "umbrella review*") OR ((TI multi* OR AB multi*) N2 (TI paramet* OR AB paramet*) N2 (TI evidence OR AB evidence) N2 (TI synthesis OR AB synthesis)) OR ((TI multiparamet* OR AB multiparamet*) N2 (TI		

#	Query	Limiters/Expanders	Results
	evidence OR AB evidence) N2 (TI synthesis OR AB synthesis)) OR ((TI multi-paramet* OR AB multi-paramet*) N2 (TI evidence OR AB evidence) N2 (TI synthesis OR AB synthesis)))		
S14	((MH "Experimental Studies+") OR (MH "Multicenter Studies") OR (MH "Random Sample+") OR (MH "Placebos") OR (MH "Control (Research)+") OR (MH "Crossover Design") OR ((TI random* OR AB random*) OR (TI sham OR AB sham) OR (TI placebo* OR AB placebo*)) OR (((TI singl* OR AB singl*) OR (TI doubl* OR AB doubl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR (((TI tripl* OR AB tripl*) OR (TI trebl* OR AB trebl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR ((TI control* OR AB control*) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*) OR (TI group* OR AB group*))) OR ((TI clinical OR AB clinical) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI Nonrandom* OR AB Nonrandom*) OR (TI "non random*" OR AB "non random*") OR (TI "non-random*" OR AB "non-random*") OR (TI "quasi-random*" OR AB "quasi-random*") OR (TI quasirandom* OR AB quasirandom*)) OR ((TI phase OR AB phase) N6 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI crossover OR AB crossover) OR (TI "cross-over" OR AB "cross-over")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI multicent* OR AB multicent*) OR (TI "multi-cent*" OR AB "multi-cent*")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (TI allocated OR AB allocated) OR (((TI "open label" OR AB "open label") OR (TI "open-label" OR AB "open-label")) N5 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI equivalence OR AB equivalence) OR (TI superiority OR AB superiority) OR (TI "non-inferiority" OR AB "non-inferiority")) OR (TI noninferiority OR AB noninferiority)) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI "pragmatic study" OR AB "pragmatic study") OR (TI "pragmatic studies" OR AB "pragmatic studies")) OR (((TI pragmatic OR AB pragmatic) OR (TI practical OR AB practical)) N3 (TI trial* OR	Expanders - Apply equivalent subjects Search modes - Proximity	1,276,779

#	Query	Limiters/Expanders	Results
	AB trial*)) OR (((TI quasiexperimental OR AB quasiexperimental) OR (TI "quasi-experimental" OR AB "quasi-experimental")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (TI trial))		
S13	S5 OR S12	Expanders - Apply equivalent subjects Search modes - Proximity	9,436
S12	S6 OR S7 OR S8 OR S9 OR S10 OR S11	Expanders - Apply equivalent subjects Search modes - Proximity	6,095
S11	(MH "Catheters, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	2,461
S10	(MH "Urinary Catheterization+")	Expanders - Apply equivalent subjects Search modes - Proximity	3,603
S9	(MH "Urinary Catheter Insertion (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S8	(MH "Urinary Catheter Care (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S7	(MH "Catheter Removal")	Expanders - Apply equivalent subjects Search modes - Proximity	834
S6	(MH "Catheter Care, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	651
S5	S1 OR S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Proximity	6,333
S4	TI ("in and out" N2 catheter*) OR AB ("in and out" N2 catheter*) OR TI in/out catheter* OR AB in/out catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	24
S3	TI in out catheter* OR AB in out catheter* OR TI in-out catheter* OR AB in-out catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	144
S2	TI catheter* N6 urological OR AB catheter* N6 urological OR TI Catheter N6	Expanders - Apply equivalent subjects Search modes - Proximity	124

#	Query	Limiters/Expanders	Results
	transurethra* OR AB Catheter N6 transurethra*		
S1	TI urin* N6 catheter* OR AB urin* N6 catheter* OR TI urethra* N6 catheter* OR AB urethra* N6 catheter* OR TI bladder* N6 catheter* OR AB bladder* N6 catheter* OR TI vesic* N6 catheter* OR AB vesic* N6 catheter* OR TI intermittent* N6 catheter* OR AB intermittent* N6 catheter* OR TI self N6 catheter* OR AB self N6 catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	6,184

The Search filter used to identify Systematic Reviews is that developed by the CDA-AMC (formerly CADTH), SR / MA / HTA / ITC - CINAHL. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/98>. Accessed 2024-09-25.

The Search filter used to identify Controlled Clinical Trials is that developed by the CDA-AMC (formerly CADTH) All Clinical Trials - CINAHL. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/104>. Accessed 2024-09-25.

Appendix B1b: Search for controlled Comparative Studies published between 1 January 2021 and most recent available, inclusive

Name of the Database	No of hits
MEDLINE – Ovid	176
Embase – Ovid	435
CINAHL - EBSCOhost	318
Cochrane Library (CENTRAL) - Wiley	561
INAHTA	10
Total number of records before deduplication	1500
Total number of duplicates removed	372
Total number of studies to screen	1128

Searches were undertaken: 3-4 October 2024

Database(s): **Ovid MEDLINE(R) ALL** 1946 to October 03, 2024, Date of search: 4 October 2024

Search Strategy:

#	Searches	Results
1	Intermittent Urethral Catheterization/	389
2	(catheter* adj3 intermittent).tw,kf.	4255
3	in out catheter*.tw,kf.	10
4	(self adj3 catheter*).tw,kf.	1990
5	or/1-4	5054
6	(Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Clinical Study or Adaptive Clinical Trial or Equivalence Trial).pt.	721290
7	(Clinical Trial or Clinical Trial, Phase I or Clinical Trial, Phase II or Clinical Trial, Phase III or Clinical Trial, Phase IV or Clinical Trial Protocol).pt.	621829
8	Multicenter Study.pt.	355492
9	Clinical Studies as Topic/	845
10	exp clinical trial/	1005512
11	multicenter study/	355492
12	Random allocation/	107699
13	Double-Blind Method/	180641
14	single-blind method/	34047
15	Placebos/	36001
16	Control Groups/	2132
17	cross-over studies/	57576
18	Interrupted time series analysis/	2212
19	(random* or sham or placebo*).tw,kf.	1726081
20	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	207072
21	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	1924
22	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1331264
23	(clinical adj3 (study or studies or trial*)).tw,kf.	850846
24	Interrupted time series.tw,kf.	6845
25	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	58735
26	(phase adj6 (study or studies or trial*)).tw,kf.	198585
27	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	55181
28	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	172186
29	allocated.tw,kf.	91440
30	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	49258
31	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	13294

#	Searches	Results
32	(pragmatic study or pragmatic studies).tw,kf.	674
33	((pragmatic or practical) adj3 trial*).tw,kf.	6905
34	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	14438
35	trial.tw,kf.	842898
36	or/6-35	3927714
37	exp animals/	27534487
38	exp animal experimentation/	10580
39	exp models animal/	662462
40	exp animal experiment/	10580
41	exp vertebrate/	26762118
42	or/37-41	27536466
43	exp humans/	22270116
44	exp Human Experimentation/	12697
45	or/43-44	22270775
46	42 not 45	5266319
47	36 not 46	3497606
48	5 and 47	955
49	limit 48 to yr="2021 -Current"	176

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filter was originally a multfile search which has been adapted for use in MEDLINE. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters to make the size of the search more manageable. (Terms tested but not used as they increased the screening burden without identification of potentially relevant studies were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that very poorly reported studies may be missed.

Database(s): **Embase** (on Ovid) 1974 to 2024 October 03, Date of search: 4 October 2024

Search Strategy:

#	Searches	Results
1	Intermittent Urethral Catheterization/	2618
2	(catheter* adj3 intermittent).tw,kf.	6573
3	in out catheter*.tw,kf.	24
4	(self adj3 catheter*).tw,kf.	3198
5	or/1-4	10205
6	Clinical Studies as Topic/	167830
7	exp clinical trial/	1950809
8	multicenter study/	405537
9	Random allocation/	94875
10	Double-Blind Method/	199483
11	single-blind method/	54490
12	Placebos/	361868
13	Control Groups/	110811
14	cross-over studies/	72427
15	Interrupted time series analysis/	261818
16	(random* or sham or placebo*).tw,kf.	2362157
17	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	294588
18	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	2429
19	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1855438
20	(clinical adj3 (study or studies or trial*)).tw,kf.	1219256
21	Interrupted time series.tw,kf.	8474
22	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	75913
23	(phase adj6 (study or studies or trial*)).tw,kf.	380477
24	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	73090
25	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	284875
26	allocated.tw,kf.	118172
27	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	95178
28	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	19733
29	(pragmatic study or pragmatic studies).tw,kf.	1055
30	((pragmatic or practical) adj3 trial*).tw,kf.	8993

Late-stage assessment report: GID-HTE10049 Intermittent catheters for chronic incomplete bladder emptying in adults

Date: January 2025

175 of 319

#	Searches	Results
31	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	17633
32	trial.tw,kf.	1234339
33	or/6-32	5879065
34	exp animals/	32476713
35	exp animal experimentation/	3250523
36	exp models animal/	1892017
37	exp animal experiment/	3250523
38	exp vertebrate/	31671111
39	or/34-38	32832579
40	exp humans/	27152752
41	exp Human Experimentation/	672913
42	or/40-41	27155657
43	39 not 42	5678859
44	33 not 43	5241453
45	5 and 44	2086
46	limit 45 to yr="2021 -Current"	435

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filter was originally a multfile search which has been adapted for use in Embase. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters in order to make the size of the search more manageable. (Terms tested but not used as they increased the screening burden without identification of potentially relevant studies were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that very poorly reported studies may be missed.

CINAHL

CINAHL on EBSCOhost covering from inception to 31092024 inclusive. Date of search: 4 October 2024

#	Query	Limiters/Expanders	Results
S15	S13 AND S14	Limiters - Publication Date: 20210101-20240931 Expanders - Apply equivalent subjects Search modes - Proximity	318
S14	((MH "Experimental Studies+") OR (MH "Multicenter Studies") OR (MH "Random Sample+") OR (MH "Placebos") OR (MH "Control (Research)+") OR (MH "Crossover Design") OR ((TI random* OR AB random*) OR (TI sham OR AB sham) OR (TI placebo* OR AB placebo*)) OR (((TI singl* OR AB singl*) OR (TI doubl* OR AB doubl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR (((TI tripl* OR AB tripl*) OR (TI trebl* OR AB trebl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR ((TI control* OR AB control*) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*) OR (TI group* OR AB group*))) OR ((TI clinical OR AB clinical) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI Nonrandom* OR AB Nonrandom*) OR (TI "non random*" OR AB "non random*") OR (TI "non-random*" OR AB "non-random*") OR (TI "quasi-random*" OR AB "quasi-random*") OR (TI quasirandom* OR AB quasirandom*)) OR ((TI phase OR AB phase) N6 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI crossover OR AB crossover) OR (TI "cross-over" OR AB "cross-over")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI multicent* OR AB multicent*) OR (TI "multi-cent*" OR AB "multi-cent*")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (TI allocated OR AB allocated) OR (((TI "open label" OR AB "open label") OR (TI "open-label" OR AB "open-label")) N5 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI equivalence OR AB equivalence) OR (TI superiority OR AB superiority) OR (TI "non-inferiority" OR AB "non-inferiority") OR (TI noninferiority OR AB noninferiority)) N3 ((TI study OR AB	Expanders - Apply equivalent subjects Search modes - Proximity	1,276,096

	study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*)) OR ((TI "pragmatic study" OR AB "pragmatic study") OR (TI "pragmatic studies" OR AB "pragmatic studies")) OR (((TI pragmatic OR AB pragmatic) OR (TI practical OR AB practical)) N3 (TI trial* OR AB trial*)) OR (((TI quasiexperimental OR AB quasiexperimental) OR (TI "quasi-experimental" OR AB "quasi-experimental")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*)) OR (TI trial))		
S13	S5 OR S12	Expanders - Apply equivalent subjects Search modes - Proximity	9,431
S12	S6 OR S7 OR S8 OR S9 OR S10 OR S11	Expanders - Apply equivalent subjects Search modes - Proximity	6,094
S11	(MH "Catheters, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	2,460
S10	(MH "Urinary Catheterization+")	Expanders - Apply equivalent subjects Search modes - Proximity	3,603
S9	(MH "Urinary Catheter Insertion (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S8	(MH "Urinary Catheter Care (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S7	(MH "Catheter Removal")	Expanders - Apply equivalent subjects Search modes - Proximity	834
S6	(MH "Catheter Care, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	651
S5	S1 OR S2 OR S3 OR S4	Expanders - Apply equivalent subjects	6,328

		Search modes - Proximity	
S4	TI ("in and out" N2 catheter*) OR AB ("in and out" N2 catheter*) OR TI in/out catheter* OR AB in/out catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	24
S3	TI in out catheter* OR AB in out catheter* OR TI in-out catheter* OR AB in-out catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	144
S2	TI catheter* N6 urological OR AB catheter* N6 urological OR TI Catheter N6 transurethra* OR AB Catheter N6 transurethra*	Expanders - Apply equivalent subjects Search modes - Proximity	124
S1	TI urin* N6 catheter* OR AB urin* N6 catheter* OR TI urethra* N6 catheter* OR AB urethra* N6 catheter* OR TI bladder* N6 catheter* OR AB bladder* N6 catheter* OR TI vesic* N6 catheter* OR AB vesic* N6 catheter* OR TI intermittent* N6 catheter* OR AB intermittent* N6 catheter* OR TI self N6 catheter* OR AB self N6 catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	6,179

The search filter used to identify controlled comparative studies is that developed by CADTH. All Clinical Trials - CINAHL. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/104>. Accessed 2024-09-30.

Cochrane Library (CENTRAL) on Wiley – CENTRAL 2024, issue 9

Date of search: 3 October 2024

#	Searches	Hits
1	(self NEAR/3 catheter*):ti,ab,kw (Word variations have been searched)	272
2	((((catheter* NEAR (urological or transurethra* or bladder))))):ti,ab,kw (Word variations have been searched)	1877
3	("intermittent catheterisation"):ti,ab,kw (Word variations have been searched)	463
4	("intermittent catheter"):ti,ab,kw (Word variations have been searched)	50
5	MeSH descriptor: [Urinary Catheterization] explode all trees	983
6	#1 or #2 or #3 or #4 or #5	2843
7	Custom Year Range 2021 to 2024	561

International HTA Database (INAHTA) = 10 hits Date of search: 3 October 2024

Search terms:

(intermittent catheter)[Title] OR (urinary catheterisation)[Title] OR (urinary catheterization)[Title] OR (urinary catheter)[Title] OR (urinary catheterization)[mh]
FROM 2021 TO 2024

Appendix B1c: Search for controlled comparative studies published from 1 January 2000 to 31 December 2020 inclusive

Name of the Database	No of hits
MEDLINE – Ovid	581
Embase – Ovid	1476
CINAHL - EBSCOhost	1385
Cochrane Library (CENTRAL) - Wiley	1831
INAHTA	18
Total number of records before deduplication	5291
Total number of duplicates removed	1221
Total number of studies to screen	4070

Searches were conducted 10 October 2024

Database(s): **Ovid MEDLINE(R) ALL** 1946 to October 09, 2024. Date of search 10 October 2024

Search Strategy:

#	Searches	Results
1	Intermittent Urethral Catheterization/	389
2	(catheter* adj3 intermittent).tw,kf.	4257
3	in out catheter*.tw,kf.	10
4	(self adj3 catheter*).tw,kf.	1988
5	or/1-4	5054

#	Searches	Results
6	(Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Clinical Study or Adaptive Clinical Trial or Equivalence Trial).pt.	721617
7	(Clinical Trial or Clinical Trial, Phase I or Clinical Trial, Phase II or Clinical Trial, Phase III or Clinical Trial, Phase IV or Clinical Trial Protocol).pt.	621972
8	Multicenter Study.pt.	355706
9	Clinical Studies as Topic/	845
10	exp clinical trial/	1005869
11	multicenter study/	355706
12	Random allocation/	107712
13	Double-Blind Method/	180727
14	single-blind method/	34068
15	Placebos/	36005
16	Control Groups/	2132
17	cross-over studies/	57606
18	Interrupted time series analysis/	2214
19	(random* or sham or placebo*).tw,kf.	1727643
20	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	207209
21	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	1935
22	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1332419
23	(clinical adj3 (study or studies or trial*)).tw,kf.	851677
24	Interrupted time series.tw,kf.	6853
25	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	58778
26	(phase adj6 (study or studies or trial*)).tw,kf.	198773
27	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	55215
28	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	172374
29	allocated.tw,kf.	91525
30	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	49299
31	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	13314
32	(pragmatic study or pragmatic studies).tw,kf.	676
33	((pragmatic or practical) adj3 trial*).tw,kf.	6916
34	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	14474
35	trial.tw,kf.	843685
36	or/6-35	3930790
37	exp animals/	27545781

#	Searches	Results
38	exp animal experimentation/	10587
39	exp models animal/	662829
40	exp animal experiment/	10587
41	exp vertebrate/	26773079
42	or/37-41	27547760
43	exp humans/	22279970
44	exp Human Experimentation/	12698
45	or/43-44	22280629
46	42 not 45	5267759
47	36 not 46	3500507
48	5 and 47	955
49	limit 48 to yr="2000 - 2020"	581

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filter was originally a multfile search which has been adapted for use in MEDLINE. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters in order to make the size of the search more manageable. (Terms tested but not used as they increased the screening burden without identification of potentially relevant studies were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that very poorly reported studies may be missed.

Database(s): **Embase** (on Ovid)1974 to 2024 October 09. Date of search 10 October 2024

Search Strategy:

#	Searches	Results
1	Intermittent Urethral Catheterization/	2623

#	Searches	Results
2	(catheter* adj3 intermittent).tw,kf.	6579
3	in out catheter*.tw,kf.	24
4	(self adj3 catheter*).tw,kf.	3201
5	or/1-4	10215
6	Clinical Studies as Topic/	167883
7	exp clinical trial/	1952484
8	multicenter study/	406019
9	Random allocation/	94902
10	Double-Blind Method/	199761
11	single-blind method/	54566
12	Placebos/	362123
13	Control Groups/	110811
14	cross-over studies/	72475
15	Interrupted time series analysis/	247261
16	(random* or sham or placebo*).tw,kf.	2364636
17	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	294845
18	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	2436
19	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1857373
20	(clinical adj3 (study or studies or trial*)).tw,kf.	1220903
21	Interrupted time series.tw,kf.	8491
22	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	75986
23	(phase adj6 (study or studies or trial*)).tw,kf.	380922
24	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	73134
25	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	285217
26	allocated.tw,kf.	118320
27	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	95302
28	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	19768
29	(pragmatic study or pragmatic studies).tw,kf.	1057
30	((pragmatic or practical) adj3 trial*).tw,kf.	9014
31	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	17669
32	trial.tw,kf.	1235992
33	or/6-32	5872252
34	exp animals/	32505570

#	Searches	Results
35	exp animal experimentation/	3252967
36	exp models animal/	1893813
37	exp animal experiment/	3252967
38	exp vertebrate/	31699447
39	or/34-38	32861509
40	exp humans/	27178540
41	exp Human Experimentation/	673418
42	or/40-41	27181456
43	39 not 42	5681999
44	33 not 43	5234527
45	5 and 44	2088
46	limit 45 to yr="2000 - 2020"	1476

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/117>. Accessed 2024-09-17. The filter was originally a multfile search which has been adapted for use in Embase. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters in order to make the size of the search more manageable. (Terms tested but not used as they increased the screening burden without identification of potentially relevant studies were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that very poorly reported studies may be missed.

CINAHL

CINAHL on EBSCOhost covering from 1 Jan 2000 to 31 Dec 2020 inclusive. Date of search: 10 October 2024

#	Query	Limiters/Expanders	Results
S15	S13 AND S14	Limiters - Publication Date: 20000101-20201231 Expanders - Apply equivalent subjects Search modes - Proximity	1,385
S14	((MH "Experimental Studies+") OR (MH "Multicenter Studies") OR (MH "Random Sample+") OR (MH "Placebos") OR (MH "Control (Research)+") OR (MH "Crossover Design") OR ((TI random* OR AB random*) OR (TI sham OR AB sham) OR (TI placebo* OR AB placebo*)) OR (((TI singl* OR AB singl*) OR (TI doubl* OR AB doubl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR (((TI tripl* OR AB tripl*) OR (TI trebl* OR AB trebl*)) W1 ((TI blind* OR AB blind*) OR (TI dumm* OR AB dumm*) OR (TI mask* OR AB mask*))) OR ((TI control* OR AB control*) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*) OR (TI group* OR AB group*))) OR ((TI clinical OR AB clinical) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI Nonrandom* OR AB Nonrandom*) OR (TI "non random*" OR AB "non random*") OR (TI "non-random*" OR AB "non-random*") OR (TI "quasi-random*" OR AB "quasi-random*") OR (TI quasirandom* OR AB quasirandom*)) OR ((TI phase OR AB phase) N6 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI crossover OR AB crossover) OR (TI "cross-over" OR AB "cross-over")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI multicent* OR AB multicent*) OR (TI "multi-cent*" OR AB "multi-cent*")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI allocated OR AB allocated) OR (((TI "open label" OR AB "open label") OR (TI "open-label" OR AB "open-label")) N5 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR (((TI equivalence OR AB equivalence) OR (TI superiority OR AB superiority) OR (TI "non-inferiority" OR AB "non-inferiority") OR (TI noninferiority OR AB noninferiority)) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*))) OR ((TI "pragmatic study" OR AB "pragmatic study") OR (TI "pragmatic studies" OR AB "pragmatic studies")) OR (((TI pragmatic	Expanders - Apply equivalent subjects Search modes - Proximity	1,278,346

	OR AB pragmatic) OR (TI practical OR AB practical)) N3 (TI trial* OR AB trial*)) OR (((TI quasiexperimental OR AB quasiexperimental) OR (TI "quasi-experimental" OR AB "quasi-experimental")) N3 ((TI study OR AB study) OR (TI studies OR AB studies) OR (TI trial* OR AB trial*)) OR (TI trial))		
S13	S5 OR S12	Expanders - Apply equivalent subjects Search modes - Proximity	9,441
S12	S6 OR S7 OR S8 OR S9 OR S10 OR S11	Expanders - Apply equivalent subjects Search modes - Proximity	6,101
S11	(MH "Catheters, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	2,464
S10	(MH "Urinary Catheterization+")	Expanders - Apply equivalent subjects Search modes - Proximity	3,606
S9	(MH "Urinary Catheter Insertion (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S8	(MH "Urinary Catheter Care (Saba CCC)")	Expanders - Apply equivalent subjects Search modes - Proximity	1
S7	(MH "Catheter Removal")	Expanders - Apply equivalent subjects Search modes - Proximity	834
S6	(MH "Catheter Care, Urinary+")	Expanders - Apply equivalent subjects Search modes - Proximity	651
S5	S1 OR S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Proximity	6,333
S4	TI ("in and out" N2 catheter*) OR AB ("in and out" N2 catheter*) OR TI in/out catheter* OR AB in/out catheter*	Expanders - Apply equivalent subjects	24

		Search modes - Proximity	
S3	TI in out catheter* OR AB in out catheter* OR TI in-out catheter* OR AB in-out catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	144
S2	TI catheter* N6 urological OR AB catheter* N6 urological OR TI Catheter N6 transurethra* OR AB Catheter N6 transurethra*	Expanders - Apply equivalent subjects Search modes - Proximity	124
S1	TI urin* N6 catheter* OR AB urin* N6 catheter* OR TI urethra* N6 catheter* OR AB urethra* N6 catheter* OR TI bladder* N6 catheter* OR AB bladder* N6 catheter* OR TI vesic* N6 catheter* OR AB vesic* N6 catheter* OR TI intermittent* N6 catheter* OR AB intermittent* N6 catheter* OR TI self N6 catheter* OR AB self N6 catheter*	Expanders - Apply equivalent subjects Search modes - Proximity	6,184

The search filter used to identify controlled comparative studies is that developed by CADTH. All Clinical Trials - CINAHL. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/104>. Accessed 2024-09-30.

Cochrane Library (CENTRAL) on Wiley – CENTRAL 2024, issue 9

Date of search: 10/10/2024

ID	Search	Hits
#1	(self NEAR/3 catheter*):ti,ab,kw (Word variations have been searched)	= 272
#2	((((catheter* NEAR (urological or transurethra* or bladder))))):ti,ab,kw (Word variations have been searched)	= 1877
#3	("intermittent catheterisation"):ti,ab,kw (Word variations have been searched)	= 463
#4	("intermittent catheter"):ti,ab,kw (Word variations have been searched)	= 50
#5	MeSH descriptor: [Urinary Catheterization] explode all trees	= 983
#6	#1 or #2 or #3 or #4 or #5	= 2843

#7 Custom Year Range 2000 to 2020 = 1831

International HTA Database (INAHTA) = 18 hits. Date of search: 10 October 2024

Search terms:

(intermittent catheter)[Title] OR (urinary catheterisation)[Title] OR (urinary catheterization)[Title] OR (urinary catheter)[Title] OR (urinary catheterization)[mh]
FROM 2000 TO 2020

Appendix B2: Search for economic evidence

Appendix B2a: Searches of NHS EED and searches for systematic reviews of economic evaluations or modelling

Name of the Database (purpose of search)	No of hits
NHS EED (any SR of EEs or any EE)	61
MEDLINE – Ovid (SR of EEs only)	48
Embase – Ovid (SR of EEs only)	142
Total number of records before deduplication	251
Total number of duplicates removed	42
Total number of studies to screen	209

Searches were undertaken in NHS EED for any economic evaluations (or systematic reviews of economic evaluations) related to intermittent urethral catheters on 7 October 2024. All available years of coverage were searched (from inception to 31 December 2014 when addition of records to NHS EED ceased). Searches were then undertaken in MEDLINE and Embase for sys reviews of EEs from 1 Jan 2015 to most recent available record to cover those years since the end of NHS EED coverage. A search for EEs will be undertaken from the date of last search of any relevant SR of EEs or if none found from 1 Jan 2015 to most recent available.

NHS EED Database (on CRD website) searched on 7 October 2024

Line	Search	Hits
1	((urin* NEAR catheter*)) OR ((catheter* NEAR urin*)) IN NHSEED	50
2	MeSH DESCRIPTOR urinary catheterization EXPLODE ALL TREES IN NHSEED	32
3	MeSH DESCRIPTOR urinary catheters EXPLODE ALL TREES IN NHSEED	3
4	(self NEAR catheter*) OR (catheter* NEAR self) IN NHSEED	5
5	(in out catheter*) OR (intermittent NEAR catheter*) OR (catheter* NEAR intermittent) IN NHSEED	13
6	(urethra* NEAR catheter*) OR (catheter* NEAR urethra*) IN NHSEED	8
7	(transurethra* NEAR catheter*) OR (catheter* NEAR transurethra*) IN NHSEED	1

Line	Search	Hits
8	(bladder NEAR catheter*) OR (catheter* NEAR bladder) IN NHSEED	17
9	(urological NEAR catheter*) OR (catheter* NEAR urological) IN NHSEED	0
10	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9	61

Search was undertaken on 7 October 2024

Database(s): **Ovid MEDLINE(R) ALL** 1946 to October 04, 2024. Date of search: 7 October 2024

Search Strategy:

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15246
2	Urinary Catheters/	1529
3	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	18244
4	in out catheter*.tw,kf.	10
5	(self adj5 catheter*).tw,kf.	2257
6	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	5517
7	1 or 2 or 3 or 4 or 5 or 6	30568
8	(systematic review or meta-analysis).pt.	363486
9	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	406097
10	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	383043
11	((quantitative adj3 (review* or overview* or syntheses*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	18279
12	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	44083
13	(data syntheses* or data extraction* or data abstraction*).ti,ab,kf.	47391
14	(handsearch* or hand search*).ti,ab,kf.	11766
15	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	39572

#	Searches	Results
16	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13454
17	(meta regression* or metaregression*).ti,ab,kf.	17169
18	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	541604
19	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	399163
20	(cochrane or (health adj2 technology assessment) or evidence report).jw.	22103
21	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	19768
22	(outcomes research or relative effectiveness).ti,ab,kf.	11976
23	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4774
24	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	317
25	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	182
26	umbrella review*.ti,ab,kf.	2269
27	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	15
28	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
29	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	13
30	or/8-29	784086
31	Economics/	27539
32	exp "Costs and Cost Analysis"/	273581
33	Economics, Nursing/	4013
34	Economics, Medical/	9292
35	Economics, Pharmaceutical/	3148
36	exp Economics, Hospital/	25991
37	Economics, Dental/	1922
38	exp "Fees and Charges"/	31534
39	exp Budgets/	14265
40	budget*.ti,ab,kf.	38851
41	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	302629
42	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	419303
43	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	233394
44	(value adj2 (money or monetary)).ti,ab,kf.	3302

#	Searches	Results
45	exp models, economic/	16539
46	economic model*.ab,kf.	4568
47	markov chains/	16487
48	markov.ti,ab,kf.	31607
49	monte carlo method/	33340
50	monte carlo.ti,ab,kf.	64537
51	exp Decision Theory/	13867
52	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	45292
53	or/31-52	971341
54	7 and 30 and 53	87
55	limit 54 to yr="2015 -Current"	48

The search filter used to identify systematic reviews is that developed by CDA-AMC (formerly CADTH) (lines 8-31) (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cda-amc.ca/link/33> Accessed 7 October 2024.

The filter used to identify economic evaluation studies was also developed by CDA-AMC (formerly CADTH) Economic Evaluations & Models - MEDLINE. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/16>. Accessed 2024-10-07.

Database(s): **Embase** (on Ovid) 1974 to 2024 October 04. Date of search: 7 October 2024

Search Strategy:

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	11708
2	Urinary Catheters/	9882
3	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	29067
4	in out catheter*.tw,kf.	24
5	(self adj5 catheter*).tw,kf.	3619
6	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	9098
7	1 or 2 or 3 or 4 or 5 or 6	44400
8	(systematic review or meta-analysis).pt.	0
9	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	710637
10	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	463388
11	((quantitative adj3 (review* or overview* or syntheses)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	20989
12	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	61820
13	(data syntheses* or data extraction* or data abstraction*).ti,ab,kf.	57610
14	(handsearch* or hand search*).ti,ab,kf.	14359
15	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	52266
16	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	22749
17	(meta regression* or metaregression*).ti,ab,kf.	20948
18	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	840798
19	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	517774
20	(cochrane or (health adj2 technology assessment) or evidence report).jw.	32466
21	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	28931
22	(outcomes research or relative effectiveness).ti,ab,kf.	17279
23	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	8344
24	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	455
25	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	265
26	umbrella review*.ti,ab,kf.	2393
27	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	36
28	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	22
29	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	31
30	or/8-29	1122265

#	Searches	Results
31	Economics/	246809
32	exp "Costs and Cost Analysis"/	425586
33	Economics, Nursing/	34891
34	Economics, Medical/	35821
35	Economics, Pharmaceutical/	14712
36	exp Economics, Hospital/	1096306
37	Economics, Dental/	36817
38	exp "Fees and Charges"/	45741
39	exp Budgets/	35210
40	budget*.ti,ab,kf.	51232
41	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	371758
42	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	584752
43	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	319783
44	(value adj2 (money or monetary)).ti,ab,kf.	4407
45	exp models, economic/	4451
46	economic model*.ab,kf.	6831
47	markov chains/	11948
48	markov.ti,ab,kf.	41510
49	monte carlo method/	55053
50	monte carlo.ti,ab,kf.	68295
51	exp Decision Theory/	1889
52	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	60284
53	or/31-52	1878004
54	7 and 30 and 53	232
55	limit 54 to yr="2015 -Current"	142

The search filter used to identify systematic reviews is that developed by CADTH (lines 8-31) (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cda-amc.ca/link/33> Accessed 2024-10-07.

The filter used to identify economic evaluation studies is Economic Evaluations & Models - Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/15>. Accessed 2024-10-07.

Appendix B2b: Searches for economic evaluations or models published since NHS EED ceased (published from 1 January 2015 to most recent record available)

Name of the Database	No of hits
MEDLINE – Ovid	398
Embase – Ovid	1644
Total number of records before deduplication	2042
Total number of duplicates removed	301
Total number of studies to screen	1741

Searches were undertaken 14 October 2024

Database(s): **Ovid MEDLINE(R) ALL** 1946 to October 11, 2024. Date of search: 14 October 2024

Search Strategy:

#	Searches	Results
1	Economics/	27540
2	exp "Costs and Cost Analysis"/	273704
3	Economics, Nursing/	4013
4	Economics, Medical/	9292
5	Economics, Pharmaceutical/	3149
6	exp Economics, Hospital/	26002
7	Economics, Dental/	1922
8	exp "Fees and Charges"/	31541
9	exp Budgets/	14265
10	budget*.ti,ab,kf.	38892
11	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	302917
12	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	419895
13	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	233800
14	(value adj2 (money or monetary)).ti,ab,kf.	3307
15	exp models, economic/	16541
16	economic model*.ab,kf.	4575
17	markov chains/	16499
18	markov.ti,ab,kf.	31656
19	monte carlo method/	33364
20	monte carlo.ti,ab,kf.	64614
21	exp Decision Theory/	13868
22	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	45401
23	or/1-22	972479
24	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15249
25	Urinary Catheters/	1533
26	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	18262
27	in out catheter*.tw,kf.	10
28	(self adj5 catheter*).tw,kf.	2257
29	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	5518
30	24 or 25 or 26 or 27 or 28 or 29	30588
31	23 and 30	885

#	Searches	Results
32	limit 31 to yr="2015 -Current"	398

The filter used to identify economic evaluation studies is Economic Evaluations & Models - MEDLINE. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/16>. Accessed 2024-10-14.

Database(s): **Embase** (on Ovid) 1974 to 2024 October 11. Date of search: 14 October 2024

Search Strategy:

#	Searches	Results
1	Economics/	246897
2	Cost/	65108
3	exp Health Economics/	1097647
4	Budget/	35238
5	budget*.ti,ab,kf.	51302
6	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	372223
7	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	585748
8	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	320434
9	(value adj2 (money or monetary)).ti,ab,kf.	4415
10	Statistical Model/	179464
11	exp economic model/	4471
12	economic model*.ab,kf.	6841
13	Probability/	159392
14	markov.ti,ab,kf.	41574
15	monte carlo method/	55113
16	monte carlo.ti,ab,kf.	68377
17	Decision Theory/	1890
18	Decision Tree/	26144
19	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	60445
20	or/1-19	2159537
21	urinary catheter/ or urological catheter/ or antimicrobial urinary catheter/ or coude catheter/ or straight catheter/	10218
22	urethral catheter/	4549
23	urethral drainage catheter/	50
24	bladder catheterization/ or urethral catheterization/	11223
25	intermittent catheterization/	5088
26	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	29091
27	in out catheter*.tw,kf.	24
28	(self adj5 catheter*).tw,kf.	3622
29	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	9101
30	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	47452
31	20 and 30	2710
32	limit 31 to yr="2015 -Current"	1644

The filter used to identify economic evaluation studies is Economic Evaluations & Models - Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: <https://searchfilters.cadth.ca/link/15>. Accessed 2024-10-14.

Appendix B3: Search for ongoing studies

A search of clinical trials registries and platforms (ClinicalTrials.gov and WHO ICTRP) was undertaken but due to resource constraints the records retrieved by these searches were not screened. The focus of this review was on completed studies rather than ongoing studies and although clinical trials registries can be a source of study results (for instance the results tab in ClinicalTrials.gov) information on ongoing studies would not have been informative for this late-stage assessment (LSA). The search terms used and the results of the search are presented below. CENTRAL contains records for RCTs and quasi RCTs from ClinicalTrials.gov and WHO ICTRP these records were included in the screening. Searches of ClinicalTrials.gov and WHO ICTRP were undertaken. The results were limited to 1 January 2015 onwards (to cover the last 10 years). No study status limits were applied.

Name of the Database	No of hits
ClinicalTrials.gov	531
WHO ICTRP	442
Total number of records pre-duplication	973
Total number of records to screen	642

Clinical trials.gov - Date of Search: 17 October 2024

Search terms and number of records retrieved by each search string.

("urinary catheterisation" OR "urinary catheterization") | First posted on or after 01/01/2015 = 68

("urinary catheter") OR ("urethral catheter") OR ("intermittent catheter") | First posted on or after 01/01/2015 = 258

("bladder catheter") OR ("transurethral catheter") OR ("urological catheter") | First posted on or after 01/01/2015 - 205

WHO ICTRP – Date of Search: 17 October 2024

Search terms and number of records retrieved by each search string.

57 records for 56 trials found for: ("urinary catheterisation" OR "urinary catheterization")

339 records for 334 trials found for: ("urinary catheter") OR ("urethral catheter") OR ("intermittent catheter")

46 records for 43 trials found for: ("bladder catheter") OR ("transurethral catheter") OR ("urological catheter")

One of the information specialists (JB) had divided the results into two different categories based on presence or not of the term 'intermittent catheter' to aid prioritisation of screening results:

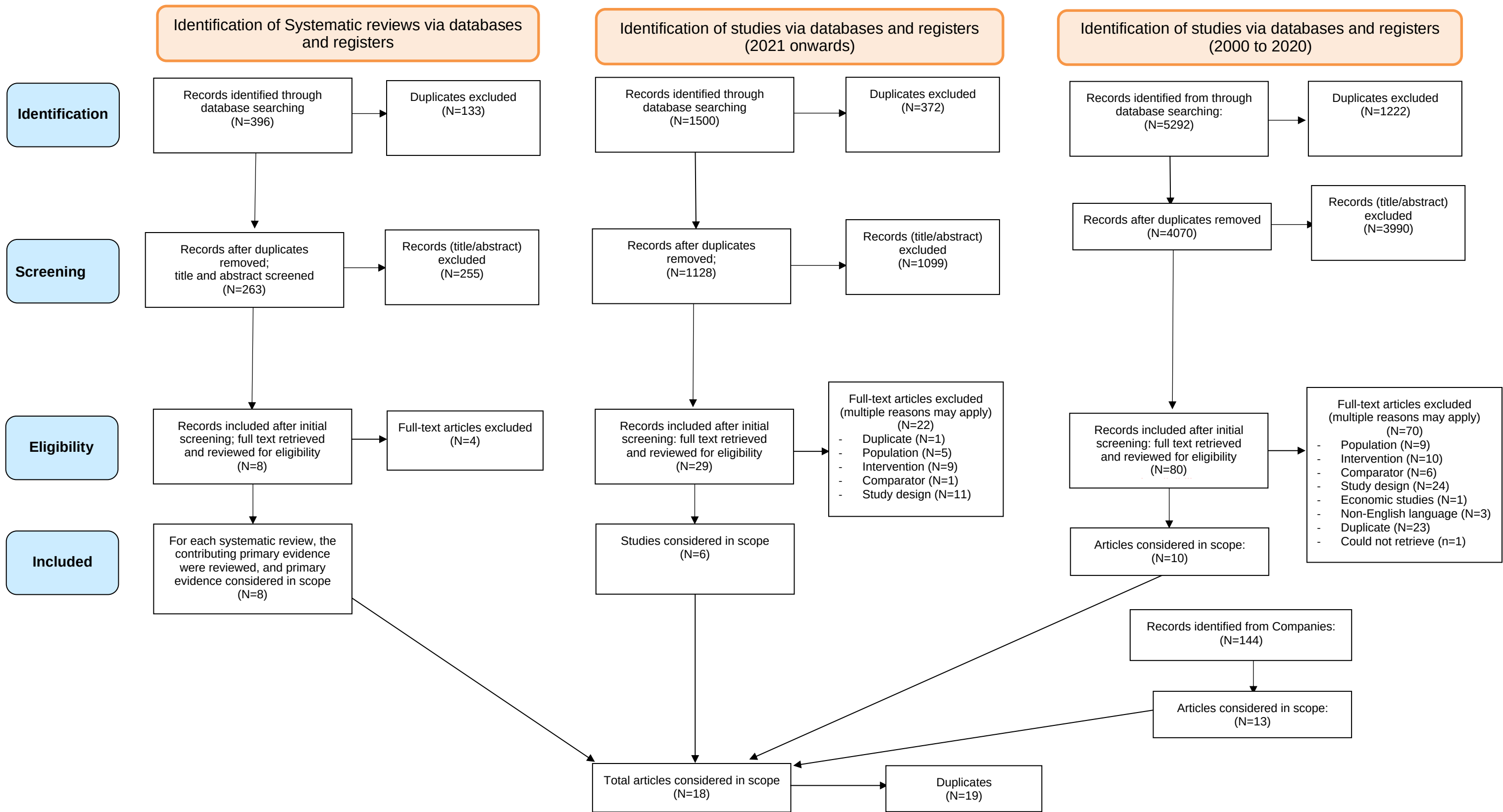
ClinicalTrials.gov "Intermittent Catheter" only = 31 Studies

ClinicalTrials.gov Other variations = 171 Studies

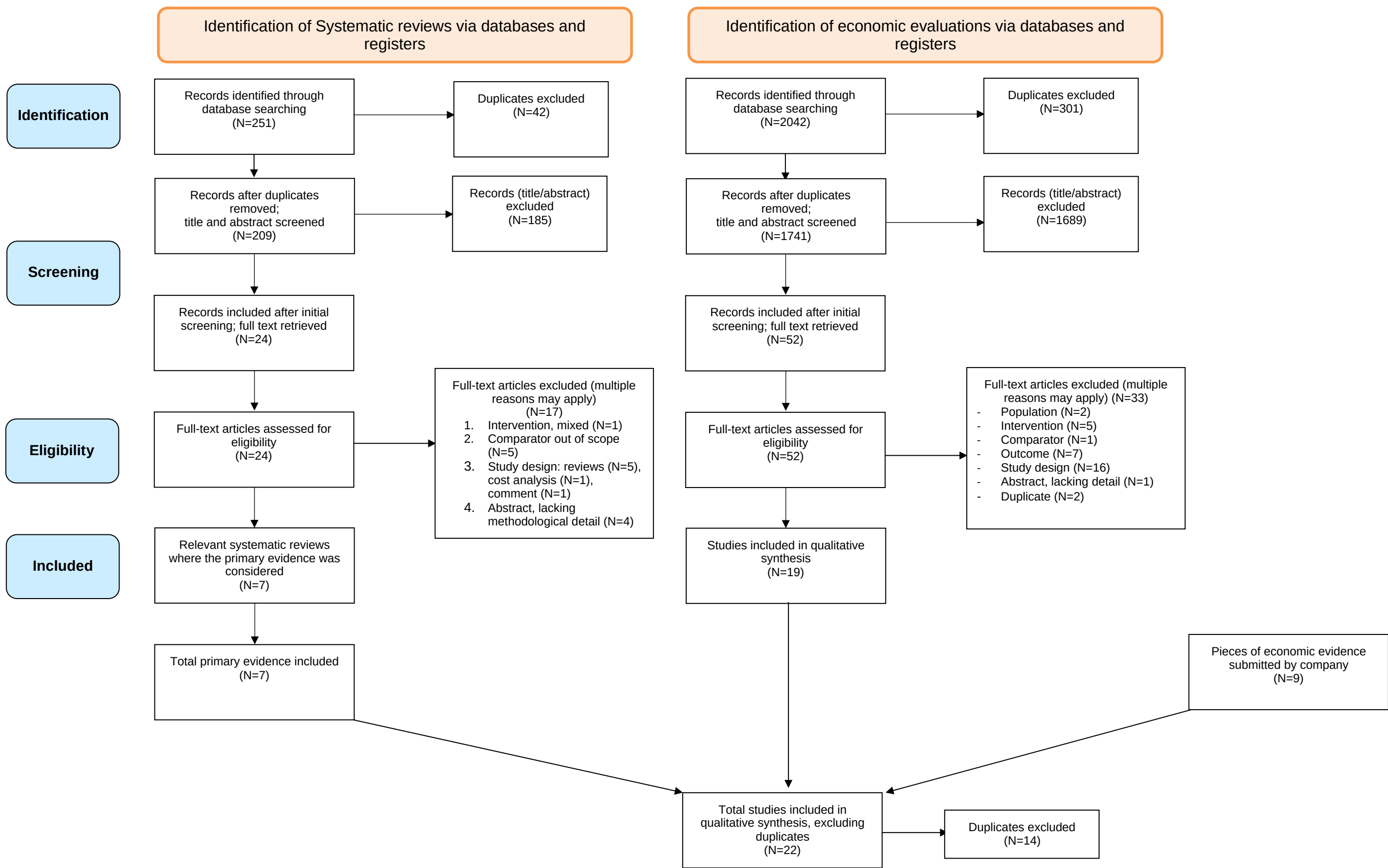
WHO ICTRP - "intermittent catheter" only = 37 Studies

WHO ICTRP other variations = 403 studies

Appendix B4: PRISMA diagram - clinical evidence



Appendix B5: PRISMA diagram - economic evidence



Appendix C: Published evidence

Appendix C1: Study characteristics of included comparative evidence

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
1.	Athanasiadou (Nephrology Dialysis Transplantation, 2023; i250) [NCT04445051, NCT04543136 and NCT04557787; same studies as reported in Landauro (J Wound Ostomy Continence, 2023; 504-511)] Abstract/Poster <i>Funding/Declaration of interest:</i> Majority of authors from Coloplast Ltd	<i>Study design:</i> Laboratory study of efficacy in drainage; 60 subjects taken from 3 clinical trials (180 samples of clear urine, 20 cloudy urine with visible particles, 4 cloudy urine without visible particles). <i>Intervention:</i> 2 new intermittent micro-hole zone catheter prototypes AMBER <i>Comparator:</i> SpeediCath Male/Female [from trial registration] GREEN	<i>Inclusion:</i> NR (assumed same as Landauro et al. 2023) <i>Exclusion:</i> NR (assumed same as Landauro et al. 2023). AMBER Recruitment period: assumed same as Landauro et al. 2023. Setting: Samples taken during visits to urology department (Denmark, N=1) Follow-up: NR	Ability to drain sediment in urine (sediment size and composition, drainage efficiency, visible particles) AMBER	Abstract only; limited information. Catheter feature of interest: micro-hole. Authors acknowledge that number and size of visible particles in urine samples may inform choice of intermittent catheters with micro-holes (due to difficulty in drainage with micro-holes compared with comparator).
2.	Biering-Sørensen (Spinal Cord, 1999; 299-300) <i>Funding:</i> Coloplast Ltd <i>Declaration of interest:</i> NR	<i>Study design:</i> Cross-over RCT (n=20). Randomisation method not reported. <i>Intervention (n=20):</i> LoFric GREEN <i>Comparator (n=20):</i> EasiCath GREEN	<i>Inclusion:</i> patients with spinal cord lesions, before enrolment into the study participants' urine was free of bacteria and white cells (dipslide). <i>Exclusion:</i> NR AMBER <i>Recruitment period:</i> NR <i>Setting:</i> Hospital (Denmark, N=1). Catheterisation conducted by hospital personnel (n=7) and clean self-catheterisation (n=13). <i>Follow-up:</i> 24 hours for each catheter type	<i>Primary:</i> Number of urethral epithelia cells found on catheter in 5 cm sections (from last catheter used in each period under microscopy). AMBER	Mixed self and hospital personnel catheterisation. Catheter feature of interest: NR. Number of urethral epithelia cells used as a proxy measure of urethral trauma. Unclear how study was powered
3.	Bonello (ESTIMA, 2021; e2321) <i>Funding/ Declaration of interest:</i> authors acknowledge "to all companies that contributed with the donation of the technologies used in this study"	<i>Study design:</i> Exploratory cross-sectional study (4 catheters evaluated in randomised order); qualitative and quantitative approach (n=32). Participants were randomised into groups of four, each participant then evaluated 4 different catheters (randomised sequence), with each catheter used for 1 day. <i>Intervention (n=32 each):</i> - Actreen Lite - SpeediCath - LoFric Primo GREEN <i>Comparator (n=32):</i> Conventional PVC catheter (EAG assume that separate lubrication was used) AMBER	<i>Inclusion:</i> Users registered at the outpatient clinic, age over 18 years old, with urinary retention and who underwent clean intermittent catheterisation as a form of bladder emptying, able to perform self-catheterisation and use catheters with gauges No. 10 or No. 12 provided by the health service. <i>Exclusion:</i> Users with contraindications for the use of the technologies of the study; who did not perform self-catheterisation; who were dependent on third parties (family, caregivers, friends and others); and who did not use a catheter with a diameter of 10 or 12. AMBER <i>Recruitment period:</i> February to March 2020 <i>Setting.</i> Catheterisation training at the clinic but self-catheterisation at home. (Brazil, N=1) <i>Follow-up:</i> 1 day	Ease of use, qualitative data from participants regarding the positive and negative attributes of each catheter. AMBER	62.5% of the participants (20 out of 32) were already using the Coloplast Ltd SpeediCath Standard catheter prior to the study. Authors reported that the SpeediCath and conventional PVC urethral catheter without lubrication had been provided by the health service regularly. Catheter feature of interest: NR (multiple catheters, includes easy to open packaging). Direction of scoring not explicitly reported; EAG assume 01 very easy to 05 very difficult. Unclear of unit of reporting procedure time; in table states "procedure time in minutes (01 to 05)"; therefore the EGA has not extracted results. Multiple pair-wise statistical comparisons, lack of adjustment for multiple statistical tests.
4.	Cardenas (PM&R, 2011; 408-417) [NCT00318591] <i>Funding:</i> supported by Coloplast Ltd	<i>Study design (n=224):</i> RCT, open-label. Computer-generated randomisation list, stratified for gender, randomised in blocks of 4.	<i>Inclusion:</i> Adults aged 18 years or older, traumatic spinal cord injury less than 3 months before inclusion, neurogenic bladder dysfunction due to spinal cord injury, intermittent	<i>Primary:</i> time from first catheterisation to first antibiotic-treated symptomatic UTI <i>Secondary:</i> Total number of symptomatic UTIs during the	Study powered to detect a difference in UTI between arms. Catheter feature of interest: hydrophilic coating compared with uncoated.

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
	<i>Declaration of interest:</i> One author report consulting for Neuralstem, Inc; one author employed by Coloplast Ltd	<i>Intervention (n=108):</i> SpeediCath GREEN <i>Comparator (n=116):</i> Conveen uncoated PVC catheter (EAG assumed SelfCath used from product description in Methods section) GREEN	catheterisation needed at least 3 times a day to maintain bladder emptying. <i>Exclusion:</i> Symptoms of UTI or treatment with prophylactic antibiotics to prevent UTI; history of unresolved vesico-ureteral reflux and/or urolithiasis; intermittent catheterisation for more than 10 days before study inclusion; pregnancy, or plans to become pregnant during the study period; participation in other clinical, pharmaceutical or urology studies. GREEN <i>Recruitment period:</i> April 2006 to July 2009 <i>Setting:</i> Recruited from the acute care phase of recovery [US and Canada; N=15]; two phases including a) institutional period (in acute care or rehabilitation unit) and b) community period (after discharge from acute care or rehabilitation unit). Self-catheterisation or catheterisation by nursing staff/caregivers <i>Follow-up:</i> Maximum study period: 6 months; maximum community period: 3 months.	study period; Catheter performance and overall satisfaction; Safety of the catheters; Presence of microhaematuria GREEN	Authors noted a high dropout rate 48% and mention challenges of conducting research with individuals with acute spinal cord injury. Data interpretation was complicated by uneven premature discontinuation rates (n=32 in intervention arm; n=48 in comparator arm). Authors note that possible differences between the institutional and community periods (with respect to factors such as UTI risk and level of monitoring) raise questions regarding the relevance of pooling of data from the 2 periods.
5.	Cardenas (2009, Arch Phys Med Rehab; 1668-1671) <i>Funding:</i> National Institute on Disability and Rehabilitation Research, Office of Special Education and Rehabilitation Services, United States Department of Education (grant number: H133N000003) <i>Declaration of interest:</i> None	<i>Study design (n=56):</i> RCT, open-label; randomisation method not reported. <i>Intervention (n=28):</i> LoFric GREEN <i>Comparator (n=28):</i> 'Usual non-coated catheter with clean technique' (EAG assume uncoated catheter that needs lubrication not provided with no additional features) GREEN	<i>Inclusion:</i> Spinal cord injury 6 months or more ago; self-reported history of 2 or more UTIs during the past year; use of intermittent catheterisation with a uncoated catheter and an open system; no plan to change the method of bladder drainage during the study period; naive to hydrophilic catheters; and at least 18 years of age. <i>Exclusion:</i> Evidence of upper urinary tract abnormalities or renal or bladder calculi in a screening renal ultrasound. Recruitment delayed for any subjects with ongoing bacteriuria until after antibiotic treatment. GREEN <i>Recruitment period:</i> NR <i>Setting:</i> Community (US). All but 1 participant with C4 American Spinal Injury Association Impairment Scale grade A SCI had adequate hand function and were able to perform self-catheterisation on a routine basis. <i>Follow-up:</i> 12 months, with inventory of UTI symptoms and urine samples collected once a month for the first 3 months and then at months 6, 9, and 12.	<i>Primary:</i> Symptomatic UTI defined as bacteriuria ($\geq 10^5$ CFU per ml) plus at least 1 sign or symptom suggestive of UTI (pain or discomfort over the kidney or bladder, or during urination, onset of urinary incontinence, fever, increased spasticity, autonomic hyperreflexia, cloudy or foul-smelling urine, and feeling sick, tired, or uneasy). GREEN	Powered to detect 2-point difference in symptomatic UTI. Catheter feature of interest: hydrophilic coating compared with uncoated. EAG note that eligibility criteria includes spinal cord injury was within <u>6 months or longer</u>, but self-reported count of UTIs is within <u>prior 12 months</u> (may include period of non-catheterisation); unclear if this was considered in analysis. The authors acknowledge sample size may be underpowered to detect differences between groups. Low proportion of females in intervention group, possibly confounding results. Self-reported symptoms potentially leading to recall bias. Authors conducted Poisson regression to determine variables associated with UTI.

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
6.	Chartier-Kastler (Spinal Cord, 2011; 844-850) [NCT00990093] <i>Funding:</i> Supported by Coloplast Ltd <i>Declaration of interest:</i> authors declared relationship with multiple companies (Coloplast Ltd, Astellas, Allergan, Ipsen Biotech, Medtronic, AB Sciences, Astra Zeneca, Zambon, Takeda)	<i>Study design:</i> Cross-over RCT, open-label, non-inferiority (n=36) Randomisation by computer, block allocation using sealed randomisation envelopes. <i>Intervention (n=32):</i> SpeediCath Compact Male GREEN <i>Comparator (n=34):</i> SpeediCath Male GREEN	<i>Inclusion:</i> males aged ≥18 years with spinal cord lesion and neurogenic bladder dysfunction who reported having some sensation in the urethra and self-catheterised at least 4 times a day, use of clean, intermittent self-catheterisation for at least 14 days at enrolment, the ability to prepare the catheters for catheterisation. <i>Exclusion:</i> Participants with a symptomatic urinary tract infection as assessed by the investigator (could be reassessed for enrolment 5 days after termination of treatment) or were mentally unstable and unable to comply with study procedures. GREEN <i>Recruitment period:</i> November 2009 to March 2010. <i>Setting:</i> community; each participant made 3 hospital visits (one baseline, one crossover, one study end) [France N=3, Denmark N=2] <i>Follow-up:</i> 28 days (14 days ± 2 days in each arm)	<i>Primary:</i> Discomfort measured on a VAS. <i>Secondary:</i> Questions relating to discretion and privacy and ease of use; both on five-point scale. VAS used to assess influence on daily activities, general satisfaction and overall quality of life. GREEN	Powered for difference in VAS (non-inferiority). Catheter feature of interest; compact catheter case. Total of 30 included in ITT analysis, 23 in PP analysis. Discontinuation of intervention (n=3) because participants perceived lack of efficacy. Four patients were n=4 n=4 excluded from analysis because of protocol violations (2 in each arm). Difference in results between those recruited in Denmark and France.
7.	De Ridder (Eur Urol, 2005; 991-995) <i>Funding:</i> NR <i>Declaration of interest:</i> NR	<i>Study design:</i> RCT, open-label (n=123). Randomised blocks of 4; generated using Medstat software. <i>Intervention (n=61):</i> SpeediCath (hydrophilic-coated) GREEN <i>Comparator (n=62):</i> Conveen (uncoated) with water-soluble lubricant gel (EAG assumed SelfCath used from product description in Methods section) GREEN	<i>Inclusion:</i> Male spinal cord injured patients, who were 16 or more years old and had been injured less than 6 months. Included patients presented with neurogenic bladder emptying disorders, needing intermittent catheterisation at least 3 times a day. <i>Exclusion:</i> Patients with symptomatic UTI, urethral stenosis or fibrosis, mentally unstable patients and those participating in another clinical trial. Patients who received prophylactic antiseptic or antibiotic treatment were excluded as well as those in whom a permanent catheter was used for a period of more than 10 days. GREEN <i>Recruitment period:</i> January 2001 to June 2002 <i>Setting:</i> patients were recruited from a hospital, but catheterisation occurred in the community after recovery [Spain N=5; Belgium N=3]. Unclear if self-catheterisation. <i>Follow-up:</i> 12 months	<i>Primary:</i> UTI, haematuria. <i>Secondary:</i> Development of urethral strictures, convenience of use. GREEN	Catheterisation by individual or carer. Catheter feature of interest: hydrophilic coating compared with uncoated. Assumed powered to detect a difference in UTI. Powered to detect a group difference (unclear which outcome measure). Authors acknowledged high dropout rate (54%), and that inclusion of patients within 6 months of injury (still hospitalised at study inclusion) resulted in a less stable patient population, impacting the dropout rate; large number of patients either recovered their bladder function during the study or their condition deteriorated so that further operations were needed and bladder management changed to permanent catheter.

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
8.	Domurath (Spinal Cord, 2011; 817-821) [NCT01048541] <i>Funding:</i> Funded by Coloplast Ltd <i>Declaration of interest:</i> The authors declared no conflict of interest.	<i>Study design:</i> Cross-over RCT, non-inferiority; nurse was blinded (n=37). Randomised in permuted blocks. <i>Intervention (n=36):</i> SpeediCath Compact Male GREEN <i>Comparator (n=36):</i> SpeediCath GREEN	<i>Inclusion:</i> Male, spinal cord injury, intermittent catheter users, at least 18 years old, able to self-catheterise, used hydrophilic-coated intermittent catheters for at least 1 month before the study. <i>Exclusion:</i> Symptoms of urinary tract infection, known abnormalities in the lower urinary tract GREEN <i>Recruitment period:</i> Jan 2010 to June 2010 [from trial registration] <i>Setting:</i> Community. 3 visits at investigational site (baseline, crossover visit, termination visit) [Germany N=3] <i>Follow-up:</i> 5-8 days in each arm	<i>Primary:</i> residual urinary volume. <i>Secondary:</i> adverse events, user evaluation. GREEN	Study powered to detect difference in residual urine volume (non-inferiority). Catheter feature of interest: compact catheter case.
9.	Gopalakrishnan (Continence Reports, 2022; 100010) [NCT05003999] <i>Funding:</i> Coloplast Ltd <i>Declaration of interest:</i> 2 authors are on the advisory board for Coloplast Ltd, one authors is also on the advisory board for Wellspect HealthCare. 2 authors were employees of Coloplast Ltd (but not at the time of manuscript submission).	<i>Study design (n=20):</i> Cross-over RCT (pilot). Random sequence generator <i>Intervention (n=20):</i> SpeediCath (hydrophilic catheter) GREEN <i>Comparator (n=20):</i> Self-Cath with lubrication jelly GREEN	<i>Inclusion:</i> age ≥18 years, presenting with chronic (>1-year post-injury) spinal cord injury at any spinal level, hand function sufficient to perform intermittent catheterisation, fluent in English, not pregnant, without history of urinary diversion. <i>Exclusion:</i> acute medical issues that would adversely affect participation in the cross-over RCT, members of the investigational team or their immediate family. GREEN <i>Recruitment period:</i> December 2018 to April 2019 <i>Setting:</i> [Canada N=1], self catheterisation <i>Follow-up:</i> 5 to 10 days	<i>Primary Outcomes:</i> Time to perform intermittent catheterisation (overall time and time for each of 13 pre-determined steps) satisfaction with both types of catheters (assessed using a Likert scale) <i>Secondary Outcomes:</i> Time needed to perform intermittent catheterisation with respect to the participants' neurological level of injury and catheter use in daily life GREEN	The target sample size was 20 participants. This was a convenience sample. Catheter feature of interest: hydrophilic coating compared with uncoated.
10.	Gregghi (ESTIMA, 2022; e2522) <i>Funding:</i> Devices donated by company <i>Declaration of interest:</i> not provided	<i>Study design:</i> Prospective cohort (n=50) <i>Intervention (n=25):</i> Actreen Glys (pre-lubricated PVC catheter) with bag GREEN <i>Comparator (n=25):</i> SpeediCath Compact (Hydrophilic polyurethane, pre-activated) with bag GREEN Pre-established frequency of 6 times per day.	<i>Inclusion:</i> over 18 years of age, literate, not complaining of [UTI] symptoms, having post-voiding residue as an indication for clean intermittent catheterisation, not being dependent on a caregiver to perform the bladder catheterisation technique. <i>Exclusion:</i> signs of [UTI] or urinary tract complications during the study. AMBER <i>Recruitment period:</i> Between September and November 2020 <i>Setting:</i> Rehabilitation clinic [Brazil N=1] <i>Follow-up:</i> 7 consecutive days	Patient satisfaction, ease of use, comfort GREEN	Catheter feature of interest: hydrophilic coating compared with uncoated. The authors acknowledge that the similarity in satisfaction scores between the two catheters may be due to their analogous characteristics (safety, no-touch technique, hygienic insertion, ready for use, and ease of transport). Additionally, they highlight the influence of prior catheterisation experience and habits among the participants. EAG note that the order of using the two catheters was held fixed; which may have influenced results.

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
11.	Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster] Funding: NR Declaration of interest: 1 author employee of Coloplast Ltd	Study design: (n=72) Cross-over RCT Intervention (n=72): SpeediCath GREEN Comparator 1 (n=72): LoFric Comparator 2 (n=72): EasiCath AMBER	Inclusion: able to empty bladders themselves and use intermittent catheter (at least once per day over more than 3 months). Understand aims of study, and the questionnaire. Exclusion: NR GREEN Recruitment period: NR Setting: outpatient department of rehabilitation centres (the Netherlands, N=8) Follow-up: 12 weeks total; 4 weeks per catheter	User friendliness, preference GREEN	Some participants (n=14) already using intervention before study start. Unclear how study powered. Catheter feature of interest: ready to use (ready to insert from packaging, no additional preparation needed).
12.	Landauro (J Wound Ostomy Continence, 2023; 504-511) [NCT04445051, NCT04543136, and NCT04557787] Funding: Coloplast Ltd Declaration of interest: Authors were paid or employees of Coloplast Ltd.	Study design: (n=59) 3 cross-over RCTs with results combined (3-armed). Computer-generated randomisation scheme. Single-blinded, participants were not aware of which catheter they were using at each visit. Intervention (n=59): micro-hole catheter two prototypes: - short micro-hole zone catheter prototype; 21x4 eyelets in male, 14x4 eyelets for female - long micro-hole zone catheter prototype; 38x4 eyelets in male, 17x4 eyelets for female AMBER Comparator (n=59): SpeediCath Flex and SpeediCath Standard (conventional eyelet catheter) AMBER	Inclusion: Healthy controls: willingness to refrain from analgesics 24 hours prior to catheterisation visits; negative urinalysis for haematuria. Intermittent catheter users: bladder management via clean intermittent catheterisation for at least 3 months with at least 2 catheterisations daily prior to study start and the ability to self-catheterise. Exclusion: NR AMBER Recruitment period: March 2020 to May 2021. Setting: Hospital, self-catheterisation and catheterisation by healthcare professional [Denmark; N=1] Follow-up: 3 single visits	Primary: Residual urine volume at first flow-stop. Secondary: Post-void residual volume and discomfort rankings. Exploratory Outcomes: Number of flow-stop incidents per catheterisation, incidents of visual blood on the catheter, and incidents of positive haematuria (as a proxy for microtrauma) GREEN	Study used prototype with micro-holes. Study findings are based on single catheterisations from single test days. The age range was lower for HV participants than for IC users. Intermittent catheter participants were enrolled 3:2 neurogenic:non-neurogenic to ensure evaluation of the catheters in a broad population.
13.	Landauro (J Clin Med, 2023; 5266) [NCT05485922] Funding: study was supported by Coloplast Ltd A/S. No funding was received Declaration of interest: Several authors declaring payment or employment with Coloplast Ltd.	Study design: Cross-over RCT (n=42). Web-based randomisation. Intervention (n=42): Micro-hole zone catheter (single-use, sterile, ready-to-use, hydrophilic coated, flexible, and sleeved catheter). AMBER Comparator (n=42): Hollister Ltd VaPro (conventional eyelet, single-use, sterile, ready-to-use, hydrophilic coated, flexible, and sleeved catheter) GREEN	Inclusion: Adult males (>18 years) had used clean intermittent catheterisation (Fr/Ch 12 or 14) as primary bladder emptying method for at least one month, willing and able to follow study procedures, given written consent, signed a letter of authority. Exclusion: Participation in any other clinical study during the investigation, symptoms of urinary tract infection as judged by the investigator, any known allergies to ingredients in the products, relevant medical history that would prevent the subject to participate in the investigation (investigators' judgement). GREEN Recruitment period: August 2022 to November 2022. Setting: [Denmark; N=1]	Primary: residual volume at first stop, number of flow-stops. Exploratory: residual urine post-catheterisation, intra-catheter pressures, haematuria (dipstick test). AMBER	Catheter feature of interest: micro-holes. Assume powered to detect difference in residual volume. Authors acknowledge that outcomes were only possible to measure with healthcare professional-led catheterisations in a hospital setting from two hospital visits only, meaning the study does not simulate long-term self-catheterisation in a real-world setting. Differences pertaining to underlying disease were not investigated. Origin of haematuria, only theoretically linked to the bladder wall as a result of the associated intra-catheter peak pressure.

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
			<i>Follow-up:</i> NR but 3 visits where catheterisation was undertaken by a healthcare professional only.		
14.	Pascoe (Br J Nurs, 2001; 325-329) <i>Funding:</i> Sponsored by Coloplast Ltd <i>Declaration of interest:</i> NR	<i>Study design:</i> Cross-over RCT; open label (n=27). Computer randomisation. <i>Intervention (n=27):</i> SpeediCath (packaged in saline) GREEN <i>Comparator (n=27):</i> LoFric (requiring immersion in water before use) GREEN	<i>Inclusion:</i> must have been using a coated catheter for intermittent self-catheterisation, have been performing at least two catheterisations per day for at least 3 months, ≥18 years of age, must use size Ch 10, 12, or 14 catheters. <i>Exclusion:</i> Congenital abnormalities in the urogenital tract, major strictures in the urethra, extra lubrication requirements for catheterisation. GREEN <i>Recruitment period:</i> NR <i>Setting:</i> Community (UK, N=2) <i>Follow-up:</i> 7 days in each arm	Ease of use, speed of catheterisation, catheter handling, preference, effect on overall quality of life GREEN	Catheter feature of interest: ready to use (ready to insert from packaging, no additional preparation needed). Sample size calculation not reported. No trial registration identified. Urethral sensation and infection rates not measured within study. Barplots of categories, lack of reporting of numerical values (no reported 95% confidence intervals). Aim: Ease of use through speed of catheterisation and the concept of water as an integral part of the packaging.
15.	Sarica (Eur J Phys Rehab Med, 2010; 473-480) <i>Funding:</i> Authors reported "no support for the study" was received. <i>Declaration of interest:</i> NR	<i>Study design:</i> Cross-over RCT (n=25) <i>Intervention 1 (n=25):</i> Intro-Gel, Rüschi (gel-lubricated non-hydrophilic catheter). (EAG has assumed Flocath Intro Gel) <i>Intervention 2 (n=25):</i> Flocath, Rüschi (hydrophilic-coated catheter, requiring water activation) (EAG is assuming Flocath Hydro based on features described and date of publication) GREEN <i>Comparator (n=25):</i> Standard PVC (with water soluble lubricant) AMBER	<i>Inclusion:</i> Males, ≥18 years, with spinal cord injury (injury less than 6 months), able to perform intermittent self-catheterisation at least 4-6 times per day. <i>Exclusion:</i> With UTI, unexplained haematuria, bladder calculi, urethral stenosis or fibrosis, mentally unstable, participation in other trials. During study patient were excluded if received prophylactic antiseptic antibiotic, or when a permanent catheter was used for more than 10 days. GREEN <i>Recruitment period:</i> between 2006 and 2007 (month not specified) <i>Setting:</i> Physical Medicine and Rehabilitation Department at university hospital, inpatient setting (Turkey; N=1) <i>Follow-up:</i> 18 weeks (6 weeks per catheter type)	Urethral cytology, urinalysis, urine culture, patient satisfaction AMBER	Catheter features of interest: uncoated, gel-lubricated, hydrophilic coating. Authors acknowledge that a power calculation was not conducted before the study started, and that study was conducted in an in-patient setting. General lack of reporting numerical results. From flow diagram: 21 patients used 1 catheter, 20 used 2, only 10 patients used all 3 catheters; unclear reporting in results as to the relevant denominator.
16.	Thiruchelvam (Br J Nursing, 2024; 834-843) [NCT05814211] <i>Funding:</i> Coloplast Ltd <i>Declaration of interest:</i> All 6 investigators employed by or funded by Coloplast Ltd	<i>Study design:</i> Cross-over RCT, open-label (n=82) <i>Intervention (n=82):</i> micro-hole zone catheter female compact, Coloplast Ltd AMBER <i>Comparator (n=82):</i> conventional eyelet catheter (EAG assumes SpeediCath Compact Eve) AMBER	<i>Inclusion:</i> women aged ≥18 years who had been carrying out clean intermittent catheterisation (catheter sizes Ch12 or Ch14) for at least 1 month up to inclusion, emptied their bladder by clean intermittent catheterisation at least three times a day and had used a compact catheter for at least half the catheterisations undertaken during the 2 weeks before enrolment, willingness and ability to adhere to intervention procedures and no participation in other studies throughout duration of investigation.	<i>Primary:</i> Residual volume at 1st flow-stop <i>Secondary:</i> number of flow-stops, number of flow-stop episodes, average residual volume post catheterisation (bladder scan), number of adverse events. <i>Exploratory:</i> Perception questionnaire on a 5-point Likert scale AMBER	Catheter feature of interest: micro-holes. Sample size calculations were based residual volume of urine at first flow-stop obtained from three exploratory studies that investigated prototypes of the intervention; included men, women and healthy volunteers. Some outcomes were based on healthcare led and self-catheterisation combined. Authors acknowledge that "a few unexpectedly high RV1 values were observed for both catheters, with 16 of 289

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
			<i>Exclusion:</i> participants with any conditions that could affect their safety or the integrity of results (such as signs of a UTI), were pregnant or breastfeeding, had excessive production of urinary mucus/sediments/debris that potentially contraindicated the use of a regular intermittent catheter or were hypersensitive to the ingredients in the catheters being tested. GREEN <i>Recruitment period:</i> between August and November 2023 <i>Setting:</i> Community, self-catheterisation and catheterisation by healthcare professional [Denmark N=4, UK N=4, France N=3] <i>Follow-up:</i> approximately 2 weeks each arm		<i>total catheterisations (eight for each catheter) resulting in an RV1>100ml”</i> which may have influenced the results.
17.	Thiruchelvam (Neurourology Urodynamics, 2024; 464-478) [NCT05485935] <i>Funding:</i> Funded by Coloplast Ltd <i>Declaration of interest:</i> All authors were either paid or employed by Coloplast Ltd.	<i>Study design:</i> Cross-over RCT (n=73), open-label. Block randomisation <i>Intervention (n=73):</i> micro-hole zone catheter AMBER <i>Comparator (n=73):</i> SpeediCath Flex (n=69); VaPro (n=4); basic hydrophilic catheters AMBER	<i>Inclusion:</i> Adult males (age >18 years) who had used clean intermittent catheterisation (size Fr/Ch 12 or 14) as their only bladder emptying method, were self-catheterising using a hydrophilic sleeved soft/flexible catheter, of brand/type Hollister Ltd VaPro or Coloplast Ltd SpeediCath Flex for at least 3 months before study entry. Willingness and adherence to a 2-month study procedure, written consent and a signed letter of authority were mandatory. <i>Exclusion:</i> UTI symptoms at enrolment, allergies to device ingredients, participation in other clinical studies during the study period GREEN <i>Recruitment period:</i> August 2022 to January 2023 <i>Setting:</i> community with 4 clinic visits, [Denmark, France, Germany, UK; N=6] <i>Follow-up:</i> 4 weeks in each arm (approximately 9 weeks in total for each participant).	<i>Primary:</i> residual urine at first flow and number of flow stops (healthcare professional and self-led catheterisation) <i>Secondary:</i> Intra-catheter pressure at first flow-stop, residual urine post-catheterisation, discomfort during catheterisation (VAS), dipstick haematuria (presence or absence), catheter perception (5-point scale covering ease of insertion, confidence in bladder emptying), and overall satisfaction. GREEN	Catheter feature of interest: micro-holes. Sample size calculation was based on two previous exploratory studies (available at NCT04445051 and NCT04543136) based on residual urine at first flow-stop (RV1). Combination of catheters in comparator arm (95% is SpeediCath Flex) Authors acknowledged a potential limitation related to the dipstick haematuria assessment. The test was performed by participants in a home setting, who may not have had experience interpreting dipstick results. This could have led to inaccuracies in the data.
18.	Waller (Spinal Cord, 1997; 229-233) <i>Funding:</i> NR <i>Declaration of interest:</i> NR, although noted that comparative studies had previously been requested by a number of catheter manufacturers	<i>Study design:</i> Cross-over RCT (n=14); randomisation method not reported. <i>Intervention (n=14):</i> LoFric GREEN <i>Comparator (n=14):</i> EasiCath GREEN	<i>Inclusion:</i> consecutive male patients with spinal cord injury <i>Exclusion:</i> NR GREEN <i>Recruitment period:</i> Between August and December 1994 <i>Setting:</i> Hospital spinal injuries unit (Sweden [N=1]); Nurse conducted all catheterisations. <i>Follow-up:</i> 10 days per catheter.	Maximum friction during standardised removal of the catheter (using electronic dynamometer), duration of emptying procedure, UTI (identified on urine culture) GREEN	Catheter feature of interest: comparison of different types of hydrophilic coated catheters. The study primarily designed for tap-water to be used as lubricator. However, during introductory period there were cases of severe adhesion to urethra when using EasiCath the design of the study to the use of saline as lubricator. No sample size calculation reported. Authors acknowledge difficulty blinding participants and healthcare professionals

#	Author (year)	Design and intervention(s)	Participants and Setting (N centres)	Outcomes	EAG comments
					to the catheter being used. The same experienced nursed conducted all catheterisations in a hospital setting; therefore the EAG consider that results may not be generalisable to self-catheterisation conducted in a community setting.

Key: **GREEN** aspect of study in scope; **AMBER** aspect of study not in scope; **RED** aspect of study in scope, or elements of this are not in scope. Abbreviations: ISC Intermittent self-catheterisation; ITT, intention to treat; NR, not reported; PP, per protocol; PVC Polyvinyl chloride; RCT, randomised controlled trial; RV1; residual volume of urine at the first flow-stop; UTI, urinary tract infection; VAS, visual analogue scale.

Appendix C2: Critical appraisal

Randomised studies (N=16)

Cochrane tool for assessing risk of bias ([Higgins et al. 2011](#)).

Biering-Sørensen (Spinal Cord, 1999; 299-300)

Reviewer 1: KB, Reviewer 2: HD, KK

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Allocation to which catheter was used first was 'randomly determined'. No further details.	Unclear
	Allocation concealment	No allocation concealment reported	Unclear
Performance bias	Blinding of participants and personnel	No blinding of participants/ personnel reported	Unclear
Detection bias	Blinding of outcome assessment	' <i>The total number of cells was counted without knowledge of the type of catheter.</i> ' This suggests that the assessment of the primary outcome was successfully blinded. No blinding of assessment of secondary outcome measures (gender, catheterisation technique) was reported.	Low
Attrition bias	Incomplete outcome data	n=20 included and data for n=20 provided.	Low
Reporting bias	Selective reporting	All results, whether statistically significant or not, are presented, suggesting that there is no indication of selective outcome reporting.	Low
Other bias	Anything else, ideally pre-specified.	Coloplast Ltd provided financial support for this study (which manufacturer the EasiCath) Short term outcome, number of cells not routinely reported across other included studies; unclear on interpretation of outcome. No trial registration, no power calculation, no additional outcomes reported	High

*Assessments should be made for each main outcome or class of outcomes.

Cardenas (PM&R, 2011; 408-417) [NCT00318591]

Reviewer 1: KB, Reviewer 2: HD

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	A centralized, computer-generated randomization list was generated, and sealed envelopes were provided to all investigational sites.	Low

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
	Allocation concealment	The investigator opened the envelope with the lowest randomization number to determine the participant's allocation. Sequentially numbered, sealed envelopes were used.	Low
Performance bias	Blinding of participants and personnel	It was not possible to blind the participants or the clinical staff due to the difference in appearance and handling of the two types of catheters.	High
Detection bias	Blinding of outcome assessment	There is no mention of any measures taken to blind the outcome assessment.	Unclear
Attrition bias	Incomplete outcome data	Only 114 of the 224 randomised participants (50%) completed the trial. A total of 5 participants withdrew before receiving their allocated intervention, while 105 discontinued prematurely. The primary reason for discontinuation was a change in bladder management, affecting 29 (64%) participants in the uncoated catheter group and 34 (57%) in the hydrophilic-coated catheter group. Additional reasons included loss to follow-up, consent withdrawal, protocol violations, adverse events, and urethral bleeding. The authors do not mention any data re-inclusions. With an attrition rate of 48% potential attrition bias cannot be ruled out.	High
Reporting bias	Selective reporting	The paper reports both primary and secondary outcomes, including statistically significant and non-significant findings.	Low
Other bias	Anything else, ideally pre-specified.	The study acknowledges financial support from Coloplast Ltd, which manufactures the hydrophilic-coated catheter (SpeediCath) used in the trial.	High

Cardenas (2009, Arch Phys Med Rehab; 1668-1671)

Reviewer 1: KB, Reviewer 2: HD, KK

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Participants were "randomly assigned" to either the intervention group or the control group. No further details	Unclear

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Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
		provided on the allocation sequence.	
	Allocation concealment	The authors do not describe the method used to conceal the allocation sequence.	Unclear
Performance bias	Blinding of participants and personnel	The authors do not mention blinding of participants and personnel (different lubrication methods so assume unblinded)	High
Detection bias	Blinding of outcome assessment	The authors do not provide information on blinding of outcome assessment.	Unclear
Attrition bias	Incomplete outcome data	45 out of 56 (80%) completed the study (22 in the treatment group, 23 in the control group). The authors do not mention any re-inclusions in the analysis.	High
Reporting bias	Selective reporting	The study reports both the primary outcome (symptomatic UTIs) and secondary outcomes (antibiotic treatment episodes)	Low
Other bias	Anything else, ideally pre-specified.	Difference in sex (men vs. women): The control group had a significantly higher proportion of women compared with the treatment group (48% vs. 23%). This imbalance, along with the finding that women were more likely to develop UTIs regardless of catheter type, raises concerns about potential bias in the results. However, statistical analysis did control for sex. This is highlighted as a limitation of the study and a possible source of bias in the commentary on the study by Moore and Fader (2010). Self-reported symptoms: The study relied on self-reported symptoms of UTI collected through monthly questionnaires. Data regarding symptoms was collected from the patient from a list of symptoms, potentially leading to recall bias. This is acknowledged as a limitation by the authors. Limited follow-up frequency: After the first three months, follow-up was only conducted every three months, potentially missing symptoms or leading to recall issues. Moore and Fader (2010) suggest that more frequent follow-up would have	Low

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
		improved data reliability. No trial registration identified.	

Chartier-Kastler (Spinal Cord, 2011; 844-850) [NCT00990093]

Reviewer 1: KB, Reviewer 2: HD, KK

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Participants were randomised to one of two treatment groups by computer; specific method used by the computer program to generate the random allocation sequence is not described.	Unclear
	Allocation concealment	Sealed randomisation envelopes were provided, and participants were randomised in blocks of four within each investigational site.	Low
Performance bias	Blinding of participants and personnel	This was an open-label study, which was unavoidable due to the different sizes of the catheters.	High
Detection bias	Blinding of outcome assessment	Outcomes measure were unblinded and subjective (assessed using VAS). Analysis of outcome measures were unblinded.	High
Attrition bias	Incomplete outcome data	30 out of 36 participants were included in the intention-to-treat analysis. 23 out of 36 were included in the per-protocol analysis. Nine participants discontinued the study: two because of adverse events, two chose to discontinue, three discontinued because of perceived lack of efficacy, and two for other reasons. Reasons for discontinuation varied between the groups. The authors do not mention any re-inclusions in the analysis.	Low
Reporting bias	Selective reporting	Authors report both primary and secondary outcomes, including discomfort, ease of use, discretion and the degree of pain, stinging or resistance.	Low
Other bias	Anything else, ideally pre-specified.	Difference in discomfort scores between participants in Denmark and France, however covariate analysis was undertaken to control for this. Coloplast Ltd provided financial support for this study, both	High

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
		catheters were manufactured by Coloplast Ltd.	

De Ridder (Eur Urol, 2005; 991-995)

Reviewer 1: KB, Reviewer 2: HD

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Patients were randomised in blocks of 4 using a randomisation list produced automatically using Medstat software version 2.1	Low
	Allocation concealment	The investigators used sealed, coded envelopes provided by the study sponsor to conceal the allocated treatment. This likely prevented foreseeing of intervention allocations.	Low
Performance bias	Blinding of participants and personnel	Open-label and unblinded	High
Detection bias	Blinding of outcome assessment	The authors do not mention any blinding of outcome assessment.	Unclear
Attrition bias	Incomplete outcome data	The authors reported a high dropout rate of 54%. 57 out of 123 participants completed the 12-month study. Dropout in the PVC catheter arm was n=29/62 (47%) and in the SpeediCath arm n=36/61 (59%) The primary reasons for dropout were: • Restored urinary function, eliminating the need for catheterisation. • Switching to an indwelling catheter. • Withdrawal of consent. Not all patients who completed the study were included in the outcome measures (UTI: n=61 for both arms; bleeding episodes: n=55 SpeediCath and n=59 PVC)	High
Reporting bias	Selective reporting	The study reports on both primary (symptomatic UTI and haematuria) and secondary outcomes (strictures and convenience of use). No detailed results are provided for secondary outcomes.	Low
Other bias	Anything else, ideally pre-specified.	Despite the random allocation, there was a significant difference in microscopic	Low

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
		haematuria and bacteriuria between the groups at the initial study visit at baseline. However, there was no SD between the two catheters and this difference in microscopic haematuria and bacteriuria was eliminated by day 15. Funding source not reported. No trial registration identified.	

Domurath (Spinal Cord, 2011; 817-821) [NCT01048541]

Reviewer 1: KB, Reviewer 2: HD, KK

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Randomisation in permuted blocks without details on the sequence generation method.	Unclear
	Allocation concealment	The authors do not explicitly describe a method for allocation concealment.	Unclear
Performance bias	Blinding of participants and personnel	Single-blinded (nurse was blinded to the type of catheter during measurements). Participants themselves were aware of which catheter they were using.	High
Detection bias	Blinding of outcome assessment	Study nurse, responsible for measuring residual urine volume and other outcomes, was blinded to the catheter type throughout the measurement procedures. No mention of outcomes being analysed blinded.	Low
Attrition bias	Incomplete outcome data	One out of 37 patient withdrew on the day of randomisation due to dissatisfaction with the catheter.	Low
Reporting bias	Selective reporting	The paper presents results for both the primary outcome (residual urine volume) and secondary outcomes (safety, user experience).	Low
Other bias	Anything else, ideally pre-specified.	Coloplast Ltd provided financial support for this study, manufactured both catheters used in the trial. Monitoring for the occurrence of adverse events was limited to a period of 6–9 days.	High

Gopalakrishnan (Continence Reports, 2022; 100010) [NCT05003999]

Reviewer 1: KB, Reviewer 2: HD

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Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Participants were randomised into two groups using a random sequence generator, though the method is not specified.	Low
	Allocation concealment	The authors do not provide information regarding allocation concealment.	Unclear
Performance bias	Blinding of participants and personnel	Open label study. Neither the participants nor the researchers were blinded to the intervention.	High
Detection bias	Blinding of outcome assessment	The investigator responsible for timing each step of the catheterisation process was separated from the participant by a curtain. This suggests an attempt to blind the outcome assessor to the catheter type. Participant-reported subjective outcomes, like satisfaction with catheter use, were collected directly from the participants, and therefore were not blinded. The authors do not mention whether outcomes were analyses blinded.	Low
Attrition bias	Incomplete outcome data	One eligible individual withdrew due to personal reasons before the intervention began and was replaced by a backup participant. No further attrition or exclusions from the analysis are reported. All 20 participants completed the study.	Low
Reporting bias	Selective reporting	The authors state primary outcome objectives: time needed to perform IC and participant satisfaction between hydrophilic-coated and non-hydrophilic catheters. Results for both primary outcomes are reported, including subgroup analyses based on neurological level of injury and daily catheter use. The methodology and statistical analyses are described in detail	Low
Other bias	Anything else, ideally pre-specified.	Small sample size (n=20) may limit generalisability of results. Coloplast Ltd provided financial support for this study, manufactured both catheters used in the trial.	High

Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]

Reviewer 1: HD

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Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Participants randomly used three catheters. No further details provided.	Unclear
	Allocation concealment	The authors do not mention the method used to conceal the allocation sequence	Unclear
Performance bias	Blinding of participants and personnel	Participants and personnel were unblinded	High
Detection bias	Blinding of outcome assessment	Unblinded of outcome assessments. Self-reported outcomes (VAS)	High
Attrition bias	Incomplete outcome data	67 out of 72 patients (93%) completed the study. 5 patients withdraw for non-experiment related reasons.	Low
Reporting bias	Selective reporting	All primary and secondary outcomes were reported.	Low
Other bias	Anything else, ideally pre-specified.	Higher ratio of males to females recruited in the trial, with no additional statistical analysis to control for this. Limited information within poster; no trial registration identified, no power calculation reported. Funding source not reported; author employed by Coloplast..	Unclear

Landauro (J Wound Ostomy Continence, 2023; 504-511) [NCT04445051, NCT04543136, and NCT04557787]

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Randomisation scheme, generated automatically by a computer.	Low
	Allocation concealment	The authors did not mention the method used to conceal allocation.	Unclear
Performance bias	Blinding of participants and personnel	Single blinded; unclear how implemented as visual difference in catheter tip (can see micro-holes as per figure in paper).	High
Detection bias	Blinding of outcome assessment	The study nurse obtained the first catheterisation. Second samples were obtained via the participants themselves. There is no mention of the outcome assessments being blinded.	Unclear
Attrition bias	Incomplete outcome data	58 out of 59 participants (98%) completed the study. One participant discontinued after visit two. All 59 participants were included in the ITT analysis.	Low

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Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Reporting bias	Selective reporting	All primary and secondary outcomes were reported. The results are reported in detail, including mean differences, 95% confidence intervals, and p-values for the primary and secondary endpoints. Degree of discomfort was measured via VAS.	Low
Other bias	Anything else, ideally pre-specified.	An assumption was made during the analysis that haematuria would be independent of sex, length of drainage zone of the study catheter, and who performed the catheterisation (self-catheterisation or healthcare professional). The study findings are based on single catheterisations from single test days and may not represent the effects of prolonged catheter use. Funded by Coloplast Ltd; manufacturer of all catheters used in trial.	High

Landauro (J Clin Med, 2023; 5266) [NCT05485922]

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Participants were randomly assigned to two intervention sequences in block sizes of four. The randomisation was centralised using the web-based iMedidata RAVE RTSMTM.	Low
	Allocation concealment	No allocation concealment reported. The source does not provide information on whether intervention allocations could be foreseen before or during enrolment	Unclear
Performance bias	Blinding of participants and personnel	Open-label, unblinded to both healthcare professional and participants	High
Detection bias	Blinding of outcome assessment	Outcome assessments did not appear to be blinded.	High
Attrition bias	Incomplete outcome data	41 out of 42 (97%) completed the study. Data missing for one participant for visit two. Reason for data missing not provided. All 42 participants included in analysis.	Low

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Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Reporting bias	Selective reporting	All primary and secondary outcomes were reported in the study.	Low
Other bias	Anything else, ideally pre-specified.	Only males were included in the study. The study was financially supported by Coloplast Ltd. One author was paid a fixed price by Coloplast Ltd to conduct the study. The catheter device names were not provided in the paper to determine whether there was a financial incentive in conducting the study. The authors acknowledge that the study findings are based on two hospital visits only and may not represent the effects of prolonged catheter use.	Unclear

Pascoe (Br J Nurs, 2001; 325-329)

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Each subject was allocated to one of two groups determined by computer randomisation. No further details provided.	Unclear
	Allocation concealment	Group 1 used SpeediCath for 7 days, then used LoFric for 7 days. Group 2 used LoFric for 7 days, then used SpeediCath for 7 days. The method used to conceal the allocation sequence is not specified	Unclear
Performance bias	Blinding of participants and personnel	As a result of the obvious differences between the catheters being evaluated, it was not possible to conduct a blinded trial.	High
Detection bias	Blinding of outcome assessment	Participants completed two questionnaires (subjective) and self-reported the time taken for catheterisation	High
Attrition bias	Incomplete outcome data	25 out of 27 participants (93%) completed the study. One participant was withdrawn having experienced pain on insertion of a catheter; and the other was withdrawn due to problems experienced with the slipperiness of a catheter. All 25 participants were included in the final analysis.	Low

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Reporting bias	Selective reporting	Primary and secondary outcomes were reported. The results are presented in detail	Low
Other bias	Anything else, ideally pre-specified.	The study was sponsored by Coloplast Ltd, which manufactured SpeediCath. No trial registration identified, no power calculation reported.	High

Sarica (Eur J Phys Rehab Med, 2010; 473-480)

Reviewer 1: HD, Reviewer 2: KK

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	The sequence of the use of the catheters were determined according to a table of random numbers	Low
	Allocation concealment	The authors did not mention the allocation concealment	Unclear
Performance bias	Blinding of participants and personnel	The participants and personnel were unblinded to the catheter type.	High
Detection bias	Blinding of outcome assessment	Urethral cytology was undertaken blinded. Blinding of urinalysis and urine culture was not mentioned. Patient satisfaction was reported via VAS.	Low
Attrition bias	Incomplete outcome data*	10 out of 25 participants completed the use of 3 catheters (40%). The reasons for the drop-out of the 11 participants have been provided in Figure 1.	High
Reporting bias	Selective reporting	All primary and secondary outcomes were reported.	Low
Other bias	Anything else, ideally pre-specified.	Study was carried out in an in-patient setting, which would make results non-generalisable to community/outpatient settings. Authors declared that no support for study was received. No trial registration identified.	Low

Thiruchelvam (Br J Nursing, 2024; 834-843) [NCT05814211]

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Randomisation but the authors not specify the randomisation sequence generation	Unclear
	Allocation concealment	The authors did not mention allocation concealment. The	Unclear

		source does not provide information on whether intervention allocations could be foreseen before or during enrolment	
Performance bias	Blinding of participants and personnel	Open-label	High
Detection bias	Blinding of outcome assessment	The authors did not mention whether the bladder emptying performance, RV1 and flow stops was blinded. VAS and questionnaire responses were self-reported by the participant.	High
Attrition bias	Incomplete outcome data	79 out of 82 females (96%) completed the study. The authors provided the reasons for drop-out.	Low
Reporting bias	Selective reporting	All primary and secondary outcomes were reported. The results are reported in detail, including mean differences, 95% confidence intervals, and p-values.	Low
Other bias	Anything else, ideally pre-specified.	Study was performed on females only. The definition of an empty bladder was based on male models. The study relied on an average urine flow rate to identify flow-stops and did not use a pressure sensor to distinguish between flow-stops caused by mucosal suction and other causes. This may have impacted the accuracy of the flow-stop data. Funded by Coloplast Ltd	High

Thiruchelvam (Neurourology Urodynamics, 2024; 464-478) [NCT05485935]

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Randomization was done centralized, randomly assigning subjects to two intervention sequences in block sizes of 4. The source doesn't explicitly state if the randomization produced comparable groups. However, baseline characteristics of the participants are presented in Table 1	Unclear
	Allocation concealment	The first group was catheterised with the investigational device at visits 0 and 1, followed by a test period at home (T1) and a follow-up visit (V2). The	Unclear

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
		comparator device was tested during the next test period at home (T2), followed by a visit 3 which also terminated the study. The second group tested the devices in reversed order. The total study duration was approximately 9 weeks for the individual subject. The method used to conceal the allocation sequence is not described	
Performance bias	Blinding of participants and personnel	Open-label.	High
Detection bias	Blinding of outcome assessment	The authors do not mention whether investigators were blinded to the number of flow-stop episodes, residual urine volume at first flow-stop, and haematuria dipstick test. Participants completed a self-reported questionnaire (VAS) related to discomfort.	High
Attrition bias	Incomplete outcome data	66 out of 73 participants (90%) completed the study. Seven subjects discontinued the study. Four subjects discontinued at their own request, and three discontinued due to an adverse event	Low
Reporting bias	Selective reporting	All primary and secondary outcomes have been reported.	Low
Other bias	Anything else, ideally pre-specified.	>95% of the included participants used SpeediCath Flex, rather than VaPro. So, the study did not necessarily compare hydrophilic vs. conventional. This factor was also not controlled for in the analysis of the results. Funded by Coloplast Ltd	High

Waller (Spinal Cord, 1997; 229-233)

Reviewer 1: HD, Reviewer 2: KB

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Selection bias	Random sequence generation	Patients were randomly allocated. No further details provided.	Unclear
	Allocation concealment	Participants used of one of the catheters for 10 days and then crossed over to the other for the same amount of time. No further details provided.	Unclear

Bias domain	Source of bias	Support for Judgement	Review authors' judgement (assess as low, unclear, or high risk of bias)
Performance bias	Blinding of participants and personnel	The patients were not told which catheter was being used, as was a third person who read the dynamometer. However, this person was probably not completely 'blind' as the colour of the two catheters varied slightly. It was impossible to 'blind' the nurse performing the catheterisations due to the different characteristics of the two catheters when soaked into saline solution.	High
Detection bias	Blinding of outcome assessment	The maximum friction force during the removal of the catheters after bladder emptying was blinded by the third person reading the dynamometer. Osmolality measurements of the catheters were obtained from independent centres.	Low
Attrition bias	Incomplete outcome data	Friction results are based on n=14; however unclear on whether all participants had full follow-up for all outcomes (for example infection)	Unclear
Reporting bias	Selective reporting	The primary and secondary outcomes are not explicitly stated, and so it is difficult to determine whether the authors have reported all the results.	High
Other bias	Anything else, ideally pre-specified.	Some analyses were performed on the various influences on frictional force; however this was not explicitly stated in the methods, and statistical analysis was not performed to control for this. Funding source not reported. No trial registration identified, no power calculation reported. Prior to the study, all patients had been using the LoFric catheter, which was used as the control in this study, since the day of their injury. This prior experience with one of the catheters could potentially have influenced the study results.	Unclear

Cohorts (N=3)

Joanna Briggs Institute Critical Appraisal Checklist for Cohort Studies ([Joanna Briggs Institute, 2017](#))

Athanasiadou (Nephrology Dialysis Transplantation, 2023; i250)

Reviewer 1: HD

#	Question	Yes	No	Unclear	Not applicable
1.	Were the two groups similar and recruited from the same population?	-	-	X	-
2.	Were the exposures measured similarly to assign people to both exposed and unexposed groups?	X	-	-	-
3.	Was the exposure measured in a valid and reliable way?	X	-	-	-
4.	Were confounding factors identified?	-	-	X	-
5.	Were strategies to deal with confounding factors stated?	-	-	X	-
6.	Were the groups/participants free of the outcome at the start of the study (or the moment of exposure)?	-	-	X	-
7.	Were the outcomes measured in a valid and reliable way?	X	-	-	-
8.	Was the follow up time reported and sufficient to be long enough for outcomes to occur?	-	-	X	-
9.	Was follow up complete, and if not, were the reasons to loss to follow up described and explored?	-	-	X	-
10.	Were strategies to address incomplete follow up utilised?	-	-	X	-
11.	Was appropriate statistical analysis used?	-	X	-	-

Bonello (ESTIMA, 2021; e2321)

Reviewer 1: HD

#	Question	Yes	No	Unclear	Not applicable
1.	Were the two groups similar and recruited from the same population?	X	-	-	-
2.	Were the exposures measured similarly to assign people to both exposed and unexposed groups?	X	-	-	-
3.	Was the exposure measured in a valid and reliable way?	X	-	-	-
4.	Were confounding factors identified?	X	-	-	-
5.	Were strategies to deal with confounding factors stated?	X	-	-	-
6.	Were the groups/participants free of the outcome at the start of the study (or the moment of exposure)?	-	X	-	-
7.	Were the outcomes measured in a valid and reliable way?	-	X	-	-
8.	Was the follow up time reported and sufficient to be long enough for outcomes to occur?	X	-	-	-

#	Question	Yes	No	Unclear	Not applicable
9.	Was follow up complete, and if not, were the reasons to loss to follow up described and explored?	-	-	X	-
10.	Were strategies to address incomplete follow up utilised?	-	X	-	-
11.	Was appropriate statistical analysis used?	X	-	-	-

Gregghi (ESTIMA, 2022; e2522)

Reviewer 1: HD

#	Question	Yes	No	Unclear	Not applicable
1.	Were the two groups similar and recruited from the same population?	X	-	-	-
2.	Were the exposures measured similarly to assign people to both exposed and unexposed groups?	X	-	-	-
3.	Was the exposure measured in a valid and reliable way?	X	-	-	-
4.	Were confounding factors identified?	X	-	-	-
5.	Were strategies to deal with confounding factors stated?	X	-	-	-
6.	Were the groups/participants free of the outcome at the start of the study (or the moment of exposure)?	-	-	X	-
7.	Were the outcomes measured in a valid and reliable way?		X	-	-
8.	Was the follow up time reported and sufficient to be long enough for outcomes to occur?	X	-	-	-
9.	Was follow up complete, and if not, were the reasons to loss to follow up described and explored?	-	-	X	-
10.	Were strategies to address incomplete follow up utilised?	-	X	-	-
11.	Was appropriate statistical analysis used?	X	-	-	-

Appendix C4: Raw results from the included evidence

C4.1: Residual volume (N=5)

A narrative for the outcome of residual volume can be found in section 4.2.4.3.

Study	Study design	Intervention	Comparator	Who is conducting catheterisation?	Outcome measure	Outcome intervention arm, mean (SD) or (95%CI)	Outcome in comparator arm	Difference (intervention-comparator)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT	SpeediCath Compact Male	SpeediCath Male	Self	Residual volume	12.44 (15.66) ml	9.35 (11.43) ml	Median: 2.06 (95%CI - 1.94 to 7.72) Non-inferiority met
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Self	Post-void residual volume	7.7 (13.9) ml	9.3 (20.5) ml	NR
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	Residual urine post-catheterisation	12.1 (-1.8 to 25.9) ml	31.6 (17.8 to 45.5) ml	19.6 (1.70 to 37.43) ml; p=0.033
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Healthcare professional	Post-void residual volume	4.8 (16.4) ml	12.0 (40.4) ml	NR
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Healthcare professional and self	Post-void residual volume	Male: 25 (51) ml Female: 8 (45) ml	Male: 21 (36) ml Female: 4 (10) ml	Male: -4.30 (-17.0 to 8.82); p=0.551 Female: -4.09 (-17.60 to 9.41); p=0.519

Study	Study design	Intervention	Comparator	Who is conducting catheterisation?	Outcome measure	Outcome intervention arm, mean (SD) or (95%CI)	Outcome in comparator arm	Difference (intervention-comparator)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	Residual urine post-catheterisation	5.8 (2.2 to 9.3) ml	16.6 (2.8 to 30.3) ml	10.8 (-2.8 to 24.5) ml; p=0.118
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Self	RV1	19.88 (5.73 to 34.04) ml	27.77 (12.14 to 43.40) ml	7.89 ml (-11.24 to 27.04) ml; p=0.414
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	RV1	8.2 (-5.6 to 22.1) ml	36.8 (23.1 to 50.5) ml	28.5 (9.5 to 47.6) ml; p=0.004
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Healthcare professional	RV1	23.22 (4.65 to 41.80) ml	15.87 (6.09 to 25.65) ml	-7.35 (-28.00 to 13.30) ml; p=0.480
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	RV1	18.0 (7.1 to 28.9) ml	63.9 (37.9 to 90.0) ml	45.9 (19.2 to 72.6) ml; p=0.001
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Healthcare professional	RV1	5.10 (2.79 to 7.42) ml	39.4 (19.92 to 58.89) ml	34.3 (14.69 to 53.91) ml; p=0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Healthcare professional and self-catheterisations	Proportion RV1 < 10ml	83 (76 to 89)%	71 (63 to 78)%	OR: 0.49 (0.27 to 0.87); p=0.016
Thiruchelvam (Neurourology)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	Percentage residual volume < 50ml	97.8%	82.6%	NR

Study	Study design	Intervention	Comparator	Who is conducting catheterisation?	Outcome measure	Outcome intervention arm, mean (SD) or (95%CI)	Outcome in comparator arm	Difference (intervention-comparator)
Urodynamics, 2024; 464-478)								
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	Percentage residual volume <50 ml	91.8%	61.2%	NR
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Healthcare professional and self	Percentage RV1 >50 ml	Male: 3.6% Female: 1.1%	Male: 25.6% Female: 17.8%	Male: p<0.001 Female: p<0.001
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	Proportion residual volume >100 ml	0%	10.9%	NR
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	Proportion residual volume >100 ml	4.1%	24.5%	NR
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Healthcare professional and self	Percentage RV1 >100 ml	Male: 0% Female: 0%	Male: 14% Female: 8.9%	-
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Healthcare professional	Residual urine post-catheterisation	5.92 (-2.17 to 14.01) ml	7.13 (-2.39 to 16.64) ml	p=0.846

Abbreviations: NR, not reported; OR, odds ratio; RCT, randomised controlled trial; RV1, residual volume of urine at the first flow-stop.

C4.2: Flow stops (N=3)

The three studies reporting flow stops all suggest an improvement in flow stops when using a micro-hole catheter.

Study	Study design	Intervention	Comparator	Who is conducting catheterisation	Flow stops in intervention arm	Flow stops in comparator arm	Difference (intervention-comparator)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet	Self	0.28 (0.12 to 0.63)	0.71 (0.52 to 0.95)	RR: 2.52 (1.06 to 6.00) comparator compared with intervention; p=0.036
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	0.13 (0.04 to 0.37)	0.96 (0.65 to 1.43)	RR: 0.13 (0.04 to 0.40); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet	Healthcare professional	0.21 (0.10 to 0.44)	0.57 (0.39 to 0.82)	RR: 2.74 (95%CI 1.14 to 6.54) comparator compared with intervention, p=0.024
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	0.20 (0.09 to 0.43)	1.32 (0.96 to 1.180)	RR: 0.15 (0.07 to 0.35); p<0.001
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Healthcare professional	0.17 (0.06 to 0.45)	1.09 (0.75 to 1.60)	RR: 0.16 (0.05 to 0.44); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	Conventional eyelet (undefined)	Healthcare professional and self	<u>Proportion with 0 flow stops</u> : 87 (80 to 92)%	<u>Proportion with 0 flow stops</u> : 57 (48 to 65)%	OR: 0.20 (0.11 to 0.36); p<0.001

Abbreviations: CI, confidence interval; NR, not reported; OR, odds ratio; RCT, randomised controlled trial; RR, risk ratio.

C4.3: Intra-catheter pressure (N=2)

The two studies identified reporting outcomes related to intra-catheter pressure both reported greater pressure in the comparator arm compared with the interventions, which both used micro-hole catheters (Thiruchelvam 2024a; Landauro 2023). Both of these studies suggest an improvement in pressure when using micro-hole based catheters.

Study	Study design	Intervention	Comparator	Who is conducting catheterisation	Intra-catheter pressure in intervention arm	Intra-catheter pressure stops in comparator arm	Difference (intervention-comparator)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Self	-13.56 (-20.52 to -6.6) cmH2O	-148.90 (-197.73 to -100.03) cmH2O	-132.73 (-180.75 to -84.7) cmH2O; p<0.001
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Healthcare professional	-7.48 (-42.99 to 28.02) cmH2O	-152.21 (-204.36 to -100.02) cmH2O	-144.72 (-207.37 to -81.99) cmH2O; p<0.001
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Healthcare professional	-16.5 (-22.9 to -10.0) cmH2O	-113.0 (-156.4 to -71.7) cmH2O	-97.6 (-140.4 to -54.8) cmH2O; p<0.001

Abbreviations: RCT, randomised controlled trial.

C4.4: Sediment (N=2)

The two studies identified reporting outcomes related to sediment drainage utilised varying catheters. One study found no significant change in urine sediment between a hydrophilic catheter and non-hydrophilic catheter (Sarica 2010). The second study reported the Luja prototypes had improved drainage of large size sediment, compared with conventional catheters. However, both had issues with visible particles (Athanasiadou 2023). Due to limited evidence, the EAG cannot provide conclusion on which catheter or features improve sediment drainage.

Study	Study design	Intervention	Comparator	Setting	Sedimental outcomes
Athanasiadou (Nephrology Dialysis Transplantation, 2023; i250) Abstract/Poster	Automated microscopy analysis of samples from 3 clinical trials	Luja, 2 prototypes	Conventional 2 eyelet catheter	Samples obtained from patients during hospital visit	Intervention arm drained sediment of larger size in clear urine compared with comparator catheter. Both catheters drained cloudy urine but had challenges draining samples with visible particles (n=20); intervention catheter drained 12, comparator drained 18.

Study	Study design	Intervention	Comparator	Setting	Sedimental outcomes
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel Flocath Intro-Gel	PVC	Inpatient	Hydrophilic catheter use did not significantly change the urine sediment, $p>0.05$; no additional details provided.

Abbreviations: RCT, randomised controlled trial; PVC, Polyvinyl chloride.

C4.5 UTI, including recurrent UTI and CAUTI (N=6)

For the outcome of UTI a CNMA was undertaken, the results can be seen in section 4.2.4.1.

Study	Study design	Intervention	Comparator	Setting	Infection	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Healthcare professional and self: healthy volunteers	UTI (definition NR)	0/59	2/59	-
Cardenas (PM&R, 2011; 408-417)	Prospective, RCT	SpeediCath	Conveen	Hospital, rehabilitation centre	Clinical symptomatic UTI (antibiotics prescribed) Institutional period	0.539 (60/111.3 UTI/month)	0.682 (97/142.2 UTI/month)	Reduction of 21%, RR: 1.40; $p=0.38$
Cardenas (PM&R, 2011; 408-417)	Prospective, RCT	SpeediCath	Conveen	Hospital, rehabilitation centre	Strict UTI incidence (antibiotic treated, bacteriuria $\geq 10^2$ CFU/ml, symptomatic, positive dipstick) Institutional period	0.189 (21/111.3 UTI/month)	0.295 (42/142.2 UTI/month)	Reduction of 36%, RR:1.67; $p=0.022$ Time to first symptomatic UTI: Hazard ratio 0.64 (0.39 to 1.03); $p=0.067$
Cardenas (PM&R, 2011; 408-417)	Prospective, RCT	SpeediCath	Conveen	Hospital, rehabilitation centre, community	Clinical symptomatic UTI (antibiotics prescribed)	0.479 (99/206.7 UTI/month)	0.478 (167/349.2 UTI/month)	$p=0.426$

Study	Study design	Intervention	Comparator	Setting	Infection	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
					Full study period			
Cardenas (PM&R, 2011; 408-417)	Prospective, RCT	SpeediCath	Conveen	Hospital, rehabilitation centre, community	Strict UTI incidence (antibiotic treated, bacteriuria $\geq 10^2$ CFU/ml, symptomatic, positive dipstick)	0.198 (41/206.7 UTI/month)	0.218 (76/349.2 UTI/month)	p=0.248
					Full study period			
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Community	Symptomatic UTIs (12 months)	No UTIs: 22/61 (36%) ≥ 1 UTIs: 39/61 (64%)	No UTIs: 11/62 (18%) ≥ 1 UTIs: 51/62 (82%)	p=0.02
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel, Flocath Intro-Gel	PVC	Inpatient	Clinical UTIs (bacterial colony count of 100,000 cfu or greater, and at least one clinical symptom such as fever, chills, malodorous urine, increased spasticity, or malaise)	Flocath Hydro Gel: 1/25; Flocath Intro-Gel: 1/25	4/25 Gel-lubricated non-hydrophillic catheter (n=1)	No statistical difference noted; p>0.05.
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	LoFric	Standard uncoated catheter	Community	Total symptomatic UTIs (bacteriuria of 100,000 cfu or greater, and at least one clinical symptom)	Mean: 1.18 (SD: 1.30)	Mean: 1.00 (SD: 1.00)	p=0.61
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	LoFric	Standard uncoated catheter	Community	Subjects who had at least 1 symptomatic UTI (bacteriuria of 100,000 cfu or greater, and at least	12 (54%)	14 (61%)	p=0.67

Study	Study design	Intervention	Comparator	Setting	Infection	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
					one clinical symptom)			
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Community	Median number of UTIs per 1000 catheter days	5.4 (n=61)	8.1 (n=61)	p-value NR; no statistical difference reported
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	LoFric	EasiCath	Inpatient (healthcare professional)	UTI (all treated with antibiotics according to resistance pattern)	2 episodes	3 episodes	-
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Community	Occurrence of leukocyturia or bacteriuria	NR	NR	At initial study visit higher number of patients in SpeediCath group compared with PVC group, p=0.03. Difference eliminated at day 15.
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath, Intro-Gel	PVC	Inpatient	Number of leucocytes (urethral cytology)	NR	NR	Elevated in PVC catheter arm; p<0.05
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel	PVC	Inpatient	Pyuria score	NR	NR	p>0.05
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Intro-Gel	PVC	Inpatient	Pyuria score	NR	NR	Reduced score in gel-lubricated arm; p<0.05.
Cardenas (Arch Phys Med Rehabil,	RCT (n=56)	LoFric	Standard uncoated catheter	Community	Total antibiotic treatment episodes (over 1 year)	Mean: 0.77 (SD: 0.87)	Mean: 1.65 (SD: 1.46)	p=0.02

Study	Study design	Intervention	Comparator	Setting	Infection	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
2009; 1668-1671)								
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	LoFric	Standard uncoated catheter	Community	Subjects who had at least one antibiotic treatment episode	11 (50%)	16 (70%)	p=0.18
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	LoFric	Standard uncoated catheter	Community	Most frequent UTI symptoms (descending order)	1. Cloudy urine 2. Incontinence 3. Feeling tired 4. Increased frequency 5. Foul-smelling urine	1. Cloudy urine 2. Foul-smelling urine 3. Incontinence 4. Feeling tired 5. Increased frequency	NR

Abbreviations: NR, not reported; PVC, Polyvinyl chloride; RCT, randomised controlled trial; RR, risk ratio; SD, standard deviation; UTI, urinary tract infection; UTI:HR urinary tract infection hazard ratio.

C4.6 Urethral trauma, bleeding, haematuria, strictures, and urethritis (N=10)

For the outcome of haematuria, the EAG conducted a CNMA, which can be seen in section 4.2.4.2.

Study	Study design	Intervention	Comparator	Outcome	Outcome in intervention arm	Outcome in comparator arm	p-value
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Incidents of haematuria	9.6%	17.2%	OR: 2.00 p=0.156
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Probability of positive haematuria	0.17 (95% CI 0.14 to 0.19)	0.19 (95% CI 0.17 to 0.22)	OR: 1.21 (95% CI 0.96 to 11.53); p=0.110
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Incidents of haematuria	3.4%	3.3%	OR: 0.95; p=0.961
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Probability of a positive haematuria	0.10 (95% CI 0.03 to 0.24)	0.29 (95% CI 0.17 to 0.45)	RR: 0.26 (95% CI 0.07 to 0.96); p=0.043
Landauro (J Wound Ostomy Continence, 2023; 504-511)	3 cross-over RCTs combined	Micro-hole catheter (SpeediCath Flex, SpeediCath)	SpeediCath Flex, SpeediCath	Incidents of haematuria in normal micturition after catheterisation	5.1%	23.3%	OR: 5.84; p=0.053
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel, Flocath Intro-Gel	PVC	Macroscopic haematuria	0	1	-

Study	Study design	Intervention	Comparator	Outcome	Outcome in intervention arm	Outcome in comparator arm	p-value
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Microhaematuria (erythrocyte dipstick)	23%	34%	p<0.0001
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Bleeding (undefined)	14 cases (7 led to premature discontinuation)	6 cases (2 led to premature discontinuation)	p<0.05
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Visible bleeding	2/36	0/36	-
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Visible bleeding	38/55	32/59	p-value NR; no statistical difference reported
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Occurrence of haematuria (microbiological and cytological examination)	NR	NR	At initial study visit higher number of patients in SpeediCath group compared with PVC group, p=0.02. The difference was eliminated at day 15
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	LoFric	EasiCath	Haemorrhage	No cases reported	No cases reported	-
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Burning in urethra (mild)	1/36	0/36	-

Study	Study design	Intervention	Comparator	Outcome	Outcome in intervention arm	Outcome in comparator arm	p-value
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath, Intro-Gel	PVC	Erythrocyte count	-	-	Increased with PVC catheter (p<0.05), no difference with gel-lubricated (p>0.05)
Biering-Sørensen (Spinal Cord, 1999; 299-300);	Crossover RCT (n=20)	LoFric	EasiCath	Number of urethral epithelia cells on used catheter	NR	NR	No difference (p=0.97), including no difference related to age, level of lesion, ASIA impairment scale or time since spinal cord lesion
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	LoFric	EasiCath	Maximum removal friction (recorded twice daily)	Median 1: 0.87 N Median 2: 0.84 N	Median 1: 1.38 N Median 2: 1.27 N	55% difference between arms; p<0.001
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	LoFric	EasiCath	Variation in maximum removal friction	0.01 N to 1.69 N	0.24 N to 7.50 N	-
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	LoFric	EasiCath	Removal friction measurements greater than 2.0 N	0 cases (0.0%) in 0 patients	50 cases (20.2%) in 12 patients	-

Abbreviations: CI, confidence interval; N Newtons; NR, not reported; OR, odds ratio; PVC, polyvinyl chloride; RCT, randomised controlled trial.

C4.7 Other device-related adverse events (N=6)

Across the six studies reporting further adverse events, all events were commonly low across the different catheters, see below.

Study	Study design	Intervention	Comparator	Definition	Adverse events in intervention arm	Adverse event in comparator arm
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Epididymitis	-	1/34
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Stenosis	-	1/61
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel, Flocath Intro-Gel	Uncoated PVC	Percentage ratio of polymorphs to epithelial cells (urethral cytology)	NR	Increased after use (p<0.05)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Adverse event related to catheter (including UTI, haematuria, dysuria)	3	4
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Any adverse event	0/36	0/36
Landauro (2023, J Clin Med; 5266)	Cross-over RCT	Micro-hole zone catheter	VaPro	Any adverse event	0/42	0/42

Abbreviations: NR, not reported; PVC, polyvinyl chloride; RCT, randomised controlled trial; UTI, urinary tract infection.

C4.8 Adherence and compliance (N=3)

Three studies reported adherence. Two of these studies compared the SpeediCath to either Conveen (Cardenas 2011) or an uncoated catheter (De Ridder 2005), with both studies reporting similar discontinuation numbers in each arm of the trial. However, Cardenas et al 2011 did report a higher number of discontinuations in the hospital setting for the SpeediCath (n = 48) compared with Conveen (n = 32). There was no statistical analysis undertaken. The final study reported similar discontinuation numbers between the SpeediCath compact and SpeediCath, although, three of the compact catheter discontinuations were related to a perceived lack of efficacy. None of the standard SpeediCath participants discontinued due to this (Chartier-Kastler 2011). Due to the limited data, the EAG cannot draw conclusions regarding the impact of different catheters and their features on adherence and compliance.

Study	Study design [Follow-up duration]	Intervention	Comparator	Setting	Outcome in intervention arm	Outcome in comparator arm
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority) [14 ± 2 days in each arm]	SpeediCath Compact Male	SpeediCath Male	Community	Discontinuation (n=4): - 3 perceived lack of efficacy - 1 adverse event	Discontinuation (n=5) - 2 wished to discontinue - 1 adverse event - 2 other
Cardenas (PM&R, 2011; 408-417)	RCT	SpeediCath	Conveen	Hospital, rehabilitation centre	Discontinued study while in institutional period (n=48) - 8 consent withdrawn - 1 protocol violation - 9 adverse event - 2 urethral bleeding - 28 change of bladder management (2 normal voiding, 7 indwelling, 15 different IC catheter, 2 urinary sheath, 2 disliked catheter)	Discontinued study while in institutional period (n=32) - 4 lost to follow-up - 3 Consent withdrawn - 2 protocol violation - 2 adverse event - 21 change of bladder management (4 normal voiding, 9 indwelling, 7 different IC catheter, 1 disliked catheter)
Cardenas (PM&R, 2011; 408-417)	RCT	SpeediCath	Conveen	Community	Discontinued while in community period (n=12) - 4 lost to follow-up - 1 withdrawn consent - 1 adverse event - 6 change of bladder management (4 normal voiding, 1 indwelling catheter, 1 different IC catheter)	Discontinued while in community period (n=13) - 5 lost to follow-up - 8 change of bladder management (2 normal voiding, 4 indwelling catheter, 2 different IC catheter)
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Community	Discontinued during 12 months: - 4 adverse events - 17 protocol violations - 10 withdrawal of consent - 4 lost to follow-up - 1 death	Discontinued during 12 months: - 3 adverse events - 11 protocol violations - 8 withdrawal of consent - 6 lost to follow-up - 1 unknown

Abbreviations: IC, intermittent catheterisation; ITT, intention to treat; PVC, Polyvinyl chloride; RCT, randomised controlled trial.

C4.9 Comfort or pain (N=7)

See section [4.2.4.4](#)

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Discomfort (VAS)	10.1 (16.65) mm	6.8 (9.77) mm	p=0.30
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc Set	SpeediCath Compact	Discomfort when performing procedure with the catheter [scale unclear]: in those with urethral sensitivity	Median: 1	Median 1	p=0.083
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Discomfort (VAS)	mean (SD): 1.59 (2.24)	mean (SD): 1.94 (2.28)	-0.35 (95% CI -1.49 to 0.80; ITT) Non-inferiority met -0.9 (95% CI -1.66 to 0.14; PP)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Discomfort (VAS) on insertion	Mean (SD): 0.3 (0.8)	Mean (SD): 1.1 (2.3)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Discomfort (VAS) during emptying	Mean (SD): 0.2 (0.7)	Mean (SD): 0.9 (1.8)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Discomfort (VAS) by completion	Mean (SD): 0.3 (0.7)	Mean (SD): 1.2 (2.3)	NR
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Discomfort (VAS) at withdrawal	Mean (SD): 0.4 (1.2)	Mean (SD): 1.3 (2.4)	NR

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Gentle to empty	• 55 strongly agree • 16 agree • 3 neither • 1 disagree • 0 strongly disagree • 0 don't know	• 32 strongly agree • 30 agree • 3 neither • 6 disagree • 4 strongly disagree • 0 don't know	Better in intervention arm, OR: 3.85 (1.87 to 7.96); p<0.001
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Pain during insertion	Severe: 2/36 Mild/moderate: 1/36 No: 33/36	Severe: 0/36 Mild/moderate: 2/36 No: 34/36	p=0.4375
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Comfort during insertion (0-10 scale)	Mean (SD): 9.3 (1.2)	Mean (SD): 8.9 (1.4)	NR; no statistical difference reported
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Gentle to insert	• 51 strongly agree • 19 agree • 1 neither • 2 disagree • 2 strongly disagree • 0 don't know	• 29 strongly agree • 32 agree • 3 neither • 5 disagree • 5 strongly disagree • 0 don't know	Better in intervention arm, OR 3.30 (1.64 to 6.64); p=0.001
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	No pain	80.0% (24/36)	73.3% (22/36)	p=0.6675
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Stinging during insertion	Severe: 0/36 Mild/moderate: 5/36 No: 31/36	Severe: 0/36 Mild/moderate: 3/36 No: 33/36	p=0.5000
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Pinching or stinging	• 1 strongly agree • 3 agree • 2 neither	• 7 strongly agree • 11 agree	OR 3.01 (1.60 to 5.67); odds of disagreeing

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
					• 27 disagree • 42 strongly disagree • 0 don't know	• 5 neither • 24 disagree • 26 strongly disagree • 0 don't know	with statement; p<0.001
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	No stinging	80% (24/36)	76.6% (23/36)	p=0.6831
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Blocking sensation	• 0% strongly agree • 6% agree • 15% neither • 29% disagree • 50% strongly disagree	• 4% strongly agree • 12% agree • 21% neither • 40% disagree • 24% strongly disagree	OR 3.15 (95%CI 1.65 to 6.01), p<0.001
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Resistance during insertion	Severe: 3/36 Mild/moderate: 11/36 No: 22/36	Severe: 2/36 Mild/moderate: 15/36 No: 19/36	p=0.8604
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	No resistance	53.3% (16/36)	30% (9/36)	OR 2.69 (95%CI 1.12 to 6.49); p=0.0273
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Comfort during withdrawal	9.4 (1.1)	9.0 (1.5)	NR; no statistical difference reported
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Gentle to withdraw	• 54 strongly agree • 18 agree • 1 neither • 3 disagree • 0 strongly disagree • 0 don't know	• 26 strongly agree • 28 agree • 5 neither • 7 disagree • 7 strongly disagree	Better in intervention arm, OR 3.21 (1.62 to 6.37); p=0.001

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
						• 0 don't know	
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Did not feel burning (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [3, 5]	p=0.043; not significant after adjustment for multiple comparisons
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Did not feel pain (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [4, 5]	4 [3, 5]	p=0.173
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glys Set	SpeediCath Compact	Feeling while using the catheter [scale unclear]	Median: 3	Median 3	p=0.272

Abbreviations: CI, confidence interval; ITT, intention to treat; NR, not reported; NS, no statistically significant difference; OR, odds ratio; PP, per protocol; PVC Polyvinyl chloride; RCT, randomised controlled trial; SD, standard deviation; VAS, visual analogue scale.

C4.10 Ease of use (N=11)

See section 0.

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Controlling	-	-	OR 13.30 (2.51 to 70.60); p=0.0024
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Need to touch the coated part of the catheter	-	-	OR 0.09 (0.02 to 0.035)

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Control during insertion	• very easy or easy 32 • not easy nor difficult 2 • difficult or very difficult 2	• very easy or easy 18 • not easy nor difficult 10 • difficult or very difficult 8	p<0.0001
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters qualitatively evaluated in randomised order)	Actreen Lite, SpeediCath, LoFric Primo	PVC	Ease of opening (01 very easy to 05 very difficult)	Actreen Lite: 2.4; SpeediCath: 1.8; LoFric Primo: 2.6	PVC: 2.8	Pair-wise comparisons reported; SpeediCath lower than all other 3 catheters (p<0.05), also difference between Actreen Lite and PVC (p<0.05)
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glys Set	SpeediCath Compact	Ease of package opening [scale unclear]	Median: 4	Median 4	p=0.796
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	SpeediCath	LoFric	Difficult in opening the packaging	12%	4%	NR
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	SpeediCath	LoFric	Handling of packaging (preference)	46%	54%	p=0.839
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT	SpeediCath	LoFric	Time taken to perform catheterisation	-	-	p=0.015 (shorter than normal in 68% using the intervention catheter)
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of use of catheter	• 57 strongly agree • 17 agree • 1 neither • 3 disagree	• 38 strongly agree • 21 agree • 7 neither	OR 3.11 (95%CI 1.54 to 6.29); p=0.002

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
					• 0 strongly disagree • 0 don't know	• 11 disagree • 0 strongly disagree • 0 don't know	
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of opening the catheter	• 46 strongly agree • 23 agree • 7 neither • 2 disagree • 0 strongly disagree • 0 don't know	• 25 strongly agree • 26 agree • 8 neither • 15 disagree • 3 strongly disagree • 0 don't know	OR 3.84 (2.01 to 7.34); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of emptying the bladder	• 51 strongly agree • 19 agree • 5 neither • 3 disagree • 0 strongly disagree • 0 don't know	• 28 strongly agree • 35 agree • 10 neither • 2 disagree • 2 strongly disagree • 0 don't know	OR 2.96 (1.56 to 5.60); p=0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of re-closing the catheter	• 27 strongly agree • 34 agree • 6 neither • 6 disagree • 2 strongly disagree	• 25 strongly agree • 16 agree • 9 neither • 15 disagree	OR 2.03 (1.11 to 3.72); p=0.022

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
					• 3 don't know	• 10 strongly disagree • 2 don't know	
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Speed of emptying bladder using catheter	• 34 strongly agree • 22 agree • 15 neither • 5 disagree • 2 strongly disagree • 0 don't know	• 17 strongly agree • 30 agree • 18 neither • 6 disagree • 5 strongly disagree • 1 don't know	OR 2.06 (1.14 to 3.73); p=0.017
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Confidence that catheter empties bladder completely	• 43 strongly agree • 24 agree • 4 neither • 6 disagree • 0 strongly disagree • 1 don't know	• 22 strongly agree • 29 agree • 12 neither • 11 disagree • 3 strongly disagree • 0 don't know	OR 3.27 (1.74 to 6.14); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Lack of worry about urine left in bladder	• 47 strongly agree • 15 agree • 9 neither • 5 disagree • 2 strongly disagree	• 24 strongly agree • 30 agree • 8 neither • 11 disagree	OR 2.68 (1.45 to 1.95); p=0.002

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
					0 don't know	4 strongly disagree 0 don't know	
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Overall confidence in catheter	57 strongly agree 13 agree 3 neither 4 disagree 1 strongly disagree 0 don't know	35 strongly agree 26 agree 7 neither 5 disagree 4 strongly disagree 0 don't know	OR 3.06 (1.57 to 5.93); p=0.001
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in randomised order)	Actreen Lite, SpeediCath, LoFric Primo	PVC	Ease of manipulation (01 very easy to 05 very difficult)	Actreen Lite: 2.7; SpeediCath: 1.9; LoFric Primo: 2.6	PVC: 3.3	Pair-wise comparisons reported; SpeediCath lower than all other 3 catheters (p<0.05), also difference between LoFric Primo and PVC (p<0.05)
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in randomised order)	Actreen Lite, SpeediCath, LoFric Primo	PVC	Ease of sliding on the urethra (01 very easy to 05 very difficult)	Actreen Lite: 2.4; SpeediCath: 1.6; LoFric Primo: 2.3	PVC: 3.3	Pair-wise comparisons reported; all statistically significant with the exception of comparison of Actreen Lite and LoFric Primo.
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc Set	SpeediCath Compact	Ease of sliding into the urethra [scale unclear]	Median: 3.5	Median 3	p=0.643

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Need rotation to empty	• 3% strongly agree • 6% agree • 11% neither • 41% disagree • 39% strongly disagree	• 6% strongly agree • 16% agree • 16% neither • 35% disagree • 27% strongly disagree	OR 1.98 (1.16 to 3.39), p=0.013
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Need slow withdrawal to empty	• 6% strongly agree • 12% agree • 15% neither • 38% disagree • 29% strongly disagree	• 18% strongly agree • 32% agree • 18% neither • 24% disagree • 9% strongly disagree	OR 4.32 (2.31 to 8.06), p<0.001
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Need withdraw in small steps to empty	• 9% strongly agree • 18% agree • 12% neither • 35% disagree • 26% strongly disagree	• 22% strongly agree • 44% agree • 4% neither • 25% disagree • 4% strongly disagree	OR 4.42 (2.24 to 8.72), p<0.001

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Confident bladder is empty when flow stops	• 46% strongly agree • 41% agree • 6% neither • 6% disagree • 2% strongly disagree	• 28% strongly agree • 34% agree • 24% neither • 12% disagree • 3% strongly disagree	OR 2.85 (0.47 to 5.53), p=0.003 [likely error in results]
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Confident catheter empties completely	• 49% strongly agree • 38% agree • 9% neither • 2% disagree • 3% strongly disagree	• 28% strongly agree • 44% agree • 19% neither • 6% disagree • 3% strongly disagree	OR 2.50 (1.32 to 4.71), p=0.005
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Easy to empty the bladder	• 70% very easy • 23% easy • 6% neither • 2% difficult • 0% very difficult	• 43% very easy • 47% easy • 7% neither • 2% difficult • 0% very difficult	OR 2.73 (1.40 to 5.35), p=0.004.
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Speed (preference)	76%	25%	p=0.015

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Convenience (preference)	88%	12%	p=0.000
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to perform IC (Median [Q1,Q3])	283 [242, 342] seconds	373 [249, 441] seconds	p=0.01
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to perform IC (Median [Q1,Q3]) Tetraplegia (n=9)	300 [249, 352] seconds	421 [398, 515] seconds	p-value NR; reported as no statistically significant difference
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc Set	SpeediCath Compact	Time taken to perform IC [scale unclear]	Median: 2	Median 2	p=0.592
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to perform IC (Median [Q1,Q3]) Paraplegia (n=11)	272 [210, 353] seconds	296 [225, 443] seconds	p-value NR; reported as no statistical significant difference
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to prepare catheter (Median [Q1,Q3]) All individuals (n=20)	15 [10, 20] seconds	41 [20, 69] seconds	p=0.02
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to prepare catheter (Median [Q1,Q3]) Tetraplegia (n=9)	16 [11, 20] seconds	67 [46, 81] seconds	p=0.038; not significant following adjustment for multiple comparisons
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Overall time taken to prepare catheter (Median [Q1,Q3]) Paraplegia (n=11)	15 [9, 24] seconds	21 [14, 25] seconds	p=0.023; not significant following adjustment for multiple comparisons
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Easy to handle before insertion (Likert scale: 1	4 [2, 5]	4 [2, 5]	p=0.806

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Reports, 2022; 10010)				strongly disagree to 5 strongly agree)			
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Inserting	-	-	OR 4.09 (95%CI 1.35 to 12.36); p=0.0127
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of handling the catheter during insertion	• 45 strongly agree • 24 agree • 5 neither • 3 disagree • 1 strongly disagree • 0 don't know	• 31 strongly agree • 22 agree • 15 neither • 8 disagree • 1 strongly disagree • 0 don't know	OR 2.32 (1.35 to 3.99); p=0.003
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Introduction of catheter to urethra and bladder (preference)	62%	38%	p=0.383
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Ease of inserting catheter	• 52 strongly agree • 18 agree • 5 neither • 2 disagree • 1 strongly disagree • 0 don't know	• 33 strongly agree • 29 agree • 7 neither • 7 disagree • 1 strongly disagree • 0 don't know	OR 2.61 (1.42 to 4.79); p=0.002
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Easy to insert (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [2, 5]	4 [2, 4]	p=0.748

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Ease of insertion [0-10 very difficult to very easy]	9.2 (1.6)	8.6 (1.6)	NR; reported as not statistically significant.
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Able to drain bladder (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.756
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Easy to remove (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.984
Greghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc Set	SpeediCath Compact	Ease of removal of catheter from urethra [scale unclear]	Median: 34	Median 4	p=0.561
Greghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc Set	SpeediCath Compact	Difficult catheter removal [scale unclear]	Median: 5	Median 2	p=0.317
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Withdrawal of catheter from urethra and bladder (preference)	60%	40%	p=0.503
Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321);	Cross-section study (4 catheters evaluated in randomised order)	Actreen Lite, SpeediCath, LoFric Primo	PVC	Ease of withdrawal (01 very easy to 05 very difficult)	Actreen Lite: 2.2; SpeediCath: 1.7; LoFric Primo: 2.0	PVC: 3.0	Pair-wise comparisons reported; all statistically significant with the exception of comparison of Actreen Lite and SpeediCath, and SpeediCath compared with LoFric Primo.

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Easy to dispose (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [4, 5]	4 [4, 5]	p=0.553
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT (n=20)Cross over RCT, pilot (n=20)	Hydrophillic catheters	Non-hydrophillic catheters	Easy to prepare (Likert scale: 1 strongly disagree to 5 strongly agree)	5 [(4, 5)]	4 [(2, 4)]	p=0.047; not significant after adjustment for multiple comparisons p=0.047
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Preparation of catheter in usual surroundings [0-10 very difficult to very easy]	8.9 (1.4)	8.5 (1.8)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Catheterisation procedure in usual surroundings [0-10 very difficult to very easy]	9.3 (1.1)	8.8 (1.5)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Preparation of catheter outside usual surroundings [0-10 very difficult to very easy]	7.6 (2.8)	6.8 (2.7)	NR; reported as not statistically significant.
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Catheterisation procedure outside of usual surroundings [0-10 very difficult to very easy]	7.7 (2.7)	6.8 (2.7)	NR; reported as not statistically significant.
Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]	Crossover RCT	SpeediCath	LoFric, EasiCath	Use of friendliness (numerical scale, 1-10)	7.8 (1.8)	LoFric: 6.9 (1.6); EasiCath: 6.7 (1.7)	p=0.32

Study	Study design	Intervention	Comparator	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (intervention compared with comparator)
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	EasiCath	LoFric	Number of cases of catheter 'sticking'	42 cases in 9 patients	3 cases in 2 patients	-
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	EasiCath	LoFric	Catheterisation time	Mean: 4.4 minutes (range: 3.3 minutes to 9.6 minutes)	Mean: 4.3 minutes (3.5 minutes to 8.2 minutes)	-

Abbreviations: CI, confidence interval; IC, intermittent catheterisation; NR, not reported; OR, odds ratio; PVC Polyvinyl chloride; RCT, randomised controlled trial.

C4.11 General satisfaction (N=7)

Seven studies were identified reporting satisfaction of catheters. Three of these studies reported the SpeediCath, which showed no statistically significant difference in satisfaction compared with an uncoated catheter in one study (De Ridder 2005), and higher satisfaction compared with a Conveen, LoFric and EasiCath in two studies (Cardenas 2011; Koenen 2004). One study reported no statistically significant difference in satisfaction between the SpeediCath compact and Actreen Glys catheters (Gregghi 2022). Another reported statistically significant improved satisfaction when using a gel-lubricated non-hydrophilic catheter, compared with a regular catheter (Sarica 2010). Satisfaction was also deemed to be statistically higher when using a micro-hole catheter compared with a conventional eyelet catheter in one study (Thiruchelvam 2024a). Finally, one study reported no statistically significant difference in satisfaction between hydrophilic and non-hydrophilic catheters (Gopalakrishnan 2022). Overall, there is not enough data based on different features to determine which catheter was consistently being reported as providing greater satisfaction.

Study	Study design	Intervention	Comparator	Setting	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	NR (catheterisation conducted by individual or caregiver)	Overall satisfaction (VAS)	9.3 (1.4)	8.6 (1.3)	p=0.007
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Multicentre hospital	Very satisfied [6 months]	10 (33.0%)	6 (15.4%)	p-value NR; no statistical difference reported
De Ridder (Eur Urol, 2005; 991-995)	RCT	SpeediCath	Uncoated PVC	Multicentre hospital	Very satisfied [12 months]	9 (36.0%)	7 (21.9%)	p-value NR; no statistical difference reported
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross-over RCT, pilot (n=20)	Hydrophilic catheters	Non-hydrophilic catheters	Community	Overall satisfaction (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [3, 5]	3 [2, 5]	p=0.344

Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Community	General satisfaction	• 41 strongly agree • 22 agree • 6 neither • 7 disagree • 2 strongly disagree • 0 don't know	• 16 strongly agree • 30 agree • 9 neither • 13 disagree • 9 strongly disagree • 0 don't know	Better in intervention arm, OR 3.64 (1.96 to 6.75); p<0.001
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Community	Overall confidence in catheter	• 57 strongly agree • 13 agree • 3 neither • 4 disagree • 1 strongly disagree • 0 don't know	• 35 strongly agree • 26 agree • 7 neither • 4 disagree • 5 strongly disagree • 0 don't know	Higher in intervention arm, OR 3.06 (95%CI 1.57 to 5.93); p=0.001.
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	Flocath Hydro Gel, Flocath Intro-Gel	PVC	Inpatient	Overall satisfaction (VAS score)	-	-	Gel-lubricated non-hydrophilic catheter significantly higher; p<0.05
Gregghi (ESTIMA, 2022; e2522); Brazil	Prospective cohort (n=50)	Actreen Glyc	SpeediCath Compact	Community	Grade for catheter [scale unclear]	Median: 4	Median 4	p=0.146

Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]	Crossover RCT	SpeediCath	LoFric, EasiCath	Rehabilitation centre	Preference for catheters after study	38/66	LoFric: 16/66; EasiCath: 9/66	p=0.003

Abbreviations: NR, not reported; OR, odds ratio; PVC, Polyvinyl chloride; RCT, randomised controlled trial; VAS, visual analogue scale.

C4.12: Discretion (N=4)

Four studies reported outcomes related to the discretion of using the catheter. In two studies, the SpeediCath compact was rated higher in preference of easy to use for discretion compared with the standard SpeediCath (Chartier-Kastler 2011; Domurath 2011). While the SpeediCath was rated high for discretion compared with the LoFric in one study (Pascoe 2011). Finally, the use of a micro-hole catheter compared with a conventional catheter was rated as being preferred in one study (Thiruchelvam 2024a).

Study	Study design	Intervention	Comparator	User	Outcome measure
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Intervention rated higher: OR 20.40 (95% 4.91 to 84.67); p<0.0001
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Intervention rated higher: Intervention: very easy (26/36), not easy or difficult (8/36), difficult or very difficult (2/36) Comparator: very easy (15/36), not easy or difficult (13/36), difficult or very difficult (8/36); p<0.0001
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Community	Preference for intervention: 88% versus 12%; p=0.000 Outside of a home environment: 20/25 users stated that it more <u>discreet</u> to use a catheter that was ready to use (SpeediCath).
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Community	Preference for intervention: OR 2.57 (1.40 to 4.70); p=0.003

Abbreviations: OR, odds ratio; RCT, randomised controlled trial.

C4.13: Hygiene (N=2)

Two studies reported hygiene related outcomes. Mixed results were observed between the studies, which both included a micro-hole based catheter intervention arm. One study suggested no difference between the catheters for hygienic catheterisation, while

the other suggested improved hygiene using the micro-hole catheter. Due to the limited evidence, the EAG cannot make any conclusions regarding which catheter may be more hygienic to use.

Study	Study design	Intervention	Comparator	Setting	Outcome measure
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Community	No difference between arms: OR 1.79 (95% CI 0.94 to 3.39); p=0.074
Thiruchelvam (Neurourology Urodynamics, 2024; 464-478)	Cross-over RCT	Micro-hole catheter (Coloplast Ltd)	SpeediCath Flex, VaPro	Community	Hygienic catheterisation was perceived as easier with intervention catheter: OR 2.07 (95%CI 1.10 to 3.90), p=0.025.

Abbreviations: CI, confidence interval; OR, odds ratio; RCT, randomised controlled trial.

C4.14: Storing or carrying (N=1)

A singular study reported data of storing or carrying, with the SpeediCath having statistically significant odds of being easier to carry and store than the standard SpeediCath (Chartier-Kastler 2011). Given the lack of evidence, the EAG cannot make any further conclusions.

Study	Study design	Intervention	Comparator	Outcome measure
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Storing: Intervention rated higher: OR 28.91 (7.66 to 109.06); p<0.001
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Carrying: Intervention rated: OR 47.32 (12.15 to 184.34); p<0.0001

Abbreviations: OR, odds ratio; RCT, randomised controlled trial.

C4.15: Disposal (N=3)

Three studies reported on the outcome of disposal. One study observed similar results for disposal of the SpeediCath compared with the Conveen catheter (Cardenas 2011). The other two studies showed statistically significant improvement of disposal for the SpeediCath compact compared with the SpeediCath (Chartier-Kastler 2011; Domurath 2011).

Due to the lack of evidence, the EAG cannot make recommendations which catheters may be easier to dispose of than others. Evidence from two studies suggest the SpeediCath compact is more easily disposed of than the standard SpeediCath, however a different study stated there was no statistical difference.

Study	Study design	Intervention	Comparator	Setting	Outcome measure	Outcome in intervention	Outcome in comparator	Difference (between intervention and comparator)
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Difficult (measured in 5 categories: very difficult, difficult, neutral, easy, very easy)	-	-	OR 17.66 (5.61 to 55.55) favouring compact catheter; p<0.0001
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Difficulty (measured in 3 categories: very easy or easy, not easy or difficult, difficult or very difficult)	- very easy or easy (29/36) - not easy or difficult (7/36) - difficult or very difficult (0/36)	- very easy (20/36) - not easy or difficult (12/36) - difficult or very difficult (4/36)	p<0.0001
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Hospital, rehabilitation centre, community	0-10 scored very difficult to very easy	9.0 (1.4)	8.8 (1.7)	NR; no statistically significant difference

Abbreviations: NR, not reported; OR, odds ratio; PVC, Polyvinyl chloride; RCT, randomised controlled trial.

C4.16: Overall preference of catheter choice (N=5)

Five studies reported overall preference. Two of these studies showed a tendency towards the SpeediCath Compact, compared with the SpeediCath. However, only one of these was statistically significant (Chartier-Kastler 2011). Another study showed

statistically significant preference for the SpeediCath compared with the LoFric catheter (Pascoe 2001). One study reported a statistically significant odds of preferring a micro-hole catheter compared with a conventional catheter (Thiruchelvam 2024a). Finally, a single study showed no statistically significant difference in preference of hydrophilic vs non-hydrophilic catheters (Gopalakrishnan 2022).

Overall, there is a lack of evidence for preference of catheter choice. There are indications that certain catheters may be more preferred than others but further evidence is needed.

Study	Study design	Intervention	Comparator	Setting	Outcome measure
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	<u>Overall preference for intervention</u> : 70.0%; p=0.0285
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	<u>Overall preference for intervention</u> : 61.1% (95%CI 43.5% to 76.9%); p=0.24
Thiruchelvam (Br J Nursing, 2024; 834-843)	Cross-over RCT	Micro-hole catheter	Conventional eyelet	Community	<u>Would like to use catheter in future</u> : higher in intervention arm, OR 4.01 (2.17 to 7.40); p<0.001 <u>Would recommend catheter to others</u> : higher in intervention arm, OR 5.12 (2.71 to 9.68); p<0.001
Gopalakrishnan (Continence Reports, 2022; 10010)	Cross over RCT, pilot (n=20)	Hydrophilic catheters	Non-hydrophilic catheters	Community	<u>Prefer this catheter</u> (Likert scale, 1 strongly disagree to 5 strongly agree): 3.[2,5] compared with 2[1,5]; p=0.232
Pascoe (Br J Nurs, 2001; 325-329)	Cross-over RCT (n=27)	SpeediCath	LoFric	Community	<u>Overall preference for intervention</u> : 78% compared with 22%; p=0.011

Abbreviations: CI, confidence interval; NR, not reported; OR, odds ratio; RCT, randomised controlled trial.

C4.17 Health-related quality of life, PROMs (N=1)

A total of 1 study reported on quality of life, however the quality and completeness of data was poor. One additional study (Pascoe et al. 2001) reported that 84% considered it a good idea to have water as an integral part of the packaging, and 72% anticipated that this feature would improve their quality of life. However no formal quality of life measure was reported.

Study	Study design	Intervention	Comparator	Setting	Questionnaire	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Influence on daily activities (VAS)	NR	NR	p=0.0323
Chartier-Kastler (Spinal Cord, 2011; 844-850)	Cross-over RCT (non-inferiority)	SpeediCath Compact Male	SpeediCath Male	Community	Overall quality of life (VAS)	NR	NR	No significant difference (p-value not reported)

Abbreviations: NR, not reported; RCT, randomised controlled trial; SD, standard deviation; VAS, visual analogue scale.

C4.18 Learning curve (N=1)

One study reported learning curve, with both studied catheters rating as highly easy to use on the scale. The EAG can make no conclusions based on the limited evidence available.

Study	Study design	Intervention	Comparator	Learning curve
Cardenas (PM&R, 2011; 408-417)	Prospective RCT	SpeediCath	Conveen	Measured on 11-point scale from 0-10 (very difficult to very easy): 9.0 (1.6) for SpeediCath compared with 8.7 (1.8) Conveen. No p-value reported, but no statistically significant differences reported.

Abbreviations: PVC, Polyvinyl chloride; RCT, randomised controlled trial.

Appendix C5: Excluded studies (N=264)

#	Source	Author (year); country †Abstract	Reasons for exclusion
1.	EAG literature search (clinical)	Ali (BMC Urology, 2024; 122)	<u>Intervention and comparator</u> : Coated versus uncoated, no device names to determine whether additional features (above that of 'standard') were present
2.	Primary evidence included in SR by Barken et al. 2022	Asfar (Spinal Cord, 2013; 645-649)	<u>Intervention and comparator</u> : Comparison of indwelling and intermittent catheter; no device names to determine whether additional features (above that of 'standard') were present
3.	RFI (B. Braun Medical Ltd)	Assis (Cogitare Enferm, 2015; 805-812)	<u>Intervention</u> : Device not named (EAG cannot confirm presence of additional features)
4.	RFI (B. Braun Medical Ltd, Coloplast Ltd, and AstraTech (now Wellspect)))	Auger (Minerva Urol Nefrol, 2007; 115-124)	<u>Study design</u> : in vitro, sperm motility
5.	RFI (CliniMed Ltd)	Bagi (Urol Int, 2011; 179-184)	<u>Population</u> : healthy volunteers
6.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Bakke (Br J Urol, 1997; 85-90)	<u>Intervention</u> : Mixed intervention, included LoFric, PVC and glass catheter.
7.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Bakke (J Urol, 1993; 527-531)	<u>Intervention</u> : unnamed
8.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Bakke (Scand J Urol Nephrol, 1993; 55-61)	<u>Comparator</u> : Other PVC catheters, unnamed (EAG unable to confirm presence of other features)
9.	RFI (CliniMed Ltd)	Bardsley (2015, Br J Nurs; S6-S13)	<u>Study design</u> : procedural narrative review
10.	EAG literature search (clinical, economic)	Barken (BMC Urology, 2022; 1-18)	<u>Study design</u> : Systematic review; EAG reviewed primary evidence
11.	Primary evidence included in SR by Shamout et al. 2017	Bennett (J Urol, 1997; 519-521)	<u>Intervention</u> : O'Neil catheter with introducer, not listed in Drug Tariff (not available); EAG unable to verify additional features

#	Source	Author (year); country †Abstract	Reasons for exclusion
12.	EAG literature search (economic)	Benseler (Female Pelvic Medicine & Reconstructive Surgery, 2021, S104)	<u>Comparator:</u> Study comparing intermittent catheterisation with indwelling and suprapubic catheterisation following pelvic surgery.
13.	EAG literature search (economic)	Benseler (Journal of Obstetrics & Gynaecology Canada, 2021; 661)	<u>Comparator:</u> Study comparing intermittent catheterisation with indwelling and suprapubic catheterisation following pelvic surgery. <u>Duplicate:</u> potential duplicate of Benseler et al. 2021.
14.	EAG literature search (economic)	Benseler (Urogynecology, 2024, 805-813)	<u>Comparator:</u> Study comparing intermittent catheterisation with indwelling and suprapubic catheterisation following pelvic surgery.
15.	Primary evidence included in SR by Barken et al. 2022	Biardeau (Ann Phys Rehabil Med, 2016; 125-129)	<u>Study design:</u> Narrative review (non-systematic)
16.	Primary evidence included in SR by Prieto et al. 2021; Shamout et al. 2017; Chartier-Kastler et al. 2011. RFI (Coloplast Ltd)	Biering-Sørensen (Scand J Urol Nephrol, 2007; 341-345)	<u>Comparator:</u> Mixed, 62.5% LoFric, 16.7% SpeediCath, 12.5% Pennine, 4.2% EasiCath, 4.2% Unomedical.
17.	Primary evidence included in SR by Barken et al. 2022; Feng et al. 2020; Shamout et al. 2017; Chartier-Kastler et al. 2011 RFI (Coloplast Ltd)	Bjerklund Johansen (Eur Urol, 2007; 213-220)	<u>Study design:</u> single-arm (LoFric Primo)
18.	RFI (Convatec Ltd)	Balaban (Hum Reprod, 2003; 1887-1889)	<u>Study design:</u> unrelated to catheters: sperm
19.	Primary evidence included in SR by Barken et al. 2022	Boucher (Can Urol Assoc J, 2010; 5)	<u>Population:</u> Children
20.	RFI (Convatec Ltd)	Borrini (2012, Prog Urol; 482-486)	<u>Study design:</u> in vitro, flow rates <u>Language:</u> French
21.	RFI (Convatec Ltd)	Brackett (J Urol, 1996; 1632-1635)	<u>Intervention:</u> sperm plasma is not a catheter
22.	EAG literature search (economic)	Buckley (Br J Gen Pract, 2015; 419)	<u>Study design:</u> narrative review
23.	Primary evidence included in SR by Barken et al. 2022	Burki (J Pediatr Urol, 2019; 646-650)	<u>Population:</u> Children
24.	RFI (Convatec Ltd)	Burns (ICS Madrid, 2024; S24). [abstract]	<u>Study design:</u> pig model development

#	Source	Author (year); country †Abstract	Reasons for exclusion
25.	RFI (Convatec Ltd)	Burns (ACS Omega, 2024; 22410-22422)	<u>Study design</u> : in vitro, biomimetic uretral model cultured from human cells on silicone sheets
26.	EAG literature search (clinical)	Cameron (Neurourol Urodynamics, 2009; 844-845)	<u>Study design</u> : survey of bladder management after spinal cord injury
27.	EAG literature search (clinical)	Cardenas (Int Urogynecol J Pelvic, 2010; S186-S187)	<u>Duplicate</u> : of Cardenas (PM&R, 2011; 408-417)
28.	EAG literature search (clinical)	Cardenas (Neurourol Urodynamics, 2010; 990-991)	<u>Duplicate</u>
29.	EAG literature search (economic)	Carpeti (Ann Royal College Surg England, 1996; 59-60)	<u>Intervention</u> , <u>Comparator</u> : sterile versus non-sterile urethral catheterisation
30.	RFI (Convatec Ltd)	Carson (Br J Nurs, 2022; 1-7)	<u>Study design</u> : procedural narrative review
31.	Primary evidence included in SR by Shamout (Spinal Cord, 2017; 629-643)	Charbonneau-Smith (Rehab Nurs, 1993; 305)	<u>Intervention</u> : O'Neil catheter with introducer, not listed in Drug Tariff (not available); EAG unable to verify additional features
32.	Primary evidence included in SR by Barken et al. 2022	Chartier-Kastler (Neurourol Urodyn, 2011; 21-31)	<u>Study design</u> : Systematic review. EAG considered primary evidence.
33.	Primary evidence included in SR by Prieto et al. 2021 RFI (Coloplast Ltd)	Chartier-Kastler (J Urol, 2013; 942-947)	<u>Comparator</u> : participants usual catheter mixed
34.	RFI (B. Braun Medical Ltd)	Chartier-Kastler (Eur Urol Open Sci, 2022; 79-87)	<u>Intervention</u> : primarily Actreen product range from B. Braun Medical Ltd <u>Comparator</u> : primarily SpeediCath product range from Coloplast Ltd Potential mix of catheters, EAG unable to verify additional features
35.	Primary evidence included in SR by Ye et al. 2021	Chick (J Clin Nurs, 2013; 513-520)	<u>Population</u> : includes children (age range 3 to 20 year, mean 13 years) <u>Comparator</u> : single-use hydrophilic compared with reusable uncoated

#	Source	Author (year); country †Abstract	Reasons for exclusion
36.	Primary evidence included in SR by Barken et al. 2022	Christison (J Neurotrauma, 2018; 985-989)	<u>Study design</u> : Reanalysis of Prieto et al. 2014
37.	RFI (Coloplast Ltd)	Cindolo (Urol Int, 2004; 19-22)	<u>Intervention</u> : EasiCath (basic hydrophilic)
38.	RFI (Convatec Ltd)	Convatec Ltd [CiC] "Internal post marketing study, 2018"	<u>Study design</u> : [REDACTED]
39.	RFI (Convatec Ltd)	Cortese (2018; J Healthc Eng; 2986742)	<u>Study design</u> : narrative review
40.	Primary evidence included in SR by Prieto et al. 2021	Costa (Spinal Cord, 2013; 772-775)	<u>Intervention</u> : Apogee not available on Drug Tariff, additional features above basic unknown. <u>Comparator</u> : Catheter of different lengths (Apogee 30cm compared with 40cm).
41.	EAG literature search (clinical)	Croghan (Eur Urol Open Sci, 2021; S13) [Abstract 30]	<u>Intervention</u> : Mixed intervention (results not separated)
42.	Primary evidence included in SR by Ye et al. 2021	Day (Urol Nurs, 2003; 143-147)	<u>Intervention</u> : gel-lubricated single-use <u>Comparator</u> : uncoated single-use EAG assume comparison of basic feature catheters only.
43.	RFI (Hollister Ltd)	Dean (2024, Journal of wound, ostomy, and continence nursing; 66–73)	<u>Study design</u> : in vitro, bacteria transfer using no-touch method
44.	EAG literature review (economic)	Dechao (Eur Urol Open Sci, 2020; e2070)	<u>Abstract</u> : of systematic review, not enough detail regarding methodology or included papers.
45.	Primary evidence included in SR by Prieto et al. 2021	De Foor (J Ped Uro, 2017; 373)	<u>Population</u> : children (2-17 years)
46.	Primary evidence included in SR by Ye et al. 2021; Feng et al. 2020; Shamout et al. 2017 RFI (Hollister Ltd)	Denys (Spinal Cord, 2012; 853-858)	<u>Comparator</u> : Mixed: 40.2% SpeediCath, 33.0% LoFric, 18.6% SpeediCath Compact, 8.2% EasiCath
47.	Primary evidence included in SR by Barken et al. 2022	D'Hondt (Curr Infect Dis Rep, 2011; 544-551)	<u>Study design</u> : Opinion review
48.	Primary evidence included in SR by Barken et al. 2022	Di Benedetto (Eur J Phys Rehabil Med, 2011; 651-659)	<u>Study design</u> : Narrative review (non-systematic)
49.	Primary evidence included in SR by Shamout et al. 2017	Diokno (J Urol, 1995; 349-351)	<u>Comparator</u> : reusable catheter
50.	RFI (Teleflex)	Doherty (Br J Nurs, 2005; 170-175)	<u>Study design</u> : technical review
51.	RFI (Hollister Ltd)	Domshy (2023)	<u>Study design</u> : nurse evaluation of catheter

#	Source	Author (year); country †Abstract	Reasons for exclusion
52.	RFI (Bard Ltd)	Dow Corling (2006)	Cannot retrieve with information provided
53.	Primary evidence included in SR by Prieto et al. 2021	Duffy (J Am Ger Soc, 1995; 865-870)	<u>Intervention and Comparator:</u> clean versus sterile intermittent catheterisation, reusable
54.	EAG literature search (clinical)	Du (Biotech Genetic Engineer Rev, 2023; 1255-1272)	<u>Intervention:</u> indwelling catheter
55.	RFI (Hollister Ltd)	Easton (Br J Nurse 2000; 357-359)	<u>Study design:</u> single arm (InstantCath)
56.	EAG literature search (SRs)	Elliot (Eur Urol Focus, 2023; 888-890)	<u>Comparator:</u> comparing single-use with multi-use
57.	Primary evidence included in SR by Barken et al. 2022	Ercole (Rev Lat Am Enfermagem, 2013; 459-68)	<u>Study design:</u> Opinion review
58.	RFI (B. Braun Medical Ltd)	EVEA (2020) Packaging bench test	<u>Design:</u> bench test
59.	Primary evidence included in SR by Shamout et al. 2017, Chartier-Kastler et al. 2011; RFI (Coloplast Ltd)	Fader (BJU Int, 2001; 373-377)	<u>Intervention:</u> Comparison of EasiCath and LoFric (basic hydrophilic) and AquaCath and Silky (not on drug tariff and therefore EAG unable to confirm presence of additional features).
60.	EAG literature search (economic)	Faleiros (Rehab Nurs, 2018; 46-51)	<u>Population:</u> included children
61.	Primary evidence included in SR by Barken et al. 2022; EAG literature search (economic)	Feng (Asian J Surg, 2020; 633-635)	<u>Study design:</u> Systematic review. EAG considered primary evidence
62.	RFI (Hollister Ltd)	Fergusson (2017, Journal of Stomal Therapy Australia; 18-19)	<u>Study design:</u> Case report (n=1)
63.	EAG literature search (clinical)	Fernandez-Lasquetty (J Clin Med, 2023; 2928)	<u>Intervention:</u> Mixed intervention (results not separated)
64.	RFI (Teleflex)	Gamé (Prog Urol, 2020; 1134-1139)	<u>Study design:</u> single arm (Liquick Base)
65.	RFI (Convatec Ltd)	Ganesan (BJU Int, 2017, 919-925)	<u>Intervention/Comparator:</u> device NR
66.	EAG literature search (SRs)	Gauhar (J Clin Med, 2022; 4463)	<u>Study design:</u> Systematic review <u>Intervention:</u> coated indwelling catheter <u>Comparator:</u> uncoated indwelling catheter

#	Source	Author (year); country †Abstract	Reasons for exclusion
67.	Primary evidence included in SR by Ye et al. 2021	Giannantoni (J Urol, 2001; 130-133)	<u>Intervention</u> : gel-lubricated single-use <u>Comparator</u> : uncoated single-use EAG assume comparison of basic feature catheters only.
68.	RFI (Bard Ltd)	Gloekner (2017, Internal White Paper)	<u>Study design</u> : bench test
69.	RFI (Teleflex)	Goessaer (2013, J Advance Nurs; 2000-2007)	<u>Population</u> : caregivers and student nurses
70.	EAG literature search (economic)	Goldstine (Wound, Ostomy, Contin Nurs Soc, 2019; 513-518)	<u>Outcome</u> : barriers and facilitators to intermittent catheterisation [See section 4.2.4]
71.	RFI (B. Braun Medical Ltd)	Gonzalez Chiappe (2016, Neurourol Urodyn; 528-534)	<u>Comparator</u> : cannot separate out device type(s)
72.	RFI Hollister Ltd	Gordon (2024, International Continence Society, Madrid; 634) [abstract]	<u>Intervention</u> : devices not named
73.	EAG literature search (economic)	Gray (Wound, Ostomy, Continence Nurse Soc, 2023; 443-444)	<u>Study design</u> : Editorial
74.	EAG literature search (economic)	Gray (Wound, Ostomy, Continence Nurse Soc, 2019; 477-478)	<u>Study design</u> : Editorial
75.	RFI (Teleflex)	Grosch (2017, Contact Dermatitis; 186–187)	<u>Study design</u> : single arm (Safetecath Active)
76.	RFI (Hollister Ltd)	Haire (2020, Hollister Ltd ref-03102)	<u>Study design</u> : n<10 patients. No further publication details
77.	Primary evidence included in SR by Barken et al. 2022	Håkansson (2014, Rev Curre Status Spinal Cord; 511-516)	<u>Study design</u> : Narrative review
78.	RFI (Wellspect HealthCare)	Håkansson (2015, Urol Nurs; 239-247)	<u>Intervention</u> : LoFric family of catheters (catheters not separated, different features present).
79.	RFI (Wellspect HealthCare)	Wellspect HealthCare “1.Håkansson (2015), Europe and the USA”	Cannot retrieve with information provided (potential overlap with Håkansson (2015, Urol Nurs; 239-247))
80.	EAG literature search (clinical)	Hannibalsen (Urologic Nurs, 2023; 300)	<u>Comparator</u> : mixed (SpeediCath Flex, Coloplast Ltd or VaPro, Hollister Ltd)
81.	RFI (Convatec Ltd)	Hasan (2022, World J Urol; 483-487)	<u>Comparator</u> : not in scope

#	Source	Author (year); country †Abstract	Reasons for exclusion
82.	Primary evidence included in SR by Barken et al. 2022	Hedlund (Scand J Urol Nephrol, 2001; 49-53)	<u>Study design</u> : Opinion review
83.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Hellstrom (Eur Urol, 1991; 117-121)	<u>Study design</u> : single arm
84.	EAG literature search (economic)	Herbert (Int J Environmental Res Public Health, 2023; 6079)	<u>Study design</u> : Narrative review
85.	EAG literature search (economic)	Herve (Neurolurol Urodyn, 2018; S1378-S1379)	<u>Outcome</u> : Factors influencing choice of intermittent catheterisation (survey of urologists)
86.	Primary evidence included in SR by Barken et al. 2022	Hill (Can Urol Assoc J, 2013; 122)	<u>Study design</u> : Narrative review (non-systematic)
87.	RFI (Hollister Ltd)	Hollister Ltd IMPACT Study II US Q1711 Final Report CiC	<u>Study design</u> : [REDACTED]
88.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "FMR Global, Hollister Ltd Incorporated Data on file. User evaluation of VaPro"	<u>Study design</u> : [REDACTED]
89.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "User preference study to compare a 40cm intermittent catheter to a 30cm"	<u>Comparator</u> : [REDACTED]
90.	RFI (Hollister Ltd)	Newman (Consortium of Multiple Sclerosis Centers, 2024) [poster]	<u>Intervention</u> : device not reported (No further publication details supplied by company)
91.	RFI (Hollister Ltd)	Onli product evaluation, Italy and Spain LCR-00646	<u>Study design</u> : internal company report, single arm <u>Intervention</u> : Onli device not on drug tariff.
92.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "3495-ID Report USICSysUSArm"	<u>Study design</u> : [REDACTED]
93.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "3519-IC Report US Final"	<u>Study design</u> : [REDACTED]

#	Source	Author (year); country †Abstract	Reasons for exclusion
94.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "3488-ICE Report IncureAdvand AdvPlus"	Study design: [REDACTED] for primary outcome)
95.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "Hollister Ltd Incorporated Data on file. User appreciation of the characteristics"	Study design: [REDACTED]
96.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "Hollister Ltd Incorporated Data on file. User assessment of a hydrophilic male"	Study design: [REDACTED]
97.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "Hollister Ltd Incorporated Data on file. Final Report: VaPro Intermittent Catheter"	Study design: [REDACTED]
98.	RFI (Hollister Ltd)	Hollister Ltd [CiC] "Hollister Ltd Incorporated Data on file. VaPro 2 40 cm"	Study design: [REDACTED]
99.	RFI (Hollister Ltd)	Hollister Ltd "InfynaChic GlobalProductEval IE FinalReport"	Study design: internal company report, non comparative product evaluation
100.	RFI (Hollister Ltd)	Hollister Ltd "Microbial containment purse/handbag study"	Study design: internal company report, in vitro, liquid inoculum prepared in lab, placed in case, into handbag
101.	RFI (Hollister Ltd)	Hollister Ltd "Infyna Chic odour containment study"	Population: internal company report, clinician cohort judgement
102.	RFI (CliniMed Ltd)	Holroyd (Br J Nurs, 2018; S4-S10)	Study design: procedural narrative review
103.	RFI Hollister Ltd	Hudson (Spinal Cord, 2005; 611-614)	Study design: in vitro, bacteria transfer using no-touch method
104.	RFI (Convatec Ltd)	Irwin (ICS Madrid, 2024; S346) [abstract]	Study design: pig model
105.	Primary evidence included in SR by Feng et al. 2020; Shamout et al. 2017 and RFI (ClinMed); EAG literature search (clinical)	Johansson (Scand J Urol, 2012; 33-37) [NCT01295281]	Comparator: PVC unnamed (EAG unable to confirm presence of innovative features)
106.	RFI (Convatec Ltd)	Julinová (J Environ Manage, 2018; 213- 222)	Study design: environmental impact narrative review
107.	RFI (Convatec Ltd)	Kathiresan (Spinal Cord, 2012; 891-894)	Intervention: method of ejaculation, not catheters

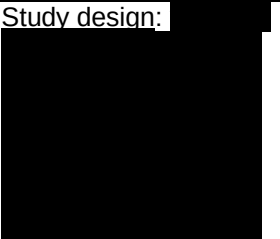
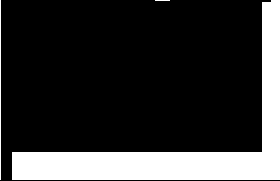
#	Source	Author (year); country †Abstract	Reasons for exclusion
108.	RFI (Convatec Ltd)	Kato (Reprod Med Biol, 2012; 165-176)	<u>Study design</u> : technical review
109.	RFI (Convatec Ltd)	Kato (Theriogenology, 2009; 624-635)	<u>Study design</u> : animal model
110.	Primary evidence included in SR by Barken et al. 2022	Kennelly (Adv Urol, 2019; 2757862)	<u>Study design</u> : Narrative review (non-systematic)
111.	Primary evidence included in SR by Prieto et al. 2021	Kiddoo (Ped Urol, 2015; 174-179)	<u>Population</u> : children
112.	Primary evidence included in SR by Prieto et al. 2021	King (Arch Phys Med Rehab, 1992; 798-802)	<u>Comparator</u> : single-use compared with multi-use.
113.	RFI (Wellspect HealthCare)	Koeter (Nurs Open, 2019; 116-125)	<u>Study design</u> : single arm (LoFric Origo)
114.	EAG literature search (clinical)	Ko (Int Neurourol J, 2022; 308-316)	<u>Study design</u> : single arm (SpeediCath)
115.	RFI (Convatec Ltd)	Kurakula (J Drug Deliv Sci Technol, 2020; 102046)	<u>Study design</u> : technical assessment not of catheters
116.	EAG literature search (economic)	Lamin (Int Urol Nephrol, 2016; 931-939)	<u>Study design</u> : narrative review
117.	RFI (B. Braun Medical Ltd)	Lampuré (2020 Report 2597294) [CiC]	<u>Study design</u> : subset of data in public domain in Chartier-Kastler (2022, Eur Urol Open Sci; 79-87) which was subsequently excluded. 
118.	EAG literature search (clinical)	Landauro (J Wound Ostomy Continence, 2023; 504-511)	<u>Study design</u> : Erratum (of included paper)
119.	RFI (Peak Medical Ltd)	Lapides (J Urol, 1972; 458-461)	<u>Study design</u> : historical case examples
120.	Primary evidence included in SR by Prieto et al. 2021	Leek (Australian and New Zealand Continence Journal, 2019; 64-73)	<u>Intervention</u> : uncoated multi-use <u>Comparator</u> : uncoated single-use
121.	Primary evidence included in SR by Ye et al. 2021	Leek (Neurourol Urodyn, 2013; 759-760)	<u>Intervention</u> : uncoated multi-use <u>Comparator</u> : uncoated single-use

#	Source	Author (year); country †Abstract	Reasons for exclusion
122.	Primary evidence included in SR by Prieto et al. 2021, Barken et al. 2022; RFI (Coloplast)	Leriche (Prog Urol, 2006; 347-351)	<u>Language</u> : Non-English (French); lack of detail of study methodology in translated Abstract; comparison of SpeediCath Set and Actreen Set (components of set unclear)
123.	EAG literature search (economic)	Lim (Neurolurol Urodyn, 2016; 395-399)	<u>Population</u> : paediatric <u>Outcome</u> : perceived barriers and facilitators or intermittent catheterisation
124.	Primary evidence included in SR by Barken et al. 2022	Li (Arch Phys Med Rehabil, 2013; 782-787)	<u>Study design</u> : Systematic review. EAG reviewed primary evidence.
125.	RFI (B. Braun Medical Ltd)	Lin (Annu Rev Microbio, 1976; 535-578)	<u>Study design</u> : chemical review of glycerol dissimulation and regulation in bacteria
126.	Primary evidence included in SR by Barken et al. 2022, and Chartier-Kastler et al. 2011	Lindehall (J Urol, 2004; 1686-8)	<u>Population</u> : Children <u>Intervention</u> : Device unnamed (EAG unable to confirm presence of additional features)
127.	EAG literature search (clinical)	Litherland (Tidsskr Nor Laegeforen, 2006; 153-154)	<u>Language</u> : non-English (Norwegian) <u>Duplicate</u> : n=196 patients, same number as reported in Litherland (Br J Nurs, 2007; 284-287); which was included by the EAG.
128.	EAG literature search (clinical)	Litherland (Br J Nurs, 2007; 284-287)	<u>Population</u> : not long-term intermittent catheterisation (catheterised as part of their gynaecological outpatient department; many never catheterised before)
129.	EAG literature search (clinical)	Logan (Br J Nurs, 2017; 82-88)	<u>Study design</u> : single arm
130.	RFI (Bard Ltd)	Logan (Br J Nurs, 2015; S30, S32-S34)	<u>Study design</u> : single arm (HydroSil gripper)
131.	Primary evidence included in SR by Ye et al. 2021; EAG literature search (clinical)	Lucas (J Pediatr Urol, 2016; 172 e1-8) [NCT01305681]	<u>Population</u> : Includes mixture of children and adults (age range 1 to 42 years)

#	Source	Author (year); country †Abstract	Reasons for exclusion
132.	Primary evidence included in SR by Prieto et al. 2021	Madero-Morales (J Urol, 2019; 153-158)	<u>Population</u> : Included children and adults (age range 2-56 years) <u>Comparator</u> : comparison of single and multiple use PVC catheters (devices not named in Prieto et al.)
133.	Primary evidence included in SR by Barken et al. 2022; EAG literature search (economic)	Madersbacher (Curr Bladder Dysfunct Rep, 2017; 349-353)	<u>Study design</u> : Narrative review (non-systematic)
134.	Primary evidence included in SR by Plata et al. 2023; Barken et al. 2022; Rognoni et al. 2017	Massa (J Spinal Cord Med, 2009; 568-573)	<u>Intervention</u> , <u>Comparator</u> : Unnamed (EAG unable to confirm presence of features)
135.	Primary evidence included in SR by Shamout et al. 2017	Mauroy (Ann Urol (Paris), 2001; 223-228)	<u>Language</u> : article in French
136.	EAG literature search (economic)	McClurg (Neurourol Urodynam, 2015; S311)	<u>Outcome</u> : factors affecting the continuity of use of intermittent self-catheterisation
137.	EAG literature search (economic)	Meconi (CADTH, 2020)	<u>Intervention</u> : local anaesthesia for urinary catheterisation
138.	EAG literature search (economic)	Meconi (CADTH, 2020)	<u>Intervention</u> : local anaesthesia for urinary catheterisation
139.	RFI (Convatec Ltd)	Meredith (ICS Madrid, 2024; S248) [abstract]	<u>Study design</u> : bench test
140.	RFI (Convatec Ltd)	Meredith (ICS Toronto, 2023; S139) [abstract]	<u>Study design</u> : bench test
141.	EAG literature search (clinical)	Moore (Evidence Based Nursing, 2010; 45-46)	<u>Study design</u> : commentary on Cardenas (Arch Phys Med Rehab, 2009; 1668-1671)
142.	EAG literature search (clinical)	Moore (Neurourol Urodynamics, 2009; 772-773)	<u>Abstract</u> : limited information
143.	Primary evidence included in SR by Prieto et al. 2021	Moore (Clin Rehab, 2006; 461-468)	<u>Comparator</u> : comparison of clean and sterile techniques (devices not named in Prieto et al.)
144.	Primary evidence included in SR by Prieto et al. 2021	Moore (Rehab Nurs, 1993; 306-309)	<u>Population</u> : exclusively in children (age 3-16 years) <u>Comparator</u> : comparison of single and multiple use PVC catheters (devices not named in Prieto et al.)
145.	RFI (B. Braun Medical Ltd)	Morcillo Marín (Rev ROL Enferm, 2022; 659-664)	<u>Language</u> : Spanish

#	Source	Author (year); country †Abstract	Reasons for exclusion
146.	EAG literature search (economic)	Murphy (Proc Instit Mech Engineer, 2019; 48-57)	<u>Study design:</u> narrative review
147.	EAG literature search (clinical)	Nazarko (Br J Nurs, 2010; S4-S6)	<u>Study design:</u> narrative review
148.	EAG literature search (clinical)	NCT00324233	<u>Population:</u> healthy volunteers
149.	EAG literature search (clinical)	NCT00804557	<u>Intervention:</u> Uro-Ease (not on Drug Tariff, EAG unable to confirm presence of features)
150.	EAG literature search (clinical)	NCT00832078	<u>Population:</u> healthy volunteers <u>Comparator:</u> Non-CE marked devices
151.	EAG literature search (clinical)	NCT01292941	<u>Population:</u> healthy volunteers <u>Comparator:</u> Non-CE marked devices
152.	EAG literature search (clinical)	NCT01523743	<u>Duplicate:</u> trial registration of studies already included in clinical evidence section: Chartier- Kastler et al (J Urol 2013; 942-947)
153.	EAG literature search (clinical)	NCT01800903	<u>Population:</u> Healthy volunteers <u>Intervention:</u> ZN-C, ZN-D new coatings (not on Drug Tariff, EAG unable to confirm presence of features)
154.	EAG literature search (clinical)	NCT02697162	<u>Intervention:</u> GuardianCath (not on Drug Tariff, EAG unable to confirm presence of features)
155.	EAG literature search (clinical)	NCT02965066	<u>Intervention:</u> non- commercially available (test catheter)
156.	EAG literature search (clinical)	NCT00318591	<u>Duplicate:</u> trial registration of (Cardenas (PMR, 2011; 408-417)
157.	EAG literature search (clinical)	NCT03684941	<u>Intervention:</u> non- commercially available coating
158.	EAG literature search (clinical)	NCT04231149	<u>Comparator:</u> undefined (unable to confirm presence of features)
159.	EAG literature search (clinical)	NCT05224544	<u>Population:</u> healthy volunteers only
160.	EAG literature search (clinical)	NCT05408533	<u>Intervention:</u> indwelling catheter

#	Source	Author (year); country †Abstract	Reasons for exclusion
161.	EAG literature search (clinical)	NCT05485922	<u>Duplicate</u> : Study registration of included study: Landauro (J Clin Med, 2023; 5266)
162.	EAG literature search (clinical)	NCT05485935	<u>Duplicate</u> : Study registration of included study: Thiruchelvam (Neurourol Urodynamics, 2024; 464-478)
163.	EAG literature search (clinical)	NCT05814211	<u>Duplicate</u> : Study registration of included study: Thiruchelvam (Br J Nursing, 2024; 834-843)
164.	EAG literature search (clinical)	NCT05848037	<u>Intervention</u> : indwelling catheter
165.	Primary evidence included in SR by Barken et al. 2022	Newman (Int Urol Nephrol, 2020; 1443-1451)	<u>Intervention</u> : mixture of catheters <u>Comparator</u> : reusable catheters
166.	Primary evidence included in SR by Barken et al. 2022	Newman (Neurourol Urodyn Suppl ICS, 2018; S135-136)	<u>Intervention</u> : catheter not named <u>Comparator</u> : reusable catheters
167.	Primary evidence included in SR by Barken et al. 2022	Neovius (Value Health, 2015; A52)	<u>Intervention</u> : Device name not reported; EAG unable to confirm presence of innovative features.
168.	RFI (Wellspect HealthCare)	Newman (Int Urol Nephrol, 2020; 1443-1451)	<u>Comparator</u> : reuse of catheters
169.	Primary evidence included in SR by Barken et al. 2022	Nicolle (Antimicrob Resist Infect Control, 2014; 8)	<u>Study design</u> : Opinion review
170.	EAG literature search (economic)	Nyman (Int J Nurs Studies, 2013; 1589-1598)	<u>Comparator</u> : Indwelling catheters
171.	RFI Hollister Ltd	O'Neil (The Australian & New Zealand journal of obstetrics & gynaecology, 1982; 151-152)	<u>Intervention</u> : catheter with no additional features
172.	Primary evidence included in SR by Barken et al. 2022	Health Quality Ontario (2006)	<u>Duplicate</u> : Replaced with Health Quality Ontario (2019)
173.	EAG literature search (economic)	Health Quality Ontario (2019; 1-153)	<u>Study design</u> : Systematic review. EAG reviewed primary evidence
174.	RFI (CliniMed Ltd)	Orme (ND, Company Clinical Report - Curan Lady) [CiC]	<u>Study design</u> : [REDACTED]
175.	RFI (CliniMed Ltd)	Orme (ND, Company Clinical Report - Curan Advantage) [CiC]	<u>Study design</u> : [REDACTED]

#	Source	Author (year); country †Abstract	Reasons for exclusion
176.	Primary evidence included in SR by Plata et al. 2023	Pachler (BJU Int, 1999; 767-769)	<u>Comparator</u> : comparing single-use with multi use.
177.	EAG literature search (economic)	Patel (Curr Bladder Dysfunction Rep, 2018; 215-223)	<u>Study design</u> : Narrative review
178.	Primary evidence included in SR by Shamout et al. 2017	Pearman (Br J Urol, 1991; 483-490)	<u>Intervention</u> : O'Neil (not available on drug tariff; unable to confirm presence of additional features).
179.	RFI (Pennine Healthcare)	Pennine Healthcare "User Post Market Information Pennine Intermittent Urethral Catheters"	<u>Intervention</u> : technology not in scope
180.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Pettersson-Hammerstad (J Urol, 2008; 187-191)	<u>Study design</u> : single arm (all treated with LoFric, main focus of paper is glomerular filtration rate over time)
181.	RFI (Convatec Ltd)	Place, J. (Br J Nurs, 2018; S2-S20)	<u>Study design</u> : product review, no comparator
182.	EAG literature search (clinical)	Plata (World J Urol, 2023; 491-499)	<u>Study design</u> : Systematic review with meta-analysis, includes studies in children and studies comparing hydrophilic with uncoated. EAG have reviewed all primary evidence separately.
183.	RFI (Convatec Ltd)	Pollard [CiC] (Internal Technical Assessment, 2024; WHRI8695 TA2057)	<u>Study design</u> : 
184.	RFI (Convatec Ltd)	Pollard [CiC] (Internal Technical Assessment, 2024; WHRI9439 TA2728)	<u>Study design</u> : 
185.	RFI (Convatec Ltd)	Pollard (Biotribology, 2022; 100223)	<u>Study design</u> : in vitro, agar model, compare catheters potential sticking and shedding of the surface on removal

#	Source	Author (year); country †Abstract	Reasons for exclusion
186.	EAG literature search (economic)	Polliack (Spinal Cord, 2005; 615-619)	<u>Intervention</u> : volume-dependent intermittent catheterisation <u>Comparator</u> : time-dependent intermittent catheterisation
187.	Primary evidence in SR Barken et al. 2022	Prieto (Cochrane Database Syst Rev, 2014)	<u>Duplicate</u> : retracted by 2017 version, replaced by 2021 version.
188.	EAG literature search (clinical)	Prieto (Neurourol Urodynamic, 2014; 861-862)	<u>Duplicate</u>
189.	EAG literature search (clinical)	Prieto (Neurourol Urodynamic, 2015; 648-653)	<u>Duplicate</u>
190.	EAG literature search (clinical, economic)	Prieto (Cochrane Database Syst Rev, 2021; CD006008)	<u>Study design</u> : Systematic review with meta-analysis, includes studies in children and studies comparing single and reusable catheters, and hydrophilic and uncoated. EAG have reviewed all primary evidence separately. No cost effectiveness analysis conducted.
191.	Primary evidence included in SR by Prieto et al. 2021	Prieto-Fingerhut (Rehab Nurs, 1997; 299-302)	<u>Intervention</u> : O'Neil, gel-reservoir, uncoated, single-use, sterile <u>Comparator</u> : uncoated, multi-use, clean (devices not named in Prieto et al.)
192.	EAG literature search (SR)	Quallich (J Wound Ostomy Cont Nurs Soc, 2023; 497-501)	<u>Intervention</u> : focus on effectiveness of education
193.	Primary evidence included in SR by Ye et al. 2021	Quigley (Rehab Nurs, 1993; 26-29)	<u>Intervention</u> : gel-lubricated single-use <u>Comparator</u> : uncoated single-use EAG assume comparison of basic feature catheters only.
194.	EAG literature search (clinical)	RBR-32592zd	<u>Study design</u> : trial registration <u>Intervention</u> : Indwelling catheter
195.	RFI (B. Braun Medical Ltd)	Rew (Br J Nurs, 2013; S12, S14-18)	<u>Study design</u> : single arm (Actreen)
196.	RFI (B. Braun Medical Ltd)	Rew (Br J Neuroscie Nurs, 2007; 54-60)	<u>Study design</u> : review

#	Source	Author (year); country †Abstract	Reasons for exclusion
197.	RFI (B. Braun Medical Ltd)	Rew (Br J Nurs, 2018; S18-S25);	<u>Intervention</u> : Catheters combined. Aim of the study was to determine awareness and usage of Tiemann tip.
198.	RFI (CliniMed Ltd)	Rigby (Nursing Times, 2014, p.15-17)	<u>Intervention and comparator</u> : device NR
199.	EAG literature search (clinical, economic)	Roberson (Neurourol Urodynam, 2021; 2008-2019)	<u>Intervention</u> : Mixed intervention (outcomes reported across all catheters)
200.	Primary evidence included in SR by Barken et al. 2022; EAG literature search (clinical, economic)	Rognoni (BMC Urology; 2017; 4-14)	<u>Study design</u> : Systematic review with meta-analysis. EAG considered primary evidence.
201.	Primary evidence included in SR by Barken et al. 2022	Romo (World J Urol, 2018; 1555-1568)	<u>Study design</u> : Literature review (non-systematic)
202.	EAG literature search (economic)	Saadat (Can Urol Assoc J, 2019; 64-69)	<u>Study design</u> : Systematic review (mixed comparator). EAG reviewed primary evidence.
203.	RFI (B. Braun Medical Ltd)	Saegeman (Burns, 2008; 205-211)	<u>Study design</u> : cadveric
204.	Primary evidence included in SR by Barken et al. 2022	Salameh (CMAJ, 2015; 807-811)	<u>Study design</u> : Narrative review (non-systematic)
205.	Primary evidence included in SR by Prieto et al. 2021, Barken et al. 2022	Samal (Ceska Urologie, 2011; 229-236)	<u>Language</u> : Not available in English
206.	Primary evidence included in SR by Barken et al. 2022	Samal (Eur Urol Suppl, 2012; 101) [Abstract]	<u>Intervention</u> : devices not named (EAG unable to confirm presence of innovative features)
207.	RFI (B. Braun Medical Ltd)	Santos-Pérez de la Blanca (J Wound Ostomy Continence Nurs, 2023; 400-405)	<u>Study design</u> : Cross sectional not separated out by valve type
208.	Primary evidence included in SR by Prieto et al. 2021	Schlager (Pediatrics, 2001; E71)	<u>Population</u> : paediatric <u>Intervention</u> : uncoated, single-use), clean <u>Comparator</u> : uncoated, multi-use, clean (devices not named in Prieto et al.)
209.	RFI (Coloplast)	Schröder (Sci Rep, 2024; 2268)	<u>Study design</u> : pig model
210.	Primary evidence included in SR by Shamout et al. 2017	Sekiguchi (Int J Urol, 2007; 426-430)	<u>Intervention</u> : TiO2 coated reusable <u>Comparator</u> : conventional reusable

#	Source	Author (year); country †Abstract	Reasons for exclusion
211.	Primary evidence included in SR by Barken et al. 2022	Selius (Am Fam Phys, 2008; 643-650)	<u>Study design:</u> Narrative review (non-systematic)
212.	EAG literature search (economics)	Shamout (Spinal Cord, 2023; 269-275)	<u>Comparator:</u> Indwelling and suprapubic catheter
213.	EAG literature search (economic)	Shamout (Can Urol Assoc J, 2021; S139)	<u>Duplicate:</u> Poster of full paper: Shamout (Spinal Cord, 2023; 269-275)
214.	Primary evidence included in SR by Barken et al. 2022; EAG literature search (economic)	Shamout (Spinal Cord, 2017; 629-643)	<u>Study design:</u> Systematic review. EAG considered primary evidence.
215.	EAG literature search (clinical)	Sharma (J Urol, 2014; 874-875)	<u>Study design:</u> comment on Chartier-Kastler (J Urol, 2013; 942-947)
216.	RFI (Convatec Ltd, Hollister)	Skountrianos (2024, International Continence Society, Madrid; S261) [abstract]	<u>Intervention:</u> Catheters not reported. Aim of study is to determine presence of mucous and sediment among individuals using ISC in relation to UTI incidence.
217.	Primary evidence included in SR by Barken et al. 2022	Spinu (J Med Life, 2012; 21-28)	<u>Intervention:</u> comparison of hydrophilic with uncoated, however devices unnamed therefore EAG unable to confirm whether additional features present.
218.	RFI (Coloplast)	Stærk (BJUI Compass, 2024; 217-223)	<u>Study design:</u> pig model
219.	EAG literature search (economic)	Stafford (Br J Comm Nurs, 2017; 214-217)	<u>Study design:</u> comment
220.	Primary evidence included in SR by Ye et al. 2021; Barken et al. 2022; Feng et al. 2020	Stensballe (Eur Urol, 2005; 978-983)	<u>Population:</u> healthy volunteers only
221.	RFI (Coloplast Ltd)	Stewart (J Pediatr Urol, 2017; e371-377 e376)	<u>Study design:</u> bench test
222.	RFI (Wellspect HealthCare)	Stripple (2008, Journal of Cleaner Production; 1764-1776)	<u>Study design:</u> ecological and environmental impact of polymers
223.	RFI (Wellspect HealthCare)	Sundqvist (CiC)	<u>Study design:</u> [REDACTED]
224.	Primary evidence included in SR by Prieto et al. 2021	Sutherland (J Urol, 1996; 2041-2043)	<u>Population:</u> paediatric <u>Comparator:</u> Mentor (uncoated, multi-use)

#	Source	Author (year); country †Abstract	Reasons for exclusion
225.	Primary evidence included in SR by Barken et al. 2022	Tambyah (Curr Opin Infect Dis, 2012; 365-370)	<u>Study design</u> : Narrative review (non-systematic)
226.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Taskinen (J Pediatr Urol, 2008; 367-371)	<u>Population</u> : included paediatrics
227.	RFI (Teleflex)	Teleflex "guideline by Vahr et al"	<u>Study design</u> : national guidance document
228.	Teleflex	Teleflex "Antolini, flocath quick montecatone study - 1 english"	<u>Study design</u> : company report, comparator NR
229.	Teleflex	Teleflex "Moroni, Flocath quick Italian Study October 2004"	<u>Study design</u> : company report, comparator NR
230.	Teleflex	Teleflex "Mantiero, AbstrSIUDInfermiere flocath ISC TFX - Copy"	<u>Population</u> : no breakdown of age or if parents completed questionnaire - likely as age 4 years upwards.
231.	Primary evidence included in SR by Barken et al. 2022	Tenke (Curr Opin Infect Dis, 2014; 102-107)	<u>Study design</u> : Opinion review
232.	EAG literature search (economic)	Tradewell (Translational Andro Urol, 2018; S205-219)	<u>Study design</u> : Systematic review. EAG reviewed primary evidence.
233.	EAG literature search (clinical)	UMIN000022591	<u>Intervention</u> , <u>Comparator</u> : unnamed (EAG unable to confirm presence of features)
234.	RFI (Convatec Ltd)	Vaidyanathan (Spinal Cord, 2005; 269-277)	<u>Study design</u> : case report
235.	EAG literature search (economic)	van Doorn (BMJ Open, 2022; e056649)	<u>Study design</u> : protocol <u>Comparator</u> : comparison of single and reusable intermittent catheters
236.	Primary evidence included in SR by Prieto et al. 2021	Vapnek (J Urol, 2003; 994-998)	<u>Comparator</u> : hydrophilic single-use compared with uncoated multi-use.
237.	RFI (Convatec Ltd)	Velaer (Top Spinal Cord Inj Rehabil, 2021; 83-91)	<u>Study design</u> : survey undifferentiated by catheter type
238.	EAG literature search (SRs)	Vopni (Urology Practice, 2021, 705-712)	<u>Study design</u> : SR <u>Intervention</u> : coated indwelling catheters <u>Comparator</u> : uncoated indwelling catheters
239.	Primary evidence included in SR by Chartier-Kastler et al. 2011	Waller (J Urol, 1995; 345-348)	<u>Study design</u> : single arm (LoFric)
240.	EAG literature search (clinical)	Walter (Neurourol Urodynam, 2021; S130-S131) [abstract 82]	<u>Duplicate</u> : Abstract of Gopalakrishnan (Continence Reports, 2022; 10010)

#	Source	Author (year); country †Abstract	Reasons for exclusion
241.	EAG literature search (economic)	Wein (J Urol, 2015; 1644)	<u>Study design:</u> Editorial
242.	EAG literature search (economic)	Welk (Neurol Urodyn, 2021; 1643-1650)	<u>Outcomes:</u> choices of bladder management post spinal injury
243.	EAG literature search (economic)	Welk (Neurol Urodyn, 2022; 1002-1011)	<u>Intervention:</u> mixed intervention (catheters not differentiated)
244.	RFI (Wellspect HealthCare)	Wellspect HealthCare [CiC] "Analysis II LoFric Elle"	<u>Study design:</u> [REDACTED]
245.	RFI (Wellspect HealthCare)	Wellspect HealthCare [CiC] "Analysis II LoFric Elle Users"	<u>Study design:</u> [REDACTED]
246.	EAG literature search (economic)	Weynants (Int Neurourol J, 2017; 189-196)	<u>Outcome:</u> factors contributing to offering intermittent catheterisation (survey of urologists)
247.	RFI (Coloplast)	Willumsen (Sci Rep, 2024; 15035)	<u>Study design:</u> pig model
248.	RFI (CliniMed Ltd)	Wilson (Br J Nurs, 2015; 76, 78, S80)	<u>Study design:</u> procedure review
249.	Primary evidence included in SR by Shamout et al. 2017	Witjes (J Urol, 2009; 2794-2798)	<u>Comparator:</u> PVC-free catheter (unnamed); EAG unable to confirm presence of features
250.	EAG literature search (clinical)	Witjes (Neurolurol Urodynamics, 2008; 688-689)	<u>Duplicate:</u> abstract of Witjes (J Urol, 2009; 2794-2798)
251.	EAG literature search (clinical)	Wolff (Neurolurol Urodynamics, 2015; S37-S38)	<u>Study design:</u> survey of urologists
252.	Primary evidence included in SR by Barken et al. 2022; Chartier-Kastler et al. 2011	Woodbury (Can J Urol, 2008; 4065-72)	<u>Study design:</u> Survey of users on intermittent catheters, not specific to catheter device.
253.	RFI (CliniMed Ltd)	Woodward (Br J Nurs, 2013; S20, S22-S25)	<u>Study design:</u> Narrative review, including case reports (N=3).
254.	Primary evidence included in SR by Barken et al. 2022	Wyndaele (Spinal Cord, 2000; 97-99)	<u>Intervention:</u> Urocathe-Gel, not available on Drug Tariff; EAG unable to confirm whether additional features present.
255.	Primary evidence included in SR by Barken et al. 2022	Wyndaele (Spinal Cord, 2002; 536-541)	<u>Study design:</u> Opinion review
256.	EAG literature search (economic)	Xi (BJUI Compass, 2020; 71-81)	<u>Study design:</u> Systematic review of economic evaluations. EAG have reviewed all primary evidence separately.

#	Source	Author (year); country †Abstract	Reasons for exclusion
257.	Barken (BMC Urol, 2022; 1-18)	Yamanishi (Int Urogynecol, 2017; S261)	<u>Study design</u> : abstract with no results <u>Comparator</u> : mixed reusable & single-use combined
258.	EAG literature search (clinical)	Yang (PMR, 2011; 418)	<u>Study design</u> : commentary
259.	RFI (CliniMed Ltd)	Yates (2013; Nursing Times; 22-25)	<u>Study design</u> : procedural narrative review
260.	EAG literature search (clinical)	Ye (Spinal Cord, 2021; 587-595)	<u>Study design</u> : Systematic review with meta-analysis, comparing coated with uncoated, and single and multi-use. EAG have reviewed all primary evidence separately.
261.	Primary evidence included in SR by Barken et al. 2022; EAG literature search (economic)	Ye (J Endourol, 2019; 114-115) [abstract]	<u>Duplicate</u> : Abstract of full paper (already reviewed for relevance to decision problem).
262.	EAG literature search (clinical)	Ye (Eur Urol, 2019; e1198) [abstract]	<u>Duplicate</u> : Abstract of full paper (already reviewed for relevance to decision problem).
263.	Primary evidence included in SR by Barken et al. 2022 RFI (Coloplast Ltd)	Yoshida (J Jpn Soc Wound Ostomy Cont Manag, 2018; 335-344)	<u>Comparator</u> : Safeed (uncoated PVC catheter); not available on drug tariff, EAG unable to confirm presence of features
264.	EAG literature search (economic)	Zhao (Value in Health, 2019; S385) [abstract]	<u>Intervention</u> : Patient support program (Coloplast Ltd)

Abbreviations: EAG External assessment group, ISC, Intermittent self-catheterisation; NR, not reported; PVC Polyvinyl chloride; RFI Request for information, UTI, urinary tract infection.

Appendix D: Correspondence with clinical experts

Questions sent 18/10/2024

#	Date responses received	Name, Affiliation
1	23/10/2024	[REDACTED]
2	23/10/2024	[REDACTED]
3	23/10/2024	[REDACTED]
4	23/10/2024	[REDACTED]

Question 1	Is there a national registry capturing information on intermittent catheters in <u>community or primary care setting</u> or <u>secondary care setting</u> in the UK?
Expert 1:	No there is no national registry that I am aware of. Individual HB's etc may be able to gain how many individuals use ISC by the implementation of a company delivery service and data base which may record prescriptions, but this is not universal
Expert 2:	No
Expert 3:	No
Expert 4:	No response
Question 2	What key clinical or patient features are considered when selecting a intermittent catheter?
Expert 1:	Patient manual dexterity, if they require aids, if they need different sorts i.e. at home compared with work / out (this could be whether they need a fixed bag/ bag attachment or not, or need lubrication or are self lubricating), lubrication type and access to this i.e. do they need access to water if out? Infection control and ease of manipulation if they have sleeves, rigidity of catheter for ease of insertion, whether individual can undertake procedure independently or require another person to undertake. This is very individual as each patient may require different clinical features, and also may require them at different times
Expert 2:	How easy do they find it to use: this has a few components: - Is it easy to carry around with them? - Is it easy to 'prep' the catheter? - Is it easy to open? Is it easy to insert – - in men, with either enlarged prostates or tortuous urethras – one of the key features I look for is the catheter tip. I also tend to avoid products that are difficult to handle – sleeves are very tricky to use, and seem to require too many hands. - In women, with high tone non relaxing sphincters (those women who find ISC painful – which is a small minority), again I would look at the tip of the catheter and how it is lubricated
Expert 3:	No response
Expert 4:	No response

Question 3	Additional innovative features of intermittent catheters are outlined in the NICE Final Scope, however more have been suggested by the companies in their documentation provided to the EAG. Are the following features considered innovative and of importance when choosing an appropriate intermittent catheter for a patient: 1. Recyclable components 2. Ability to connect to an external draining bag (when one is not included as part of a “kit”) 3. Universal connector for attaching to an external drain bag 4. “ready to use” [Comes out of the packaging ready and does not need to “wetted” with either an integrated or external solution] 5. Polished eyelets [Note: this seem to be a common feature that is highlighted in a lot of the company submission. Is this considered innovative by it’s own right (or do all catheters have polished eyelets)? Or is the method of polishing innovative for example fire polishing something that would inform catheter choice?] 6. Anti-reflux valves on drain bags 7. Hangers on outer packaging 8. Unique shaped handles for hand comfort and stability during preparation 9. Tips other than Nelaton (e.g. Tiemann, Olive, Flexible) 10. Transparent catheter tubing to allow easy viewing of urine during use. [Or are all catheter tubes transparent for this reason?] 11. Enhanced or advanced sterilisation techniques of the product such as E-beam 12. Firmer tubes for stability 13. Additional indications such as Mitrofanoff catheterisation (considered out of scope for this evaluation which is based on urethral catheterisation).
Expert 1:	1. Yes – More patients / professionals are looking at the impact on environmental factors 2. Variable – It would be beneficial to be able to connect to a bag 3. Should be standard 4. This is of importance but not particularly innovative as there are many ISC available which are ready to use. However sometimes the different coatings are innovative with differing properties 5. I would state that it is the method of polishing the eyelets is the innovation rather than polished eyelets. Some manufacturers eyelets are a lot smoother than others 6. If a kit bag, then yes it would be innovative. However most external drainage bags used in catheterisation already have anti leak valves 7. No – Varies most ISC catheters have some sort of either hangers or sticker to attach to wall etc 8. Yes 9. This varies as there is not as much use for these tips as the standard tip 10. No 11. Yes – Not sure if this is currently used for ISC catheters 12. Variable – Helps with poor dexterity but can be too ridge for some patients 13. No response

Expert 2:	1. No – This is not commonly important at the moment, although I can understand that it might become more important in the future 2. Yes – This is important for wheelchair users – and may mean that they can use a product without having to transfer to the toilet 3. Yes – This is the same as above essentially 4. Yes – Not always essential, but can be very useful in those who find complex instructions difficult – for example some elderly people with declining cognitive function 5. Yes – Useful for women who find withdrawal of the catheter painful – there is a difference in eyelet feel between catheters 6. No 7. Yes – Can be useful in public toilets 8. No – Some people with limited dexterity can find a handle helpful – but this can be added for that individual 9. Yes – Very useful in men with difficult urethras, where inserting a nelaton tip can be impossible or at least very traumatic – perhaps the most useful thing on this list 10. No – By default all are transparent, but it is not essential for the use of a catheter 11. No – Intermittent catheterisation is clean 12. No – I think the tip is more important 13. Yes – Additional drainage holes can be helpful even with urethral catheterisation if there has been augmentation of the bladder with bowel
Expert 3:	1. Probably many components are recyclable whether the company informs the user or not. 2. No – Very common – and if this feature were needed for the patient you would choose a variant that has this feature. Most users would not need it. 3. No – As above 4. No – I would say that ‘ready to use’ is the same as ‘pre-lubricated’ 5. No – Almost universal 6. Its not clear that they are needed 7. Probably convenient for some users 8. Hard to know if needed. 9. Many catheters come with a Tiemann tip variant for passing through the prostate. 10. Most are transparent – and not innovative. 11. If the product ends up sterile hard to see how this is important to the user 12. Personal preference of user – prescribers might choose this feature. 13. No We noticed that the additional features listed in the protocol do not include: • ‘Hard or specialised cases’ – these are additional features and should be included in the intervention category and NOT in the ‘basic’ or comparator catheter category. • Telescopic – should be included in the Intervention category as an additional feature

Expert 4:	1. Yes 2. No 3. No 4. Yes 5. No 6. No 7. No 8. No 9. No 10. Yes 11. Yes 12. Yes 13. No
Question 4	Are Tiemann tip catheters used in any patient (to help navigate through urethral strictures)? Or are they used in patients with prostate only?
Expert 1:	No response
Expert 2:	They are used in patients with strictures too
Expert 3:	I don't know
Expert 4:	No response
Question 5	In terms of comparator the EAG has considered the following: • Basic hydrophilic lubricant coated catheter (no additional features) • Basic uncoated catheter (with lubrication provided) • Basic uncoated catheter (requires separate lubrication gel sachet) Are these suitable comparators for all patients? Or is the comparator restricted for some subgroups of patients (or certain features)?
Expert 1:	Happy with these comparators
Expert 2:	Suitable for all patients
Expert 3:	don't think these comparators should be restricted to specific sub-groups. I don't think these comparators are quite right yet – and are still confusing. See below: For hydrophilic coated catheters i.e. point 1 above – I think there needs to be 3 categories: • Basic hydrophilic coated catheter (requires added water) • Basic hydrophilic coated catheter (with integrated water sachet) • Basic hydrophilic coated catheter (with pre-lubrication) For the uncoated catheters the two categories above are confusing – I think these should be: • Basic uncoated catheter (requires separate/externally applied lubricant) • Basic uncoated catheter (with gel pre-lubrication)
Expert 4:	No response

Question 6	Outcomes listed in the NICE Final Scope are the following, please can you rank in order of importance (highest importance to lowest): 1 – 13 (1 being the highest and 13 being the lowest) • Successful drainage (e.g. post-void residual volume) • Frequency of use per day • UTI and recurrent UTI (including CAUTI) • Sepsis • Urethral trauma, bleeding, haematuria, structures and urethritis • Bladder or kidney stones • Other device-related adverse events (e.g. retained fragment) • Hospitalisation • Adherence and compliance • Comfort and ease of use • Satisfaction • Preference • Health-related quality of life.				
All experts combined table	Outcome	Expert 1	Expert 2	Expert 3	Expert 4
	Successful drainage (e.g. post-void residual volume)	1	1	9	2
	Frequency of use per day	11	10	13	3
	UTI and recurrent UTI (including CAUTI)	2	6	1	12
	Sepsis	3	7	3	13
	Urethral trauma, bleeding, haematuria, structures and urethritis	4	2	2	11
	Bladder or kidney stones	12	13	11	10
	Other device-related adverse events (e.g. retained fragment)	5	12	12	9
	Hospitalisation	13	11	4	8
	Adherence and compliance	6	4	10	7
	Comfort and ease of use	7	3	6	1
	Satisfaction	8	5	8	4
	Preference	9	8	7	5
	Health-related quality of life	10	9	5	6
Question 7	Setting is poorly reported. Therefore, it is difficult to unpick patients using intermittent catheters at home but recruited in a hospital clinic, from patients using intermittent catheters in hospital. Therefore, may be difficult to determine evidence exclusively conducted in community or primary care. Can the EAG consider evidence conducted in hospital setting as generalisable to community/hospital care? Or should we exclude evidence from hospital setting (or treat as separate subgroup)?				
Expert 1:	I would say treat as a separate group as the venue for teaching, the amount of time for teaching and follow up availability would vary from acute to community. Also the availability of certain catheters in acute may be restricted via procurement				

Expert 2:	It can be generalisable to community care – as very few inpatients use ISC
Expert 3:	Tricky. I think that it should probably be about who conducts the intermittent catheterisation in the hospital. If it is clear that it is the user or their home-carer carrying out the IC in the hospital, then include. If the catheterising person is a healthcare professional, then exclude. Some studies in hospital rehab settings are in the latter group and therefore do not reflect a community situation.
Expert 4:	No response
Question 8	How important (if at all) is shelf life of the product to the user? Is there a variation between the shelf life of Coated, Uncoated, Ready to use? Is this something that is given during patient education?
Expert 1:	While an important question most individuals doing ISC would use they catheters frequently and have a new supply monthly. Only if their circumstances change i.e. reduction in ISC would this be likely to be an issue
Expert 2:	Shelf life is not normally important to an end user – most catheters have a life of 2 years, so even a box of 60 catheters in a stricture patient will generally be used prior to them expiring
Expert 3:	I don't think it is important.
Expert 4:	No response
Question 9	<u>Economic model assumptions:</u> For the base case we will assume: • an average 5 catheters will be used per day • 5 lubricant sachets per day (where additional external lubricant needed) • most of the patients use water based external lubricant, however an average of 5% of them use lidocaine lubricant. Do these assumptions look reasonable?
Expert 1:	Yes
Expert 2:	5 catheters a day is reasonable for someone who is catheter dependant, but many use it less if they have incomplete emptying, 5 sachets a day is reasonable if you need external lubricant I would think the number using lidocaine is less than 5% - I can't remember the last time I recommended it.
Expert 3:	• It is likely to fewer – 4-5 (based on preliminary results of MultiCath) • Many patients use a tube of lubricant rather than sachets – but I don't know the split. • No response Do these assumptions look reasonable? Probably – but I don't know.
Expert 4:	No response
Question 10	<u>Economic model assumptions:</u> We have assumed an average of 12 additional catheters will be needed during treatment per Symptomatic UTI or First-line antibiotic resistant UTI in intermittent catheter users. Does this assumption look appropriate?
Expert 1:	Yes
Expert 2:	Yes
Expert 3:	Sounds too many – are we basing this data on anything?
Expert 4:	No response

Question 11	<u>Economic model assumptions:</u> Can we assume that occurrence of urethral complications, haematuria and bladder stones is the same across comparators?
Expert 1:	Yes an unaware of any research that has done any comparisons on this particular topic
Expert 2:	Yes
Expert 3:	Yes - but It depends on what question is being asked. If catheters are being compared on different coatings – then they might be different i.e. more urethral bleeding in one group than another.
Expert 4:	No response
Question 12	In your opinion what the split of use between the following broad types of catheter? 1. Catheter coated with hydrophilic gel (needs soaking with water) 2. Catheter coated with lubricant gel 3. Uncoated catheter, with lubricant sachet included or obtained separately
Expert 1:	1. 5% 2. 80% 3. 15%
Expert 2:	1. 15% 2. 80% 3. 5%
Expert 3:	Can't answer this question because catheter types listed here are confusing.
Expert 4:	1. 10% 2. 80% 3. 10%
Question 13	Are the following antibiotics used to treat a symptomatic UTI responsive to <u>first-line</u> therapy? • Trimethoprin • Nitrofurantoin • Cefalexin • Pivmecillinam
Expert 1:	Ciprofloxacin and Nitrofurantoin
Expert 2:	Yes to all, Pivmecillinam less frequently
Expert 3:	Unable to answer
Expert 4:	Yes to all
Question 14	Are the following antibiotics used as second-line to treat a symptomatic UTI resistant to first-line therapy? • Ciprofloxacin • Cefaclor • Cefixime • Norfloxacin • Ofloxacin • Pivmecillinam
Expert 1:	Ciprofloxacin and Pivmecillinam
Expert 2:	Ciprofloxacin

Expert 3:	Unable to answer
Expert 4:	Yes to all, Ciprofloxacin only by hospital consultant in serious cases due to side effects

Questions sent 25/11/2024

#	Date responses received	Name, Affiliation
1	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]

Question 1	The EAG has aggregated results from 4 published which reported UTI (similar definition, similar reporting) all were conducted in spinal cord injury patients. Could the reduction in UTI with the catheters investigated be generalised to other non-spinal cord injury patients?
Expert 1:	From memory I am not sure that these studies are so similar – would be good to double check this. Also – don't think findings re UTI concur with Cochrane? What about sex differences? Males usually dominate SCI literature. Spinal cord injury are an important but minority group doing ISC. So maybe a stretch.?
Expert 2:	Yes they could
Question 2	The majority of evidence included in the EAG report has been conducted in a non-UK setting. Would you consider the published evidence conducted outwith UK as generalisable to the UK NHS? Is intermittent catheter care or patient pathways likely to differ by country?
Expert 1:	Rather hard to say how different patient pathways are. The NHS offers a very wide range of catheters on the drug tariff (as noted in the report) possibly more than other countries, so clinicians in the UK have a wide choice.. Differences in Dutch prescribing for example indicates that IC more prevalent than in the UK. Rather more important would be whether studies were funded by industry rather than the country in which the study took place.
Expert 2:	Pathways may be different, but I suspect that the evidence can be generalisable to the UK
Question 3	The EAG has identified intermittent catheters prescribed from the NHS Drug Tariff, and subsequently excluded catheters which were supplied as part of a kit or set (due to the components of the kit/set differing between manufacturers, and all catheters were available in isolation out with a kit). Is this approach appropriate?
Expert 1:	V confusing terminology used by manufacturers/drug tariff here. Some catheters with integrated bags are named a 'set' but some have other names like 'plus' – hence the confusion - we can check on as many of these as we can as I have a sample of most (not quite all)
Expert 2:	I'm not sure why you are planning to exclude them so not quite sure how to answer – we did in our meetings agree that integral bags were an important feature for some people so I am not sure that it is correct to remove them

Question 4	Related to the above, the EAG has classified the following catheters as having an integrated drainage bag, which are <u>not part of a kit or set</u>. Is this correct? Are any missing from this list? • Advance Plus (by Hollister Ltd) • VaPro Plus (by Hollister Ltd) • VaPro Plus Pocket (by Hollister Ltd) • Infyna Plys (by Hollister Ltd) • VaPro Plus F-style (by Hollister Ltd) • InstantCath Protect (by Hollister Ltd) • Mtg Cath-lean (by Pioneer medical) • Mtg AZ-advance (by Pioneer medical) • Mtg EZ-Gripper (by Pioneer medical) • Flocath Intro Gel (by Teleflex) • Liquick X-treme Plus (by Teleflex)
Expert 1:	Teams call 26/11/2024 – all of the above confirmed as having an integrated bag, or unknown.
Expert 2:	This list is correct – they are in effect sets or kits by another name
Question 5	There has been mixed terminology used by companies and in the literature to describe “integrated handle”, “sleeve” or “gripper” intermittent catheter features. Clinically is there a distinction between these?
Expert 1:	Main difference is between male and female length catheters. Sleeves and grippers are usually designed primarily to prevent any direct handling of the catheter tube but also to aid insertion of (usually) male length catheters. Integrated handles are usually on female length catheters and are primarily designed to aid insertion although they may also help to avoid direct handling. All of these features may make catheterising more difficult for some patients so their functionality cannot be assumed. From a clinical perspective they all should reduce direct handling of the catheter and may aid insertion so in that sense they could be grouped together.
Expert 2:	No there is no difference

Questions sent 12/12/2024

#	Date responses received	Name, Affiliation
1	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]

Question 1	The EAG have stated in their report the following: <i>“Intermittent catheterisation is typically taught by a urology or continence specialist nurse in an acute hospital setting (outpatient or inpatient appointment) where specific recommendations may be made in consideration of issues such as complex anatomical features (Rew et al., 2018). Ongoing intermittent catheterisation support typically occurs in a community setting where the catheters are prescribed by a GP or prescribing nurse specialist and dispensed by a local chemist or delivered to patients through a Dispensing Appliance Contractor.”</i> We have tried to state these scenarios as “typical” to reflect the most common practice in the NHS. However this has been challenged by one company. Can you please advise whether the text above (quoted from the EAG report in italics) is correct?
Expert 1:	This scenario seems typical/common to me (although this is difficult to say as we don't have a national picture). I would be interested to know what the challenge from the company is about?
Expert 2:	I would say that typically commencement of ISC is within the acute setting however it can be commenced by District Nursing within the community setting following instruction from GP or acute services in the event that the patient cannot mobilise well enough to attend acute setting.
Question 2	Is it clinically plausible that the micro-holes feature could improve patient comfort?
Expert 1:	I don't see how they could improve patient comfort. The holes allow for urine drainage over a longer length of the catheter – it is hard to understand how the holes in themselves could improve comfort.
Expert 2:	Reading the literature regarding micro holed IC, it is designed for complete emptying which in turn would potentially lower the risk of urinary tract infections. Due to its function in draining the bladder completely, this would reduce the requirement for repositioning the catheter which can be uncomfortable for the patient. [REDACTED] using this type of catheter and their incidences of UTI's has reduced and does feel more comfortable.
Question 3	The majority of eligible studies included in the EAG report include neurogenic indications for catheterisation (with some studies including a mixture of neurogenic and non-neurogenic indications). Please can you comment on the generalisability of evidence on neurogenic indication to other populations. That is, would a difference in a) UTI, b) haematuria, c) residual volume, d) discomfort or pain, and e) ease of use outcomes be expected between neurogenic and non-neurogenic indications for intermittent catheterisation?

Expert 1:	I don't think I would expect there to be much difference between the neuro and non-neuro groups in terms of UTI and residual volume. Non-neurogenic causes would include obstructive reasons (more common in men than women) and this might mean that some non-neuro people are more likely to have traumatic catheterisations or difficulties with passing the catheter through the urethra/prostate – this could lead to more haematuria in a non-neurogenic group. People with neurogenic causes may have loss of sensation and therefore there could be differences in feeling pain and discomfort compared to a non-neuro group. For ease of use – people with neurogenic causes are more likely to have disabilities that affect ease of use of catheters so there may be differences in the types of catheters that they find easiest to use.
Expert 2:	No response

Appendix E: CNMA WinBUGS analysis code

Appendix E1: UTI analyses

Key for features: $d_{lubric}=f6_{lubric}$, $d_{design\_pack}=f8_{packaging}$, $d_{lubxpack}$ =a combination of $f6_{lubric}$ and $f8_{packaging}$, $d[1]=U1$

Pair-wise CMA

```
model{
  for(i in 1:Ntrials){
    mu[i] ~ dnorm(0,.0001)          # LOOP THROUGH STUDIES
                                     # vague priors for all trial baselines

    for(k in 1:na[i]) {              # LOOP THROUGH ARMS
      r[i,k] ~ dbin(p[i,k],n[i,k]) # binomial likelihood
      logit(p[i,k]) <- mu[i] + d[2]*dlubric[i, k]

      rhat[i,k] <- p[i,k] * n[i,k] # expected value of the numerators
#Deviance contribution
      dev[i,k] <- 2 * (r[i,k] * (log(r[i,k])-log(rhat[i,k]))
        + (n[i,k]-r[i,k]) * (log(n[i,k]-r[i,k]) - log(n[i,k]-rhat[i,k]))) }
# summed residual deviance contribution for this trial
      resdev[i] <- sum(dev[i,1:na[i]])

    }

    # total residual deviance
    totesdev <- sum(resdev[])

    # treatment effect is zero for control arm
    d[1]<-0

    # vague priors for treatment effects - loop through treatments
    for (k in 2:nt){
      d[k] ~ dnorm(0,.001)
    }
    # Provide estimates of treatment effects T[k] on the natural (probability) scale
# Given a Mean Effect, meanA, for 'standard' treatment A,
# with precision (1/variance) precA
A ~ dnorm(meanA,precA)
for (k in 1:nt) { logit(T[k]) <- A + d[k] }

# Provide estimates of number needed to treat NNT[k], Risk Difference RD[k],
# and Relative Risk RR[k], for each treatment, relative to treatment 1
for (k in 2:nt) {
  RR[k] <- T[k]/T[1]
}
}

#Initial values 1
list(d=c(NA,0), mu=c(0,0,0,0))
{{{
```

```
#Initial values 2
list(d=c(NA,0.5), mu=c(-1,-1,-1,-1))
```

Independent effects model

```
model{
  for(i in 1:Ntrials){                                # LOOP THROUGH STUDIES
    mu[i] ~ dnorm(0,.0001)                             # vague priors for all trial baselines

    for (k in 1:na[i]) {                                # LOOP THROUGH ARMS
      r[i,k] ~ dbin(p[i,k],n[i,k]) # binomial likelihood
      logit(p[i,k]) <- mu[i] + d[2]*dlubric[i, k] + d[3]*ddesign_pack[i,k]

      rhat[i,k] <- p[i,k] * n[i,k] # expected value of the numerators
#Deviance contribution
      dev[i,k] <- 2 * (r[i,k] * (log(r[i,k])-log(rhat[i,k]))
        + (n[i,k]-r[i,k]) * (log(n[i,k]-r[i,k]) - log(n[i,k]-rhat[i,k])))    }
# summed residual deviance contribution for this trial
      resdev[i] <- sum(dev[i,1:na[i]])

    }

    # total residual deviance
    totesdev <- sum(resdev[])

    # treatment effect is zero for control arm
    d[1]<-0

    # vague priors for treatment effects - loop through treatments
    for (k in 2:nt){
      d[k] ~ dnorm(0,.001) }

    # Provide estimates of treatment effects T[k] on the natural (probability)
scale
# Given a Mean Effect, meanA, for 'standard' treatment A,
# with precision (1/variance) precA
A ~ dnorm(meanA,precA)
for (k in 1:nt) { logit(T[k]) <- A + d[k] }

# Provide estimates of number needed to treat NNT[k], Risk Difference RD[k],
# and Relative Risk RR[k], for each treatment, relative to treatment 1
for (k in 2:nt) {
  RR[k] <- T[k]/T[1]
}
}
}
```

```
#Initial values 1
```

```
list(d=c(NA,0,0), mu=c(0,0,0,0))
```

```
#Initial values 2
```

```
list(d=c(NA,0.5,0.5), mu=c(-1,-1,-1,-1))
```

Combination effects model

```
model{
  for(i in 1:Ntrials){
    mu[i] ~ dnorm(0,.0001) # LOOP THROUGH STUDIES
                           # vague priors for all trial baselines

    for (k in 1:na[i]) { # LOOP THROUGH ARMS
      r[i,k] ~ dbin(p[i,k],n[i,k]) # binomial likelihood
      logit(p[i,k]) <- mu[i] + d[2]*dlubric[i, k] + d[3]*ddesign_pack[i,k]
      +d[4]*dlubxpack[i,k]
    }
    rhat[i,k] <- p[i,k] * n[i,k] # expected value of the numerators
    #Deviance contribution
    dev[i,k] <- 2 * (r[i,k] * (log(r[i,k])-log(rhat[i,k]))
      + (n[i,k]-r[i,k]) * (log(n[i,k]-r[i,k]) - log(n[i,k]-rhat[i,k]))) }
    # summed residual deviance contribution for this trial
    resdev[i] <- sum(dev[i,1:na[i]])

  }

  # total residual deviance
  totesdev <- sum(resdev[])

  # treatment effect is zero for control arm
  d[1]<-0

  # vague priors for treatment effects - loop through treatments
  for (k in 2:nt){
    d[k] ~ dnorm(0,.001)
  }
  # Provide estimates of treatment effects T[k] on the natural (probability)
  scale
  # Given a Mean Effect, meanA, for 'standard' treatment A,
  # with precision (1/variance) precA
  A ~ dnorm(meanA,precA)
  for (k in 1:nt) { logit(T[k]) <- A + d[k] }

  # Provide estimates of number needed to treat NNT[k], Risk Difference RD[k],
  # and Relative Risk RR[k], for each treatment, relative to treatment 1
  for (k in 2:nt) {
    RR[k] <- T[k]/T[1]
  }
}

#Initial values 1
list(d=c(NA,0,0,0), mu=c(0,0,0,0))
```

```
#Initial values 2  
list(d=c(NA,0.5,0.5,0.5), mu=c(-1,-1,-1,-1))
```


Appendix E2: Haematuria analyses

Key for features code: dmicro=f5_{micro-hole}, ddesign_cath=f7_{case}, d[1]=U1

Independent effects model

```
model{
  for(i in 1:ns2){                                # LOOP THROUGH STUDIES
    y[i,2] ~dnorm(delta[i,2],prec[i,2])
    var[i,2] <-pow(se[i,2],2)
    prec[i,2] <-1/var[i,2]
    dev[i,2] <- (y[i,2]-delta[i,2])*(y[i,2]-delta[i,2])*prec[i,2]
    delta[i,2] ~ dnorm(md[i,2], tau)                # treatment effect is zero for
    control arm
    md[i,2] <-d[2]*dmicro[i,2]+d[3]*h_three[i,2] + d[4]*ddesign_cath[i,2]
  }

  # total residual deviance
  toresdev <- sum(dev[,2])
  # treatment effect is zero for control arm
  d[1]<-0
  # vague priors for treatment effects - loop through treatments
  for (k in 2:nt){
    d[k] ~ dnorm(0,.001)
  }
  # vague prior for between-trial SD
  sd ~ dunif(0,5)

  # between-trial precision = (1/between-trial variance)
  tau <- pow(sd,-2)

  # Provide estimates of treatment effects T[k] on the natural (probability) scale
  # Given a Mean Effect, meanA, for 'standard' treatment A,
  # with precision (1/variance) precA
  A ~ dnorm(meanA,precA)
  for (k in 1:nt) { logit(T[k]) <- A + d[k] }

  # Provide estimates of number needed to treat NNT[k], Risk Difference RD[k],
  # and Relative Risk RR[k], for each treatment, relative to treatment 1
  for (k in 2:nt) {
    RR[k] <- T[k]/T[1]
  }
} # *** PROGRAM ENDS

#Initial values 1
list(d=c( NA, 0,0,0), sd=0.5)

#Initial values 2
list(d=c( NA, -1, -1, -1), sd=0.8)
```

Appendix F: Multivariable regression modelling for intermittent catheter price – exploratory univariate analysis

The linear regression model was characterized as follows:

Price per catheter

$$= \text{Reference price} + \beta_1 * \text{catheter sex} + \beta_2 * \text{catheter tip} + \beta_3 * \text{lubrication method} + \delta_1 * \text{Urine bag} + \delta_2 * \text{Handle} + \delta_3 * \text{Sleeve} + \delta_4 * \text{tip protector} + \delta_5 * \text{Micro hole zone} + \delta_6 * \text{enhanced coating} + \delta_7 * \text{case} + \delta_8 * \text{packaging}$$

Where the variables β control for the impact on price *basic product features*: catheter sex, type of catheter tip, and method of lubrication as categorised and described in Section 3.1. Variables δ control for the impact on price of the *additional features* as described in detail in Section 3.1. The linear approximation assumes that each feature has an independent additive impact on the cost of an individual catheter.

Coating

The EAG aggregated the intermittent catheter coating and method of lubrication into two categories (uncoated and hydrophilic). This showed hydrophilic coated catheter to be statistically lower in cost (£0.11 less). The features significantly contributing to catheter price as the same as that described in section 3.2; minor changes in magnitude of effect. Goodness of fit was largely unchanged: R-squared statistic=0.7679.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.39	0.02	-
Male	Ref	-	-
Female	-0.00	0.02	0.83
Unisex	0.15	0.08	0.06
Standard Nelaton tip	Ref	-	-
Tiemann tip	-0.00	0.03	0.99
Other tip (Coude, Ergothan)	0.07	0.05	0.18
Uncoated	Ref	-	-
Hydrophilic	-0.11	0.02	<0.0001***
No innovative features	Ref	-	-
Urine bag	0.81	0.03	<0.0001***
Handle or markings	0.16	0.03	<0.0001***
Protective sleeve	-0.01	0.02	0.54
Tip protector	0.33	0.03	<0.0001***

Feature	Price (£)	Std. Err.	p-value
Micro-hole zone	-0.05	0.10	0.56
Enhanced coating	0.25	0.02	<0.0001***
Special case	0.01	0.03	0.65
Special packaging	0.08	0.03	0.001**

Key: * p-value<0.05, ** p-value< 0.01, *** p-value<0.001

The EAG also tried removing method of lubrication from the regression model completely. The same intermittent catheter features were considered significant contributors to the catheter price, however the magnitude of effect dropped (between £0.01 to £0.08 per catheter). Goodness of fit was largely unchanged: R-squared statistic=0.7607.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.33	0.02	-
Male	<i>Ref</i>	-	-
Female	-0.00	0.02	0.69
Unisex	0.14	0.08	0.07
Standard Nelaton tip	<i>Ref</i>	-	-
Tiemann tip	-0.00	0.03	0.96
Other tip (Coude, Ergothan)	0.09	0.05	0.10
No innovative features	<i>Ref</i>	-	-
Urine bag	0.81	0.03	<0.0001***
Handle or markings	0.18	0.03	<0.0001***
Protective sleeve	-0.01	0.03	0.57
Tip protector	0.36	0.03	<0.0001***
Micro-hole zone	-0.10	0.10	0.31
Enhanced coating	0.19	0.02	<0.0001***
Special case	0.04	0.02	0.14
Special packaging	0.07	0.03	0.01*

The EAG then also removed enhanced coating (in addition to removal of lubrication method) which resulted in specially designed catheter case becoming a significant contributor to price (£0.10 more per catheter) and a change to the model fit; that is less of the catheter price variation could be justified by the presence of the remaining features: R-squared statistic=0.7341.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.38	0.02	-
Male	<i>Ref</i>	-	-
Female	0.00	0.02	0.73
Unisex	0.06	0.08	0.49
Standard Nelaton tip	<i>Ref</i>	-	-
Tiemann tip	0.01	0.03	0.64
Other tip (Coude, Ergothan)	0.03	0.06	0.64
No innovative features	<i>Ref</i>	-	-
Urine bag	0.83	0.03	<0.0001***
Handle or markings	0.15	0.03	<0.0001***
Protective sleeve	-0.04	0.03	0.14
Tip protector	0.43	0.03	<0.0001***
Micro-hole zone	-0.03	0.10	0.71
Special case	0.10	0.03	<0.0001***
Special packaging	0.07	0.03	0.01*

Handle, sleeve or grip

Due to inconsistent terminology making categorisation difficult the EAG aggregated the features of integrated handle or markings with the integrated sleeve or grip together. The influence of additional features on the catheter price was similar to that described in section 3.2, however the presence of a handle, sleeve or gripper significantly reduced the catheter price (£0.08 less per catheter). Goodness of fit was largely unchanged: R-squared statistic=0.7749.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.37	0.02	-
Male	<i>Ref</i>	-	-
Female	-0.01	0.02	0.50
Unisex	0.20	0.08	0.01*
Standard Nelaton tip	<i>Ref</i>	-	-
Tiemann tip	-0.01	0.03	0.76
Other tip (Coude, Ergothan)	0.05	0.05	0.37
Uncoated: no lubricant provided	<i>Ref</i>	-	-
Uncoated: lubricant provided	0.17	0.07	0.02*
Uncoated: pre-lubricated	0.21	0.04	<0.0001***
Hydrophilic: no liquid provided	-0.12	0.03	0.0004***
Hydrophilic: liquid provided	-0.00	0.04	0.90
Hydrophilic: pre-activated	0.07	0.04	0.08
No innovative features	<i>Ref</i>	-	-
Urine bag	0.89	0.03	<0.0001***

Handle or gripper	-0.08	0.03	0.001**
Tip protector	0.26	0.03	<0.0001***
Micro-hole zone	0.06	0.09	0.55
Enhanced coating	0.25	0.02	<0.0001***
Special case	0.04	0.03	0.15
Special packaging	0.09	0.03	0.01**

Key: * p-value<0.05, ** p-value< 0.01, *** p-value<0.001

Tip

Due to the low number of other tips present, the EAG aggregated Tiemann, Coude and Ergothan into the same category (making tip a binary covariate). The same trends of additional features contributing the catheter price as noted in section 3.2 occurred. Goodness of fit was largely unchanged: R-squared statistic=0.7749.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.37	0.02	-
Male	<i>Ref</i>	-	-
Female	-0.01	0.02	0.60
Unisex	0.18	0.08	0.03
Standard Nelaton tip	<i>Ref</i>	-	-
Other tip (Coude, Ergothan)	0.00	0.02	0.86
Uncoated: no lubricant provided	<i>Ref</i>	-	-
Uncoated: lubricant provided	0.10	0.07	0.17
Uncoated: pre-lubricated	0.15	0.04	0.0008***
Hydrophilic: no liquid provided	-0.13	0.03	0.0002***
Hydrophilic: liquid provided	-0.03	0.03	0.38
Hydrophilic: pre-activated	0.01	0.04	0.75
No innovative features	<i>Ref</i>	-	-
Urine bag	0.82	0.03	<0.0001***
Handle	0.10	0.03	0.001**
Protective sleeve	-0.03	0.03	0.33
Tip protector	0.29	0.03	<0.0001***
Micro-hole zone	-0.00	0.09	0.94
Enhanced coating	0.24	0.02	<0.0001***
Special case	-0.00	0.03	0.88
Special packaging	0.06	0.03	0.04*

Key: * p-value<0.05, ** p-value< 0.01, *** p-value<0.001

Responding manufacturers

As the EAG identified the presence of feature using information in the public domain for some manufacturers, the EAG conducted sensitivity analysis by excluding intermittent catheters from manufacturers who did not respond to NICE or EAG

queries. The same trends of additional features contributing the catheter price as noted in section 3.2 occurred with the addition that other tips significantly increased the catheter price (£0.09 more), all methods of lubrication were significantly associate with catheter price (uncoated less, hydrophilic more). All features contributed to cost except for micro-holes, specially designed catheter case and specially design packaging. Goodness of fit was increased slightly: R-squared statistic=0.8239.

Feature	Price (£)	Std. Err.	p-value
Base price (associated with reference features "Ref")	1.29	0.03	-
Male	<i>Ref</i>	-	-
Female	-0.01	0.02	0.67
Unisex	0.25	0.08	0.001**
Standard Nelaton tip	<i>Ref</i>	-	-
Tiemann tip	0.02	0.03	0.47
Other tip (Coude, Ergothan)	0.09	0.05	0.07
Uncoated: no lubricant provided	<i>Ref</i>	-	-
Uncoated: lubricant provided	0.19	0.07	0.008**
Uncoated: pre-lubricated	0.19	0.05	<0.0001***
Hydrophilic: no liquid provided	-0.19	0.04	<0.0001***
Hydrophilic: liquid provided	-0.11	0.04	0.008**
Hydrophilic: pre-activated	0.05	0.04	0.25
No innovative features	<i>Ref</i>	-	-
Urine bag	0.83	0.03	<0.0001***
Handle	0.08	0.03	0.003**
Protective sleeve	0.11	0.03	0.0007***
Tip protector	0.19	0.03	<0.0001***
Micro-hole zone	-0.02	0.09	0.81
Enhanced coating	0.35	0.02	<0.0001***
Special case	0.03	0.03	0.33
Special packaging	-0.04	0.03	0.21

Key: * p-value<0.05, ** p-value< 0.01, *** p-value<0.001

Appendix G: AdViSHE tool

Assessment of the Validation Status of Health-Economic decision models (AdViSHE)

AdViSHE ([Vemer et al. 2015](#)) contains 13 items that modellers can complete to report on the efforts performed to improve the validation status of their health-economic (HE) decision model. The tool is not intended to replace validation by model users but rather to inform the direction of validation efforts and to provide a baseline for replication of the results. In addition to using it after a model is finished, AdViSHE can be used to guide validation efforts during the modelling process. The modellers are asked to comment on the validation efforts performed while building the underlying HE decision model and afterwards. Many of the items can be answered simply by referring to the model documentation. AdViSHE is divided into five parts, each covering an aspect of validation:

- Part A: Validation of the conceptual model (2 questions)
- Part B: Input data validation (2 questions)
- Part C: Validation of the computerized model (4 questions)
- Part D: Operational validation (4 questions)
- Part E: Other validation techniques (1 question)

No final validation score is calculated, as the assessment of the answers and the overall validation effort is left to the model users. It is assumed that the model has been built according to prevailing modelling and reporting guidelines. For instance, the model builders would presumably adhere to the ISPOR-SMDM1 Modeling Good Research Practices (Caro et al., 2010) and/or CHEERS1 Statement (Husereau et al., 2013). Some questions may not be applicable to a particular model. If this is the case, the model builder should take the opt-out option and provide a justification of why this item is not deemed applicable.

Part A: Validation of the conceptual model (2 questions)

Part A discusses techniques for validating the conceptual model. A conceptual model describes the underlying system (e.g., progression of disease) using a mathematical, logical, verbal, or graphical representation. Please indicate where the conceptual model and its underlying assumptions are described and justified.

There was no conceptual model. The model structure used for this appraisal was directly based on a previously validated model of intermittent self-catheterisation (ISC in NICE CG139 and published in Bermingham et al. (2013). This is reported in Section 6.1.1 along with the details of the model structure.

This same model structure has been used in multiple economic evaluations of ISC beyond its first publication. In addition to this, some of the structural assumptions were reviewed by the EAG team alongside clinical expert opinion to adapt the model to the current decision problem.

A1/ Face validity testing (conceptual model):

Have experts been asked to judge the appropriateness of the conceptual model?

If yes, please provide information on the following aspects:

- Who are these experts?
- What is your justification for considering them experts?
- To what extent do they agree that the conceptual model is appropriate?

If no, please indicate why not.

The EAG sought feedback from Clinical Expert (for names and affiliations, see Acknowledgements), with questions and responses documented in Appendix D.

Experts ratified by NICE were considered to have clinical expertise in the area of urology or with ISC directly within the UK NHS context.

The initial model from Bermingham et al. (2013) had a lifetime horizon. The time horizon was reduced to a two-year horizon to account for the length of follow-up available in the included evidence. One Expert advised that an unpublished survey of 200 intermittent catheter users that approximately half changed their catheter model since their first prescribed one. NICE methods guidance recommends that the time horizon is long enough to cover all outcomes relevant to the patient, therefore the sensitivity analysis included multiple time horizons including the lifetime horizon.

Moreover, the model assumes that patients maintain the same catheter type over the time horizon; which was considered a strong assumption, but was kept in the base-case due to lack of data on patient adherence to each catheter.

Aspects to judge include: appropriateness to represent the underlying clinical process/disease (disease stages, physiological processes, etc.); and appropriateness for economic evaluation (comparators, perspective, costs covered, etc.).

A2/ Cross validity testing (conceptual model):

Has this model been compared to other conceptual models found in the literature or clinical textbooks? If yes, please indicate where this comparison is reported. If no, please indicate why not.

Yes, Section 5.2 and Table 13 present a summary of the previous economic models found in the literature, which included multiple iterations of the initial model submitted to NICE and compare their distinct features.

Part B: Input data validation (2 questions)

Part B discusses techniques to validate the data serving as input in the model. These techniques are applicable to all types of models commonly used in HE modelling. Please indicate where the description and justification of the following aspects are given:

- search strategy;
- data sources, including descriptive statistics;
- reasons for inclusion of these data sources;
- reasons for exclusion of other available data sources;
- assumptions that have been made to assign values to parameters for which no data was available;
- distributions and parameters to represent uncertainty;
- data adjustments: mathematical transformations (e.g., logarithms, squares); treatment of outliers; treatment of missing data; data synthesis (indirect treatment comparison, network meta-analysis); calibration; etc.

B1/ Face validity testing (input data):

Have experts been asked to judge the appropriateness of the input data?

If yes, please provide information on the following aspects:

- Who are these experts?
- What is your justification for considering them experts?
- To what extent do they agree that the conceptual model is appropriate?

If no, please indicate why not.

Yes, opinion was sought on the experts listed in the acknowledgements section, see response to question A1. Experts were shown Figure 7, and clinical parameters extracted from the literature in Sections 6.1.5-7.

If alternative parameters were suggested but evidence was not available, they were used for the scenario analysis in Section 6.1.8.

Aspects to judge include: appropriateness to represent the underlying clinical process/disease (disease stages, physiological processes, etc.); and appropriateness for economic evaluation (comparators, perspective, costs covered, etc.).

B2/ Model fit testing:

When input parameters are based on regression models, have statistical tests been performed? If yes, please indicate where the description, the justification and the outcomes of these tests are reported. If no, please indicate why not.

Yes, regression models were used to derive features prices from public data sources and information from the manufacturers, this is detailed in Section 3.2.

Statistical models for clinical effectiveness between features are reported in Section 4.

No further parameter inputs based on statistical models were used to inform the decision model.

Examples of regression models include but are not limited to: disease progression based on survival curves; risk profiles using regression analysis on a cohort; local cost estimates based on multi-level models; metaregression; quality-of-life weights estimated using discrete choice analysis; mapping of disease-specific quality-of-life weights to utility values. Examples of tests include but are not limited to: comparing model fit parameters (R^2 , Akaike information criterion (AIC), Bayesian information criterion (BIC)); comparing alternative model specifications (covariates, distributional assumptions); comparing alternative distributions for survival curves (Weibull, lognormal, logit); testing the numerical stability of the outcomes (sufficient number of iterations); testing the convergence of the regression model; visually testing model fit and/or regression residuals.

Part C: Validation of the computerized model (4 questions)

C1/ External Review:

Has the computerized model been examined by modelling experts?

If yes, please provide information on the following aspects:

- Who are these experts?
- What is your justification for considering them experts?
- To what extent do they agree that the conceptual model is appropriate?

If no, please indicate why not.

The model was developed and coded by Nawaraj Bhattarai, the lead health economist in this appraisal. Tests of the computerised model were made by Giovany Orozco Leal and Luke Vale, both members of the EAG team. No external expert was sought to examine the model.

Model appropriateness for the decision problem has been assessed by the EAG, and expert opinion has been used to assess and validate the assumptions incorporated into the model, see answers to question A1.

Aspects to judge include: appropriateness to represent the underlying clinical process/disease (disease stages, physiological processes, etc.); and appropriateness for economic evaluation (comparators, perspective, costs covered, etc.).

C2/ Extreme value testing:

Has the model been run for specific, extreme sets of parameter values in order to detect any coding errors?

If yes, please indicate where these tests and their outcomes are reported.

If no, please indicate why not.

Yes, parameter values were altered and tested during the development of this model by the lead health economist to check for coding errors. The model was then tested by another health economist separately.

Section 6.1.8 reports sensitivity analyses for alternative or extreme sets of parameter values.

Examples include but are not limited to: zero and extremely high (background) mortality; extremely beneficial, extremely detrimental, or no treatment effect; zero or extremely high treatment or healthcare costs.

C3/ Testing of traces:

Have patients been tracked through the model to determine whether its logic is correct?

If yes, please indicate where these tests and their outcomes are reported. If no, please indicate why not.

Yes, this was tested during the development of the model to check the logic of patient flow through the model. The executable model file in Excel includes the proportion of patients in each health-state at each model cycle. The sheets "Comparator" and "Intervention" contains this information.

In cohort models, this would involve listing the number of patients in each disease stage at one, several, or all time points (e.g., Markov traces). In individual patient simulation models, this would involve following several patients throughout their natural disease progression.

C4/ Unit testing:

Have individual sub-modules of the computerized model been tested?

If yes, please provide information on the following aspects: - Was a protocol that describes the tests, criteria, and acceptance norms defined beforehand? - Please indicate where these tests and their outcomes are reported. If no, please indicate why not.

This is not applicable here, as there were no sub-models built into the main model used.

Examples include but are not limited to: turning sub-modules of the program on and off; altering global parameters; testing messages (e.g., warning against illegal or illogical inputs), drop-down menus, named areas, switches, labelling, formulas and macros; removing redundant elements.

Part D: Operational validation (4 questions)

Part D discusses techniques used to validate the model outcomes.

D1/ Face validity testing (model outcomes):

Have experts been asked to judge the appropriateness of the model outcomes?

If yes, please provide information on the following aspects:

- Who are these experts?
- What is your justification for considering them experts?
- To what extent did they conclude that the model outcomes are reasonable?

If no, please indicate why not.

Yes, members of the EAG were invited to comment on the appropriateness and interpretation of the decision model results throughout the report. Moreover, feedback has been collected from stakeholders including catheter manufacturers, and further errors or matters of factual accuracy have been implemented.

Outcomes may include but are not limited to: (quality-adjusted) life years; deaths; hospitalizations; total costs.

D2/ Cross validation testing (model outcomes):

Have the model outcomes been compared to the outcomes of other models that address similar problems?
If yes, please provide information on the following aspects: - Are these comparisons based on published outcomes only, or did you have access to the alternative model? - Can the differences in outcomes between your model and other models be explained? - Please indicate where this comparison is reported, including a discussion of the comparability with your model.
If no, please indicate why not.
No models evaluating the catheter features included in this appraisal were found in the published literature. Table 13 in the EAG report shows the results of the economic models for ISC found in the literature, and Section 6.1.1 discusses the model structure in this context.
Other models may include models that describe the same disease, the same intervention, and/or the same population.

D3/ Validation against outcomes using alternative input data:

Have the model outcomes been compared to the outcomes obtained when using alternative input data?
If yes, please indicate where these tests and their outcomes are reported. If no, please indicate why not.
Yes, this was presented in the sensitivity analysis detailed in the EAG Report Section 6.1.8 and results presented in Section 6.2.2. Due to the absence of published data, scenarios were informed by expert opinion during the appraisal.
Alternative input data can be obtained by using different literature sources or datasets, but can also be constructed by splitting the original data set in two parts, and using one part to calculate the model outcomes and the other part to validate against.

D4/ Validation against empirical data:

Have the model outcomes been compared to empirical data?
If yes, please provide information on the following aspects: - Are these comparisons based on summary statistics, or patient-level datasets? - Have you been able to explain any difference between the model outcomes and empirical data? - Please indicate where this comparison is reported. If no, please indicate why not.
D4.A/ Comparison against the data sources on which the model is based (dependent validation).
No, due to the absence of evidence between the impact of catheters features and utilities in the literature, the model tests multiple scenarios based on expert opinion, see Section 6.1.5.
D4.B/ Comparison against a data source that was not used to build the model (independent validation).

No, additional published data was not available reporting Life Years or Quality-Adjusted Life Years (QALYs) for the catheter features included in this appraisal.

Part E: Other validation techniques (1 question)

E1/ Other validation techniques:

Have any other validation techniques been performed?

If yes, indicate where the application and outcomes are reported, or else provide a short summary here.

As reported in the answer to C1, the model was independently coded by the lead health economist, and was tested and validated by two other health economists. In addition, structured "walk-throughs" were given weekly by the health economics lead to a senior health economist during the development of the conceptual model. Additional testing of extreme values on input parameters were conducted by the EAG team.

Examples of other validation techniques: structured "walk-throughs" (guiding others through the conceptual model or computerized program step-by-step); naïve benchmarking ("back-of-the-envelope" calculations); heterogeneity tests; double programming (two model developers program components independently and/or the model is programmed in two different software packages to determine if the same results are obtained).

Appendix H: Additional economic analyses

After the submission of the EAG report to NICE and the feedback received from multiple stakeholders, a matter of factual accuracy was identified where utility weights for calculating patient health-related quality of life (HRQoL) had not been adjusted for gender and age following the latest NICE methods guidance (NICE, 2022).

The following appendix presents the base-case economic analysis in the EAG report for each catheter feature before and after adjusting utility weights. The updated economic model allowed for two methodologies to adjust population utilities for age and gender: a) an absolute adjustment: subtracting the impact of age and gender population values; and b) a relative adjustment: multiplying by the proportional difference between full health and age and gender adjusted utility.

Results are reported in Table 26. There were no meaningful differences between using an absolute adjustment versus a relative adjustment methodology. Moreover, the impact on incremental results from either approach did not lead to meaningful changes in the estimates. The EAG considers the utility adjustment is having an equivalently sized impact on interventions and comparators, therefore incremental results were not significantly impacted. Although the results and implications for practice from the EAG report did not change, the analysis presented shows that the EAG was committed to aligning its methodology with the latest NICE guidance.

Table 26 Additional feature results for each utility adjustment

Feature	Total Costs (£)	Total QALYs	Inc. Costs (£)	Inc. QALYs	ICER
Comparator (U1) - Reference					
Base-case	£7,228	1.6355	-	-	-
Absolute adjustment	£7,228	1.6328	-	-	-
Relative adjustment	£7,228	1.6330	-	-	-
Integrated drainage bag					
Base-case	£9,771	1.6389	£2,543	0.0034	£752,525
Absolute adjustment	£9,771	1.6362	£2,543	0.0034	£752,525
Relative adjustment	£9,771	1.6363	£2,543	0.0034	£752,525
Integrated handle or markings					
Base-case	£6,890	1.6389	-£338	0.0034	Dominates U1
Absolute adjustment	£6,890	1.6362	-£338	0.0034	Dominates U1
Relative adjustment	£6,890	1.6363	-£338	0.0034	Dominates U1
Insertion sleeve or grip					

Base-case	£6,526	1.6389	-£703	0.0034	Dominates U1
Absolute adjustment	£6,526	1.6362	-£703	0.0034	Dominates U1
Relative adjustment	£6,526	1.6363	-£703	0.0034	Dominates U1
Tip protector or introducer					
Base-case	£7,547	1.6389	£318	0.0034	£94,231
Absolute adjustment	£7,547	1.6362	£318	0.0034	£94,231
Relative adjustment	£7,547	1.6363	£318	0.0034	£94,231
Micro-hole zone technology					
Base-case	£6,487	1.6462	-£741	0.0107	Dominates U1
Absolute adjustment	£6,487	1.6435	-£741	0.0107	Dominates U1
Relative adjustment	£6,487	1.6436	-£741	0.0107	Dominates U1
Enhanced coating					
Base-case	£7,398	1.6431	£170	0.0076	£22,296
Absolute adjustment	£7,398	1.6404	£170	0.0076	£22,296
Relative adjustment	£7,398	1.6406	£170	0.0076	£22,300
Specially designed catheter case					
Base-case	£6,574	1.6298	-£654	-0.0058	£113,724*
Absolute adjustment	£6,574	1.6270	-£654	-0.0058	£113,724*
Relative adjustment	£6,574	1.6272	-£654	-0.0058	£113,724*
Specially designed packaging					
Base-case	£6,606	1.6431	-£622	0.0076	Dominates U1
Absolute adjustment	£6,606	1.6403	-£622	0.0076	Dominates U1
Relative adjustment	£6,606	1.6405	-£622	0.0076	Dominates U1

Abbreviations: ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life years; U1, uncoated catheter with no lubrication provided (required separately)

*ICER for U1 catheter with no features vs specially designed catheter case, U1 is not considered cost-effective at the £20,000 per QALY threshold from NICE

Health Tech Programme

LSA - Intermittent urethral catheters for chronic incomplete bladder emptying in adults

EAG Responses – Collated Comments

Please try to ensure that, where possible, comments do not compromise the identity of individuals or organisations

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
Factual inaccuracies					
1.	BD	28	3.5 Regulatory	[REDACTED]	Thank you for your comment. [REDACTED]
2.	CliniMed Ltd	148	Curan Lady	Curan Lady – it is not clear from the table headings that Curan Lady is a catheter with a hydrogel coating. Please see IFU:	Thank you for your comment. The EAG have updated appendix A lubrication or coating material column to state "Hydrogel".
3.	CliniMed Ltd	148	Curan Man	Curan Man – it is not clear from the table headings that Curan Man is a catheter with a hydrogel coating. Please see IFU:	Thank you for your comment. The EAG have updated appendix A lubrication or coating material column to state "Hydrogel".

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
4.	CliniMed Ltd	256	4 - RFI (B. Braun Medical Ltd, CliniMed Ltd, Coloplast Ltd, ConvaTec Ltd)	The catheters used in this research were: SpeediCath® (Coloplast A/S, Denmark) with a hydrophilic ready-to-use coating Actreen® Glys (B. Braun Medical SAS, Boulogne, France), a glycerin pre-lubricated catheter The hydrophilic coated LoFric® (AstraTech, Sweden) catheter The RFI says it is (B. Braun Medical Ltd, CliniMed Ltd, Coloplast Ltd, ConvaTec Ltd), but it should be - B. Braun Medical Ltd, Coloplast Ltd, and AstraTech (now Wellspect). https://www.researchgate.net/publication/6266264_Effect_of_short-term_exposure_to_two_hydrophilic-coated_and_one_gel_pre-lubricated_urinary_catheters_on_sperm_vitality_motility_and_kinematics_in_vitro	Thank you for your comment. The EAG has updated appendix C5 #4 to remove mention of CliniMed.
5.	CliniMed Ltd	272	209 – RFI (CliniMed Ltd)	The paper referenced is from Coloplast, not CliniMed. CliniMed haven't undertaken any ISC research with a pig model.	Thank you for your comment. The EAG has updated appendix C5 #209 to refer to the RFI by Coloplast.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
6.	CliniMed Ltd	273	218 – RFI (CliniMed Ltd)	The paper referenced is from Coloplast, not CliniMed. CliniMed haven't undertaken any ISC research with a pig model. https://bjui-journals.onlinelibrary.wiley.com/doi/full/10.1002/bco2.295	Thank you for your comment. The EAG has updated appendix C5 #275 to refer to the RFI by Coloplast.
7.	CliniMed Ltd	275	247 – RFI (CliniMed Ltd)	The paper referenced is from Coloplast, not CliniMed. CliniMed haven't undertaken any ISC research with a pig model.	Thank you for your comment. The EAG has updated appendix C5 #247 to refer to the RFI by Coloplast.
8.	CliniMed Ltd	275	248 – RFI (CliniMed Ltd)	CliniMed did reference Wilson, but it was Wilson (Br J Nurs, 2015; Vol 24, No 2)	Thank you for your comment, The EAG does not consider this to be a factual inaccuracy (same reference: https://pubmed.ncbi.nlm.nih.gov/25615991/). To remain consistent, we have not added the volume and issue number to Appendix C5 #248, but have checked the page numbers align with the PubMed citation.
9.	Coloplast	14	2. Clinical Context	<i>'Intermittent catheterisation is typically taught by a urology or continence specialist nurse in an acute hospital setting (outpatient or inpatient appointment).'</i> <i>There is insufficient evidence provided to support this claim. Community continence services can initiate, it is not always a hospital-focused intervention.</i>	Thank you for your comment. The EAG asked the clinical experts to comment specifically on this and the next sentence. Two clinical experts considered that the intermittent catheterisation was typically taught in an acute setting, 1 expert advised that intermittent catheterisation could be commenced in community care by a district nurse if the patients could not mobilise well to attend acute care. The EAG has added a sentence to reflect this feedback in section

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
					2 of the report (and questions and responses from the 2 experts have been inserted into Appendix D).
10.	Coloplast	76	Pain	Cardenas et al., 2011a and Cardenas et al., 2011b are the same article.	Thank you for your comment. This was a duplicate reference (same content different formatting of journal name), 2011b has been removed (EAG have confirmed not referred to anywhere else in the report)
11.	Coloplast	76	Pain	References are unclear: ' <i>One study reported no difference in feeling of pain or burning between an uncoated catheter with no additional features, and a pre-activated hydrophilic coated catheter with enhanced coating and specially designed package (Cardenas et al., 2011a; Gopalakrishnan et al., 2022).</i> ' Two references were included here.	Thank you for your comment. One study is correct. The EAG have removed reference to Cardenas (which reports on comfort on insertion and withdrawal (rather than pain).

12.	Convatec	Page 7	Abbreviations	In the final scope document, it was recognised that there is difference in lubrication methods and benefits of good lubrication for user comfort and protection of the urethral lining, the first line of defence to UTIs. Within the technologies section it recognised (page 6 of Scope Document): · basic traditional lubrication (pre-lubrication or lubrication applied externally) or hydrophilic coated. · innovation enhanced lubrication or coating technology. The enhanced lubrication refers to Convatec's FeelClean Technology (a hydrophilic non PVP integrated amphiphilic surfactant or IAS) which is a unique innovation in lubrication and scientifically is not a coating and as such provides protection to the urethral lining. This difference in lubrication technology is significant across the LSA and is clearly part of the scope as noted on page 9 of Scope Document of the Decision Problem in the intervention section. The factual inaccuracies in the External Assessment Report and Model, and the exclusion of the fundamental difference in lubrication technology and categorisation of the categories is flawed. The Abbreviations clearly identifies f6lubric Catheter feature: enhanced coating, this is	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The EAG have assigned "enhanced coating" to 2 Convatec catheters (see Appendix A); using the description and definitions listed in Table 1 of the EAG report. Within Appendix A, the EAG had also previously specified "integrated amphiphilic surfactant" to differentiate this technological difference from the other types of enhanced lubrication (as this feature is a composite of multiple types as per NICE final scope). There was lack of consensus amongst clinical experts regarding catheter categorisation and mixed terminology amongst companies. This limitation has been reported in the EAG report. Regardless of features present, the EAG did not identify any controlled comparative evidence for any Convatec catheters, so cannot determine the efficacy or effectiveness of the integrated amphiphilic surfactant, therefore it will not contribute to component network meta-analysis, and the EAG cannot comment on the value of that particular feature.

				inaccurate as the innovation it appears to be assessing should include enhanced lubrication (IAS), which factually is achieved by completely different technology. IAS which is not a coating. This term 'enhanced coating' was used 284 times throughout the document, and if it was referencing the proposed innovation in the Scoping Document it does not include enhanced lubrication of IAS. It also suggests that the categorisation put forward in the model was confusing to the experts. This is noted in Question 5 and Question 12 clearly asks about broad catheter types based on coating and it has mixed well established definitions which expert 3 noted in Question 12. The misunderstanding of the categories is further supported by how they believe the usage is split, with the major used category choosing option 2. Catheter coated with lubrication gel (3 experts stated 80%). Catheter Definitions: a) Uncoated Catheter to which a gel or other lubrication is added separately. b) Gel Coated Catheter is already pre-coated with gel. c) Hydrophilic Catheters: i) Hydrophilic catheters that have a coating (PVP) that is activated by water. Water is added via tap or either it is sat in water or has water sachet to burst ii) Hydrophilic catheters with 'coating	

				technology' (PVP) that is activated by water iii) Hydrophilic catheters with 'enhanced lubrication' (non PVP-IAS) that is activated by water	

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
13.	Convatec	Page 284	Expert Questions	The categories described in the report and posed to the experts factually mix up hydrophilic and gel. From NHS data ePACT published Sept 23/24 shows that 95% of the market is hydrophilic (c) with 1% of this being ISC enhanced lubrication (c iii). The experts interpreted option 2. Catheter coated in lubricant gel = 80% of market when in fact this was 2%. Thus, the categorisation throughout the document and the reference to enhance coating is muddled and factually incorrect. We would suggest that the following categories should be used: Basic a) Uncoated catheters b) Gel pre-coated catheters c) Hydrophilic coated catheters standard PVP d) Hydrophilic catheters with 'coating technology' (PVP, PEG) Innovative a) Hydrophilic catheters with 'enhanced lubrication' (non PVP-IAS) We would suggest that the only innovation in	Thank you for your comment. Questions posed to the clinical experts (as listed in Appendix D) occurred during the EAG assessment, and therefore the report has evolved overtime incorporating as much feedback from experts as possible. The EAG note that there was a general lack of consensus on categorisation of catheters and which additional features are innovative. However, the EAG have not identified any controlled comparative evidence which demonstrates the efficacy or effectiveness of integrated amphiphilic surfactant feature, therefore cannot comment on its value. Please also see the response to comment 12.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				this space regarding to lubrication is IAS. Evidence regarding 'coating technology' and triple action is limited and not independent or peer reviewed. PEG is added to support bonding of PVP as it sheds. It is on this basis that a lack of scientific independent peer reviewed evidence it should be classed as basic. Non PVP IAS technology has been independently researched by Queen's University Belfast School of Pharmacy and published in a peer review journal Burns et al, ACS Omega 2024,9,22410-22422 as submitted in RFI. The building of scientific evidence regarding the differences in PVP and non PVP (IAS) technology is significant. We also challenge that excluding from scope the body of evidence around PVP vs non PVP, in published articles and abstracts is also factually incorrect as there is a direct correlation regarding PVP and damage to the urethra lining. Non PVP lubricated IAS catheters show 30% less damage to the urethra.	
14.	Convatec	numerous	numerous	The company name is referenced 30 times in the document and is spelt ConvaTec, this spelling was changed in 2022 to Convatec - can this be corrected.	Thank you for your comment. The EAG had used the company name as currently listed in the Drug Tariff part IX. However, the EAG have updated the 30 instances of incorrect spelling within the report.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
15.	B Braun Medical	258 & 265	Appendix C5 Excluded Studies	The EAG report states that Lampuré et al (2020) was excluded because “<i>data [is] in public domain in Chartier-Kastler (2022)</i>” (p265, #117). This is not accurate; only one of the analyses (namely, prelubricated vs. hydrophilic catheters) was included in Chartier-Kastler (2022). The other analyses from Lampuré et al (2020) (namely, Actreen vs. SpeediCath and Actreen vs. hydrophilic catheters as a category) are not included in Chartier-Kastler (2022), which is the reason for B. Braun including it in the RFI. Given that the EAG invited evidence comparing named catheter brands, which Lampuré et al (2020) provides, its omission is significant. The above statement that Lampuré et al (2020) was excluded because Chartier-Kastler (2022) was included is in itself incorrect, because Chartier-Kastler (2022) was also excluded (p258, #34) for the reason of “potential mix of catheters, EAG unable to verify additional features.” Therefore, Lampuré et al (2020) should be included because its Actreen vs. SpeediCath analysis is not a “potential mix of catheters.” The EAG’s protocol for this LSA states that “controlled, comparative studies” will be considered for inclusion and Lampuré et al (2020) meets the eligibility criteria outlined in the PICO, including: Compares more than one intermittent	Thank you for your comment. The EAG have updated the reason for exclusion to acknowledge that Chartier-Kastler (2022) was subsequently excluded. The EAG have reviewed Lampure again and note that this is an internal report (the EAG prioritised published peer-reviewed comparative publications as stated in section 4.1.1 of the EAG report). The EAG note that the Actreen arm combined multiple catheters together (Actreen Glys Cath, Actreen Glys Set, Actreen Lite, Actreen Hi-Lite, Actreen Hi-Lite Set, Actreen Mini Cath, Actreen Mini Cath Set, Actreen SafeSet; as listed on page 24 of 128 of the Lampure et al. 2020 report). The EAG note that these catheters have different features (as stated in Appendix A of EAG report). The EAG note that the SpeediCath arm included a range of catheters not further differentiated (page 25 of the 128-page internal report). Therefore, the EAG excluded this report based on mixture of catheters and being unable to attribute effects observed to specific feature.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				catheter types, Is a study of patients in the UK (NHS) setting, Has subgroups of patients including gender, history of UTI and indication for catheterisation Reports the outcomes frequency of use per day, UTIs, and recurrent UTIs.	

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
16.	B Braun Medical	23	3.1	Actreen is a prelubricated catheter coated with a glycerin gel lubricant. The classifications used to describe this lubrication concept in the LSA describes Actreen as ‘uncoated – prelubricated’ which is inaccurate. Furthermore, classifying a prelubricated catheter as uncoated is confusing and misleading as ‘coated’ is a term used to describe both gel and hydrophilic catheters. The EAG report goes on to describe the dichotomising coatings on page 27 as either uncoated or hydrophilic. It would be more accurate to reference as uncoated and coated, with subcategorisation of “coated hydrophilic” and “coated prelubricated”. There additionally seem to be some further inaccuracies related to the misunderstanding of prelubricated catheters. For example, on p198, Appendix C1, #10, SpeediCath is described as “hydrophilic polyurethane pre-lubricated” and p78, Section 4.2.4.5, “a pre-lubricated hydrophilic coated catheter with additional features”. This language contradicts existing NICE Guidelines (CG139) around intermittent catheter types; specifically: “You should have a choice of two types of intermittent catheter for single use: these are called hydrophilic catheters and gel reservoir catheters.” NICE’s wording from this guideline demonstrates that	Thank you for your comment. There was lack of consensus amongst clinical experts regarding catheter categorisation and mixed terminology amongst companies. The definition of coating (that is hydrophilic polymer coating) is described in the technology section 3. However, the EAG have added the following sentence to be transparent: “For the remainder of this report the EAG will refer to “uncoated” to mean lacking hydrophilic polymer coating.” The EAG have replaced the 2 instances of “pre-lubricated hydrophilic” with “pre-activated hydrophilic” to ensure consistency within the report.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				prelubricated (gel reservoir) catheters are distinct from hydrophilic catheters.	
17.	B Braun Medical	147	Appendix A	In the document returned to NICE titled “B. Braun Medical Ltd features clarification table” B. Braun responded to say that Actreen catheters feature an enhanced lubrication. The table on page 147 shows a factual inaccuracy with “No” stated against each Actreen product line in the enhanced coating column.	Thank you for your comment. The EAG used the definition of enhanced coating (defined within Table 1), which the Actreen catheters do not meet as none have hydrophilic coating. The EAG has selected that the Actreen catheters are all “uncoated (pre-lubricated)” - see Appendix A. There was lack of consensus amongst experts on whether ready to use and pre-lubrication was an innovative additional feature (see question sent to experts on 18/10/2024 Appendix D Question 4). The EAG note that only 2 comparative studies using specific Actreen catheters were identified by the EAG (Bonello, Gregghi) and both reported on ease of use and comfort where only a narrative summary was possible due to heterogeneity in report. Neither study reported on UTI or haematuria. Therefore, adding

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					features to this specific catheter will not result in any changes to component network meta-analysis or economic analysis and the conclusions will remain unchanged.
18.	Coloplast	19	3.1 Intermittent catheters used in the NHS	<i>'To put this number into context, this would equate to approximately 52,300 patients assuming patients use 5 intermittent catheters a day (as advised by clinical input, Appendix D; question 9) for a year.'</i> <i>There are a wide range of routines for different patients, not every patient performs catheterisation 5+ times a day. The frequency of catheterisation is determined by a number of factors such as symptom severity and quality of life implications (RCN Catheter Care 2021) but is often driven by the post void residual urine. EAUN (Vahr 2024) guidelines state that 4-6 times a day is a typical frequency for someone unable to void without the use of a catheter. Many retain this ability despite having a degree of retention so often people may be given a regime with fewer catheterisations. This is part of individualised care based on the patient's clinical presentation and wider factors.</i> Although five catheters per day is the recommended routine for patients needing a catheter to empty their bladder (EAUN guidelines, Vahr 2024), assuming a patient population from this can only be a very rough	Thank you for your comment. The EAG does not consider this a factual inaccuracy, as it is the mid-point of the recommended 4-6. Catheters used per day were varied in one-way sensitivity analysis (3 and 7 catheters used); see Table 21 of EAG report. No change has been made.

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				approximation due to the variability in catheterisation routines.	
Clinical evidence					
19.	Coloplast	65-66	4.2.4.3 Residual volume	The EAG defines residual urine as the post-void residual volume. The studies on MHZT includes a different measure called RV1, residual urine at first flow-stop as the primary outcome and support the appearance of flow-stops that occur in conventional 2-eyelet catheters. Results show a significant difference between the different catheter types leading to increasing risk of leaving urine behind in the bladder and increasing the risk of UTIs. This is not included in the EAG evaluation (Landauro et al. 2023).	Thank you for your comment. Different definitions of residual volume were reported in the published literature (see raw data extracted from papers in Appendix C4.1 in the EAG report). Selection of evidence was outlined in section 4.2.4.3, where the EAG outlined the rules they applied in order to maximise the number of studies reporting on a common metric for residual volume. Only 3 studies report on RV1, whereas 4 studies have reported on post-void residual volume used by the EAG. Regardless of the definition used, the EAG noted within the report (summary of findings in section 4.2.4.3) that "for residual volume to be measured (most likely with portable ultrasound), the user would be needed to attend a healthcare setting. Therefore, their behaviour may change and not reflect results if the intermittent catheterisation was undertaken in user's usual setting. The additional noted skewed

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					distributions in this outcome make drawing conclusions uncertain." Therefore, the impact of this will not change the conclusions within the report.
20.	B Braun Medical	58	4.2.4.1 UTI	Within the EAG report, UTI risk is estimated to be 58% for intermittent catheter users receiving an uncoated catheter. The broad category for uncoated catheters including catheters with <i>"no lubricant provided, lubricant provided and prelubricated"</i> assumes that a prelubricated catheter has the same UTI risk as an uncoated catheter without lubricant. Newer evidence for prelubricated catheters and related UTI risk is mentioned in <i>Appendix C5: Excluded studies (point 34, B. Braun RFI)</i> . This evidence has not been included in this EAG because of the <i>potential mix of catheters and the EAG being unable to verify additional features</i> . There is value to include this positive evidence for prelubricated catheters versus hydrophilic catheters, looking at the reduced risk of symptoms suggestive of UTIs for the two different lubrication concepts.	Thank you for your comment. This is a feature based assessed to determine whether the pricing variation is justified. Inclusion of evidence with mixed catheters (with different additional features) may mask effects and increase uncertainty. Therefore, the EAG has only included evidence where specific named catheters were used (such that features could be attributed) enabling estimation of effects related to specific features.
21.	Coloplast	52	4.2.4 Key primary evidence	<i>'None of the included comparative studies reported on frequency of use, sepsis, bladder or kidney stones or hospitalisation outcomes. The EAG asked Clinical and Lay Experts to rank the 13 outcomes listed in the NICE Final scope in order of importance. Across the four Experts who responded (Appendix D) the bottom two outcomes</i>	Thank you for your comment. The outcomes ranked the lowest importance varied between individuals, therefore, the 6 outcomes listed demonstrate the lack of consensus amongst both lay and clinical experts. The EAG have added wording to the report to clarify this point. Methodology was pragmatic within the context of this LSA, where the

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				<i>considered to have lowest importance were: bladder or kidney stones, other device-related adverse events (for example retained fragment), frequency of use per day, hospitalisation, sepsis, and UTIs or recurrent UTIs.'</i> It is unclear how the lowest two outcomes can be listed as the above six outcomes (1. bladder or kidney stones, 2. other device-related adverse events (for example retained fragment), 3. frequency of use per day, 4. hospitalisation, 5. sepsis, and 6. UTIs or recurrent UTIs). <i>According to the ratings of the experts there is a clear difference between the bottom two e.g. "bladder or kidney stones" and "other device related adverse events" and the "UTIs or recurrent UTIs" and "sepsis." The methodology for the rating this is unclear and does not look scientific. Especially the UTIs are mentioned by two of the experts as number 1 and 2.</i>	EAG asked each expert to comment on the importance of the 13 outcomes listed in the NICE final scope (1=most important) as described in Section 4.2.4 and reported in Appendix D. This question was asked by the EAG and was separate to the user preference work conducted by NICE.
22.	Coloplast	36, 282	Appendix D	'The EAG considered CNMA for outcomes listed in the Final Scope which were prioritised by Clinical and Lay Experts (UTI, haematuria, residual volume, discomfort or pain, ease of use).' Discomfort, Ease of Use and Pain Outcomes: The outcomes included in the ranking task	Thank you for your comment. Questions posed by the EAG to experts when ranking outcomes (see Appendix D of EAG report) used exact wording of outcomes as listed in the NICE final scope. Where a number of studies reported on specific outcomes (e.g. comfort and ease of use which were modelled as two separate outcomes), the EAG attempted to aggregate similar

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				do not align with those included in the analyses. 'Comfort and ease of use' was presented to the stakeholders as one item. However, this outcome was decomposed into two outcomes in the economic model as 'Discomfort/pain' and 'Ease of use' (implemented as disutility). It is unclear where the boundary between "Discomfort" and "Comfort" lies, as the same studies were often analysed for both outcomes. The importance of 'pain' was not assessed by the stakeholders. Accordingly, Coloplast questions the validity of the ranking task results, as it is impossible to discern how the inclusion of pain and decomposition of outcomes would have affected the rankings.	subcategories of outcomes together, based on the definitions reported in individual studies. The EAG have noted that there was a lack of consensus regarding definition of outcomes in the published literature. The EAG considered discomfort and pain separately due to inability to determine a common scale. Raw data extracted from eligible studies is reported in Appendix C. Due to the lack of common scale and differences in reporting, the EAG was unable to conduct CNMA on any of these outcomes and provided a narrative summary where possible. The EAG would highlight that, even if the top 3 outcomes across the 4 experts were included, no change would be made to the EAG report as no studies reported on frequency of use or sepsis.

23.	Coloplast	53	4.2.4.1 UTI	<i>'Definition of UTI is standardised to proportion of patients experiencing a UTI within 30 days..... UTI (defined as patient experiencing symptoms, antibiotic treatment)'</i> <i>This is different to the definition of CAUTI from the Final Scope.</i> <i>As previously advised, this is more appropriate for indwelling catheters and not intermittent catheters. The definition of UTI was raised in the stakeholder meeting on 21st August 2024 and during that meeting no consensus was reached around which definition would be used.</i> <i>Definition of CAUTI from NICE is Catheter-associated UTI is defined as the presence of symptoms or signs compatible with a UTI in people with a catheter with no other identified source of infection plus significant levels of bacteria in a catheter or a midstream urine specimen when the catheter has been removed within the previous 48 hours (adapted from the Infectious Diseases Society of America's guideline on catheter-associated UTI [2009]).</i>	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The EAG selected a definition of UTI that was most used in the published literature in order to maximise the number of studies included in component network meta-analysis (as per description in section 4.2.4.1). CAUTI is a different outcome and not explicitly reported in the published literature. No changes to the report have been made.

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24.	Coloplast	74-75	Comfort	The catheter features included in the EAG are not the primary factors contributing to Comfort. Five studies— (Cardenas et al., 2011b; Chartier-Kastler et al., 2011; Domurath et al., 2011; Thiruchelvam et al., 2024a; Thiruchelvam et al., 2024b)—were included in the evaluation of discomfort. Only Cardenas et al., 2011b compared pre-activated hydrophilic-coated catheters with uncoated catheters. The other four studies focused on compact vs. standard designs or Micro-hole Zone Technology vs. conventional eyelets. These features were not identified as major contributors to comfort.	Thank you for your comment. The EAG looked at eligible studies which have reported on comfort or discomfort, identified the catheters used in the intervention and comparator arm, and then added the features attributed to those catheters (based on Appendix A). The presence or combination of features may impact outcome - hence the EAG used component network meta-analysis to explore the effect of each feature in isolation. Where the EAG was unable to attribute an effect to a specific feature, no comment was made.
25.	Coloplast	74-75	Comfort	The analysis on Comfort does not include all features that could potentially impact this outcome. Among the five studies included in the Comfort analysis, two focused on Micro-Hole Zone Technology vs. conventional eyelets, yet the Results section does not provide any description of this aspect.	Thank you for your comment. Please see the response to comment 24.
26.	Coloplast	72	Discomfort and Pain	<i>'When assessing patient reported discomfort the EAG attempted to conduct a CNMA (see Figure 4 for a network diagram). However, it was judged to be infeasible. The EAG tried several different models which either failed to converge or led to estimates with</i>	Thank you for your comment. Where CNMA was not possible, the EAG provided a narrative summary where able, as described in the published protocol.

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				<i>implausibly wide 95% credible intervals'</i> When the data are not suitable for the model, alternative approaches should be considered to evaluate discomfort and pain.	
27.	Coloplast	9	Executive summary; summary of technologies	Coloplast finds issue with the generalisability of the evidence base to the scoped interventions: Mapping the available evidence onto the intervention features as scoped was difficult and the EAG acknowledge that "Catheter design and features were generally poorly described, missing or open to interpretation; this may have resulted in cases of mis-categorisation by the EAG....none of the identified published literature addressed the clinical efficacy or effectiveness of these features directly." This seems to indicate a mismatch between the scope and the available evidence. Additional data collection / generation may be a better way to gather suitable evidence to assess the value of features, rather than attempting to use an existing evidence base that is not designed to do this.	Thank you for your comment. The EAG does not consider this a factual inaccuracy, and no changes were made to the report.

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28.	Coloplast	47, 53, 60, 74	4.2.2 Quality appraisal of clinical evidence 4.2.4.1 UTI 4.2.4.2 Haematuria Comfort	Generalisability of the evidence base to the scoped population: 9 of the 18 studies included only patients with spinal cord injury. For the CNMA of UTI, 4/4 studies were in this population; 3/6 for the CNMA of haematuria, and 3/4 for the CNMA of comfort. While this is a limitation of the evidence base rather than the review methods it does mean that the generalisability of any findings to the broader scoped population is questionable.	Thank you for your comment. The differences in populations are noted in section 4.2.4.1 (UTI), 4.2.4.2 (haematuria). The EAG has added the following sentence to section 4.3 to highlight generalisability across populations: <i>"The generalisability of results from studies reporting on specific catheterisation indications (for example studies exclusively in patients with spinal cord injury) to other populations is unclear."</i>
29.	Coloplast	Through out	Throughout	Throughout, the report and economic model are set up to reflect neurogenic population, specifically 'spinal cord injury' rather than the wider population that benefits from the use of the ISC, which does not align with the scope of the ISC LSA. Intermittent catheterisation is recognised as gold standard method of catheterisation for both neurogenic and non-neurogenic population. There is some commentary in Appendix D on the generalisability of data collected in secondary (hospital) settings to primary/community settings, but there is a noticeable lack of narrative around the spinal cord injury population relative to the others.	Thank you for your comment. The clinical evidence section reflects published comparative evidence. Some studies reported on the neurogenic population, with others reporting on a mixture of neurogenic and non-neurogenic participants (see Table 4 in the EAG report which summarises included studies). The EAG consulted with experts to ask about the generalisability of evidence from neurogenic to non-neurogenic indications. One clinical expert said that UTI and residual volume outcomes would not be expected to be different between groups. However, they highlighted that differences would be expected in haematuria, comfort and ease of use outcomes. The EAG have updated the report to include this feedback.

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30.	Coloplast	62	4.2.4.2 Haematuria	Regarding Table 7 – Cardenas (PM&R, 2011): Microhaematuria was measured by dipstick after 3 and 4 weeks into the study. It is a mistake to divide by 6 months as in Table 7. Furthermore, haematuria is measured once and provides evidence of how it looked at that particular day. It does not accumulate over time, so it does not make clinical sense to divide by a time period to get 30 days.	Thank you for your comment. The EAG have re-reviewed this study and confirm that the microhaematuria was measured between week 3 and 4. The EAG had attempted to map outcomes on a common scale for descriptive purposes in the table. CNMA inputs were based on dichotomous data, so these estimates are not impacted by these descriptive data. This has been clarified in the EAR. See response to Coloplast Comment 46.
31.	Coloplast	62	4.2.4.2 Haematuria	Regarding Table 7 – Chartier-Kastler (Spinal Cord, 2011): The study mentions that 2 episodes of bleeding were observed within a two-week period. However, when starting a new catheter, there is increased risk of bleeding episodes in the first week, until new technique is mastered (De Ridder 2005). Bagi et al. 2010 did not find any significant differences in healthy volunteers.	Thank you for your comment. The study by Bagi was excluded by the EAG as it was conducted exclusively in healthy volunteers (see Appendix C5, row #5) which lacks applicability to the target population. The EAG re-reviewed the study by Bagi and notes that "All catheterisations were performed by 1 of 3 trained study nurses" therefore results may not be generalisable to patients using intermittent catheterisation in primary and community care setting. Please also see the response to comment 30.
32.	Coloplast	282	Appendix D	Outcome Selection: The stakeholders ranked outcomes (defined by the NICE Final Scope) according to importance (1 = most important; 13 = least important). The outcome rankings differed between stakeholders.	Thank you for your comment. Raw data for all outcomes (regardless of ranking) are in Appendix C4 of EAG report. None of the eligible studies reported on frequency of use, as stated in the EAG report.

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				'- Expert 1 (rank = 2) and Expert 3 (rank = 1) indicated 'UTI and recurrent UTI (including CAUTI)' among their most important outcomes, while Expert 4 ranked it among their least important (rank = 12). '- Expert 1 (rank = 2) and Expert 3 (rank = 1) indicated 'Urethral trauma, bleeding, haematuria, structures and urethritis' among their most important outcomes, while Expert 4 ranked it as their least important (rank = 11). '- Expert 1 (rank = 3) and Expert 3 (rank = 3) indicated 'Sepsis' among their most important outcomes, while Expert 4 ranked it as their least important (rank = 13). '- Expert 4 (rank = 3) indicated 'Frequency of use per day' among their most important outcomes, while Expert 1 (rank = 11), Expert 2 (rank = 10) and Expert 3 (rank = 13) ranked it among their least important. As the stakeholders' affiliations are redacted and no qualitative data were elicited to provide rationale for the rankings, we cannot determine whether these results reflect meaningful differences in perspective and treatment preferences between lay users and clinicians. Given the small sample size and underrepresentation of lived experience users, we question the appropriateness of employing these methods to determine	

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				which outcomes should be included in the analyses. We note that the ranking differences are referred to by the EAG and caution that outcomes may have consequently been omitted that are important to lived experience users (e.g. 'Frequency of use per day').	
33.	Coloplast	75	Pain	The title is missing for "Pain" section.	Thank you for your comment. The missing heading has been added onto page 76.
34.	Coloplast	p. 32-33, p. 38, p. 154-179, p. 191-192	Section 4.1.1 Search methods Section 4.1.5 Protocol deviations Appendix B1 Search for clinical evidence Appendix B3 Search for ongoing studies	The EAG searched for systematic reviews (SRs) in MEDLINE, Embase, CINAHL and CDSR. Although this is a reasonable range of resources, the robustness of the methods used to identify clinical evidence SRs might have been increased by also searching databases that specifically collate records for SR publications (such as Epistemonikos and KSR Evidence) and by searching the HTA Database (searched for the controlled comparative studies search, but not for the SR search). SRs are often conducted as part of HTAs. KSR Evidence is a subscription database but Epistemonikos and the HTA Database are free to access. The EAG searched for controlled comparative studies in MEDLINE, Embase, CENTRAL, CINAHL and the HTA database. This is a reasonable range of resources. In the published protocol the EAG stated that	Thank you for your comment. The EAG used a pragmatic approach, in line with the LSA interim methods and process, and considers that the searches are fit for purpose. No additional relevant literature was identified by any stakeholders during the factual accuracy comment period. No changes have been made to the report.

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				they would search for ongoing studies in ClinicalTrials.gov and WHO ICTRP. In the report the EAG notes that these searches were undertaken “but due to resource constraints the records retrieved by these searches were not screened”. The EAG states that the focus of the LSA was on completed studies rather than ongoing studies; however, they also acknowledge that “clinical trials registries can be a source of study results (for instance the results tab in ClinicalTrials.gov)”. Given this, the robustness of the methods used to identify controlled comparative study evidence might have been increased by assessing the ClinicalTrials.gov and WHO ICTRP results. Any limitations of the database selection will have been mitigated however by supplementary search approaches used by the EAG. These included considering primary evidence in retrieved systematic reviews and identifying studies from evidence provided by the companies. We also note that the NICE interim methods and process statement explicitly suggests that searching a limited selection of databases is a rapid review method that could be included in the context of a pragmatic approach to the LSA evidence review.	

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35.	Coloplast	p. 154-157	Appendix B1a Search for systematic reviews of controlled comparative studies published since 1 January 2021 to most recent available record	Clinical evidence search for SRs of controlled comparative studies: MEDLINE strategy The MEDLINE strategy was structured: urinary catheterisation AND SRs AND controlled comparative studies. The terms for controlled comparative studies concept are based on CADTH (now CD-AMC) filter (which it seems reasonable to assume was designed to retrieve primary studies). Including a concept for controlled comparative studies in this way may have increased the risk of missing relevant SRs as the approach relies on the included study design being made explicit in the database record (using the terms in a filter designed to identify primary studies); this may not always be the case. We note that use of additional truncation in the intervention terms might have optimised the range of variant terms captured by the strategy. For example, if the term intermittent had been truncated, the strategy would retrieve records that referred to terms such as intermittently catheterized. If the term bladder had been truncated, the strategy would retrieve records that referred to catheterisation in the context of bladders plural as well as bladder singular.	Thank you for your comment. Please see response to comment 34. No changes have been made to the report.

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				The search terms for the SR and controlled comparative studies concepts are based on CD-AMC filters. We note that the validation status of both filters on the CD-AMC website is 'pragmatic'. This means the filters have been pragmatically validated rather than validated against a gold standard set of articles. This validation status means that the filter user has less confidence that the filters are appropriately robust. However, we note that despite the 'pragmatic' status, CD-AMC are a recognised source of published search filters, and CD-AMC state that their "filters have been extensively tested by the Research Information Services team and are routinely used in our projects".	

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36.	Coloplast	p.154-192	Appendix B1 Search for clinical evidence Appendix B2 Search for economic evidence Appendix B3 Search for ongoing studies	Search strategy translations: It is beyond the scope of this assessment to look in any detail at the strategy translations. We note however that there seem to be some issues with the translations that may have adversely impacted on search robustness. The following are examples of issues identified in passing. 1. In the Embase translation of the clinical evidence search for controlled comparative studies, the decision to focus the intervention terms on a reasonably explicit intermittent catheter context means that the strategy does not include Emtree headings used to index studies on specific named devices that appear to be of interest. For example, from the report (Appendix A) it seems that SpeediCath and LoFric Primo are two specific devices of interest. In Embase the scope note for the urethral catheter Emtree heading indicates it is used to index studies on these two devices. This subject heading is not included in the search strategy; including it might have increased the robustness of the Embase strategy. 2. In all the Embase translations, searching device-specific fields (e.g. the Device Trade Name and Device Index Terms Word fields) for the intervention concept textword terms might have increased the robustness of the strategy.	Thank you for your comment. Please see response to comment 34. No changes have been made to the report.

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				3. Generally, we would expect the terms used in the translations to reflect the range of terms captured by the equivalent elements in the main strategy being translated (factoring in differences between the database search interface as appropriate), unless there was a particular rationale. On several occasions however, search approaches across different databases appear to be inconsistent, without any obvious reason. Sometimes elements of the translated strategy are broader than in MEDLINE. Sometimes more focused. It is not clear what rationale there is for the different approaches taken. Examples of where a different approach is taken in the translation to that in MEDLINE include: '- The intervention concept terms included in the Embase clinical evidence SR strategy. '- The intervention concept terms included in the CENTRAL clinical evidence controlled comparative studies strategy. '- The intervention concept terms and field restrictions in the HTA Database clinical evidence controlled comparative studies strategy. '- The intervention concept terms in clinicaltrials.gov and ICTRP clinical evidence controlled comparative studies strategies (search run but results not used). When the translation takes a more focused	

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				approach than that taken in MEDLINE, this may have adversely impacted on search methods robustness, and increased the risk of missing relevant studies. Any limitations of the translations will have been mitigated however by supplementary search approaches used by the EAG. These included reviewing all the economic evidence submitted by the companies, and all the primary evidence from identified relevant systematic reviews.	
37.	Coloplast	p. 164-166	Appendix B1b: Search for controlled Comparative Studies published between 1 January 2021 and most recent available, inclusive.	Clinical evidence search for controlled comparative studies: MEDLINE strategy: The EAG states that for this search (compared to the search for SRs) “the set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters to make the size of the search more manageable.” The EAG explicitly acknowledges that this approach “could mean that poorly reported studies may be missed”.	Thank you for your comment. Please see response to comment 34. No changes have been made to the report.

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38.	Coloplast	p172-173	Appendix B1c: Search for controlled comparative studies published from 1 January 2000 to 31 December 2020 inclusive	We note also that use of additional truncation in the intervention terms might have optimised the range of variant terms captured by the strategy. For example, if the term intermittent had been truncated, the strategy would retrieve records that referred to terms such as <i>intermittently catheterized</i>. We note that the search terms for the intermittent catheter concept did not include device brand name terms. Including brand name terms for known eligible devices may have increased the robustness of the search methods. The search was restricted to controlled comparative studies using terms based on the CD-AMC 'All Clinical Trials' filter (with terms added to find interrupted time series). We note the following potential issues in restricting the search in this way that may have impacted on the robustness of the search methods: 1. Cochrane and EUnetHTA methods guidance suggests that, given the challenges, limiting a search strategy by study design when searching for nonrandomised studies of interventions may increase the risk of missing eligible studies, as suitably robust filters are not available.	Thank you for your comment. Please see response to comment 34. No changes have been made to the report.

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				2. If for pragmatic reasons a filter is used, there seem to be potential issues around the selection of the CD-AMC 'All Clinical Trials' filter for this task - if any controlled comparative study is eligible. A filter for 'all clinical trials' would not seem to be designed to retrieve all controlled comparative studies, as some of these studies may not be clinical trials. 3. When a published filter is used, unless there is a particular rationale, it is usually recommended that it is used as published (as this is the strategy that will have been used and evaluated by the filter developer). The EAG states that the original filter was originally a multifile search which they adapted for use in MEDLINE, and that terms were also added to the filter to find interrupted time series. Beyond these changes though, it appears the EAG has changed some additional elements of the published filter (without an explicit rationale) which in effect make the changed elements more focused. As an example, in the published filter most of the textword search lines search across the following fields: ti,ab,hw,kf. In the EAG strategy, the fields in these lines appear to have been changed to: tw,kf. This means the terms are no longer searched on in the Subject Heading Word (hw) field. This focuses the affected search	

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				lines, meaning these elements of the filter work differently, and potentially less robustly, than in the original filter. The robustness of search methods might have been increased if the search had not been restricted using a controlled comparative studies concept, or if the terms in this concept had been designed to identify controlled comparative studies beyond clinical trials, or if elements of the CD-AMC filter that were focused were left unchanged. Any limitations of the search strategy approach used to identify controlled comparative studies will have been mitigated however by supplementary search approaches used by the EAG. These included considering primary evidence in retrieved systematic reviews and identifying studies from evidence provided by the companies.	

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39.	Coloplast	9	Executive Summary	<i>'The heterogeneity of the population and conditions has resulted in a wide range of needed catheter features as advised by clinicians (McClurg et al., 2015). Features prioritised by users include convenience, lubrication, ease of insertion, avoidance of trauma, independence, with risk of infection and independence being highly ranked (Kimoto et al., 2015; Pinder et al., 2015; Welk et al., 2021).'</i> No consensus was reached on the definition or importance of intermittent catheter features among clinical and lay experts, the above evidence should have been used to inform the process for determining outcomes important to the user. Moreover, it is important to assess the impact on quality of life for those using intermittent catheters. Generic measures tend to be insensitive to the improvements in catheters, therefore it is difficult to fully assess the cost-effectiveness in this space. There is a need for more inclusion or acceptance of disease specific measures to accurately reflect the improvement in quality of life for ISC users.	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The EAG has stated the evidence gaps and commented on the limitations (see section 7 discussion in EAG and 'summary' subsections throughout report). No changes to the report have been made.

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40.	Coloplast	10	Executive Summary	<i>'Specially designed catheter case was found to increase the risk of haematuria'</i> - The evidence does not demonstrate this as fact. - One study, Bagi et al. (Urol Int 2010) found: The difference between the two catheters in haematuria grade distributions was not statistically significant (fig. 4). Visible blood on the catheter was recorded in 6.7% of catheterisations with the compact catheter (3 out of 45 observations; 3 different subjects) and 6.3% of catheterizations with the regular catheter (3 out of 48 observations; 3 different subjects; p = 0.89). - Although the Bagi Study was excluded from the EAR because it was performed on healthy male volunteers, for evaluating the risk of haematuria of different catheters choosing a 'naïve' population like healthy volunteers would show the effect of the tested catheters. From the study: - o 'For example, microhaematuria is an objective indicator of lesions to the urethral epithelium in individuals who are able to void voluntarily; however, in patients who are unable to do so, a urine specimen obtained by catheterization mainly indicates whether there are erythrocytes present in the bladder, and not in the urethra. - o Any potential lesions to the urethra would	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The reason for exclusion is stated in Appendix C5 (population out of scope).

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				leave erythrocytes on the outside of the catheter, but not in the urine specimen. o For this reason, it is much stronger to measure haematuria in volunteers where you test the urine following the catheterisation. '- One should also take into consideration the investigated population as men with BPH would have higher risk of bleeding due to a vascular enlarged prostate. This is not taken into consideration in the report.	

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41.	Coloplast	62	4.2.4.2 Haematuria	Table 7 shows the following improperly excluded studies: Vapnek 2003: Compare coated with uncoated. Was excluded because uncoated was multi-use, however multi-use is not expected to influence haematuria Stensballe 2005: Compare two coated with uncoated, was excluded because study was performed on healthy individuals, however that is not expected to affect outcome Chartier-Kastler 2013: Compare compact with non-compact catheters. Reason for exclusion is that the non-compact catheter group uses different types of catheters. However, in a meta study the comparator will always be mixed and the essential part is to compare two features, not two brands? Bagi 2011: Compare compact with non-compact catheters. Reason for exclusion is that the study group is healthy individuals, however that is not expected to affect outcome	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The reason for exclusion stated in Appendix C5 (regarding alignment with scope).
42.	Coloplast	73	Discomfort	The catheter features included in the EAG are not the primary factors contributing to discomfort. Three studies—Chartier-Kastler et al. (2011), Domurath et al. (2011), and Thiruchelvam et al. (2024a)—were included in the evaluation of discomfort. The catheter characteristics assessed in these studies were compact vs. standard designs or the Micro-hole Zone	Thank you for your comment. Please see the response to comment 24.

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				Technology,vs. conventional eyelets. These features were not identified as major contributors to discomfort.	
43.	Coloplast	73	Discomfort	The inclusion criteria for the studies are inconsistent: Gregghi et al. (2022) did not clearly specify how discomfort was scaled, yet it was still included in the EAG, and its results were discussed.	Thank you for your comment. The unclear scale was not a reason for exclusion (the comparative study included catheters with features in scope and reported on outcomes in scope). The EAG have reported the following in Table 10: "Discomfort during the procedure with the catheter [scale unclear]"; to make clear that the outcome definition was unclear. The EAG was unable to conduct CNMA for this outcome, and gave a narrative description only, which also reiterated that the scale was not reported: "Another study {Gregghi, 2022 #76} reported similar median discomfort levels while using the catheter between pre-lubricated uncoated catheters with features and pre-activated hydrophilic catheters with features in users with urethral sensitivity; however the scale on how this was measured was not defined {Gregghi, 2022 #76}" on page 74 of the EAG report.
44.	Convatec	Page 10	Clinical Evidence	In order, to meet the scope of the LSA evidence was requested, to then only include Clinical evidence via a RCT as relevant in the assessment and exclude any Scientific evidence means the findings are flawed and inaccurate. It does also introduce bias as	Thank you for your comment. The EAG considers it to be factually incorrect to state that the EAG restricted to RCTs only, as the EAG considered all comparative studies (as evidenced by Table 4 in the EAG report). As per

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				only a limited number of organisations have the time and resource to invest in this area. It is factually inaccurate to assess impact or superiority of a technology using only a RCT. When looking at damage to the urethra, is the first line of defence which is undisputed, the scientific studies need to be included. Unlike the LSA for wound care RCT and visual assessment plus blind studies are relevant and valid. In this space the presentation of the products makes this bias and not being able to assess the internal urethral health and micro trauma can only be scientifically achieved using scientific studies. Thus, excluding this is inaccurate of the assessment and model built.	section 4.8 of the LSA process and methods guide "When there is a large amount of relevant evidence to present during the assessment stage, the EAG can prioritise those studies or data it considers most relevant to the decision problem." The EAG note that no specific study was shared by the Company to the EAG demonstrating that presence of a specific feature has resulted in significant reduction in urethral injury.
45.	Coloplast	53	4.2.4.1 UTI Tabel C4.5 UTI, including recurrent UTI and CAUTI (N=6)	Only 4 clinical studies were included in the UTI analysis and this seems like a low number - especially when looking at other meta-reviews that include more studies. Exclusion reason "<i>Results without a follow-up duration</i>" seems not to be relevant or understood. Other published meta-analysis that should/could have been taken into consideration: 1. Rognoni and Tarricone BMC Urology (2017) 17:4 includes 7 clinical studies.	Thank you for your comment. The EAG considered the primary evidence from the following systematic reviews (as documented in Appendix C5): - Rognoni (BMC Urology; 2017; 4-14) - Barken (BMC Urology, 2022; 1-18) - Li (Arch Phys Med Rehabil, 2013; 782-787) - Shamout (Spinal Cord, 2017; 629-643) - Christison (J Neurotrauma, 2018; 985-989) was a reanalysis of Prieto (whose primary evidence was considered by the EAG).

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				2. Barken and Vaabengaard BMC Urology (2022) 22:153. Ten out of the 20 clinical studies included numbers that could be extracted and compared. 3. Christison et al. JOURNAL OF NEUROTRAUMA 35:985–989 (April 1, 2018): “In contrast to the review by Prieto and colleagues, we found that “Analysis 2.2” exhibits a trend (albeit small) toward the single use (sterile) of catheters, and “Analysis 3.2” significantly favors hydrophilic catheters (Fig. 1).” 4. Li L, et al. Arch Phys Med Rehabil. 2013;94(4):782–7. 5. Shamout S et al. Spinal Cord. 2017;55(7):629–43	All raw data from eligible studies reporting on UTI were included in Appendix C4; however CNMA restricted results to those that could be transformed onto a common scale (hence removal of studies where the timepoint at which UTI was measured was not reported).
46.	Coloplast	53	Definition of the UTI	<i>If clinical UTI data was not reported in the study, other definitions of UTI were included. For example, focus on bacteria counts or dipstick results, rather than patient symptoms.</i> From guidelines*, it is not advised to evaluate bacteria counts or dipstick results without the presence of patient symptoms in the IC population. New onset of symptoms should be present before treatment, so it is erroneous to include studies focused on bacteria counts or dipstick, rather than patient symptoms. *Guidelines: 1. <i>Kranz et al. EAU guidelines on</i>	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The EAG were summarising the definitions of UTI reported in across the published literature which varied across studies. Raw data extracted for the UTI outcome across the eligible studies is reported in Appendix C4.

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				urological infections. Summary of the 2024 Guidelines. <i>EUROPEAN UROLOGY</i> 86 (2024) 27–41. doi.org/10.1016/j.eururo.2024.03.035 2. Blok et al. <i>EAU Guidelines on Neuro-Urology</i>. Arnhem: European Association of Urology; 2022. 3. Hooton et al. <i>2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America</i>. <i>Clin Infect Dis</i>. 2010 4. Vahr et al. <i>EAUN guidelines on Urethral intermittent catheterisation in adults</i>. 2024.	
47.	Coloplast	56	Table 5: Studies reporting UTI/30 days (outcomes transformed into common scale) (n=4 studies)	The calculation of UTIs: For the 4 remaining studies included, the number of patients experiencing a clinical UTI (defined as patient-reported symptoms or antibiotic treatment) were converted into the proportion of patients experiencing a UTI per 30 days (UTI/30 days). It is uncommon to measure UTIs per month. How can this be doable, when patients on average have 2-3 UTIs per year, and then turn UTI numbers into “proportion of patients experiencing a UTI/ 30 days”? The chosen approach only shows the percentage of people having ≥ 1 UTIs and not the average number of UTIs/ year for each patient. This may not be an appropriate way to calculate the risk of getting UTIs.	Thank you for your comment. The EAG has converted the number of events into a monthly rate to enable comparison between studies onto a common scale for descriptive purposes. However, the CNMA and subsequent economic analyses were based on risk ratios and not monthly rates. This has been explained further in the report. Please also see the response to comment 46

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				In addition, the mentioned modelling is very difficult to follow and understand.	
48.	Coloplast	56 -62, Model: D20:D2 2	Section 4: Key Primary Evidence: Table 5 and 7 Model: Clinical Effects	In Table 5 and 7 for the risks associated with UTI and haematuria, the 30-day risks are calculated. However, from what is presented in the tables, the risks are calculated incorrectly throughout. A risk cannot simply be transformed to a different time period by multiplying or dividing it by the number of weeks. For example, Table 7, De Ridder (2005), the risk is used in the model for risk of bleeding. The risk of 69% is simply divided by 12 to find 5.8% - this is not correct mathematically. To find this monthly, you would have to do the following calculation: 1. Transform the annual risk into a rate: = $-\text{LN}(1 - \text{risk})$ 2. Transform the annual rate into a monthly rate: = $\text{annual rate} / 12 \text{ months}$ 3. Transform the monthly rate into a monthly risk: = $1 - \text{EXP}(- \text{monthly rate})$ This issue is evident throughout both tables and for the risk of haematuria, urethral complications and symptomatic UTI in the model.	Thank you for your comment. It is correct to note that one cannot simply divide the probability of having an event in one year by 12 to estimate the probability in one month. However, the formula quoted in the comment only applies to a 2 state model (see Welton & Ades, Med Decis Making 2005). Where there are more than 2 states (e.g., well, UTI, bleeding), the formula linking rate and probability $p = 1 - e^{-(rt)}$ does not hold. For this reason, the EAG used a simple approach for illustrative purposes; this is not intended to be anything more than a representation of the percentage of people experiencing these events per 30 days. It is a simple calculation, which is easy to understand conceptually. Additionally, this data was not used in any analyses, as the EAG used the dichotomous data as inputs to the CNMA model. This has now been explained further in the report.

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Component network meta-analysis					
49.	Coloplast	58	4.2.4.1 UTI onwards	For the CNMA of haematuria, timepoints for outcome data were not all reported and assumptions (2/6 studies) or calculations (2/6 studies) were made in order to conduct CNMA. This limits the reliability of the CNMA findings. The uncertainty associated with the evidence around the effect of certain features on UTI and haematuria rates leads to extremely large confidence intervals (CIs). All of the relative risks used in the model for UTI and haematuria have a lower CI of <1, and an upper CI of >1. This demonstrates that there is no certainty around the direction of the effect of certain features on UTI and haematuria rates. This is extremely pronounced in some cases, for example for 'Specially designed catheter case' and haematuria, the lower CI is 0.09, while the upper CI is 3.34. The point estimate of 2.05 therefore has little credibility.	Thank you for your comment. The EAG has considered the Confidence in Network Meta-analysis using the CINeMA rating, and highlighted throughout the results that confidence were very low in all CNMA analysis. The uncertainty was also stressed in the discussion and executive summary. No additional changes to the report were made.

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50.	Hollister	10	Executive Summary	The following statement would suggest that any findings are surely likely to be very speculative at best: <i>“However, the EAG note the low number of studies and patients included in these analyses, and the wide credible intervals mean that there are large uncertainties associated with these findings (the confidence in CNMA was rated as very low in all instances)”</i> Again, as per comment 3 above, is this methodology right for Intermittent Catheters?	Thank you for your comment. The methodology used within the context of the EAG report is designed for isolating the effect of individual features. However, there was a lack of published comparative evidence (in quantity and quality) to robustly quantify the effect of each feature on every outcome of interest. Therefore, the methodology has highlighted the evidence gap that needs to be filled.
51.	Hollister	88	4	Given the below statement, as per comment 8 above, any findings must be treated with extreme caution. <i>“All studies included in CNMA had an RCT design, however there were multiple limitations to these data including risk of bias (for example not adjusting for paired-data in cross-over trials, unclear reporting of allocation concealment or sequence generation method); heterogeneity; and extremely wide 95% Crls (imprecision). Therefore, for most outcomes and features, where evidence was analysed, were rated as very low certainty.”</i>	Thank you for your comment. Please see the response to comment 73.
52.	Hollister	89	4	The lack of consensus is again stated, this time for additional features. This must make any conclusions highly speculative.	Thank you for your comment. The lack of consensus mentioned on page 91 of the EAG report (“Furthermore, there was lack of consensus from the experts on the relevance of these additionally identified features.”) refers to additional features identified by the EAG. However,

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					these were not considered in detail in the EAG report and therefore have no impact.
53.	Assoc for continence Professionals	63		Found this slightly confusing and hard to follow however this may just be me	Thank you for your comment. Page 63 refers to the CNMA analysis. The EAG acknowledges that the use of component network analysis may be unfamiliar to many readers, and endeavoured as much as possible to provide a clear exposition in the report.
54.	Coloplast	p. 89-90, p.180-190	Section 5.1.1 Searches for economic evidence Appendix B2 Search for economic evidence	Economic evidence search: range of resources searched: The EAG searched MEDLINE and Embase for SRs of economic evaluations. Unlike for the clinical evidence search, CINAHL was not searched; the rationale for this difference in resource selection was not clear. The robustness of the methods used to identify economic evidence SRs might have been increased by searching CINAHL, and (as in the clinical evidence search) also searching databases that specifically collate records for SR publications (such as Epistemonikos and KSR Evidence) and by searching the HTA Database (HTAs often include an SR of economic evidence). The EAG searched NHS EED for economic	Thank you for your comment. In the EAGs view the NHS economic evidence evaluation (EED) was appropriate to comprehensively identify all economic evaluations relevant to the UK NHS published up to the end of 2014. No change made to searching prior to 2015. It is possible that an additional economic evaluation could have been identified by searching CINAHL. However, the EAG note that any existing economic evaluation would be constrained by the existing data and the de novo modelling approach adopted by the EAG was able to incorporate the best available data to provide estimates on the cost-effectiveness of catheter features. Please also see the response to comment 34.

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				evaluations published up to 2015 and MEDLINE and Embase for economic evaluations and models from 2015 onwards. Unlike for the clinical evidence search of controlled comparative studies, CINAHL and the HTA Database were not also searched (for studies from 2015 onwards); the rationale for this difference in resource selection was not clear. The robustness of the methods used to identify economic evaluations and models might have been increased by searching CINAHL and the HTA Database. In addition, it was not clear how models published up to 2015 would be identified. It might be that the EAG was relying on all relevant models being found in the economic evaluations retrieved from NHS EED but no rationale is given. The robustness of the methods used to identify economic models published up to 2015 might have been increased by conducting a search for these in addition to the search of NHS EED. Any limitations of the database selection will have been mitigated however by supplementary search approaches used by the EAG. These included reviewing all the economic evidence submitted by the companies, and all the primary evidence from identified relevant systematic reviews.	

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				We also note that the NICE interim methods and process statement explicitly suggests that searching a limited selection of databases is a rapid review method that could be included in the context of a pragmatic approach to the evidence review.	
55.	Coloplast	104	6.1.1. Model structure	One of the key assumptions in the model that was made is <i>'People continuously use the same type of catheter and do not switch between catheters throughout the 2 year time horizon'</i> '- Coloplast thinks this is an oversimplification as people don't always stick to one catheter and might also use multiple types of catheters at the same time. '- On page 35 it is also stated that 'catheter choice should be a joint decision made between clinician and patient, the EAG shared the compiled list of features with Clinical and Lay Experts to determine whether each feature listed would be likely to be considered in decision making when selecting an intermittent catheter'. '- "Catheter type and characteristics vary as do reasons why individuals need to perform IC.... Patients may use multiple	Thank you for your comment. The EAG explicitly stated this within limitations of the economic model (see section 6.3 of the EAG report): <i>"Of more material importance was the assumption that patients continued to use the same catheter type throughout the entire time horizon. In practice, patients may switch between catheters or may be prescribed multiple catheters to enable intermittent catheterisation across change in patient needs, lifestyle or preferences. Given the lack of data this would be hard to model but the modelling approach adopted still allows consideration as to whether a given feature could be cost-effective."</i> No additional changes have been made.

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				types of catheters/systems depending on their activity". EAUN guidelines 2024 (section 9.2). "The problems and limitations of ISC use outside the home impacted on daily life to such an extent that a number of people used alternative catheter models. (Kelly et al 2014).	
56.	Coloplast	112	6.1.7. Resources used and cost	<i>'Catheter and additional feature costs – the economic model assumes that patients under catheterisation attend average 10.05 GP surgery consultations a year (Pickard et al. 2018)'</i> 5. It might be unfair to assume only 10 GP surgery consultations a year for populations with many comorbidities. We think this an underestimation of the resource use related to GP visits. [REDACTED]	Thank you for your comment. The EAG has reviewed the partial paper supplied in confidence [REDACTED]
Equality considerations					
57.	Coloplast	17	3. Table 1: Integrated drainage	The inclusion of an integrated drainage bag with intermittent catheters should be considered as a necessity rather than user	Thank you for your comment.

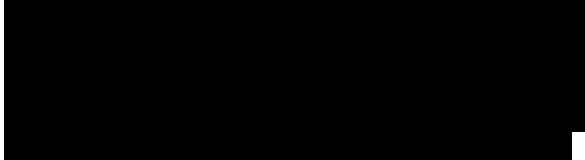
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			bag & 3.6 Equality considerations	preference as it enables the patient to measure residual volume with ease, is convenient when the patient needs to catheterise in a non-hygienic area or lying on a bed. Clinical practice shows that patients with reduced dexterity sometimes find sets easier to use because urine is contained. Sets can be used for aseptic or non-touch techniques which can help reduce the risk of infection. Complete sets usually contain a catheter suitable for IC, a drainage/reservoir bag to collect the urine, and a lubricant or activator such as water if the catheter is hydrophilic. These sets are ideal for use in confined spaces or restricted facilities such as aeroplanes, building sites, or extremely rural settings where access to toilet facilities may be limited. They are particularly useful for wheelchair users and those patients who catheterise from a seated or prone position. (EAUN guidelines, Vahr 2024).  In the absence of a user preference report to evaluate alongside this report, it is important to reference the user feedback as cited in the EAG from the clinical studies which as the EAG states on Page 15 include	As described in the LSA Process and Methods statement (sections 4.26-4.34, 4.37) the User Preference work is conducted by NICE separately to the EAG report and both are considered by the committee to inform decision making. The EAG has not identified any evidence which enabled estimation of effectiveness for integrated drainage bag as a feature. However, the EAG acknowledge that this particular feature may require separate consideration if the choice of integrated drainage bag is driven by clinical need, not preference.

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				convenience, avoidance of trauma, independence, risk of infection with independence highly ranked – this supports why an integrated bag would provide significant value to the end user and their quality of life. (Studies cited Kimoto et al 2015, Pinder et al 2015, Welk et al 2021)	
Expert input					

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58.	Coloplast	35, 36, 277	Appendix D	Stakeholder Engagement The EAG acknowledges catheter choice should be a joint decision made between the clinician and patient, and cites the involvement of Clinical and Lay Experts in selecting the features and outcomes to include in their analyses (component network meta-analysis and economic evaluation). “As catheter choice should be a joint decision made between clinician and patient, the EAG shared the compiled list of features with Clinical and Lay Experts to determine whether each feature listed would be likely to be considered in decision making when selecting an intermittent catheter.” [Page 35]. “The EAG considered CNMA for outcomes listed in the Final Scope which were prioritised by Clinical and Lay Experts (UTI, haematuria, residual volume, discomfort or pain, ease of use).” [Page 36]. While Coloplast acknowledges the pragmatic nature of the stakeholder engagement exercises (Appendix D), the sample size is small (N=4), and the ratio of clinical and lived experience stakeholders included is disproportionate (three clinical experts; one lay expert). Clinical and lived experience	Thank you for your comment. The EAG contacted all experts provided by NICE. All questions sent and received responses are summarised in the report.

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				stakeholders' treatment preferences and the relative importance of outcomes do not necessarily align. This, compounded by the limited sample size, is reflected by differences observed in the outcome rankings and evaluations of the innovativeness and importance of the additional features.	

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59.	Coloplast	277	Appendix D	Suggested Evidence Synthesis Activities Acknowledging the paucity of evidence noted by the EAG, alternative methods of assessing the relative importance of treatment outcomes and features should have been considered alongside validated methods of establishing expert consensus (e.g. two-round Delphi panel). Such analyses would enable analysts to assess differences in treatment preferences between clinicians and catheter users. Moreover, including a varied sample (i.e. patient populations beyond those with spinal cord injury) would have improved the representativeness of the modelled outcomes, given the scope considers all intermittent self-catheterization populations (discussed previously). For instance, a discrete choice experiment conducted by Pinder et al. (2015) indicated catheter users (varied populations, including spinal cord injury and neural tube defects) in the United Kingdom were four times more likely to prefer devices which were associated with no infections (OR = 4.00), twice as likely to prefer a device which was 'pre-coated with lubricant' (OR = 1.94), and over twice as likely to prefer a small and compact device (OR = 2.36). We acknowledge that the timelines allowed within the current Late Stage Assessment	Thank you for your comment.. The EAG do not consider these methods (a two round delphi process or a discrete choice experiment) practical for its assessment. The company also draw upon a DCE (Pinder), which gives a relative weighting some features/outcomes. To use data from a DCE within the economic evaluation, it would have needed to include features and outcomes relevant to the LSA. This would need to include attributes defined in terms of the presence or absence of a feature, and attributes defined in terms of outcomes that map on directly to modelled outcome e.g. UTI rates. Finally, it would have needed to provide information suitable to estimate a marginal rate of substitution between features and outcomes and a suitable numeraire to express the value of this in an economic evaluation. This was not available; no changes have been made to the report.

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				process did not enable the EAG to conduct the necessary evidence synthesis activities to inform the analyses.	
60.	Coloplast	15	2. Clinical Context	'Two Clinical Experts advised that intermittent catheter users are not routinely prescribed more than one model of catheter to cover lifestyle changes (such as travel) or changes in circumstances.' 	Thank you for your comment. The EAG do not consider this to be a factual inaccuracy. The EAG have summarised feedback received from experts. It should also be noted that this feedback would not change any of the estimates of effectiveness or cost-effectiveness.
Feature					

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61.	Coloplast	30	3.8 Protocol Deviations	'The EAG initially identified the presence of features (as listed in the NICE Final Scope) across all catheter product lines using information provided by companies (which included completed requests for information, instructions for use, patient brochures) and then asked companies to confirm the features attributed by the EAG. Responses obtained from companies identified that the catheter features, as listed in the NICE Final Scope, were open to interpretation and applied inconsistently across manufacturers. Two reviewers (EB, KK) subsequently went back through instructions for use and information on company websites for each catheter product line in order to ensure that assignment of features were applied consistently.' A lack of consistency in feature assignment to products across product experts in industry would indicate a poor description or grouping of features. Disregarding the input of industry and assigning two individuals to provide their subjective assignment of features based on reviews of company websites and IFUs is a poor methodology. Industry should have, at minimum, been given the opportunity to respond to this new feature assignment before they were used in modelling and drafting recommendations.	Thank you for your comment. There is a lack of consensus of catheter categorisation, feature definition and which features are considered innovative across companies and experts. The EAG has transparently reported the features assigned in their analysis (see Appendix A of the EAG report) and described the definitions used in their assessment (see Table 1 of the EAG report). No factual inaccuracy of the mis-assigned features has been mentioned in this comment (or any others received at stakeholder fact check). No changes to the report have been made.

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62.	Hollister	21	3	In relation to the below statement was the potential reduction in UTIs discussed in relation to sleeved catheters, not just ease of use/handling?. <i>“The EAG therefore assigned features based on claimed benefit (fixed handles based on orientation, moveable sleeves or grippers based on ease of use and handling)”</i>	Thank you for your comment. The EAG included all features in all outcomes from the eligible studies where possible. However, for some analyses, there was insufficient data to be included in the CNMA. Where this was the case, these data were summarised narratively.
63.	Hollister	9	Executive Summary	It is stated that <i>“There was no consensus on the definition or importance of intermittent catheter features among Clinical and Lay Experts.”</i> This would appear to be a very significant flaw in then producing any robust findings. It maybe suggests that the NICE LSA process is more geared to Pharma than this sector.	Thank you for your comment. The assessment was done in line with NICE's interim statement on late-stage assessment, including topic selection.
64.	Hollister	10	Executive Summary	Lack of consensus and differing definitions must call into question the validity of any analysis.	Thank you for your comment. The EAG has listed limitations throughout report, discussion and executive summary. No changes to the report have been made.
65.	Hollister	12	Executive Summary	The benefits of integrated bags are questioned – for many users these are vital. It would be worth exploring this further with user groups to understand the value/benefits these bring. In addition, it is stated further into the document (Page 29) that <i>“Catheters that have an integrated bag or can be connected to an external collection bag may provide a better user experience to some patient populations such as those in</i>	Thank you for your comment. The EAG did not identify any evidence which directly enabled the efficacy or effectiveness of integrated drainage bag feature in isolation. Please also see response to comment 57.

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				<i>wheelchairs and those who are bed bound. An integrated bag or connection to an external collection bag would also reduce the need to use an additional container.”</i> Has the value of these products been appropriately assessed?	
66.	B Braun Medical	18	Table 1: Summary of features of intermittent catheters	As already detailed in comment 2, NICE guidance on urinary catheters is included in guideline CG139 titled Healthcare-associated infections: prevention and control in primary and community care in section 1.2.3 guidance is to “Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self-catheterisation”. For this LSA, enhanced coating terminology is only available as an option for selection for the hydrophilic products, despite NICE guidance stating that gel reservoir and hydrophilic catheters are viewed as equivalents. One of the benefits of the enhanced coating is that it's preactivated and doesn't need an additional 'wetting' step. This is true of a prelubricated gel coating. Expert 3 also confirms this point on page 285, point 4 that “ready to use is prelubricated”.	Thank you for your comment. There was lack of consensus amongst experts regarding innovative features. However, the pre-activated (H3) and pre-activated (U3) were considered in all CNMA analysis where evidence was available and therefore considered in the analysis.

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67.	B Braun Medical	10	Executive Summary	In the document returned to NICE titled "B. Braun Medical Ltd features clarification table" the specially designed catheter case is described as "hard case, compact design, telescopic catheter, and resealable case". This covers a broad range of packaging types with very different packaging materials and designs. The EAG goes on to describe in the executive summary on page 10 that <i>"conversely the presence of specially designed catheter case was found to increase the risk of haematuria"</i> . It is inaccurate to make a general statement that all products that are specially designed catheter cases would lead to increased risk of haematuria. The EAG should amend its report to specify which catheter case variations increase haematuria risk.	Thank you for your comment. The EAG does not consider this to be a factual inaccuracy. The EAG has noted in the EAG report that specialised catheter case was a composite feature (as listed in NICE final scope). Further differentiation of which sub-feature contribute to outcomes would be possible when further evidence is generated. No changes have been made to the report.
68.	Coloplast	58	Summary of findings	From a clinical perspective, it is very difficult to understand that "specially designed packaging" (e.g. thumb holes or ring pulls, flip top, hanger) should have an influence on the risk of getting UTIs (also not aligned with known literature Kennelly et al 2019 and the previously mentioned meta-reviews), and therefore one could question the used approach (modelling) to show dependencies.	Thank you for your comment. The EAG proposed one possible mechanism within Table 25 of the EAG report: <i>"[Possible mechanism of action: easier to hold, better drainage or used more frequently]"</i>.

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69.	Hollister	287	Appendix D	Not totally clear what the context is around Q4 but there are many manufacturers who have products with integrated bags/kits (depending on definition), not just those listed.	Thank you for your comment. The EAG was aware of other products with "kit" or "set" in their name from the Drug Tariff. However, the question to experts was to double check that those listed catheters (in bullet points) also included an integrated drainage bag. The EAG had identified this from the information provided by companies RFI and websites, however was not confirmed by presence of "kit" or "set" on product listing on Drug Tariff.
70.	Coloplast	279	Appendix D	Additional Feature Omission: The EAG reports a lack of consensus concerning the identified additional features. However, the question presented to stakeholders conflates the features' 'importance' and 'innovativeness'. Conflating these outcomes renders interpreting the responses challenging as it is impossible to discern which aspect the stakeholders' comments concern. This is compounded by the non-standardised response format (i.e. free-text responses, with no requirement to specify which aspect their answers concerned). For instance, Expert 4 did not provide a rationale alongside their answers (indicating 'yes' or 'no'). '- "...Are the following features considered innovative and of importance when choosing an appropriate intermittent	Thank you for your comment. The EAG have acknowledged a lack of consensus on features across experts and companies. However, the EAG note that the company did not challenge the features the EAG assigned to their particular product which was used in analysis; therefore the impact of this comment on EAG conclusions is unknown.

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				catheter for a patient..." [Page 279] Coloplast believes these aspects should have been assessed separately and cautions that, as with the outcome selection process, additional features deemed important by clinical or lived experience stakeholders may have been omitted. For instance, while it is difficult to conclude consensus due to design limitations, attributes such as 'ready to use' were considered as 'important' or 'innovative' by three of the four stakeholders. Supporting this, a discrete choice experiment conducted by Pinder et al. (2015) demonstrated that catheter users were twice as likely to prefer a device which was 'pre-coated with lubricant' (OR = 1.94) (i.e. ready to use).	
71.	CliniMed Ltd	293	Coating	By categorising ISC catheters as (uncoated and hydrophilic), where do Hydrogel catheters fit in?	Thank you for your comment. The method of lubrication (catheter categorisation) has been considered on a product by product basis using the information available in the IFU, company RFI and company websites. Specific to CliniMed, the two products with hydrogel (Curan Man, Curan Lady) were categorised as "uncoated (pre-lubricated)" as described in Appendix A. The EAG has added a sentence stating: <i>"For the remainder of this report the EAG will refer to "uncoated" to mean lacking hydrophilic polymer coating."</i>
72.	Coloplast	12	Executive summary:	<i>'The EAG recommend that the product information listed on the NHS Drug Tariff be</i>	Thank you for your comment.

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			future research	<i>revised to make clear to prescribers and commissioners the differences between intermittent catheters.'</i> It is recognised that reform is needed for Part IX of the Drug Tariff. However, policy recommendations on the format and content of the Tariff are outside the scope of this NICE evaluation and the subject of a separate, targeted consultation with stakeholders by the Department of Health and Social Care. As such, they should not – regardless of their merit – form part of the evidence presented to the committee.	The EAG does not consider this to be a factual inaccuracy. The EAG is trying to determine whether the pricing variation can be justified. One potential source of variation is that some prescribers may be ordering catheters without sight of the features that it offers, meaning that prescribing is not optimised. No changes to the report have been made.
73.	Hollister	134	7	It is noted that analyses rely on the EAG's assignment of features. These were only partially corroborated by industry and furthermore there was no Expert consensus. Similarly to above, this must mean any findings can be at best, highly speculative.	Thank you for your comment. The EAG have highlighted uncertainty in the results throughout the report, discussion and executive summary. The company do not state any factual inaccuracy in the features assigned to their catheters by the EAG. Therefore, the EAG cannot conduct sensitivity analysis to determine the impact of changes in assigned features.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
74.	Coloplast	51	4.2.3 Technology features	<i>'The EAG asked Clinical and Lay Experts to rank the 13 outcomes listed in the NICE Final scope in order of importance'</i> <i>'The EAG asked the Clinical and Lay Experts to comment on whether these identified features would be considered innovative (Appendix D; Question 3). The responses received from 4 Experts were heterogenous; none of the above features were categorised as innovative by all 4 Experts.'</i> This is a very limited sample of experts to include in such an important evaluation. - Responses on outcomes across the experts were heterogenous and no consensus was identified as to the relative importance of outcomes. Despite this, prioritisation was undertaken by the EAG. It is therefore unclear whether the assessed outcomes accurately reflect the priorities of users - Features developed many years ago would not be documented with clinical studies and therefore not included in the "Final Scope" even though some patients find this "mandatory" to be able to catheterise – therefore it is a good idea to include the experts opinion, but critical to disregard the input due to low numbers of experts. - On features, the verbatim	Thank you for your comment. The user preference work was conducted separately by NICE. The EAG contacted all experts provided by NICE. All questions sent and received responses are summarised in the report (Appendix D). All outcomes from eligible studies were extracted (as documented in Appendix C4). The EAG has created the analytical pipeline (results are already extracted, CNMA coding created, and economic model developed).

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				responses (in Appendix D, question 3) show that there was consensus for some features and therefore it is plausible that, if studies of these features were not included for data extraction, relevant evidence of patient benefit may have been missed. Without the opportunity to simultaneously review the User Preference report, it is impossible to comment on the factual accuracy of this.	
75.	Hollister	31	3	Given the below statement from this page, surely any results/findings must be treated with extreme caution. <i>“However, the catheter design and features across each intermittent catheter product line was generally poorly described and open to interpretation which may have resulted in mis-categorisation by the EAG”</i>	Thank you for your comment. The EAG have acknowledged a lack of consensus on features across experts and companies. The limitations and uncertainty have been highlighted by the EAG in the EAG report. No changes have been made to the report.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
General					
76.	Coloplast	87	Protocol and pg87 of report	The review protocol states that “The EAG will focus on comparative evidence which will enable the evaluation of the effectiveness of one or more innovative features to be assessed”, with device related adverse events listed under clinical outcomes. However, the EAG did “not identify a safety signal associated with remaining catheter features across the included evidence” and the authors acknowledge “that larger cohort studies may be better suited to detect complications.” The pragmatic- and efficacy-focused LSA process may not be best placed to identify safety outcomes, particularly rare adverse events in long-term user populations.	Thank you for your comment. The EAG recognise that larger cohort studies may be best suited to determining safety of health technologies. As this LSA was a features-based assessment aiming to determine whether price variation was justified, the EAG did not identify any longitudinal study reporting safety specific to a intermittent catheter feature; this type of evidence was also not shared by any company during the assessment. The EAG note that the longest available follow-up in the included studies was 12-months and the largest total sample size was 224.

77.	Coloplast	General	General	We thank the EAG for their thorough work and the opportunity to comment on the report. In the spirit of constructive engagement, we have reviewed and added detailed responses. The aim of Late-Stage Assessment (LSA) was to “provide a value assessment (based on evidence, clinical and patient input)”. The process, scope, available evidence and execution in this instance will not allow for a safe judgement to be made that will not result in harm to patient outcomes and an increase in NHS workload. As such, any inference throughout the documents related to this LSA that it can meet its aim is considered by Coloplast to be a factual inaccuracy. Beyond the shortcomings of the LSA process as a whole, we have found specific flaws with this report and economic model, all of which will be detailed in the table below. However, some of the broader themes are worth calling attention to: Personalised care: For more than 60 years, Coloplast has been committed to providing quality products that meet the individual needs of a vast and diverse patient population. Due to the different groups of patients who have varying and often complex clinical needs, differing anatomical challenges, alongside different lifestyles, it is necessary for companies like Coloplast to innovate incrementally on the	Thank you for your comment. Aim of late stage assessment This late-stage assessment has been conducted in line with the LSA interim process and methods statement. The limitations of the assessment have been referenced throughout the associated reports. All relevant documentation will be considered by committee to inform decision making. Please note that at this stage, NICE cannot speculate on the outcome of this assessment. The process needs to proceed to the next step of the committee deliberation before being able to comment on the outcome. Personalised care NICE recognises that having a range of products available is important to accommodate patient choice and to stimulate innovation within a category. The aim of late-stage assessment is to assess if the value added by incremental innovation justifies the price variation to help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system. NICE have included the patient perspective through a user preference report, a patient survey, and a review of the literature on people’s needs, experiences, and preferences of intermittent catheter use. This ensures the committee is able to consider people’s differing preferences and needs when it makes its recommendations. Analytical approach

			features of intermittent catheters; not only does this reflect that the demand (signalling) for these products comes from patient need (and not because we want to just bring out another product) but also that patient input runs through our product development. This isn't just about accessing personalised products, it's about being able to access and maintain dignity. Coloplast can and should provide an extensive range of features across the product portfolio. This area of healthcare relies on a personalised approach to ensure patients can be supported throughout their chronic care journey and adapt their product choice over the course of their lifetime to support the circumstances they face in a dignified and discreet way that does not impact negatively on their activities of daily living and overall quality of life. It is clear from the EAG's report that this nuance of personalised care has not been properly considered. NICE has taken a broad-brush approach to analysing the clinical and economic utility of intermittent catheters and has reached some conclusions which are poorly considered and will demonstrably harm and/or discriminate against certain patient groups. Though we will address each of these issues in turn within this document, the most egregious example is the conclusion reached for the value of the integrated bag feature. For certain patient group - including wheelchair	The EAG have acknowledged the limitations of the assessment throughout the report. For comments regarding features classification please see comments under the features subheading. For comments regarding economic modelling please see comments under the sub heading economic model. Process and principles It is not an essential requirement to complete a factual accuracy check for both the EAR and UP report at the same time. The primary reason for the delay to the user preference fact check period was the low confirmed attendance for the user preference workshops. To ensure the best possible attendance, NICE decided to postpone the workshops and recruit additional members for representation. To mitigate for low attendance, NICE conducted a survey among individuals with lived experience of intermittent catheterisation. Additionally, NICE have performed a literature review to understand the needs, experiences, and preferences of people who use intermittent catheterisation. Stakeholders involved in the development of the user preference can identify any factual accuracies or misrepresentation of the user preference work. Pilot status DHSC have commissioned NICE to undertake Late-Stage Assessments (LSAs), which compare similar devices with price variation that are in widespread use across the NHS. After completing the first 8 LSA topics, the final methods and processes will be

			users and those who are bedridden or who require assistance transferring to a toilet - this feature is an absolute necessity to their care. The disregard of certain vital features of products, which have been specifically designed to meet the needs of particular patient groups, runs in complete opposition to the direction of travel for healthcare in general and the NHS in particular. Indeed, given that many intermittent catheter users are vulnerable or living with chronic disabilities, were this to become published guidance it could contribute to the post-code lottery of healthcare provision, deepen health inequalities and promote prejudice against people with disability in the UK. Therefore, any guidance of this scale and scope must be built on a solid foundation which understands and respects the different needs of intermittent catheter users. As the EAG report has made assertions on the value of product features that are based on a fundamentally flawed understanding of intimate intermittent catheter care, Coloplast do not support many of the claims made within the report and have established significant sections of the narrative contained within as factually inaccurate. Analytical approach: The EAR itself points out that the approach taken in this LSA is both flawed and limited in utility. Although NICE did make some effort to engage with clinical and lay	consulted on, and then included in NICE's methods and processes manuals. Recommendation This assessment has been conducted in line with the LSA interim methods and process statement. Stakeholders, including industry representatives, clinical experts, people with lived experience were consulted on during the assessment. NICE publicly consulted on their LSA interim processes and methods statement.

				stakeholders, it was limited to a panel of four experts and these experts did not even provide answers to all the committee's questions. The categorisation and assignment of product features, which is a keystone in the foundation of the analysis was noted as being 'imprecise,' and neither product experts in industry nor clinical experts consulted could come to a consensus on the assignment of features. To fill this gap in the analysis, the EAG assigned two researchers with limited clinical or product expertise to make the final assignment of features based on company websites and information for use manuals. Whilst the CNMA modelling for clinical evidence was adopted as the preferred methodology to analyse the value of product features, we would challenge that instead the model should have factored the user feedback cited in Kimoto et al 2015, Pinder et al 2015, Welk et al 2021 as its starting point; understanding how the various features offered across the intermittent catheter ranges supported these key user preferences; there is no account of independence as an outcome ranked as highly important by users in this evidence, let alone convenience and reduction in trauma. Furthermore, the approach to modelling the economic benefits and costs of intermittent catheters in this report has been based on poor assumptions and poor practice. For example, the time horizon of 2 years which was selected for the model is too short to	

				capture the full benefits of using intermittent catheters and will underestimate the incremental QALYs for the associated features. This is mis-aligned to the NICE Manual (2022) which states the time horizon should be set so lifetime cost and benefits are captured. Additionally, all-cause mortality was applied incorrectly to the model, with an annual mortality rate being applied to a monthly cycle analysis, an error so fundamental to the modelled outcomes that it calls the entire exercise into question. Because the conclusions reached in this report are based on this limited stakeholder engagement, imprecise assignment of features and limited analysis, we maintain that they should all be considered factually inaccurate. Process and principles The EAG notes in the report that they estimate approximately 50,000 patients across the UK use intermittent catheterisation as part of their daily lives. The implications of this guidance are therefore dramatic in scale for this population. Coloplast would argue that such an impactful guidance should be rigorous in terms of analysis and should also embrace feedback and challenges from stakeholder groups. Coloplast contends that the factual accuracy check of the draft EAG report cannot be carried out without the opportunity to simultaneously review the User Preference	

			(UP) report. NICE deviated from the standard process of releasing the 2 reports at the same time without prior notice to stakeholders with result that the comment periods will not now overlap. Despite NICE' insistence that the EAR and UP need not be reviewed together, the two reports cross-refer and are inter-dependent, so it is impossible to review either in full context independently. This is contrary to the principle of allowing stakeholders to view and comment on evidence before its presentation to the committee. Coloplast asks that the topic timelines be changed to allow a simultaneous comment period, and the topic rescheduled to a later committee meeting. To do otherwise would compromise the integrity of the process and the robustness of the review processes and would create an environment in which untested recommendations based upon factual inaccuracies become NHS practice. Pilot status The LSA process is a pilot programme FOR NICE, and a key aspect of piloting involves examining the successes and failures of the project to date and deciding if it warrants long-term acceptance. Coloplast would argue that although the pilot has been successful in calling attention to the need for greater use of evidence in Medtech, an agenda we remain committed to pushing forward with NICE, it has failed to create actionable recommendations which respect	

				the individual needs of patients and drive better patient outcomes and experiences. Interdependencies with other NHS policy and government departments Moreover, the LSA process does not help to meet the aims of the Ten-Year Plan or support the wider health inequalities agenda central to health care provision in the UK. It is our assertion that the current implementation of the LSA processes will more likely have a negative impact on patient outcomes, will create an environment which is discriminatory towards those who may be most vulnerable in society and people living with disability. Fundamentally this work will also frustrate the delivery of the NHS Ten-Year Plan by pushing intermittent catheter patients who are well-managed in the community into the acute setting as they grapple with changes to their care and product provision. This LSA policy should not exist in a silo and needs to be reviewed immediately within the wider context of the NHS, alongside patient rights and needs and the NHS Patient Constitution, as well as wider government departments and ambitions, such as the Office for Life Sciences' (OLS) ambition to have the UK as a global leader for accessing clinically cost-effective technologies; companies' desire to invest in the UK; and the want to maximise commercial and NHS investment in research and evidence in the UK.	

				Recommendation Coloplast requests again that NICE should pause live topic development to allow time for the intermediate outcomes of the in-progress evaluations to be critically reviewed, with appropriate stakeholder involvement and shared decision-making (SDM). While remaining committed to working constructively with NICE, Coloplast has consistently argued that proceeding with live LSA topics using methods which have neither been adequately researched or tested is a waste of resources and will result in unreliable and unusable guidance for patients, clinicians and the NHS. The release of this report, as with those on colostomy bags, antimicrobial dressings, bed frames and slide sheets, confirms that the feature-focused methodology for evidence identification and assessment produces inconclusive results. The absence of reliable clinical and economic evidence results in highly speculative evidence synthesis and economic modelling; this in turn creates very high-risk committee decision-making which is not in the interests of patients, clinicians and the NHS. Moreover, the LSA programme is being operated in a way which is unfair to stakeholders, with timeline adjustments and topic pauses. All of this runs contrary to NICE's principles of using robust methods and of involving stakeholders.	

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78.	Hollister	132	6	The lack of data must surely make any findings highly speculative and question whether this process is the right one for assessing intermittent catheters. <i>“A key limitation of the economic evaluation model relates to the limited availability of data”</i>	Thank you for your comment. The imitations and uncertainty of the results reported in the assessment have been highlighted by EAG in the EAG report. No change made to report.
79.	Convatec	Page 133	Discussion	The number of patients who catheterise in the UK is totally incorrect and based on inaccurate assumptions. The scope is long-term users, but the assumption is made on total units prescribed and how many they may use per day. The volume of units prescribed will also include those using for dilation - this population may be long term, but their usage will be significantly lower, and many are using off licence. Also, the use for bladder instillations. The industry estimates more like 140,000 users and this will be based on the number of patients regularly ordering ISC via the dispensing appliance contractors. Thus, the approximation is inaccurate.	Thank you for your comment. Estimation of 50,000 intermittent catheter users stated in NICE Final Scope and was based on Wilks et al. (2020), all assumptions made by EAG clearly stated in report. This figure has not been challenged by clinical experts. If there are more long-term adult intermittent catheter users in the UK, then this highlights the importance of showing whether the price associated with catheters (and their features) are worthwhile.
80.	Assoc for continence Professionals	15		limited choice - there is now an increase in prescribing models who offer choice and clinical review - most HB in Wales use this model	Thank you for your comment. Paragraph on page 15 outlines feedback from Clinical Experts on the prescribing practices. No change to report made.

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81.	Coloplast	38	4.1.5 Protocol deviations	The EAG states that although ClinicalTrials.gov and ICTRP were searched, no results from these sources were screened due to resource constraints. While the focus of the LSA is completed rather than ongoing studies, this approach means that otherwise unpublished outcome data, including outcomes, subgroups and granular detail of adverse events, may have been missed. The available timeframe to complete the review appears to have been insufficient to undertake all activities specified in the protocol.	Thank you for your comment. As stated in the external assessment report, published peer-reviewed publications were prioritised (see section 4.1.1 of the EAG report); therefore not sifting ongoing study trial registrations had limited impact on results. The EAG note that the companies have not explicitly outlined any specific missed evidence within their responses; therefore the EAG is unable to comment further.
82.	Coloplast	32-33	3.9 Summary	The report states: 'One Specialist Committee Member and members of the University of Southampton Bladder and Bowel management research group shared with the EAG two days before final report submission their independent categorisation of features for all intermittent catheters available on the Prescription Cost Analysis, which was based on information available on company website and physical review of sample catheters (where provided by manufacturers). This work is ongoing has been shared with and utilised by the modernising section IX of the Drug Tariff project. While there was no time to include this within the EAG report, the independent and clinically informed intermittent catheter feature categorisation led by the Specialist Committee Member and	Thank you for your comment. The EAG have done some additional analyses but these do not include the independent categorisation by clinical experts. In line with NICE's methods and processes, the external assessment report was shared with stakeholders for review prior to committee. Stakeholders will have an opportunity to review any additional analyses that contributed to committee decision making during the public consultation period.

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				their team could be considered in future analysis to determine the impact on regression analysis, CNMA and economic analysis.' If this work is done before, and forms part of the evidence presented to the committee, it must, beforehand, be subject to a standard factual accuracy check by stakeholders.	
83.	Coloplast	89	4.3 Summary, strengths and limitations	<i>'As such the CNMA was restricted to those features listed in the Final Scope only, which had gone through stakeholder consultation.'</i> <i>Coloplast was not consulted on the features which appeared in the final scope as no consensus was achieved with industry in the stakeholder meeting on 21st August 2024 for this LSA.</i> If Coloplast had of been consulted properly, we would have included additional narrative based on narrative and real life case studies from the information that patients communicate back to us, for example the importance of ease of use, especially outside the home; the fact that catheters which are	Thank you for your comment. The scope went out for stakeholder consultation and Coloplast participated in the scoping workshop. The classification of features were further shared with the companies relating to their catheter products.

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				pre-lubricated, ready to use out of the packaging support ease of use, the feature of “ready to use” has been overlooked in this LSA. Without the UP report being made available to review alongside the EAG report it is not possible to validate this list of features and how applicable they are to the patient in real life.	
84.	Hollister		General Comment	The timeline available to renew a very detailed and lengthy report is inappropriate. Most/all companies operating in this area of Medical Devices simply do not have the resource and/or capacity to undertake a through review and analysis in such a short period of time. In addition, companies in this field have little/no historical experience of prior working with NICE and its associated methodology and requirements. Organizations are not only doing the ‘day job’ but may also be dealing with concurrent LSAs in other product ranges which adds to capacity issues and the ability to give meaningful feedback. Such a short timeline significantly reduces the ability to give quality feedback and	Thank you for your comment. For late-stage assessment, NICE usually gives 7 calendar days for factual accuracy comment periods. Factual inaccuracies are cases in which there is an objective error of material fact in the report. It does not include disagreements about scientific or clinical interpretation or judgement, whether this refers to the appropriateness of an analysis or the report itself. NICE felt that the usual 7 calendar days was appropriate for the factual accuracy comment period for this assessment. You will have the opportunity to review and comment on the draft guidance and related documentation during the public consultation period.

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				undermines the principle of collaborative working.	
85.	B Braun Medical	N/A	Throughout	The delayed publication of the user preference report suggests that user preferences have not been considered alongside clinical and economic evidence and therefore have not contributed to the conclusions of the EAG report. For intermittent urinary catheters, the end user is the patient themselves and therefore user preferences are an essential part of their appraisal. The preparation and publication of the EAG report should have been delayed until the UPR was complete.	Thank you for your comment. In line with NICE's interim methods and process statement for late stage assessment the user preference work was conducted by the NICE team. The committee will consider both in its decision making process (see section 4 of the LSA process and methods statement).
86.	Hollister		General Comment	Clearly an extensive and detailed piece of work undertaken by the EAG It would have been helpful to have the User Preference Report at the same time though, as happened with the Colostomy LSA.	Thank you for your comment. The rationale for the different fact check periods was due to the delay for the user preference workshops (low number of confirmed attendees). This was communicated to the companies.
87.	Hollister	133	6	This page again references lack of data and evidence gaps. Similarly to above comment, any findings can only be at best, highly speculative.	Thank you for your comment. The imitations and uncertainty of the results reported in the assessment have been highlighted by the EAG in the EAG report. No change made to report.

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88.	B Braun Medical	10-11	Executive Summary	The EAG consider that there is insufficient evidence to isolate the effectiveness of the remaining intermittent catheter features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer). The patient viewpoint from the user preference report about effectiveness of catheter features such as insertion sleeve needs to be considered in parallel to the EAG so that the perceived patient value is fully appreciated. This will give a well-rounded view of the catheter features.	Thank you for your comment. In addition to the EAG report, user need and preference, and equality will be considered by the committee in their deliberations
89.	B Braun Medical	134	7 Discussion	The Equality Considerations section (Section 3.6, p29) correctly highlights that patients who are wheelchair users or who are bed-bound may have an improved user experience with catheters with an integrated drainage bag. The discussion of the economic model concludes that <i>“the EAG has not identified any evidence of efficacy in UTI, haematuria, residual volume, pain/discomfort or ease of use outcome, which could directly attribute an effect to the following features: integrated drainage bag...”</i> and throughout the economic model states an integrated drainage bag is not cost-effective as it increases costs without conferring a commensurate benefit to patients, which is contradictory to this position in the Equality Considerations	Thank you for your comment. The EAG has amended the wording to make it clear that it did not identify any published evidence to demonstrate a clinical improvement in efficacy or effectiveness associated directly with the integrated drainage bag feature. In addition to the clinical and economic evaluation, user needs and preferences, or issues relating to equality of opportunity will be considered by the committee in their deliberations.

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				section. The EAG should refrain from drawing conclusions about patient benefit until they have conducted a user preference consultation, as per the methodology described in the protocol for this LSA.	
90.	Coloplast	77	4.2.4.5. Ease of use	We advocate for including patients to evaluate the importance of “ease of use”. EAG could not find a solution to evaluate the features, and just concluded that “further data is needed to establish preference” – and that preference should be the users/ patients – and that is not included in this report (with the exception of one – outcome of Q6 in Appendix D: Correspondence with clinical experts on p.282)	Thank you for your comment. Within the EAG report, the EAG has summarised the published peer-reviewed comparative evidence available. A user preference assessment is being conducted separately by NICE and will be considered by committee members. The user preference assessment has been shared with stakeholders ahead of committee.
91.	Coloplast	26	3.2 Variation in price of intermittent catheters	The methods used to calculate the additional costs of each feature are sound and are consistent with the NHS Drug Tariff pricing of catheters. For example: - The Coloplast Luja catheter which has the following features: handle, sleeve, tip protector, enhanced coating, micro-hole zone, case and special packaging can be costed as £1.37 + £0.10 + £0.28 + £0.25 + £0.06 = £2.06. The cost of a single Coloplast	Thank you for your comment. The illustration of how predicted costs for a feature can provide similar results to those shown reported in the tariff. The EAG felt that the approach adopted is proportionate to the decision question and that any added precision in the regression estimate will not materially alter any of the evidence on cost-

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				Luja catheter was £2.05 according to the October NHS Drug Tariff. - Randomly selected, the Wellspect LoFric Sense catheter (activity of 4.3%), which has the following features: handle, enhanced coating, case. This is costed as $\text{£}1.37 + \text{£}0.10 + \text{£}0.25 = 1.72$, and this is similar to the October NHS Drug Tariff which reports a cost-per-catheter of £1.71. - One of the most prescribed sets (catheter+bag), the B. Braun Actreen Mini Set (activity of 1.1%) which included the following features: uncoated (prelubricated), bag, handle, sleeve, case, packaging. This is costed as $\text{£}1.37 + \text{£}0.15 + \text{£}0.89 + \text{£}0.10 + \text{£}0.06 = \text{£}2.57$. This is similar to the October NHS Drug Tariff which reports a cost-per-catheter of £2.61. However, the choice to exclude non-significant features from the model cost calculations is questionable as all the feature coefficients, and the base case price, depend on one another. Choosing to exclude non-significant features but not respecify the equation leads to the coefficients not fully being able to explain the data. For completeness, we believe there are two courses of action to ensure the analysis is valid:	effectiveness. Therefore, no revisions have been made.

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				-Include all coefficients (significant and non-significant features) in the model cost calculations -Respecify the regression equation to exclude any non-significant features and use the new coefficients in the model cost calculations.	
92.	Coloplast	28	3.2 Variation in price of intermittent catheters	<i>'For illustration of the impact of this on the NHS, and assuming the prevalence of 50,000 adult intermittent catheter users in the UK (estimated from NICE Final Scope), this could equate to a maximum saving of £263 million per year, although the impact is likely to be much less. As Figure 1 shows most catheters have an approximate cost per intermittent catheter of between £1.25 and £1.75. Equivalently, the NHS would save £9.13 million per year for each 10p (£0.10) reduction in the average price paid per catheter.'</i> The aim of LSA is to determine, based on the evidence, whether price variations are justified. The inclusion of speculative illustrations is unhelpful and unscientific, even when caveated, and should be removed	Thank you for your comment. The sentence quoted in the stakeholder consultation comment was for context only. Differences of pennies have great importance when the scale of purchasing is considered. The EAG have transparently stated all assumptions made in these calculations and as stated they are illustrative of the opportunity costs to the NHS consequent on changes in unit cost which in other circumstances would be considered small.

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93.	Coloplast	29	3.2 Variation in price of intermittent catheters	<i>'Moreover, as catheter product lines in the Drug Tariff are offered with multiple additional features plus basic features outside the scope, a regression analysis was deemed as the most suitable approach to estimate the average price of each feature (additional or basic) for a specific catheter product line.'</i> Please can it be clarified that this means that the price variation in the analysis presented could include products with features which are not in the NICE decision problem, or the EAG's amendments.	Thank you for your comment. Only features as specified in Appendix A were used in regression analysis. The EAG has clarified this in the report.
Economic model					
94.	Coloplast			Description of problem: The costs do not match up with the coefficients and significance p-values reported in Table 3 of the report (the price regression model results): Insertion sleeve or grip' is priced at £1.30 in the model but is reported as £-0.03 and not significant (p = 0.32) in Table 3. We believe that 'Insertion sleeve or grip' should be priced at £1.37 in the model. Specially designed packaging' is priced at £1.37 in the model but is reported as £0.06	Thank you for your comment and for noticing these inaccuracies. The EAG has re-run the model with the correction (results have been updated in the report to reflect this), however these changes do not change our conclusions.

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				and significant (p = 0.03) in Table 3. We believe that 'Specially designed packaging' should be priced at £1.43 in the model." Description of proposed amendment: Align the model inputs with the Table 3 regression coefficients. Result of amended model or expected impact on the result: Different cost results for 'Insertion sleeve or grip 'and 'Specially designed packaging'	
95.	Coloplast			Description of problem: All-cause mortality application is not correct – it uses the yearly mortality from the ONS, but in the model it is applied monthly. The QALY results should have signalled this, as there were only approximately 3.5 QALYs over 80 years. This has a large impact on the results, as now the mortality risks from other sources are more impactful and all outcomes in the model are impacted. Description of proposed amendment: Calculate the monthly risk of mortality for the cohort by using the following formula for the whole table, this formula copied and pasted downwards from F113: '=1-(EXP(-(LN(1-(D113*Prop_Males+E113*(1-Prop_Males))))/12))) Result of amended model or expected impact on the result: All results will change, in varying directions.	Thank you for your comment and for noticing this issue with the mortality. The EAG has now updated the model to account for monthly probabilities (results have been updated in the report to reflect this), however these do not appear to change the conclusions.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
96.	Coloplast			Description of problem: This is not captured explicitly in the model, which is a not reflective of the real-world experience. The major benefit of a well-fitting, comfortable catheter, with the set available to use, is that it increases the compliance of using catheters. Description of proposed amendment: Consider including adherence/compliance in the model.	Thank you for your comment. The EAG has acknowledged limited evidence of adherence and compliance in the eligible studies (see Appendix C4.8). Therefore the EAG did not explicitly include this within the economic model.
97.	Coloplast			Description of problem: The costing for specific comparisons lacks face validity. For example, there is no additional cost associated with the 'Specially designed catheter case' feature (costed at £1.37, with no additional costs for 'additional lubricant'). When this feature is compared to the main model comparator, 'Uncoated (No lubricant provided)' (costed at £1.37 plus £0.19 for additional lubricant), the mean monthly cost per catheter type is cheaper for the 'Specially designed catheter case'. This issue suggests that the model assumes the intervention catheter does not require 'additional lubricant' even if the feature does not provide lubrication. Description of proposed amendment: Consider whether the costing for the base intervention catheter is correct. Result of amended model or expected impact on the result:	Thank you for your comment. The EAG has used results from the regression modelling using prices as reported from the prescribing cost analysis and drug tariff data (from September 2024) within the economic model. Additional lubricant (£0.19 per use) was added to the "uncoated (no lubricant provided" comparator only.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				This could potentially increase the costs associated with each feature that is investigated.	
98.	Coloplast			Description of problem: Based on the previous comments, the following updates were made to the model with the results presented here. (see 18F) Description of proposed amendment: - Lifetime time horizon used (55 years set given 45 years starting age) - Mortality fixed (annual risks converted to cyclical risks before applying and the risk from multidrug resistance and bacteraemia states no longer impacted by background all-cause risk) - Number of uncoated catheters UTIs set to equivalent of 3.27 per year from Baker et al. (equivalent to monthly probability of 23.85%) 50% receiving relevant utility benefits for each feature (where 10% was previously assumed) - RR of haematuria for the catheter case set to 1 (where previously it was set at 2.05) Output from cost regression used for each cost (not just assumed no difference when variable was not significant)	Thank you for your comment. The EAG already has conducted scenario analyses using different starting age of the cohort and our conclusion do not necessarily change. We acknowledge additional scenario analyses on UTI Risks, RR haematuria and non-significant unit costs of features, could be conducted.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
99.	Coloplast			Description of proposed amendment: - With the equivalent changes as above, except utility was now updated to account for age and sex throughout the model. Result of amended model or expected impact on the result: The results here are not too dissimilar as compared with above.	Thank you for your comment. No response required
100.	Convatec			Description of proposed amendment: Based upon the inaccurate descriptors used throughout the report, the economic model is also therefore not highlighting accurate interventions and as such displays flawed analysis and outcomes.	Thank you for your comment. No response required
101.	Coloplast			Description of problem: The average starting age of the model is 45 years old. This is not based on any data source. Subsequently, the all-cause mortality is decided based on a parameter that may not reflect the current population. The standardised mortality ratio (SMR) is applied to the background mortality risk, but then the additional risk of mortality from being in the 'Multidrug resistant UTI' or 'Catheter associated bacteraemia' health states have an additional mortality risk applied, as sourced from Bermingham (2013). This study reports the absolute risk of mortality associated with these two health states, which is reflective of mortality risk regardless	Thank you for your comment. As stated in section 6.1.4 of the EAG report: "The EAG assumed a cohort population with average age 45, of which 70% of the cohort were male; as derived from the included clinical evidence.". The approach used for background mortality to states with their own mortality risk is based on the approach previously validated by NICE in CG139.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				of the background mortality risk. The standardised mortality ratio (SMR) is applied to the background mortality risk, but then the additional risk of mortality from being in the 'Multidrug resistant UTI' or 'Catheter associated bacteraemia' health states have an additional mortality risk applied, as sourced from Bermingham (2013). This study reports the absolute risk of mortality associated with these two health states, which is reflective of mortality risk regardless of the background mortality risk. Description of proposed amendment: Include an age that is reflective of the relevant population. Background mortality should not be applied to those in the health states with their own mortality risk, as it is double counting (the risk from the health state should override the background mortality risk). Use an SMR of 1, or an SMR for the entire intermittent catheter population, as the average catheter user is not that with a spinal cord injury. This overplays the impact of mortality in this population otherwise. Result of amended model or expected impact on the result: Likely to see a reduction in mortality across both arms.	

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
102.	Coloplast			Description of problem: The 'price of catheter features' regression model is not in the model, therefore, it is not included in the PSA. Further, subgroup analysis cannot be run or investigated to see if this analysis is valid when used in the model. Description of proposed amendment: Allow the PSA to vary the cost of each feature in line with the standard errors associated with the regression model to allow to show the results of each scenario are robust.	Thank you for your comment. The unit costs data estimated from the regression were estimated and used in the model. Sensitivity analysis was used to explore the variation in cost for each feature. The EAG can confirm that costs for catheters with each feature were included in the PSA, this may not have been obvious to the company since we included the variation in total catheters costs per month, rather than the variation in the cost of each catheter (either approach gives you the same result since the cost per month is the cost per catheter times the number of catheters used each month).
103.	Coloplast			Description of problem: Several important (and uncertain) parameters were not varied within the PSA. This includes the "Transition probabilities" and the "Dis utilities /Additional utilities" inputs. This could suggest that the current output from the PSA fails to adequately reflect uncertainty in the model The studies from which the transition probability inputs are sourced are primarily from a subpopulation (spinal cord injuries) and are potentially no longer relevant to the current year. Depending on the relative risk applied for the intervention, these inputs will impact the comparator and intervention differently. This suggests an importance to	Thank you for your comment. The EAG agrees, however the transition probabilities are very small numbers and majority did not have evidence of uncertainties. However, assumption of standard error could be used. Utility decrements have already been tested with 10% higher values in scenario analyses.

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				capturing the uncertainty of these inputs, as per the NICE Manual 2022. The disutility/additional utility inputs are also highly uncertain and impact the comparator and intervention differently. This is particularly true for the three additional utility parameters for improvements in discomfort/pain, ease of use, and drainage which are based on an assumed 2% of the utility of catheter users with SCI. Description of proposed amendment: Include transition probabilities and utility decrements into the PSA. Result of amended model or expected impact on the result: A greater understanding of the extent of parameter uncertainty	
104.	Coloplast			Description or problem: As reported in Averbek 2023, "A 17% lower risk for UTIs when the bladder was perceived empty (RR: 0.83; 95% CI: 0.72-0.96)". This shows that, when the bladder is perceived empty, the risk of UTIs should subsequently be lower. It would be an indirect factor, but it would be more reflective of what this feature brings. Description of proposed amendment: Include a relative risk of UTI that is lower than 1 for MHZT, reflective of the proportion of people with successful drainage.	Thank you for your comment. RR was derived from CNMA from clinical evidence section. The EAG considers that this would be the most appropriate value to use

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				Result of amended model or expected impact on the result: Increase the QALY gain and reduce costs for the intervention arm when MHZT is selected	
105.	Coloplast			Description of problem: The input value for increased risk of haematuria for the 'specially designed catheter case' does not seem plausible (RR=2.05). In lay terms this means that an individual using a catheter with a specially designed case is 2.05 times more likely to experience haematuria than were they to use one without a specially designed case. In our opinion, there is no clinical rationale as to why a case would increase the risk of haematuria, let alone to this degree of magnitude. As described in the EAG report, this value may be at risk of confounding and the certainty of evidence was very low. The source that this relative risk was calculated on Chartier-Kastler et al (2011), a small study (n=36) that investigated non-inferiority that took place over 2 weeks. This study alone is not enough to determine a relative risk, much less one that can determine that a case (which should not impact the risk of haematuria) doubles the event risk. Description of proposed amendment:	Thank you for your comment. RR used is based on CNMA from clinical evidence section. The EAG has commented on the uncertainty associated with these estimates (and note that the 95% CrI goes above and below 1). No changes were made to the report

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				Set the relative risk to 1 for risk of haematuria for 'specially designed catheter case'. If the calculated relative risk was not found to be statistically significant and with poor quality evidence, it would be expected that (clinically), the relative risk should be equal to 1. Result of amended model or expected impact on the result: Higher QALYs and lower costs in the intervention arm when 'specially designed catheter case' is selected.	
106.	Coloplast			Description of problem: The monthly risk of urethral damage is cited as from the Couchman (2022) source. No further information is provided on this source in the EAG report or model. However, the original source cites a study based in France that was conducted between 1980 to 1988, and the 0.19% is based on 21 patients over 8 years. It would be very difficult to believe this small cohort, from France over 35 years ago, would be reflective of the current UK population's risk of urethra damage. Description of proposed amendment: Select a more recent source, or set the risk to 0% in model, considering that none of the catheters have an included impact on this outcome. Result of amended model or expected impact on the result:	Thank you for your comment. Changing this to zero% will not change the results/conclusions because the EAG has assumed a RR=1 for urethral complications between the arms. No change made.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				Reduce weighting on an outcome that is not impacted by catheter use in the model.	
107.	Coloplast			Description of problem: The stated monthly value (0.08) corresponds to an annualised rate of approximately one UTI per year. This value is substantially lower than used in other published catheter models (Baker et al 2023, for instance, used an annual rate of 3.27 events per year). Underestimation of the baseline UTI rate biases against catheters that have features that are associated with reductions in UTIs as the difference between the absolute rates for these catheters and those that do not have these features is reduced. This in turn leads to an increase in feature-specific ICERs. Thus, using a robust estimation of the underlying symptomatic UTI rate is a key part of the appraisal. Description of proposed amendment: Consider using a different source for the comparator risk of UTI. Result of amended model or expected impact on the result: More people in the UTI health states across both arms, but a larger treatment effect shown for any features that reduce UTI risk.	Thank you for your comment. Baseline UTI has been varied in sensitivity analysis (0.045 and 0.19); see Table 21 of the EAG report. No changes were made to the report

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
108.	Coloplast			Description of problem: The time horizon is set to 2 years in both the report and model base-case. We anticipate that this will be too short of a time horizon to capture the full benefits of the application of intermittent catheter use. The NICE Manual (2022) states that the time horizon should be set such that all lifetime costs and benefits are captured. This time horizon does not capture all costs and benefits, when the above error is fixed regarding the application of all-cause mortality. Given that the EAG has acknowledged that there are additional, positive impacts on health related quality of life associated with some features, to only use a truncated time horizon means that the incremental QALYs for these features will be underestimated. This is a fundamental, and easily fixable problem of the modelling approach. Description of proposed amendment: Set the time horizon such that all deaths are accounted for in the model. With the all-cause mortality fixed, this is approximately 50 years. Result of amended model or expected impact on the result: Increase both costs and QALYs, with less weighting on upfront costs and QALYs.	Thank you for your comment. A range of time horizons already explored in scenario analyses (see Table 21). The time horizon reflects that the length of follow-up in the published literature is short (noting that across the 18 included comparative studies that "Follow-up varied across included studies between 1 day and 1 year" as stated in section 4.2.2 of the EAG report). No changes were made to the report.

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
109.	Coloplast			Description of problem: The 10% per cycle assumed of experiencing the benefits of a given feature is not based on any clinical data, and almost certainly counterintuitive in the context of the underlying feature. It is an assumption made by the EAG. It's varied in sensitivity analyses and, coupled with the 0.017 additional utility that is based on an assumption, the results are very subjective. This is particularly the case in instances where the features have no impact on haematuria, UTI or urethra damage risks. The rationale for labelling them as potentially counterintuitive is that the features in question (ease of use, improved residual volume, increased comfort/ less pain) are a consequence of design and component choices and are intended to be felt by the majority of users. Based on EAG's logic, a product designed to improve residual volume would only provide the positive impacts (a reduction in residual volume) in 10% of users. We understand that there is little evidence around the effects, hence we are okay with an assumption being made, but believe that the assumed value in the base-case is far too low. Description of proposed amendment: Although this is noted in the EAG report as an assumption and varied in the scenario analysis, this should be incorporated into the	Thank you for your comment. A range of percentage improvements was explored by the EAG in one-way sensitivity analysis (see Table 21 of the EAG report).

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				decision-making process clearly, as it is basing a decision entirely on assumptions. Also, at a minimum, an assumption of 50% improvement should be used as this is, in effect, saying that half of users would experience the benefit of the feature. Result of amended model or expected impact on the result: Increased clarity on the robustness of the results, and greater QALY bonuses for the intervention arms.	
110.	Coloplast			Description of problem: The approach used for the utilities does not reflect current prescribed methods by NICE: - While consistent with the NICE CG139, we caution the representativeness of the health state utility values (Bermingham et al., 2013) for the current analyses: - These data may not reflect the health-related quality of life outcomes for current catheter users, considering advancements in catheter devices, differences in treatment pathways, or the availability of catheter choices between the United Kingdom, the United States, and Canada in 2024. The EAG acknowledges this. - The sample included in the Vogel et al. study may not represent the modelled population. Namely, those who completed the SF-12 were younger and sustained a spinal cord injury during childhood (mean	Thank you for your comment. The EAG agrees and does not expect the incremental results and conclusions to change by taking this approach, as the EAG uses same utility values for all comparators. The EAG has run further sensitivity analysis to adjust the quality of life utilities of all the catheters by the gender and age composition of the population each cycle (i.e. each month). The incremental results have not changed compared with the base case results., but it aligns the methodology in the model with the NICE 2022 methods guidance.

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				age at injury = 14 years; mean age at interview = 29 years). Following NICE guidance, these values should have been adjusted for baseline age and sex. Population norms are included in the model but unutilised. - Why was a general population norm not used (that varied depending on starting age), that a utility decrement could be applied to instead? This would result in a far more reflective representation of the current age / utility of the population. - Considering the 3 other available sources for HRQoL utilities, why was Bermingham (2013) used, and no detailed consideration given for the others in scenario analyses? This surely should be investigated, particularly given the uncertainty associated with the Bermingham (2013) studies. - The EAG was unable to estimate utility decrements associated with 'discomfort/pain', 'ease of use' and 'residual volume'. Accordingly, an assumed 2% increase in the baseline utility of catheter users was implemented based on data reported by Averbek et al. 2018 ($0.831 * 0.02 = 0.017$). - We, however, are unable to identify how the EAG derived the proposed 2% increase. This assumption was not asserted	

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
				by Averbek et al. (2018). We assume the article was cited as the utility decrement aligns with the gain associated with catheters with the 'ready to use' feature (compared to single-use catheters without this feature). - The health state vignettes employed by Averbek et al. include 'Steps needed for catheterisation', 'Time needed for catheterisation', 'Pain level' and 'Frequency of UTIs'. 'Steps needed for catheterisation' and 'Time needed for catheterisation' arguably encompass the 'ease of use' feature. We question the validity of assuming equivalent health-related quality of life benefits are associated with residual volume. Description of proposed amendment: Consider using population norms. Clarity on the use of this assumption would help with understanding of the limitations in this analysis. Adjustments of the utility values such that they reflect the current population's age. The utility gain/decrement from the pain, discomfort, ease of use and successful drainage events should be considered for scenario analysis, with larger impacts considered, potentially utilising the other 3 studies with HRQoL data.	

Comment no	Organisation	Page no	Section no	Comment	Response from EAG
111.	BD			NO COMMENTS	No change to the report made.

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Late-stage assessment

**Intermittent urethral catheters for
chronic incomplete bladder emptying
in adults: late-stage assessment**

User preference report

January 2025

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1 Introduction

This late-stage assessment focuses on intermittent urethral catheters for chronic incomplete bladder emptying in adults. Alongside the assessment of the clinical and cost benefits of intermittent catheters used in the NHS, NICE is doing the following pieces of work to help the committee understand people's experiences and what is important to users when choosing which catheter to use:

- a user preference assessment,
- a review of the published literature,
- an online survey.

This report presents the key findings from the user preference assessment. It should be read alongside the findings from the online survey, summary of published literature and the external assessment group's (EAG) report on [NICE's topic page](#).

2 Background

Intermittent catheterisation is used to treat bladders that do not empty fully. It may be needed for the treatment of conditions including, but not limited to, bladder dysfunction, neurological conditions, urethral obstruction, strictures or tumours.

Intermittent catheterisation can have both positive and negative impacts on a person's quality of life. Using catheters has been reported to impact a person's independence, sense of control, confidence, intimacy and social life in a variety of ways ([Goldstine 2019](#); [Cobussen-Boekhorst 2016a](#), [2016b](#); [McClurg 2019](#); [Shaw 2013](#); [Marklewicz 2020](#)). But, every person's individual experience is likely to be different. A common complication of intermittent catheterisation is urinary tract infections (UTIs). UTIs can be painful, uncomfortable and, if left untreated, can cause severe damage to the kidneys. They can negatively impact a person's physical, social and mental wellbeing, sometimes requiring time off work, or leading to an inability to complete regular daily activities.

In community and primary care, intermittent catheters are supplied using an NHS prescription for catheters listed in [Part IXA of the Drug Tariff](#). The 'catheters' subgroup has over 20 companies listed as suppliers with approximately 1,130 product variations available. The products available can vary in the features offered including ranges of sizes, colours, lubrication type and additional potentially innovative features (a full range of feature categories are listed in the [published scope](#)).

Due to the large number of products available, there is a wide range of options to choose from. When deciding which catheter to use, it is important to consider a person's preference and clinical needs ([Royal College of Nursing, 2021](#); [European Association of Urology Nurses, 2024](#)). Decisions should be shared to ensure the most appropriate catheter is selected that meets an individual's needs. But, people with lived experience highlighted that they are not always aware, or given a choice of the range of catheters that are available to them.

The thematic review of intermittent catheter users' needs, experiences and preferences reported that people's experiences and needs are varied. Factors that impacted a person's experiences and individual needs included:

- a person's age, sex and physical or cognitive abilities,
- concerns about using a catheter such as fear or anxiety related to using a catheter,
- concerns about social perceptions of using a catheter, such as feeling embarrassed.

A person with lived experience reiterated that social perceptions also contribute to feelings of compromising a person's dignity. Another theme within the literature review summarised how people using catheters considered technology features. People considered technology features to avoid discomfort, trauma and pain, increase speed of bladder emptying and improve ease of use and discretion ([Goldstine 2019](#); [Kelly 2014](#); [Pinder 2015](#)).

3 Methods

NICE is looking at user experience and preferences when choosing an intermittent urinary catheter for urinary management in adults alongside the evaluation of the clinical and cost benefits. This user preference assessment considers the following:

- the criteria that are important to users when choosing a catheter,
- the relative importance of the criteria,
- and how the criteria can be measured.

This assessment was done in line with [NICE's interim methods and process statement for late-stage assessment](#). The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. Users are defined as those who will use the technology and are directly involved in the decision to choose one technology over another.

For this assessment, users were identified as people with lived experience of using catheters and people with experience of prescribing catheters for intermittent catheterisation. Users were recruited in line with [NICE's Interim methods and process statement for late-stage assessment](#). [NICE's policy on declaring and managing interests for NICE advisory committees](#) was considered during the recruitment process. Users who were directly employed by a company whose technologies are being evaluated were excluded from the process. A declarations of interest register will be published alongside the guidance document on [NICE's topic page](#).

The user preference assessment has been designed with Multicriteria Decision Analysis (MCDA) principles ([ISPOR Task Force Report, 2016](#)). The user preference assessment was done through participation in 2 online workshops and 2 email tasks. This was split into the following 4 stages:

- Stage 1: identifying and defining criteria (workshop 1)
- Stage 2: ranking criteria in order of importance (email task 1)

- Stage 3: weighting criteria (email task 2)
- Stage 4: developing performance rules (workshop 2)

Stage 1: identifying and defining criteria

Users were asked to identify key factors that are important when choosing a catheter. Criteria and definitions were identified and agreed on during an online workshop with users. Users considered criteria related to a person's clinical presentation and criteria related to preference separately to create 2 lists.

Stage 2: ranking criteria in order of importance

Users were then asked to rank the criteria related to preference in order of importance to them via an email task. Ranked lists from all respondents were collated, averaged and ordered from most important to least important, creating a final ranked list of criteria and definitions (using the SMART ranking technique; [see appendix C for a detailed definition](#)).

Stage 3: weighting criteria

Users were then asked to weight the criteria related to preference to show how much more important 1 criterion was compared with the criterion ranked below (using the swing weighted technique, [see appendix C for a detailed definition](#)). To weight the criteria, users were asked to give each criterion a score from 0 to 100%. A score of 0% meant that there was no difference in importance between a criterion and the criterion ranked below, and a score of 100% meant that it was considered twice as important. Weighted lists for all respondents were collated, averaged and weights were calculated.

Stage 4: developing performance rules

During the second online workshop, performance rules were created by consensus for each criterion related to preference. To do this, users were asked how they would measure performance of a technology against each criterion. For rules with multiple possible outcomes, users were asked what would be considered acceptable or unacceptable levels of performance. In

some cases, a level of acceptable performance could not be reached due to variation in opinion. Where this was the case, it is highlighted in table 3.

User engagement for all stages of the assessment is in table 1.

Table 1: Overview of user engagement at each stage of the assessment

Stage	People with lived experience [n=4]	People with experience of prescribing [n=5]
1	2	5
2	3	5
3	2	2
4	4	4

4 Results

4.1 Identifying and defining criteria

During the first workshop, users identified and defined criteria that are important when selecting an intermittent catheter for bladder drainage. Users highlighted that choice is driven by both a person's clinical presentation as well as the needs and preferences of the individual person. So, criteria were split into those related to clinical presentation, and those related to preference. Anonymised individual responses from the ranking exercise and the comparison between user groups is in [appendix A](#) (tables 5 and 6).

Criteria related to clinical presentation

A total of 7 criteria related to clinical presentation were identified and defined by users during the first workshop (table 2). It was not considered appropriate to rank the criteria related to clinical presentation due to the variation in what may be considered important for each person.

Users stated that an individual clinical assessment is necessary to be able to choose the most appropriate catheter, and that this will vary from person to person. Users explained that the length of catheter needed is typically based

on a person's physiological characteristics, such as length of the urethra. Users noted that longer catheters may also be needed for different clinical scenarios, such as loading antibiotics to treat infections. Additionally, users highlighted that a person's manual dexterity and cognitive ability would be reviewed to ensure that they had the ability to open and manage packaging, as well as use the catheter appropriately. Users with experience prescribing stated that, if a person was experiencing issues managing or using their catheter, they may look for a catheter with packaging that is simpler to open, handle and use. They also highlighted that if a person is unable to perform self-catheterisation (for example, due to manual dexterity issues, cognitive impairment, or injury) they would assess whether a person requires assistance to complete the procedure.

Users said that if a person was experiencing chronic or recurrent infections, that they would perform a review to make sure that the person was using the appropriate catheterisation technique and to check if they were experiencing difficulties with bladder emptying or using the catheter more generally. They noted that, if a person continued to experience infections, they may suggest changing the type of catheter being used. But, highlighted that, to their knowledge, it is unclear whether one type of catheter can improve or reduce infections compared with another.

Finally, users explained that some people may experience difficulty inserting the catheter due to differences in urethral or prostatic anatomy that cause obstructions. They stated that this would be assessed, and a smaller or more flexible catheter tip may be more appropriate.

During the workshop, it was also noted that some of the criteria related to clinical presentation are closely linked to criteria related to preference. For example, the length of a catheter needed may also be linked to a person needing options to suit their individual lifestyle. Users with lived experience stated that some people may prefer more discreet and compact catheters when out of the house but may find less compact catheters easier and more acceptable to use at home. Users also noted that someone's manual dexterity

or cognitive ability could make it more difficult to open and manage packaging, and users may have a preference for a catheter with features that make it easy to remove from packaging and prepare for use.

Users with lived experience explained that using catheters that cause pain or discomfort on insertion or removal may impact how they use their catheter and could lead to avoidance or incorrect use. They stated that incorrect use or lack of adherence may lead to infection, which can negatively impact their quality of life. Users with experience prescribing noted that catheters that are not comfortable to use may also cause injury, which in turn could lead to infection. So, infection was included in both the criteria related to clinical presentation and criteria related to preference.

Table 2: Criteria related to a person's clinical presentation

Criteria	Definition
Length of catheter needed	Various lengths of catheters needed for a person's individual needs (e.g. physiological or environmental factors, different urethral lengths, procedure required).
Manual dexterity	A person's ability to open and manage packaging and use the catheter in relation to their manual dexterity.
Mobility of the person using the catheter	A person's ability to sit, stand or manoeuvre in various situations.
Assistance required for catheterisation	Whether a person requires assistance with catheterisation (either partially or fully), for example, due to manual dexterity, injury or cognitive ability.
Susceptibility to infection	Whether a person may be experiencing recurrent infections (for example, urinary tract infections), at a higher risk of infections or if a person is likely to become very ill from an infection.
Cognitive ability	A person's ability to open and manage packaging and use the catheter in relation to their cognitive ability.

Difficulty of catheter insertion related to urethral or prostatic anatomy	Urethral or sphincteric obstruction may require a different catheter tip.

Criteria related to preference

Criteria related to preference are factors related to the product features and characteristics which may influence the user when choosing a catheter to prescribe or use. A total of 9 criteria were identified and defined by users in the first workshop. Some users attended the second workshop only and minor changes were suggested to some of the criteria and definitions. These were agreed by group consensus and amended in the second workshop. Where this took place, it is summarised in section 4.1.3. The final list of criteria related to preference and definitions is in table 3.

4.3 Ranking criteria in order of importance

Eight users returned the criteria ranking email exercise. Criteria in ranked order are presented in table 3 and the comparison of ranking between user groups is presented in table 6. The most important criteria to consider when choosing an intermittent catheter is whether it is comfortable to insert and comfortable to remove. This was followed by full bladder drainage, risk of infection and having options to suit individual needs and lifestyles.

When comparing the ranking between people with lived experience and people with experience prescribing, having a catheter that is comfortable to insert and remove remained the most important factors to consider for both user groups. People with lived experience ranked full bladder drainage and level of catheter flexibility as more important than people with experience prescribing. But, people with experience prescribing prioritised having options to suit individual needs and lifestyles. Both user groups ranked risk of infection as the fourth most important criterion to consider when choosing a catheter. Both groups also ranked ease of disposal and reduced environmental impact as the least important criteria. However, users reiterated throughout the assessment that, although they had carefully

considered how to order the criteria, all 9 criteria are important and should be considered when choosing which catheter to use.

Two users who did not attend the first workshop highlighted that it is likely that individual perception of importance may change for people with different experiences, conditions and lifestyles. They noted that some criteria, such as comfortable to insert, will be important for everyone in every situation, but for other criteria, importance may vary depending on their individual circumstances.

Table 3: Criteria ranked in order of importance

Order of importance	Criteria	Definition
1	Comfortable to insert	Can be inserted with minimal difficulty, pain or discomfort.
2	Comfortable to remove	Can be removed with minimal difficulty, pain or discomfort.
3	Full bladder drainage	Drains the bladder fully, as quickly as possible and without the need for repositioning the catheter.
4	Risk of infection	A low risk of developing an infection.
5	Options to suit individual needs and lifestyles	Available in various options (such as different sizes, designs or styles) that are as convenient and discreet as possible, suitable for various activities (such as travelling) and have options that create minimal mess (such as less liquid).
6	Easy to remove from packaging and prepare for use	Can be removed from the packaging and prepared for use easily (for example, with minimal spillage of lubrication [for pre-lubricated catheters], minimal handling, or a self-adhesive tab that remains stuck to a hard surface during catheter preparation).
7	Level of catheter flexibility	Appropriate flexibility for a person's individual and situational needs to enable insertion and removal with minimal pain or discomfort.
8	Ease of disposal	Can be disposed of at a person's earliest convenience without leakages.
9	Reduced environmental impact	Minimal packaging, with components that can be recycled. A catheter that can be recycled

		(where appropriate) that is manufactured using sustainable practices and materials, with the option for a reusable catheter.

4.3 Weighting criteria and creating performance rules

Weighting criteria

All 9 criteria were weighted by users and are shown in the performance matrix (table 4). Anonymised raw data of weighting scores and the comparison of weighting between user groups is in appendix B (tables 7 and 8).

Four users participated in the weighting email exercise. Nearly half of the total weighting was given to comfortable to insert (25.7%) and comfortable to remove (21.9%). This was followed by 15.3% for full bladder drainage and 11.9% for risk of infection. The weights given to the remaining criteria were all under 10%. When comparing weightings between user groups, they were generally consistent. But, people with lived experience weighted risk of infection slightly higher than people with experience of prescribing (13.0% compared with 10.9%).

Creating performance rules

Performance rules were not created for the 7 criteria related to clinical presentation, as users considered it inappropriate to define how to measure aspects that routinely go into the clinical assessment of a healthcare professional prescribing the catheter.

During the second workshop, users were given the choice to create performance rules only for criteria with a weight of more than 5%, as per NICE's user preference methods, or for all 9 criteria related to preference. Users agreed that rules should be created for all criteria as they are all considered important when choosing a catheter. Performance rules are listed in the performance matrix (table 4).

Users were able to create performance rules for all criteria, with all but 1 criterion having multiple performance rules. Some rules can be answered with

a simple yes or no, whereas others may have a number of answers. For those with a number of answers, users were asked to state acceptable or unacceptable levels of performance. This was achievable for some rules but for others, a consensus could not be reached.

Criterion 1: Comfortable to insert

During the second workshop, users agreed to slightly amend the definition by changing the word 'effort' to 'difficulty', as they felt that this captured their experience more accurately. Performance rules included the level of force needed, or difficulty experienced when inserting the catheter, the level and impact of pain experienced, the level and impact of discomfort experienced and the presence of blood from catheter insertion. A consensus could not be reached on what would be considered acceptable or unacceptable levels of force needed, or pain or discomfort experienced. Users agreed that tolerable levels of, force, pain or discomfort may vary from person to person, including variation between different clinical presentations. Users did agree that no amount of pain on catheter insertion was an aspirational aim, but noted that this was likely not possible for everyone. Users highlighted that the presence of blood may be a result of trauma and can sometimes appear without the presence of pain. One user with lived experience noted that seeing blood can be quite disturbing psychologically, as well as physically traumatic, even if this isn't accompanied by any pain or discomfort. Users agreed that no amount of blood present from catheter insertion is considered acceptable.

Criterion 2: Comfortable to remove

In line with criterion 1, users agreed to amend the definition to replace 'effort' with 'difficulty' during the second workshop. Performance rules included the level of difficulty or resistance experienced when removing the catheter, the level and impact of pain experienced, the level and impact of discomfort experienced, presence of blood on catheter removal and the rates of 'sticking' and 'gripping' when removing the catheter. Users agreed that no amount of resistance, pain, discomfort or blood present when removing a catheter is considered acceptable, and that it should 'glide out' when being removed.

They also agreed that no level of catheter 'sticking' is considered acceptable.

Users with experience prescribing noted that some people experience spasms, or 'gripping', when removing the catheter, due to their clinical presentation. They stated that this is sometimes unavoidable, so minimal gripping may be considered acceptable for these people.

Criterion 3: Full bladder drainage

Users agreed to add further clarification to the definition to make sure that it was clear that the criteria related to repositioning of the catheter itself. Performance rules included whether the catheter fully drains the bladder, the number of times the catheter needs to be repositioned, time to full bladder drainage and the amount of urine drained. A consensus could not be reached on the number of acceptable or unacceptable times to reposition a catheter, as users agreed that is likely to vary from person to person and between settings. Users with lived experience stated that a catheter that can drain the bladder fully more quickly may be beneficial when using public toilets in a busy setting, but noted that this may be less important when at home. In relation to the amount of urine, one user with lived experience said that for people who cannot feel that their bladder is empty, for example people with spinal injuries, it is possible to estimate whether the bladder had drained fully based on the amount of urine drained in relation to the person's lifestyle. One user with experience of prescribing noted that, in their experience, improving how fast and fully a catheter can drain a bladder had not been a priority in choosing a catheter, and noted that this preference may vary greatly from person to person. But, a user with lived experience stated that it is an important factor to them to try and reduce the amount of residual urine left in the bladder.

Criterion 4: Risk of infection

The performance measure for criterion 5 was the number of infections experienced per year. Users agreed that no infections is aspirational, but acknowledged that this was unlikely for a lot of people. A consensus could not be reached on acceptable or unacceptable numbers of infection per year, as users stated that this may vary from person to person based on a number of

factors, including predisposed risk and clinical presentation. Users with
GID-HTE10049 Intermittent urinary catheters for chronic incomplete bladder emptying in
adults: late-stage assessment
User preference report
January 2025

experience prescribing stated that there isn't a catheter currently available that is proven to reduce the risk of infection directly. But, users from both groups explained that a number of factors external to the catheter may impact the risk of infection, such as keeping a clean environment during preparation, technique when using the catheter, whether the bladder empties fully, adherence to the procedure, amount of lubrication and injury when removing or inserting the catheter. Users with lived experience explained that catheters that are easier and more comfortable to use may improve adherence and, in turn, reduce the risk of developing infections. Users with lived experience reiterated the negative impact that chronic and recurrent infections have on a person's quality of life and ability to perform daily activities.

Criterion 5: Options to suit individual needs and lifestyles

During the workshop, users agreed to amend the definition to include 'different styles and designs' to add extra detail without changing the meaning of the definition. Performance rules included measuring whether the catheter (or combination of catheters) meet a person's individual needs across various environments and the impact using the catheter has on a person's lifestyle. A user with lived experience stated that a catheter must allow someone to maintain their functionality, not have a negative impact on their quality of life and be as unrestrictive as possible on a person's lifestyle. Users agreed that catheters should enable people to continue with their lifestyle without stigma or exclusion. Users noted that 1 type of catheter may not be suitable for all situations or settings in a person's life, and the acceptability of each catheter may vary depending on setting or activity. For example, when travelling, a person may need a catheter that is smaller, more discreet, with less packaging and liquid to allow them to be placed in hand luggage. But, when at home, they may be happy to use a longer, less discreet catheter that is easier to use and where the catheter and the packaging can be disposed of easily. Users with experience of prescribing highlighted that typically, only 1 type of catheter is prescribed for each person. They stated that this may impact costs if a person uses a more convenient and costly catheter for discretion when out of the house, when a cheaper catheter with less features may be acceptable

at home. One user highlighted that, although some catheters may be more convenient or discreet than others, that some people may never find using a catheter to be either, but stated the importance of trying to optimise this for every individual person as much as possible in order to maintain quality of life.

Criterion 6: Easy to remove from packaging and prepare for use

Performance rules for criterion 6 included time to prepare catheter for use, the number and complexity of steps involved in the preparation of catheter, additional components required that are not included in the packaging, the number of unsuccessful preparation attempts and whether it leaks before use. A consensus could not be reached on acceptable or unacceptable levels for all performance rules as users explained that it is likely that there is variation from person to person, as well as in different settings and situations. Users with lived experience explained that packaging containing liquid can sometimes leak when travelling due to pressure changes, and agreed that no amount of leakage prior to use in any setting was considered acceptable.

Criterion 7: Level of catheter flexibility

During the second workshop, users agreed to add further detail to the definition to clarify that flexibility is dependent on a person's individual and situational needs. Performance rules included whether the catheter has the appropriate level of flexibility to allow ease of use for the individual person, the level and impact of pain experienced when inserting and removing the catheter, the level and impact of discomfort experience when inserting and removing the catheter and the presence of blood from insertion, during drainage, or on removal of the catheter. Users with experience prescribing highlighted that the appropriate flexibility will vary from person to person, and is often linked with a person's manual dexterity, which is clinically assessed. Users from both groups agreed that having a catheter with the appropriate flexibility for each person should allow easy handling, insertion and removal of the catheter without causing damage or trauma, both physically and psychologically. Users agreed that no amount of pain or the presence of blood caused by incorrect flexibility is considered acceptable.

Criterion 8: Ease of disposal

Finally, performance rules related to ease of disposal included how long after use a person is able to dispose of the catheter or packaging suitably, whether it leaks after use and the quantity of packaging. A consensus couldn't be made on acceptable or unacceptable limits for time to disposal or quantity of packaging, as users highlighted that it would vary from person to person, as well as setting or location. Users with lived experience explained that discreet disposal is often difficult when out in public if there is no access to sanitary bins. They highlighted that this is a particular issue in male public toilets. One user explained that having to find somewhere to discreetly dispose of the catheter after use can often be difficult to deal with psychologically due to the stigma that is sometimes associated with using catheters. Users agreed that this is an issue, and more should be done to enable people to dispose of catheters quickly and discreetly after use when in public. It was also agreed that any amount of leakage after use when finding somewhere to dispose of the catheter was unacceptable.

Criterion 9: Reduced environmental impact

Performance rules related to reduced environmental impact included the quantity of packaging, the number of recyclable components, opportunities to recycle components and the sustainability of the manufacturing process. Users stated that there is likely variation in whether environmental impact is a priority between individuals. They acknowledged that it may also sometimes conflict with other preferences, such as whether a catheter is easy to remove from packaging and prepare for use, or having options to suit individual needs and lifestyles. One user noted that if a catheter is more convenient and discreet to use out of the house, this may be prioritised over whether it is easily recycled or was manufactured sustainably. Due to this, users agreed that acceptable or unacceptable levels for all performance rules could not be made. The group also highlighted that there is variation across the country in what materials can be recycled, and this may impact a person's preferences. A user with lived experience explained that some aspects of catheters, such as the type of ink printed on packaging or coloured catheters may reduce the

likelihood of being able to recycle them. All users agreed that clear information available in a useable format from manufacturers related to environmental impact of producing and disposing of their products is welcome.

Table 4: Performance matrix

Order of importance	Weight (%)	Criteria	Performance rule (how to measure criteria and levels of performance considered acceptable)
1	25.7	Comfortable to insert	• Level of force needed, or difficulty experienced when inserting the catheter • Level and impact of pain experienced when inserting the catheter • Level and impact of discomfort experienced when inserting the catheter • Presence of blood from catheter insertion A consensus could not be reached on what would be considered acceptable or unacceptable levels of force needed, or pain or discomfort experienced. No pain on insertion was considered aspirational. No blood present from catheter insertion was considered acceptable.
2	21.9	Comfortable to remove	• Level of difficulty or resistance experienced when removing the catheter • Level and impact of pain experienced when removing the catheter • Level and impact of discomfort experienced when removing the catheter • Presence of blood on catheter removal • Rate of catheter sticking • Rate of catheter gripping No resistance, pain, discomfort or blood present when removing a catheter is considered acceptable. No sticking and minimal gripping is considered acceptable.
3	15.3	Full bladder drainage	• Does the catheter fully drain the bladder? • Number of times the catheter needs to be repositioned • Time to full bladder drainage

			Amount of urine A consensus could not be reached on acceptable or unacceptable levels of repositioning or time to drainage.
4	11.9	Risk of infection	Number of infections per year No infections is considered aspirational. A consensus could not be reached on the acceptable or unacceptable number of infections experienced per year.
5	8.3	Options to suit individual needs and lifestyles	- Does the catheter (or combination of catheters) meet a person's individual needs in various environments? - Impact on lifestyle (quality of life)
6	5.8	Easy to remove from packaging and prepare for use	- Time to prepare catheter for use - Number and complexity of steps involved in preparation of catheter - Additional components required that are not included in the packaging - Number of unsuccessful preparation attempts - Does it leak before use? It was considered unacceptable for packaging to leak before use. A consensus could not be reached on acceptable or unacceptable levels for the time to prepare the catheter, the number and complexity of steps involved, additional components needed for preparation or the number of unsuccessful attempts.
7	4.8	Level of catheter flexibility	- Does the catheter have the appropriate level of flexibility to allow ease of use for the individual person? - Level and impact of pain experienced when inserting and removing the catheter - Level and impact of discomfort experience when inserting and removing the catheter

			• Presence of blood from insertion, during drainage, or on removal of the catheter No amount of pain or blood from insertion, during drainage, or on removal of the catheter is considered acceptable.
8	3.5	Ease of disposal	• How long after use is a person able to dispose of the catheter/packaging suitably? • Does it leak after use? • Quantity of packaging It is unacceptable for catheters to leak after use. A consensus could not be made for acceptable or unacceptable levels the length of time to disposal and quantity of packaging.
9	2.9	Reduced environmental impact	• Quantity of packaging • Number of recyclable components (e.g. printing on packaging, coloured catheters with additional ink or dye) • Opportunities to recycle components • Sustainability of manufacturing process (e.g. weight of packaging may impact transportation costs) • A consensus could not be made for acceptable or unacceptable levels for all performance rules.

5 Additional considerations

Deciding which catheter to use should be a shared decision between a healthcare professional and the person using the catheter. When making the decision, it is important to consider the person's preference and clinical needs ([Royal College of Nursing \[RCN\] 2021](#); [European Association of Urology Nurses \[EAUN\] 2024](#)). During the user preference assessment, some of the users with lived experience highlighted that they were unaware that there were multiple options available for which catheter to use. One person with lived experience explained that it took them a number of years before they were aware of any other choices over the catheter that they had been prescribed. Another user stated that they had never been involved in the decision to choose which catheter was most appropriate for them. Both user groups agreed that choosing a catheter is a shared decision, and more should be done to provide people using catheters with accurate information about the range of suitable options available to them.

6 Conclusion

Five people with experience of prescribing and 4 people with lived experience took part in this user preference assessment to identify what is important to users when choosing a catheter. Users from both groups highlighted that choosing the most appropriate catheter for each person should be based on both clinical presentation and individual preferences. So, 7 criteria related to clinical presentation and 9 criteria related to preference were identified and defined by users. The 9 criteria related to preference were then ranked in order of importance and given weights based on their perceived importance. Performance rules were created to show how performance for each criterion related to preference could be measured.

Clinical criteria identified by users related to a person's individual anatomy and physiology, ability to manage packaging, handle and use the catheter, mobility and susceptibility to infection. The relevance of these criteria is

supported by the findings of the literature review, which found that age, sex, physical and cognitive ability all impacted catheter choice.

The most important criteria related to preference (agreed by both user groups) were that a catheter is comfortable to insert and comfortable to remove. They were also considered considerably more important than the other criteria with a combined weighting of almost 50%. This is supported by the results of the online survey that found that one of the main reasons for changing a catheter was to find one that was easier to use and insert, with 99% of people responding that having a catheter that is easy to insert is either important or very important. When creating performance rules, users stated that the level and impact of pain and discomfort, as well as the presence of blood from catheter insertion or from catheter removal could be used as measures of whether a catheter is comfortable to insert or remove. The thematic review reiterated that pain, discomfort and bleeding were key factors influencing the experiences of people using catheters ([Balhi 2021](#); [Bolinger 2013](#); [McClurg 2019](#); [Yilmaz 2014](#)). The EAG's analysis reported that the micro-hole feature was cost-effective and found to reduce the risk of haematuria (blood in urine).

Throughout the assessment, users with lived experience reiterated the negative impact chronic or recurrent infections can have on a person's quality of life. The online survey also reported that one of the main challenges faced by people using catheters was experiencing infections. In relation to catheters, users highlighted the uncertainty throughout the assessment around whether the choice of catheter can impact infection rates. But, users from both groups agreed that factors external to the catheter, such as whether the bladder empties fully and adherence to the procedure, can impact rate of infection. Despite the uncertainty around whether the choice of catheter directly impacts rates of infection, both user groups agreed that finding a catheter that can be handled easily and is comfortable to use is likely to improve technique, adherence and bladder emptying, which in turn, may reduce the risk of infection. Both user groups reiterated the need for more evidence related to how individual catheters impact rates of infection. The EAG's analysis reported that there was a possible reduction in urinary tract

infections linked with the enhanced coating and specifically designed packaging features, providing some evidence that features of catheters may be linked with infections. However, the EAG noted the large uncertainties associated with the findings.

During the assessment, some of the users with lived experience stated that they were not involved in the decision of which catheter to choose, or that they were unaware for a number of years that there were other options available to them. The online survey also found that only 32% of people had choice to select a suitable catheter to use when they first started using catheters. When comparing ranking between user groups, users with lived experience ranked full bladder drainage as a higher priority than people with experience of prescribing. People with lived experience also weighted risk of infection as slightly more important than people with experience of prescribing, suggesting potential variation in what's considered important between the user groups. Variation between user groups reiterates the importance of shared decision making when choosing which catheter to use. [NICE's guideline on shared decision-making](#) says that people have the right to make informed decisions about their care and should understand the choices available to them.

Users were unable to agree acceptable or unacceptable levels of performance for a number of criteria during the second workshop. Both user groups agreed that what may be considered acceptable or unacceptable is likely to vary greatly from person to person, as well as for the same person in different situations or settings. This is supported by users ranking the need to have options suitable for individual needs and lifestyle in the top 5 most important criteria when choosing which catheter to use. The online survey also found that, when comparing response for people who identified as male or female, there was a difference related to how much of a challenge they found inserting or removing the catheter. Users reiterated that 1 type of catheter may not be suitable for all situations or settings in a person's life, and the acceptability of each catheter may vary depending on setting or activity.

Users with experience of prescribing explained that only 1 type of catheter is

typically prescribed for each person. Both user groups agreed that having access to different types of catheters that fulfil a person's individual needs depending on settings or activities may lead to improved quality of life for people using catheters for intermittent catheterisation.

A limitation of this assessment was difficulty recruiting users with lived experience, which may be due to the perceived stigma that can sometimes be associated with using catheters. The online survey found that one of the top 3 challenges faced by people using catheters was 'embarrassing or public stigma'. Users employed directly by companies whose products are being evaluated were excluded from the assessment. But, due to the difficulties associated with recruitment, some users with lived experience have ambassador roles linked to some of the companies with technologies included in the assessment. Users also reiterated the possible variation between individual preference depending on the individual and their lifestyle. As a result, the findings from this user preference may not be generalisable to the wider population. But, to address this limitation, NICE also completed a thematic review of the published literature and an online survey to help the committee understand people's experiences and what is important to users when choosing which catheter to use. Out of the top 5 criteria listed as important to consider when choosing a catheter in the online survey results, only "hygiene" was not also explicitly included in the 9 criteria related to preference. The EAG's assessment report also highlighted that catheters that can be connected to an external collection bag, or those with an integrated bag may be preferred by people with limited mobility such as people who use wheelchairs. Due to the limited sample size of the user preference assessment, it is possible that the importance of preferences associated with this feature among people with limited mobility has not been captured.

Despite this, the user preference assessment highlights the importance to users of shared decision making and having a catheter, or catheters, that are comfortable to use. This will allow people that use a catheter for intermittent catheterisation to maintain their functionality, reduce restrictions to their lifestyle and improve quality of life.

Appendix A: individual responses and variation in criteria ranking

Table 5: Individual user responses for criteria ranking

Criteria	1	2	3	4	5	6	7	8	Mean	SD	Final Rank
Comfortable to insert	1	1	2	2	3	1	1	1	1.5	0.76	1
Comfortable to remove	2	5	3	3	4	2	2	3	3.0	1.07	2
Full bladder drainage	5	4	7	4	2	4	5	2	4.1	1.64	3
Risk of infection	3	2	4	1	7	6	7	4	4.3	2.25	4
Options to suit individual needs and lifestyles	9	7	1	6	1	3	3	6	4.5	2.93	5
Easy to remove from packaging and prepare for use	4	3	6	7	6	5	4	5	5.5	1.60	6
Level of catheter flexibility	8	6	8	5	5	7	6	7	6.0	1.31	7
Ease of disposal	7	8	9	8	8	8	8	8	8.0	0.53	8
Reduced environmental impact	6	9	5	9	9	9	9	9	8.1	1.64	9

SD: standard deviation

Table 6: Comparison of ranking between user groups

Rank	People with experience prescribing catheters for intermittent catheterisation	People with lived experience of using catheters
1	Comfortable to insert	Comfortable to insert
2	Comfortable to remove	Comfortable to remove
3	Options to suit individual needs and lifestyles	Full bladder drainage
4	Risk of infection	Risk of infection
5	Full bladder drainage	Level of catheter flexibility
6	Easy to remove from packaging and prepare for use	Options to suit individual needs and lifestyles
7	Level of catheter flexibility	Easy to remove from packaging and prepare for use
8	Ease of disposal	Ease of disposal
9	Reduced environmental impact	Reduced environmental impact

Appendix B: Individual responses and variation in criteria weighting

Table 7: Individual responses to criteria weighting

Criteria	1 (%)	2 (%)	3 (%)	4 (%)	Mean importance	SD	Weight (%)
Comfortable to insert	20	0	50	0	17.5	23.6	25.7
Comfortable to remove	20	20	70	60	42.5	26.3	21.9
Full bladder drainage	15	30	50	20	28.8	15.5	15.3
Risk of infection	15	20	40	100	43.8	39.0	11.9
Options to suit individual needs and lifestyles	10	30	60	70	42.5	27.5	8.3
Easy to remove from packaging and prepare for use	5	25	35	20	21.3	12.5	5.8
Level of catheter flexibility	10	0	65	80	3.8	39.7	4.8
Ease of disposal	5	0	80	0	21.3	39.2	3.5
Reduced environmental impact	-	-	-	-	-	-	2.9

SD: standard deviation

Table 8: Comparison of weighting between user groups

Criteria	Weightings for people with experience prescribing intermittent catheters	Weightings for people with lived experience of using intermittent catheters
Comfortable to insert	27.6	23.6
Comfortable to remove	22.1	21.4
Full bladder drainage	15.2	15.3
Risk of infection	10.9	13.0
Options to suit individual needs and lifestyles	8.4	8.3
Easy to remove from packaging and prepare for use	5.8	5.9
Level of catheter flexibility	4.4	5.3
Ease of disposal	3.3	3.6
Reduced environmental impact	2.4	3.5

Appendix C Glossary

Term	Definition
SMART ranking technique	A multi-criteria decision making technique that allows criteria to be ordered by importance. Individual responses from each member of a group are collated and averaged, ensuring equal say among the group (Von Winterfeldt D, Edwards W. (1993) Decision analysis and behavioral research. Cambridge: Cambridge University Press).
Swing weighting technique	A technique used for calculating and reporting the relative importance (weight) of each criterion from a ranked list. Each member of a group provides individual responses deciding how important each criterion is over the criterion below it (on a scale of 0-100%). Individual responses from each member of the sample are collated, averaged and weights are calculated (Von Winterfeldt D, Edwards W. (1993) Decision analysis and behavioral research. Cambridge: Cambridge University Press).
Performance rule	A rule (or rules) describing how users would measure the performance of a technology in relation to each criterion.
Performance matrix	A table reporting the criteria most important to users when choosing a technology and the associated performance rules.

Appendix D Participants in the user preference assessment

People with experience of prescribing catheters for intermittent catheterisation

Ann Yates, Director Continence Service – Nursing, Cardiff and Vale University Health Board

Daphne Colpman, Continence Nurse Specialist, University College London Hospitals NHS Foundation Trust

Laura Rose, Clinical Team Leader Continence Service, NHS Ayrshire and Arran

Mandy Fader, Professor of Continence Technology, University of Southampton

Sam Davison, Clinical Procurement Lead Nurse, South Tees Hospitals

People with lived experience of using intermittent catheters

Faizan Awan

Jacqueline Emkes

Keith Ford

Sarah Markham

Late-stage assessment

Intermittent urethral catheters for chronic incomplete bladder emptying in adults

People's needs, preferences and experiences of using intermittent catheters for bladder drainage: A thematic review of the literature

Summary

Intermittent catheterisation (IC) is considered the preferred option to indwelling urethral or suprapubic catheterisation for managing incomplete bladder emptying. The IC procedure requires the use of intermittent urethral catheters. When deciding on which catheter to use, it is important to consider the person's preference and clinical needs.

Given the large number of intermittent catheters available in the market and the diverse needs of a heterogeneous population, one size does not fit all. It is necessary to understand people's experiences and needs in addition to their preferences of the technology in general. Hence, a thematic review of the literature was carried out to explore this. The knowledge gained from the literature review would contextualise people's preferences and explain why diverse needs exist in real life as well as facilitating their choice in practice.

This thematic review provided a contemporary understanding of people's experiences, needs and preferences of using intermittent catheters for bladder drainage. Drawing on 19 articles, this review revealed 5 themes: 'general experience of IC', 'technology and procedure', 'internal influential factors', 'external influential factors', and 'facilitation or enablement'.

The theme of 'general experience of IC' indicated that people's experience and adherence of IC varied, and that IC could have both positive and negative impacts on their daily lives.

The theme of 'technology and procedure' illustrated that technology and procedure played a crucial role in the integration of IC in their daily lives.

People's preferences of the technology features differed due to personal needs, such as avoiding discomfort, trauma and pain, and improving ease of use. These features included catheter flexibility, diameter, material, size, coating, hygienic properties, packaging, quality, disclosure and discretion of IC use. Some people also took a broader view and considered factors beyond their personal needs, and instead, they were concerned about cost and environmental impact of IC devices as part of their decision making.

The themes of 'internal influential factors' and 'external influential factors' revealed that people's experience and adherence of IC were affected by internal and external factors. The former included 'age and sex', 'physical or cognitive function', 'psychological factors', and 'complications of IC', whereas the latter covered both physical and social environments.

To improve their journey of IC, this review drew attention to the theme of 'facilitation and enablement', which highlighted the need for education and regular follow up, supporting materials and tools, and enabling environment.

Overall, the findings of this review point out the need for the availability of different catheters to meet individual's needs across a range of situations and settings. In addition, the 5 themes (supported by 15 sub-themes) provide theories for the explanation of people's varied experiences and for the facilitation of their diverse preferences in the selection and prescription of intermittent catheters.

Introduction

This late-stage assessment (LSA) focuses on intermittent urethral catheters for chronic incomplete bladder emptying in adults. People with medical conditions, such as bladder dysfunction, neurologic deficits, and urethral obstruction, may experience chronic incomplete bladder emptying. When this happens, intermittent urethral catheterisation (also known as 'intermittent catheterisation' [IC] or 'intermittent self-catheterisation') is needed, and this procedure requires the use of intermittent urethral catheters (also known as 'intermittent catheters').

IC is recommended as the 'gold standard' for bladder drainage (Yates 2023) and should be offered before indwelling urethral or suprapubic catheterisation (National Institute for Health and Care Excellence [NICE] 2015). People who are adherent to IC have better overall quality of life (QOL) in psychological and social relationships domains than nonadherent people (Cirotti 2011). However, these benefits do not provide people with sufficient motivation to establish an IC routine in their daily lives (Norager 2019). Also, it is not always the most feasible option for people and their families. Consequently, some negative impacts associated with IC can occur, and many people shift to different bladder management options with time (McKinley 1999; Wein 2020; Welk 2018). In addition, people's experience of IC was influenced by different types of catheters used (Chartier-Kastler 2011).

Due to the large number of products available, there is a wide range of options for clinicians and people who need to do IC to choose from. When deciding on which catheter to use, it is important to consider the person's preference and clinical needs (Royal College of Nursing [RCN] 2021; European Association of Urology Nurses [EAUN] 2024). To ensure an appropriate catheter can be selected and used to meet an individual's needs, it is essential to understand their views towards IC devices in general. Therefore, this review aims to capture the experiences and needs of people using intermittent catheters for IC, and the technology features they consider when choosing a catheter to use in order to gain a better understanding of the impact of IC on their everyday life. This would address one of the objectives in the [final scope](#): ***to understand user view, experience, need and preference of the technology***.

In this review, 'people' specifically refers to those using IC for their own bladder management (patients) and is used thereafter.

Methods

A thematic review of the literature was conducted, concentrating on the themes that underpin people's experiences of IC within the available literature. A thematic synthesis method was adopted to address the key aims of this review. A thematic analysis was applied to identify, organise, and

summarise the findings from the included studies (both qualitative and quantitative research). This analysis is an appropriate method to analyse and identify theme from a diverse body of qualitative and quantitative (descriptive) evidence through an iterative process (Dixon-Woods 2005).

Search strategy and inclusion criteria

The search strategy is listed in [Appendix A](#). This review included studies that were qualitative, quantitative descriptive, or mixed methods, focusing on people's views of intermittent catheters in general: 1) people's experiences of using intermittent catheters for long-term (more than 28 days) bladder management; 2) their needs and preference of intermittent catheters for catheterisation; or 3) what factors (both internal and external) affected their experiences and adherence of IC. This review also included qualitative evidence synthesis that explored at least one of the above areas. This review only considered English-language articles.

Quality assessment and data synthesis

Data from studies that met the inclusion criteria was extracted. Quality assessment of the included papers was then conducted using the appropriate tools recommended in the NICE's manual (PMG20). CASP qualitative checklist was used for qualitative studies, Mixed Methods Appraisal Tool (MMAT) for mixed methods and quantitative descriptive studies, and Swedish Agency for Health Technology Assessment and Assessment of Social Services checklist for narrative reviews. For consistency, the overall assessment of the methodological quality of each study was described as 'high', 'moderate', or 'low'.

The included papers were systematically reviewed, coded and analysed. The analysis involved the following steps: i) reading and rereading the studies to identify the themes relating to the review question; ii) constant comparison to investigate similarities and difference across studies; iii) organise and refine the themes. This was then followed by triangulation (O'Cathain 2010; Patton 1999) to analyse the data from several research methods, thereby enhancing the quality and credibility of data analysis and synthesis.

Results

Of the 704 results identified through the searches and other sources, 19 articles were selected and analysed as the core literature, including 15 primary studies (5 qualitative studies, 8 quantitative descriptive studies and 2 mixed methods study) and 4 narrative reviews. The flow of studies screening and selection was recorded and displayed on PRISMA diagram ([Appendix B](#)). Qualitative assessment of the 19 included articles was carried out. [Table 1](#) presents study characteristics and methodological quality.

When reported, most studies were conducted in the US and Europe, and 5 studies included the UK population. Reasons for people using IC were because of neurogenic or neurologic reasons (such as SCI, multiple sclerosis), and non-neurogenic reasons (such as urinary incontinence, urinary retention or obstruction, prostate problems and bladder cancer).

According to the purpose of the review, the included studies have been grouped into 5 themes, namely 'general experience of IC', 'technology and procedure', 'internal influential factors', 'external influential factors', and 'facilitation or enablement'. Each theme was supported by several sub-themes. Themes or sub-themes are not completely separate but interrelated.

Table 1 study characteristics and methodological quality

Author(s), Year	Method	Aim	Country	Number of people	Condition or reason for IC	duration of IC	Methodological quality
Balhi 2021	narrative review	To identify barriers (internal and external) related to IC and to propose adequate solutions to avoid them	Not reported	not reported	various conditions (no detailed information)	Not reported	low
Herbert 2023	narrative review	To outline some of the significant internal and external barriers that can be encountered by people who perform IC as their long-term management option	Not reported	people (all ages including children)	neurogenic lower urinary tract dysfunction (NLUTD)	IC for long-term bladder management	moderate
Logan 2024	narrative review	To explore the quality of life and highlight the challenges that men face	Not reported	males	various conditions (no detailed information)	Not reported	low
Seth 2014	narrative review	To identify the barriers that people face when performing IC which may ultimately limit adherence	Not reported	not reported	various conditions (no detailed information)	Not reported	low
Abuzied 2023	qualitative study (semi-structured interviews)	To explore the lived experience of people with IC, including barriers and practice and how this affects their application and experience of IC	Saudi Arabia	n=10 (Arab males); mean 33.5 years	Paraplegic after SCI	mean 3 years of IC practice	high

Author(s), Year	Method	Aim	Country	Number of people	Condition or reason for IC	duration of IC	Methodological quality
Cobussen-Boekhorst 2016a	qualitative study (in-depth interviews)	To gain insight in underlying barriers and facilitators for people dealing with intermittent catheterisation in everyday life	Netherlands	n=11 (6 males and 5 females)	SCI	Not reported	high
Goldstine 2019	qualitative study (telephone interviews)	To identify themes related to barriers and facilitators to the integration of IC in people's daily lives	US, UK, Germany, France and Netherlands	n=25	neurogenic bladder dysfunction	IC for at least 1 year	high
Kelly 2014	qualitative study (in-depth interviews)	To investigate the impact of using specific intermittent self-catheters on people's daily lives and to identify key features of product design which affected ease of use	UK	n=16	SCI	long-term experience of IC	high
Shaw 2013	qualitative study (in-depth interviews)	To explore people's experiences of IC to identify psychological coping factors that might affect therapy adherence	UK	n=15 (11 men and 4 women); median 52 years	SCI	Not reported	high
Bolinger 2013	mixed methods study (questionnaires and telephone interviews)	To examine barriers, complications, adherence, and health-related quality of life in people using IC	US	n=44 (59% women); mean 56 years	Main diagnoses: multiple sclerosis, neurogenic bladder dysfunction, and SCI	IC for 2 or more months	moderate

Author(s), Year	Method	Aim	Country	Number of people	Condition or reason for IC	duration of IC	Methodological quality
McClurg 2019	mixed methods study (cohort study, telephone interviews and survey)	To determine the variables that affect continuation or discontinuation of the use of IC	UK	prospective cohort, n=56; qualitative interviews, n=20; retrospective survey, n=456	Multiple sclerosis	for the survey sample, at least a mean of 22 months	moderate
Cobussen- Boekhorst 2016b	quantitative descriptive study (questionnaires)	To explore what factors determine successful IC	Netherlands	n=129 (72 male); mean age 62 years	Main conditions: neurogenic bladder dysfunction, non- neurogenic post void residual and retention	IC for 3 months or longer (93% doing the handling independently)	moderate
Joshi 2022	quantitative descriptive study (survey)	To understand the perspectives of people with SCI along with epidemiological and demographic factors associated with the use of IC	India	n=45 (39 males and 6 females); median 31 years	SCI	Not reported	low
Marklewicz 2020	quantitative descriptive study (survey)	To explore emotional effects, social connectivity QoL associated with IC	US	n=393	most with SCI	84% doing IC for more than 2 years	moderate

Author(s), Year	Method	Aim	Country	Number of people	Condition or reason for IC	duration of IC	Methodological quality
Markiewicz 2021	quantitative descriptive study (survey)	To assess people's experience with discreet catheters	Netherlands	n=784 (314 males and 426 females)	27% having neurogenic or neurologic conditions and 73% having non-neurogenic conditions	Not reported	moderate
Pinder 2015	quantitative descriptive study (survey)	To identify and investigate individuals' preferences regarding IC devices and to investigate the willingness to pay for attributes in IC devices in the UK, France, and the Netherlands	UK, France and Netherlands	n=283 (most were male; 140 in the UK; 90 in France and 53 in the Netherlands) Mean 51 years	most with SCI	IC for at least 6 months	moderate
Roberson 2021	quantitative descriptive study (questionnaires)	To better understand people's practices with and attitudes towards IC	US	n=200 (70% male)	various conditions (most with SCI or retention)	IC (with assistance) for at least 6 months	high
Yilmax 2014	quantitative descriptive study (questionnaire)	To examine the obstacles in people with traumatic SCI face performing IC, also their worries and level of satisfaction	Turkey	n=269 (199 male, 70 female)	traumatic SCI	70% doing IC independently	moderate
Zacharia 2024	quantitative descriptive study (survey)	To assess the adherence of people to self-IC; to study the reasons and analyse the factors associated with	South India	n=121 (97 males and 24 females); mean 35.8 years	paraplegia after SCI	1 year	Moderate

Author(s), Year	Method	Aim	Country	Number of people	Condition or reason for IC	duration of IC	Methodological quality
		discontinuation of IC; and to assess their perception of IC					
Narrative reviews: 3 reviews were rated as moderate quality and 1 review was low quality. Across the 4 reviews, there was a lack of detailed information, particularly in literature search, study selection and appraisal process. For Balhi (2021), Logan (2024) and Seth (2014), there were also some concerns about synthesis outputs. Mixed methods studies: 2 studies were rated as moderate quality. For Bolinger (2013), some concerns were raised about the rigor of data analysis and findings presented for qualitative component. Also, there were some concerns about the representation of the target population and no information on the response rate. In terms of McClurg (2019), Some concerns were about the rigor of data analysis and findings presented for qualitative component. There was a lack of information about whether the outputs of the integration of qualitative and quantitative components were adequately interpreted. Qualitative studies: 5 studies were rated as high quality. Qualitative descriptive studies: 1 study was rated as high quality, 6 studies were moderate quality, and 1 study was low quality. Across the 7 studies with moderate or low quality, the main concerns were raised due to the measurements used, the risk of nonresponse bias, and/or sampling methods, even though the levels of concerns varied. It is noted that Bolinger (2013), Cobussen-Boekhorst (2016a) and Shaw (2013) were included in Balhi (2021) or Seth (2014). When reported, 6 studies (Kelly, 2014; Logan 2024; Marklewicz 2020, 2021; Pinder 2015; Roberson 2021) were funded or sponsored by manufacturers.							

Theme 1: General experience of IC

The theme of 'general experience of IC' was derived from 15 studies and was supported by 4 sub-themes, namely 'source of information', 'choice', 'adherence' and 'impact of IC on daily life'.

Source of information

In the literature, people were introduced to IC products through different channels (Kelly 2014) and could access catheter-associated information from a range of sources, such as a specialised nurse or doctor, community healthcare service, and the product brochure (Cobussen-Boekhorst 2016b; Marklewicz 2021). Marklewicz (2021) found that, of the 393 people, the majority of males (50%) and females (56%) stated their primary source of information was a specialised nurse or doctor such as a urology clinic nurse or urologist. However, 28% of males and 16% of females stated they used the internet to figure things out for themselves. Approximately 14% of all people reported that they used a community health care service, that is, those community-based healthcare services delivering products or specialised nursing support to a patient's home, as an information resource. Non-specialised doctors or nurses were generally not used as a source of catheter-related information. Cobussen-Boekhorst (2016b) found that all 129 people were positive about the information as positive, feeling that the brochure was clear, as well as the information given by the continence nurse.

Choice

Choosing an appropriate catheter was important to meet personal needs and to address catheter-related issues as well as to improve the adherence of IC (Seth 2014). However, choice was not always available to people at the beginning of their journey to IC, and inability to access the right type of catheter was often considered by people as a reason for discontinuing IC (Bolinger 2013).

Goldstine (2019) telephone interviewed 25 people using IC due to neurogenic bladder dysfunction to explore their process of selecting an IC product. The authors found that about two-thirds of people said they initially relied on a recommendation from their healthcare provider. Nevertheless, many people

reported switching IC products after proactively seeking alternatives to better meet their needs and/or because healthcare providers or other members of the IC community made them aware of alternatives.

Markiewicz (2021) carried out a cross-sectional survey with 784 users of discreet catheters (which are smaller in length, coiled in design, or foldable) in the Netherlands. The authors reported that the majority (83%) had the ability to choose the type of catheter they use. Of those stating they did not have the ability to choose their primary catheter (n=137), the reasons for that were 1) their healthcare professional did not inform them of different catheters (n=36), 2) they did not know different brands existed (n=15), and 3) they did not know they had the option to choose (n=51).

Adherence

Adherence to IC was well documented in the literature, but the rates and levels of adherence varied across the studies. Adherence was generally defined as the extent to which people follow the catheterisation schedule prescribed by their physicians (Bolinger 2013; Zacharia 2024).

Chai (1995, as cited in Balhi 2021) stated that after a mean of 5.9 years, 71% of people with spinal cord injury (SCI) were compliant with IC for bladder emptying. Girotti (2011, as cited in Balhi 2021) found that 58% of people adhered to IC after 1 year of follow up, compared with 47% of people in Cobussen-Boekhorst (2016b) and 23% (n=13) of people with multiple sclerosis in McClurg (2019).

Bolinger (2013) reported that, although most people reported catheterising based on their own schedule (n=18; 46%) or in response to a perception of bladder fullness (n=20; 21%), 77% reported a catheterisation schedule consistent with their physician's order.

Zacharia (2024) discovered that 74% (n=89) of people with SCI were continuing IC as the primary mode of bladder management after discharge. However, only 15% (n=18) of people were fully compliant with the IC technique, 59% (n=71) were partially compliant (irregular with IC and did not

follow infection control practices in the IC technique) and 26% (n=32) discontinued IC.

Marklewicz (2021) highlighted that only 41% (311 of 756) of people followed a clinician suggested regimen for catheterising; 26% (193 of 756) altered their catheterisation schedules to fit their daily activities; 33% (252 of 756) stated that they did not follow a regimen, but rather catheterised when convenient.

Impact of IC on daily life

IC could have both positive and negative impacts on people's daily lives, such as independence and control, confidence, intimacy/privacy, social connectivity and a sense of normalisation (Goldstine 2019; Cobussen-Boekhorst 2016a, 2016b; McClurg 2019; Shaw 2013; Marklewicz 2020). Although IC could be perceived as challenging, for many people the successful navigation of life's challenges was a point of pride (Goldstine 2019). To maintain a sense of 'normalisation' and to gain independence and control while on an IC programme, people applied their own coping strategies (Shaw 2013). However, it was recognised not an easy process and required hard work and striving. Some examples included active acceptance rather than denial and avoidance (Logan 2024; Goldstine 2019), flexibility in IC (such as frequency) and adjusting lifestyle (Cobussen-Boekhorst 2016a; Abuzied 2023; Bolinger 2013), and use other methods when needed (such as a diaper, condom catheter; Joshi 2022). People who went on to continue using IC stated that they 'felt more in control' and were able to go out without worrying about accessing the toilets, despite their initially feeling of 'loss of control' (McClurg 2019). In general, people's experiences of IC varied across studies.

Seth (2014) reported that only half of people claimed to be completely satisfied with IC, 41% were somewhat satisfied, and 9% were not satisfied. Similarly, Bolinger (2013) found that half (50%; n=22) of people indicated that they were completely satisfied using IC while 41% (n=18) were somewhat satisfied and 9% (n=4) were not satisfied. Interestingly, many of those who stated that they were completely satisfied with using IC also reported they had no other options for bladder management. Yilmax (2014) described that 67% of people expressed satisfaction with their catheters. The authors also

discovered that 48% (n=128) of the individuals said IC changed their QOL somewhat better, and only 3% (n=8) stated IC made their QOL much worse.

When activities outside of the privacy of home were primarily examined, such as employment activities and social activities, Marklewicz (2021) reported that overall, those employed full or part time were satisfied or very satisfied with their discreet catheter, with 85% agreeing that it was indeed discreet, and 87% agreeing that it gave them confidence to live their life the way they chose.

Satisfaction and QOL were also measured using different tools. Although satisfaction appeared to be positive in most people, there was variation in health-related QOL. For satisfaction, when visual analogue scale (VAS; 0 dissatisfied, 10 very satisfied) was used, Yilmax (2014) found that the mean score of satisfaction with the catheters was 7.86 and there was a statistically significant difference between the female (7.2) and the male (8.07) patients. Roberson (2021) found that, based on the intermittent self-catheterisation questionnaire (ISC-Q), the calculated satisfaction scores for each domain (weighted out of 100) were 82.0 for ease of use, 60.0 for convenience, 75.4 for discreetness, and 64.3 for psychological well-being. The overall satisfaction score was 70.4.

In terms of health-related QOL, Cobussen-Boekhorst (2016b) assessed QOL using a 10-point VAS of QOL regarding voiding problems and the King's Health questionnaire, a validated questionnaire which covers various aspects of bladder problems in daily life. The authors reported that, for the total group of 129 people, the VAS score improved and in the King's Health questionnaire the impact of the bladder problem in daily life, limitations in daily activities and negative emotions significantly decreased over time. Bolinger (2013) reported that the mean SF-36 physical component score of people was 33.7 and the mean mental component score was 50.8. The authors also stated that while the physical component SF-36 score in this sample was lower, the mental health component score was similar to the population norm for the age group.

Theme 2: technology and procedure

The theme of 'technology and procedure' emerged from 8 studies and was supported by 2 sub-themes of 'technology features' and 'procedure complexity and duration'. This theme illustrated the impact of the technology features and the procedure itself on people's choice, attitude and adherence of IC.

Technology features

When performing IC, the technology itself played a significant role in the adherence and success of IC. To address any technology-related issues, it was essential to choose an appropriate catheter and use catheter appliances to assist IC (Seth 2014). When choice became available, people considered various features of the technology to meet their personal needs, such as avoiding discomfort, trauma and pain, and improving ease of use and discretion. These features included catheter flexibility, diameter, material, size, coating, hygienic properties, packaging, quality, disclosure and discretion of ISC use (Goldstine 2019; Kelly 2014; Pinder 2015). People also took into account their social responsibility in terms of environmental impact and cost of the technology as part of their decision making (Kelly 2014; Pinder 2015).

Goldstine (2019) discovered that, to avoid discomfort, trauma and pain during IC, people often considered catheter design features which exerted a major influence in their comfort and perceived risk of trauma. Catheter flexibility, diameter, material, size, lubrication, and hygienic properties were the characteristics most mentioned by participants.

Similarly, Kelly (2014) identified the common features for consideration being catheter gauge/size (including discomfort and speed of voiding), rigidity (in terms of the trade-off between sufficient rigidity to assist insertion and potential damage to the urethra associated with excessive rigidity), length (e.g. relating to voiding issues), lubrication (mixed views), catheter characteristic and comfort of insertion (mixed views regarding bleeding, pain and discomfort), packaging (e.g. adhesive facilitating hands free preparation, rings pulls to assist opening), disclosure and discretion of ISC use (e.g. concealment, branding issues). Kelly (2014) also found that trust came into play for catheter selection. This trust tended to be related to the design of

products (that the IC designs were effective and non-harmful) and the product quality (i.e. consistency of product, minimal number of faulty intermittent catheters).

Pinder (2015) conducted a survey of 283 people who used IC for at least 6 months and the majority had a catheter that was either a 'small and compact' or 'moderately sized' and that was instantly ready-to-use without additional equipment or waiting time (79% in the UK, 86% in France and 87% in the Netherlands). The authors reported that, in the UK sample, the attributes relating to convenience, catheter coating, risk of infection, ease of insertion, and willingness to pay were significant predictors of choice. The most highly valued attributes included risk of infection and ease of insertion. People were almost twice as likely to prefer a device which was "pre-coated with lubricant". Notwithstanding these clinical benefits, people were over twice as likely to prefer a small and compact device compared with one considered bulky. When considering the total population from the UK, France and the Netherlands, risk of infection was the most highly valued attribute, followed by ease of insertion. "Pre-coated catheters" was found to be valued as the most preferred coating technology.

In terms of social responsibility, Kelly (2014) stated that people were concerned about the financial burden which their IC use put upon the NHS; reported trying to minimise cost through limiting use of pre-lubricated catheters (which they believed to be costly) to outside the home. People were also concerned about the environmental impact of disposable IC products, with one person modifying her choice of IC on the basis of reduced environmental impact (changed to a reusable silver IC). Pinder (2015) further revealed that cost was a significant negative predictor of choice in people in the UK, France and the Netherlands.

Procedure complexity and duration

Procedure complexity and duration could potentially affect people's attitude and adherence of IC. The complexity of IC could determine adherence (Logan 2024), and the 'simplicity' of IC was often assumed rather than factual (van Achterberg 2008, as cited in Balhi 2021). The complexity of IC was unpacked

by Cobussen-Boekhorst (2016a) who interviewed 11 people. The authors found that most people felt that the catheterisation itself was not difficult, but the preparation (washing hands, preparing the catheter, washing the genitals, where to leave the catheter afterwards) before they could actually start the catheterisation.

The duration and frequency of performing IC could potentially predict how difficult people find IC and had a knock-on-effect on the continuation and adherence of catheterisation. Roberson (2021) studied 200 people to understand their practices with, and attitudes towards, IC. The authors revealed that the length of time a person had been using intermittent catheters was a predictor of how difficult people found IC (in both intensity and frequency), with the relationship being the longer people had been performing IC the less difficult they found the practice. Cobussen-Boekhorst (2016b) surveyed 129 people and discovered that decrease in frequency (the number of IC per day) often led to IC cessation.

Theme 3: Internal influential factors

The theme of 'internal influential factors' emerged from 12 studies and was organised through 4 sub-themes, namely 'age and sex', 'physical or cognitive function', 'psychological factors', and 'complications of IC'. These factors could affect adherence but did not necessarily have an impact on whether or not people could perform successful catheterisation.

Age and sex

Age was an important factor, and self-catheterisation might become less convenient with age (Balhi 2021; Herbert 2023); so, it influenced the adherence and success of IC (Cobussen-Boekhorst 2016b). Although age alone was not an independent factor, it was often accompanied with poor self-care ability, lack of motivation, reduced ability to cope with new situations, decreased functional independence, and cognitive disorders such as dementia. Hence, these factors might preclude older people from performing IC (Balhi 2021; Herberts 2023). This finding was further echoed by Cobussen-Boekhorst (2016b), who stated that adherence could be negatively influenced by increasing age. A weak correlation was found between increasing age and

stopping catheterisation. On the contrary, McClurg (2019) carried out a mixed-methods study of people with multiple sclerosis in the UK and pointed out that age did not impact on continuation of IC.

Sex was also an influential factor to adherence and experience of IC, mainly due to the location of the urethra. As a result, the requirement of doing IC for females differs from males. Cobussen-Boekhorst (2016a) interviewed 11 people and discovered that a mirror was an important tool for all women. Men practised often while standing, because sitting on the toilet was of no further advantage for them.

In females with neurogenic lower urinary tract dysfunction (NLUTD), Herbert (2023) documented that, the requirement to perform IC often posed greater challenges than it did for males, secondary to the internal location of the female urethra. Hence, the technique for women to self-catheterise is often more involved and can prevent a woman from catheterising if she used a wheelchair. Instead, many women reported that, to perform IC, they must transfer over to a toilet to have proper urethral access. In even more problematic situations, some woman might not be able to self-catheterise in a sitting position, and instead must transfer to a supine position prior to self-catheterisation. In either situation, bladder management in a public setting is extremely challenging.

In overweight and obese women, IC was often even more problematic due to increased difficulty accessing the urethra, with data suggesting that IC was less likely to be adopted than in normal weight women (Herbert 2023). Noteworthy, gender alone might not be an independent factor to continuation of IC. As shown in McClurg (2019), gender did not affect continuation of IC in people with multiple sclerosis.

Physical or cognitive function

In the literature, IC was often challenging for individuals with physical impairment, and the catheterisation difficulties were linked to manual dexterity, body positioning, muscle spasms, negotiating the penile urethra, and so on (Balhi 2021; Bolinger 2013; Herbert 2023; Logan 2024; McClurg 2019; Yilmax 2014; Zacharia 2024).

Herbert (2023) described that impairment in upper extremity motor function prohibited people from removing pieces of clothing, holding a catheter, or accessing their genitalia. As IC generally requires 2 working upper extremities to remove clothing and provide access to the urethra, many with neurologic disease could struggle with the steps of IC. In people with SCI, over 40% have less than optimal upper extremity motor function for performing IC, with many valuing any modality that could help them regain partial hand and arm function. In those with less than adequate upper extremity motor function, choosing IC often required a reliance on caregivers to assist with bladder management.

Zacharia (2024) assessed the adherence of 121 people with SCI to self-catheterisation via a telephone survey. The authors found that the main difficulty due to physical function while performing IC was difficulty in catheter insertion (19%), followed by back pain (3%), difficulty in body positioning (1%), and muscle spasms (1%). Body positioning and dexterity were also raised in a survey of 44 people performing IC for at least 2 months (Bolinger 2013). The survey findings showed that the common difficulties relating to physical function were positioning to insert the catheter (n=11; 25%) and dexterity (n=9; 21%) reported by people with multiple sclerosis.

Physical impairment or limitations did not only affect adherence but could also lead to cessation of IC (Cobussen-Boekhorst 2016b; Herbert 2023; McClurg 2019; Yilmax 2014). For people with less than adequate upper extremity motor function caused by SCI, the inconvenience and lack of independence associated with having an around-the-clock caregiver for their bladder led to over half of the population with SCI reverting to indwelling catheterisation, with those with impaired upper extremity motor function being most likely to discontinue IC (Herbert 2023). Yilmax (2014) examined the obstacles faced by people with traumatic SCI performing IC. Of the 269 people, 26% (n=72) of people were unable to apply IC and the reasons were insufficient hand function (56%), being unable to sit appropriately (36%) and spasticity (8%). For people with multiple sclerosis, McClurg (2019) found that the symptoms of multiple sclerosis such as poor dexterity did affect continuation of IC.

Continence also played a role in IC acceptance and compliance, although the results of the published studies were mixed with regard to continence and IC (Balhi 2021). Girotti (2011, as cited in Balhi 2021) showed that the number of urinary incontinence episodes between catheterisations did not influence people's compliance, while Yavuzer (2000, as cited in Balhi 2021) pointed out that the primary factor for long-term IC acceptance was continence.

Furthermore, cognitive dysfunction was reported as a barrier to learning IC (Balhi 2021). However, this does not necessarily mean that people with cognitive dysfunction do not have the ability to learn and perform IC. Vahler (2009, cited in Balhi 2021) found that, in people with multiple sclerosis, their ability to learn depended on the number of sessions needed to acquire the skills and not on cognitive abilities.

Psychological factors

Several psychological barriers to IC were documented in the literature, including expectations, fears, shame, feeling of loss, motivation, misconceptions, anxiety, poor confidence, and embarrassment (Balhi 2021; Cobussen-Boekhorst 2016a; Goldstine 2019; Logan 2024; Seth 2014; McClurg 2019; Yilmax 2014).

Goldstine (2019) explored people's experiences of using IC through telephone interview. The authors found that some people expressed a sense of fear, at least initially, around the process of IC. For example, one person stated, "You think to yourself, oh, God, I've got to put that into me bladder, how am I going to do that?" (p.515). Similarly, Cobussen-Boekhorst (2016s) conducted in-depth interviews with 11 people to obtain insights into underlying barriers and facilitators of dealing with IC in everyday life. The authors also revealed that most people experienced IC for the first time as scary, exciting or horrible. Men stated that the length of the catheter frightened them, and also how far it had to be inserted into their body. They had to overcome a hurdle the first time. Yilmax (2014) also found that, when starting IC, people were fear of being dependent on IC (50%), accidentally injuring self (44%), embarrassment (43%), causing an infection (40%), bleeding (33%), fear of feeling pain (30%) and hygiene (25%). More women felt embarrassment, even though other items were similar in both sexes. Fear of 'loss of control' was also raised and

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was considered negatively in McClurg (2019), that when IC was first suggested with some expressing that it was the fear of 'loss of control' that was the worst thought.

Complications of IC

Catheter-related complications were highlighted in the literature as a factor of influencing people's experiences of IC, such as urinary tract infections (UTIs), pain, discomfort, and bleeding (Logan 2024; Balhi 2021; Bolinger 2013; McClurg 2019; Yilmax 2014), and in some cases, the complications could also result in cessation of IC (McClurg 2019; Zacharia 2024).

Bolinger (2013) examined barriers, complications, adherence and health-related QOL in people using IC for chronic urinary retention. The authors found that, of the 44 people, most (n=38; 86%) reported experiencing at least 1 complication. The most common complication was UTIs (77%; n=34), followed by bleeding (23%; n=10). Zacharia (2024) reiterated urethral trauma and bleeding (3%), and recurrent UTI (7%) as 2 of the main difficulties when doing IC in people with SCI. Furthermore, complications of IC and in particular UTIs were also considered one of the reasons for the discontinuation of IC (McClurg 2019; Zacharia 2024).

Risk of infection is a common but crucial factor in people's experiences with IC. Goldstine (2019) telephone interviewed 25 adults who used IC for at least 1 year. The authors found that the issue of infection was raised by all people when asked to talk about their experiences with IC, and references to UTI or the risk of UTI were common. Avoiding UTI and reducing the frequency and severity of UTI were their desire in the future due to past, unpleasant experiences.

Theme 4: External influential factors

The theme of 'external influential factors' emerged from 10 studies, with the sub-themes being 'physical environment' and 'social environment'. People's experience and adherence of IC could be affected by both physical and social factors.

Physical environment

Incorporation of IC into daily life was not considered easy for people. It required exercise, planning and location. Even though the act of IC was described as not difficult, most people preferred to catheterise at home. People who catheterised in settings outside their homes experienced circumstances that made IC more difficult for both preparing and performing the procedure (Cobussen-Boekhorst 2016a). Despite the continued efforts to make public space accessible to all and governed civil rights law, people were continuing to face barriers to bladder management in public spaces and this was particularly challenging for people with NLUTD (Herberts 2023). One of these barriers was the availability of wheelchair-accessible stalls, as smaller bathroom stalls provided limited space for proper positioning and even less room for those who required caregiver assistance for performing IC (Herberts 2023)

Generally speaking, the main barriers people faced in public space included:

- a lack of accessibility to public restrooms
- a lack of, or poor, facilities
- a lack of cleanliness
- a lack of privacy (Balhi 2021; Bolinger 2013; Cobussen-Boekhorst 2016a; Herberts 2023; Joshi 2022; Logan 2024; Seth 2014).

IC often required multiple supplies positioned near the toilet (lubricant, urine drainage receptacle, etc.) and clean shelves or tables on which to unpack and place the necessary equipment; however, these were often not available in public restrooms. Likewise, public travel could be difficult for people to do IC and in particular for those with NLUTD, due to a lack of space in airplane, train, or bus bathroom (Herberts 2023). In addition, a lack of facilities and even poor facilities in some cases (e.g. small toilets, poor lighting) might require individuals to self-catheterise in less-than-ideal scenarios and could further limit their ability to spend time in public (Cobussen-Boekhorst 2016a; Herberts 2023). Furthermore, while a lack of public restroom cleanliness was often off-putting to all individuals, IC could be compromised further in unclean facilities. This is because typical catheterising protocols which involved many

steps were often modified even in the best of situations. All the above could further reinforce one's propensity to avoid public participation or prevent adherence to IC.

Bolinger (2013) surveyed 44 adults with chronic urinary retention who had performed IC for 2 or more months and found that the most frequently reported barrier to self-catheterisation was a lack of access to a bathroom (n=15; 34%). People stated that they managed this barrier by performing IC prior to leaving their home. Public bathrooms tended to have inadequate sinks or inadequate shelves or countertops for placing supplies in preparation for IC. This barrier was reiterated in the survey of 45 people with SCI and 63% of people had difficulties in carrying out IC outdoors, with the most common reason being toilet facilities (Joshi 2022).

Social environment

This review revealed that social environment was an important factor that affected people's adherence and experience of IC. This encompassed the inappropriate use of space, availability of caregiver, and the public awareness and attitude (Herberts 2023; Joshi 2022; Seth 2014)

In addition to the lack of space and facilities to do IC outside the home environment, the suitable spaces could sometimes be occupied by others, which had a knock-on-effect on individual's privacy and independence (Herberts 2023). For people with NLUTD, Herberts (2023) stated that, in situations where people needed to urinate urgently, they might be forced to undress in the main public area of the restroom prior to being transferred into a smaller, non-wheelchair accessible stall, with the assistance of a caregiver. This was because that a wheelchair-accessible stall was occupied by individuals who were not disabled.

The availability of caregiver was found to be another social factor that impacted on the adherence of IC. Herberts (2023) mentioned that the availability of caregiver could be a challenge to IC due to the cost of hiring paid provider services. As a result, family members were often the only option for some people needing to do scheduled IC both at home and in public, but the family members might have already faced with countless other issues. In

these situations, it has been shown that adherence to a catheterising schedule was often not rigorous. Herberts (2023) explained that this was possibly because people who were reliant on their caregivers for catheterisation might be reluctant to increase the number of IC per day out of fear of increasing caregiver burden. These issues were often compounded by caregiver resistance to learning and performing IC, as the burden of care for a non-professional could become overwhelming.

The public awareness and attitude also played a role in people's experience of IC, and particularly impacted on people with NLUTD performing IC outside the home. Herberts (2023) stated that the general public lacked insights and often had negative perceived attitudes of those with NLUTD and their needs for IC. This might adversely affect people doing IC when other appropriate facilities were not present.

Theme 5: Facilitation or enablement

The theme of 'facilitation or enablement' was derived from 9 studies. Internal and external barriers created challenges to adherence, and in some cases, prevented people from doing IC. However, people could still be enabled to perform IC via a range of methods, including education and regular follow up, supporting materials or tools (such as visual aids, leaflets and videos), and enabling environment.

Education and regular follow up

Education was vital for healthcare professionals (nurses), people and their carers or family members in order to enable people to adhere to catheterisation and to successfully catheterise (Herbert 2023; Logan 2024; Seth 2014). In addition, a follow-up plan was essential to ensure that people continue to perform IC in the long term (Logan 2024).

Logan (2024) pointed out that specialist education was important for nurses to gain knowledge and to further develop the necessary skills required in teaching and supporting IC. For people and their caregivers, it was crucial to have face-to-face instructions with adequate time provided by a nurse with experience in teaching IC (Herbert 2023; Seth 2014). The way people were educated to understand IC, as well as the quality of care they received, were

significant milestones in their journey to IC. Abuzied (2023) stated that nurses supported most people in a sort of education where subsequent training might be challenging.

Despite that, clear instructions with sufficient time given was appreciated by people (Bolinger 2013; Cobussen-Boekhorst 2016a). People valued the continence nurse as a helpful, kind and patient person (Cobussen-Boekhorst 2016a). They were also very grateful for the clear instructions given and having the time to practice with different catheters and to ask questions as well as professional follow-up care about their IC practice (Cobussen-Boekhorst 2016a; Bolinger 2013). People's appreciation of training on IC was further reiterated in the study by Abuzied (2023) who interviewed 10 Arab males with at least 6 months on IC in Saudi Arabia. Most people remarked that health education about the IC was one of the positive experiences of IC, and they felt without the education, it was difficult to familiarise themselves with using this device.

When training people on how to do IC, nurses could also let them know why IC was recommended and if IC would be a long-term treatment due to their conditions. Cobussen-Boekhorst (2016a) interviewed 11 people living independently in the community. The authors discovered that the way how people were informed about IC as a treatment for their bladder problems was important to ensure they were motivated to continue IC in the long term. The authors also found that the information about the expected duration of IC had a positive impact on how they experienced IC. The urge to keep independence played a role in the motivation to maintain IC. Notably, most people stated that they hoped IC was temporary; on the other hand, they said that they got used to it. The authors also highlighted the need for guidance, typically when people experienced haematuria, pain or other problems with catheters. In addition to educating and motivating people, a nurse could also encourage caregivers to understand IC and how they could help in certain situations (Seth 2014).

After the teaching session, developing a follow-up plan was highlighted as best practice and essential to prevent lapses in the treatment programme (Logan 2024). However, Bolinger (2013) noted that people were often sent

home after one teaching session in a clinic, physician office, or hospital setting and not given any further follow up to see how they were doing. Thus, this should be addressed to encourage people to adhere to IC in the long term.

Supporting materials and tools

In addition to the verbal and practical IC teaching session, a range of aids were described in the literature (Cobussen-Boekhorst 2016a; Logan 2024; Seth 2014). Some examples included the use of:

- visual aids, leaflets and videos
- smartphone app (to help locate toilet facilities)
- catheter appliances (to help locate the urethra, such as thigh abductors, mirrors, and labia spreaders)
- information about how to aim for regular and complete bladder emptying to avoid retaining urine.

In addition, Logan (2024) described the important role that manufacturers could play in the journey of IC. Manufacturers not only helped with the delivery of good quality education and training but also with the development of competency frameworks and care pathways that could act as guidance to nurses. They could also help provide patient information materials to aid catheter users in accepting and adapting IC.

Enabling environment

Physical and social environments played a major role in people's journey of IC both inside and outside the home, and could affect their experiences and adherence. To enable people to perform IC when needed, an enabling environment was crucial. For the physical environment, it was important to improve accessibility to space with sufficient facilities while offering privacy, so that people could do IC as and when needed. For example, improvement in public restroom facilities and access to locked disability toilets (e.g. National Key Scheme) were documented in the literature (Herberts 2023; Seth 2014).

A supportive social environment was also vital for people to share information with, or to seek information from, others. This was particularly illustrated in the work by Goldstine (2019) who focused on the community among IC users and

the openness that motivated people to share information intended to benefit others. Community also provided a framework for seeking information from others when making choices about IC-related products. In addition, McClurg (2019) called attention to professional support and support at home that were important for continuation of IC. Moreover, Balhi (2021) pointed out the need for support from carers or family members to do IC. If a person did not have the capacity to perform IC correctly, an appropriate carer or family member should be identified and trained to undertake the procedure.

Moreover, Seth (2014) suggested that there was a role for industry in improving community support, that there was a need to optimise communication between primary and secondary/tertiary care and to engage with district nurses for optimising support in the community. Furthermore, a supportive social environment also included the element of shared decision making. Logan (2024) raised the significance of service users involved in decision making regarding the treatment plan, even though this required detailed discussion and assimilating large amounts of information in one session, which could be challenging.

Discussion

This thematic review analysed 19 publications focusing on people's experiences, needs or preferences of using intermittent catheters in general for long-term bladder management. Five themes emerged from the evidence, and each theme was organised through several sub-themes.

Under the theme of 'general experience of IC', people were introduced to IC technology through a range of methods and accessed catheter-related information from a number of sources, mainly specialised nurses or doctors. However, choice of selecting a suitable catheter was not always available when they initially started IC, even though catheter selection should be guided by clinical needs and personal choice recommended by RCN (2021). In terms of adherence to IC, although there was variation in the rates and levels across studies, it appeared that most people fully or partially were compliant with the IC schedule and technique. Unsurprisingly, IC could impact on people's daily lives both positively and negatively. When satisfaction and QOL were

assessed, satisfaction appeared to be positive for most people whereas there was variation in health-related QOL based on the limited evidence using different outcome measures.

This review revealed that technology and procedure played an important role in people's preferences and experiences of IC. When choice was available, people often considered various features of the technology to meet their personal needs while avoiding any technology-related complications or issues. These features included catheter flexibility, diameter, material, length, coating, hygienic properties, packaging, quality, disclosure and discretion of IC use. When considering attributes that predicted choice of the technology, risk of infection was the most highly valued attribute, followed by ease of insertion. Nevertheless, people's preferences of the technology features varied.

In addition to the features of the technology, people's concerns over IC use included social responsibility, in terms of both cost and environmental impact. They felt that these 2 aspects were not adequately addressed in the range of available products. Instead, some people took an active role in modifying their choice of IC or limiting their use of certain catheters, trying to reduce environmental impact or minimise cost. Hence, it is paramount to offer choice and provide different types of catheters to facilitate IC.

Despite the variation in adherence to IC in the literature, this was affected by both internal and external factors. It is worth noting that these factors might not necessarily affect the success of IC. Age was identified as one of the internal influential factors, and it alone was not an independent factor.

Unsurprisingly, physical function played a crucial role in IC which requires people's ability to learn and practice the procedure, especially upper extremity motor function. This review illustrated that the main difficulties to IC were relevant to manual dexterity, body positioning, muscle spasms and negotiating the urethra. This review also revealed cognitive dysfunction as a barrier to learning and doing IC in some cases. Furthermore, this review underscored several psychological barriers to IC, such as fears, misconceptions, anxiety, poor confidence and embarrassment. When sex was considered,

embarrassment was more likely felt by women than men and might also play a role in the choice of catheters.

Without a doubt, catheter-associated complications affected people's experiences of IC, with UTI being a common complication and playing a crucial role. The desire to avoid UTI or to reduce its frequency and severity was highlighted in the literature. In spite of that, complications of IC including UTI were also one of the reasons for stopping IC. Thus, catheter-related complications should be carefully addressed by a review of the technology and technique, and support from a trained healthcare professional (typically a nurse) should be available.

Regarding external factors that affected people's experience and adherence of IC, they were relevant to physical or social environment. The physical environment was mainly associated with public space, such as a lack of accessibility to public restrooms and facilities. The main barriers people faced in the social environment consisted of the inappropriate use of space by others, availability of caregiver, and the general public awareness and attitude towards IC.

Both physical and social environmental barriers could further prevent people from social participation and IC adherence. This would inevitably have a negative knock-on-effect on people's health and daily life. To help address these barriers while enabling people to do IC, this review pointed out the need for education and regular follow up, supporting materials and tools, and enabling environment.

Education for healthcare professionals, people and their caregivers was essential. Adequate training on IC provided by nurses was valued by people and follow ups were required to improve adherence in the long term. The findings reinforce the recommendation made by RCN (2021), "people who perform self-catheterisation and carers should be educated about and trained in this procedure, and all training should be undertaken by a healthcare professional who is competent in providing training".

This review also suggested a range of supporting materials and tools to be available and used (such as visual aids, videos, leaflets, and catheter

appliances) to improve people's adherence and experience of IC. The finding supports EAUN's (2013) statement that best practice involves the use of a wide range of visual and written aids as useful adjuncts to the verbal and practical teaching session. Additionally, this review drew attention to the role that manufacturers play in the IC practice for both catheter users and healthcare professionals. Furthermore, an accessible physical environment with adequate facilities and a supportive social environment (professional support, and support at home and in the community) were crucial to improve people's experiences and adherence of IC. The latter is also in line with EAUN's (2024) statement, "follow-up training and ongoing support of people who perform self-catheterisation and carers should be available to improve quality of life and prevent complications".

Although this review included 19 articles and saturation of the concepts was achieved, we have identified several limitations. First, only 5 studies were carried out in the UK (and other western countries). We do appreciate contextual differences exist in the literature, such as differences in beliefs and cultures, healthcare systems, availability of certain types of technology. Second, we only found 3 studies that focused specifically upon people's needs and preferences of the features of IC devices, even though these 3 studies included the UK population. It is worth noting that we were aiming to capture people's views towards IC devices in general but were not intending to evaluate specific features of the technology based on patient-reported outcomes. Even so, further research to explore people's preference of IC to gain in-depth knowledge would be beneficial. Third, this review captured people's views of IC products in general, but the perspectives from their carers or family members were not explored which deserve further attention.

Despite that, the limitation relating to contextual differences could be counter-balanced in this review. People's views of IC in general could be transferable, particularly relating to using the technology to meet their clinical needs. Additionally, this review included studies that were carried out in different countries and recruited a diverse population, which could in fact reflect the different users of the technology in the UK. Moreover, by selecting studies that concentrated on people's views of the technology in general rather than

specific features of the technology could also reflect users' diverse experiences of various IC products available in the UK. However, we do acknowledge that not all types of the technology included in the literature are available in the UK. The UK's almost exclusive use of single-use catheters is not the case in many other countries where re-usable catheters could be the norm and some favoured re-use for environmental reasons (Buckley 2015). Indeed, this phenomenon was also presented in this review that people were concerned about the environmental impact of disposable IC products, and to reduce such an impact, one person changed to a reusable silver IC.

Conclusion

This thematic review has explored a contemporary understanding of the experiences of using intermittent catheters for IC in a diverse population, and outlined the common features for consideration to meet personal needs as well as to address IC-related complications. This review has also gained rich insights that shed light on the actual barriers and facilitators for people dealing with IC in everyday life.

A better understanding of people's views of IC and the rationale behind their experience and behaviour is necessary, and such knowledge provides a useful context to help improve service provision and advocate the need for choice to be offered and maintained in the system. The findings of this review also point out the need for the availability of different catheters to meet individual's needs across a range of situations and settings. In addition, the 5 themes (supported by 15 sub-themes) provide theories for the explanation of people's varied experiences and for the facilitation of their diverse preferences in the selection and prescription of intermittent catheters.

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Appendices

Appendix A: Literature search strategy

Databases*	Date searched	No retrieved	Version/files
MEDLINE All (OVID)	02/08/2024	170	Ovid MEDLINE(R) ALL 1946 to August 01, 2024
EMBASE (OVID)	02/08/2024	261	Embase 1974 to 2024 August 01
Emcare (OVID)	02/08/2024	75	Ovid Emcare 1995 to 2024 Week 30
HMIC (OVID)	02/08/2024	1	HMIC Health Management Information Consortium 1979 to May 2024
CDSR (Wiley)	02/08/2024	2	Issue 8 of 12, August 2024
CENTRAL (Wiley)	02/08/2024	53	Issue 7 of 12, July 2024
HTA database (INAHTA)	02/08/2024	11	INAHTA
Epistemonikos	02/08/2024	124	epistemonikos

Database strategies:			
Ovid MEDLINE(R) ALL <1946 to August 01, 2024>			
1	patient satisfaction/ or patient preference/	102029	
2	((patient* or user*) adj2 (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)).tw.	368259	
3	or/1-2	430832	
4	Intermittent Urethral Catheterization/	383	
5	(Intermittent adj2 catheter*).tw.	4074	
6	"self catheter*".tw.	1588	
7	"hydrophilic catheter*".tw.	80	
8	or/4-7	4637	
9	3 and 8	438	
10	limit 9 to english language	408	
11	animals/ not humans/	5210707	
12	10 not 11	408	
13	limit 12 to yr="2014 -Current"	170	
Embase <1974 to 2024 August 01>			
1	patient satisfaction/ or patient preference/	206331	
2	((patient* or user*) adj2 (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)).tw.	593811	
3	or/1-2	706865	
4	intermittent catheterization/	5055	
5	(Intermittent adj2 catheter*).tw.	6303	
6	"self catheter*".tw.	2560	
7	"hydrophilic catheter*".tw.	126	
8	or/4-7	8900	
9	3 and 8	949	
10	limit 9 to english language	901	

11 nonhuman/ not (human/ and nonhuman/) 5504357
 12 10 not 11 898
 13 limit 12 to yr="2014 -Current" 490
 14 13 not (letter or editorial).pt. 481
 15 (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. 5993470
 16 14 not 15 261

Ovid Emcare <1995 to 2024 Week 30>

1 patient satisfaction/ or patient preference/ 51120
 2 ((patient* or user*) adj2 (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)).tw. 172534
 3 or/1-2 199307
 4 intermittent catheterization/ 757
 5 (Intermittent adj2 catheter*).tw. 1129
 6 "self catheter*".tw. 394
 7 "hydrophilic catheter*".tw. 35
 8 or/4-7 1493
 9 3 and 8 150
 10 limit 9 to english language 148
 11 nonhuman/ not (human/ and nonhuman/) 371148
 12 10 not 11 148
 13 limit 12 to yr="2014 -Current" 77
 14 13 not (letter or editorial).pt. 77
 15 (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. 180135
 16 14 not 15 75

HMIC Health Management Information Consortium <1979 to May 2024>

1 patient satisfaction/ or patient preference/ 2926
 2 ((patient* or user*) adj2 (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)).tw. 10932
 3 or/1-2 12361
 4 intermittent catheterization/ 0
 5 (Intermittent adj2 catheter*).tw. 15
 6 "self catheter*".tw. 8
 7 "hydrophilic catheter*".tw. 0
 8 or/4-7 16
 9 3 and 8 1

CDSR & CENTRAL

#1 [mh ^"patient satisfaction"] or [mh ^"patient preference"] 15611
 #2 ((patient* or user*) NEAR/2 (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)):ti,ab 78608
 #3 {or #1-#2} 87930
 #4 [mh ^"Intermittent Urethral Catheterization"] 30
 #5 (Intermittent NEAR/2 catheter*):ti,ab 620
 #6 (self NEXT catheter*):ti,ab 197
 #7 (hydrophilic NEXT catheter*):ti,ab 18
 #8 {or #4-#7} 671
 #9 #3 and #8 103
 #10 #9 in Cochrane Reviews 2
 #11 "conference":pt or (clinicaltrials or trialsearch):so 770307
 #12 #9 not #11 55

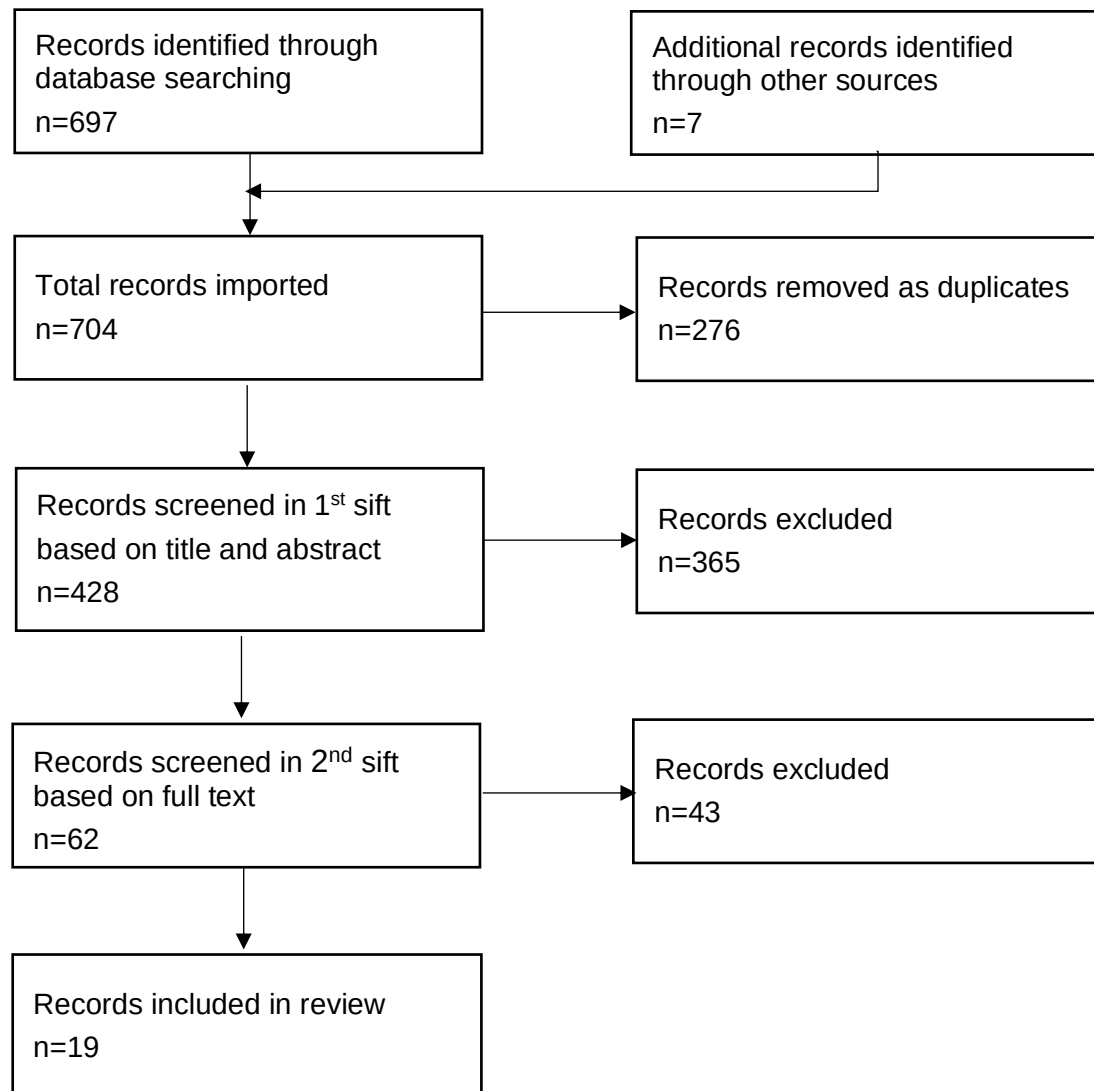
#13 #12 in Trials 53

INAHTA

10	#9 AND #4	11	
9	#8 OR #7 OR #6 OR #5	16	
8	hydrophilic catheter*	2	
7	self catheter*	10	
6	Intermittent and catheter*	8	
5	"Intermittent Urethral Catheterization"[mh]	2	
4	#3 OR #2 OR #1	4488	
3	(patient* or user*) and (need* or preference* or experience* or satisfaction or benefit* or views or decision* or feedback)	4464	
2	"Patient Preference"[mh]	21	
1	"Patient Satisfaction"[mh]	73	

:(title:(((intermittent OR self OR hydrophilic) AND catheter*) OR self-catheter*) OR abstract:(((intermittent OR self OR hydrophilic) AND catheter*) OR self-catheter*)) OR abstract:(title:(((intermittent OR self OR hydrophilic) AND catheter*) OR self-catheter*) OR abstract:(((intermittent OR self OR hydrophilic) AND catheter*) OR self-catheter*)) AND (title:(patient AND (need* OR preference* OR experience* OR satisfaction OR benefit* OR views OR decision* OR feedback)) OR abstract:(patient AND (need* OR preference* OR experience* OR satisfaction OR benefit* OR views OR decision* OR feedback))) – limited to 2014-2024

Appendix B: PRISMA diagram



Appendix C: Abbreviations

EAUN	European Association of Urology Nurses
IC	Intermittent catheterisation
ISC-Q	Intermittent self-catheterization questionnaire
LSA	Late-stage assessment
NICE	National Institute for Health and Care Excellence
NLUTD	Neurogenic lower urinary tract dysfunction
QOL	Quality of life
RCN	Royal College of Nursing
SCI	Spinal cord injury
UTI	Urinary tract infection
VAS	Visual analogue scale

Late-stage assessment

Intermittent urethral catheters for chronic incomplete bladder emptying in adults

People's needs, preferences and experiences of using intermittent urethral catheters for bladder drainage: a cross-sectional survey

Summary

This late-stage assessment (LSA) focuses on intermittent urethral catheters for chronic incomplete bladder emptying in adults. When intermittent catheterisation (IC) is recommended as the treatment option, a decision on which type of intermittent urethral catheter should be made based on clinical needs and person's preference. It is important to understand people's needs, preferences and experiences of using intermittent urethral catheters, so a cross-sectional survey was carried out to explore this.

Sixty-nine people completed the questionnaire and were included in the analysis. Only one-third of people were given a choice to select a suitable catheter to use when they initially started doing IC. People experienced various challenges, with the top 3 significant challenges being 'lack of appropriate space, facilities or accessibility for doing catheterisation', 'embarrassing or public stigma' and 'experience infections'. People's preference of catheters varied, with the top 5 very important factors they considered being 'easy to insert', 'hygiene', 'easy to hold or handle', 'pain or discomfort', and 'ready to use or easy activation'. People often looked for help from 'specialised nurse/doctor' or 'they figured it out themselves' if they had any questions or concerns about IC.

In terms of overall experiences of using IC, there was a strong sense of positivity towards using intermittent catheters and the impact of IC on daily life. However, the feeling of negativity was also expressed and could be impactful in some cases. People also pointed out the importance of support from others and the need for regular review of IC by healthcare professionals during their IC journey.

Several important conclusions could be drawn based on the key findings. Also, the valuable insights into people's preference of catheters pave the way for catheter improvement while encompassing the sustainability aspect in its design.

Introduction

The focus of this late-stage assessment (LSA) is intermittent urethral catheters for chronic incomplete bladder emptying in adults. People with various medical conditions may experience chronic incomplete bladder emptying; so the population are heterogeneous. When incomplete bladder emptying happens, intermittent urethral catheterisation (also known as 'intermittent catheterisation' [IC] or 'intermittent self-catheterisation' [ISC]) is needed, and this procedure requires the use of intermittent urethral catheters (also known as 'intermittent catheters').

IC is considered the preferred option to indwelling urethral or suprapubic catheterisation for managing incomplete bladder emptying (National Institute for Health and Care Excellence [NICE] 2015). When deciding on which type of intermittent catheter to use, it is important to consider the person's clinical needs and preference.

Given the large number of intermittent catheters available in the market and the diverse needs of a heterogeneous population, one size does not fit all. It is necessary to understand people's experiences and needs in addition to their preferences of the technology. Hence, a cross-sectional survey was conducted to investigate this.

Methods

This is a cross-sectional survey to investigate people's needs, preferences and experiences of using intermittent urethral catheters in the UK. A questionnaire was developed and used to collect data about demographics, conditions, training, length of using intermittent catheters, daily frequency of doing IC, challenges and preference of using intermittent catheters. Open-ended questions relating to people's experiences of IC were also created and

included in the questionnaire. Such questions allowed people to explain their experiences in detail.

This questionnaire was tested with a person with experience of using intermittent catheters for their own bladder management and Bladder Health UK. This was to ensure that the questions were appropriate for, and easy to understand by, the target population. An electronic version of the questionnaires was developed using SNAP. This was designed to be easy to use as much as possible.

Recruitment was done through the People and Communities Involvement and Engagement team. This was in line with NICE's Interim methods and process statement for late-state assessment. The survey ran for 3 weeks from 21 October to 10 November 2024. During this period, 2 reminders were sent out to increase the number of responses. The survey was shared with 23 patient and carer organisations (Action Bladder Cancer UK, Bladder and Bowel, Bladder Health UK, Bowel Cancer UK, Brain and Spine UK, Crohns and Colitis UK, Fight Bladder Cancer, Guts UK, IBD UK, Kidney Care UK, Kidney Research UK, MS Society, MS Trust, National Kidney Federation, Spinal Injuries Association, Urology Products User Group Coalition, Urostomy Association, Wellbeing of Women, British Menopause Society, Prostate Cancer UK, Diabetes UK, Stroke Association, and Colostomy UK).

Data analysis

Descriptive statistics was carried out to analyse the data using frequencies and proportions. Qualitative data in response to the open-ended questions was analysed using thematic analysis, with the following key stages: generating initial codes with constant comparison, identifying themes, and reviewing and defining themes.

Results

People characteristics

A total of 73 people responded to the survey. Of these 73 people, 2 people were ineligible and 2 people did not consent for the anonymous data to be used outside the NICE. Therefore, 69 responses were included and analysed,

including 67 people who used IC for managing their own incomplete bladder emptying and 2 family members or carers who completed the survey on behalf of the persons they looked after.

Table 1 presents the survey respondent demographics. Of the 69 people, there were 53 people who identified as female and 16 people who identified as male. Age ranged from 18 to 69 years, and the majority (63%) were between 50 and 69 years of age. The main reasons for using IC were due to brain and/or spinal cord disease (62%), followed by bladder dysfunction (20%). Three-quarters of people had been using IC for more than 3 years. Of the 69 people, 91% of people doing IC themselves, 7% needing support from others when catheterising and only 1 person whose carer or family member did IC for them. When catheterising, most people were sitting (53%) or standing (44%).

Table 1 respondent demographics

	Number	Percentage
Age range (years)		
18-24	1	2%
25-39	11	17%
40-49	12	19%
50-59	22	35%
60-69	17	27%
Gender		
Female	53	77%
Male	16	23%
Reasons for using IC		
Brain and/or spinal cord disease (e.g. multiple sclerosis, myelitis, tumour, cyst)	43	62%
Bladder dysfunction, e.g. overactive bladder	14	20%
Spinal cord injury, paraplegia or tetraplegia	4	6%
Post-surgical condition, e.g. neobladder, orthotopic bladder substitutes	3	4%
Neural tube defects, e.g. Spinal Bifida	2	3%
Bladder outlet obstruction, e.g. prostate hyperplasia/enlargement	1	1%
I don't know	2	3%

	Number	Percentage
Duration of using intermittent catheters		
More than 3 years	52	75%
1 to 3 years	8	12%
3 months to 1 year	4	6%
Less than 3 months	4	6%
I am not sure	1	1%
Body position during catheterisation		
Standing	27	44%
Sitting	33	53%
Lying down	2	3%

Training and choice

When started using IC, 93% of people received training from a nurse. Of those who had training, most were very satisfied (54%) or satisfied (27%) with the training they received. For those who did not receive training before they started IC, they were mainly given a video to watch, just “shown [doing IC] once and got no instruction...”, or could not remember, “...can’t remember how I learnt 43 years ago”.

In respect of catheter choice, only 32% of people had choice to select a suitable catheter to use when they first started doing IC. Nineteen people explained their choice, which was largely due to personal clinical needs and preferences, such as ‘ease of using’, different sizes and lengths, discreetness/less noticeable, and ‘best handling, most least discomfort’.

Despite that choice was available only for one-third of people, they had opportunities to switch catheters to meet their needs. Of the 69 people, 58% used 2 to 5 different types, 6% used more than 5 different types and 36% did not change the type of catheters they used (Table 2).

Table 2 training and choice

	Number	Percentage
Training received		
Yes	64	93%

	Number	Percentage
No	5	7%
Training satisfaction		
Very satisfied	34	54%
Satisfied	17	27%
Dissatisfied	6	10%
Very dissatisfied	6	10%
Choice to select a suitable catheter		
Yes	22	32%
No	38	55%
I am not sure	9	13%
Types of intermittent catheters used		
1	25	36%
2 to 5	40	58%
More than 5	4	6%

Catheterisation frequency

When the prescribed and actual numbers of IC each day were reported, the actual catheterisation frequency generally matched the prescribed schedule in most people (77%; table 3).

Table 3 Catheterisation frequency per day

	Prescribed	Actual
2 or less	11 (18%)	15 (24%)
3 to 4	21 (34%)	22 (35%)
5 to 6	9 (15%)	11 (18%)
More than 6	13 (21%)	13 (21%)
I do not know	8 (13%)	1 (2%)

Challenges and preferences

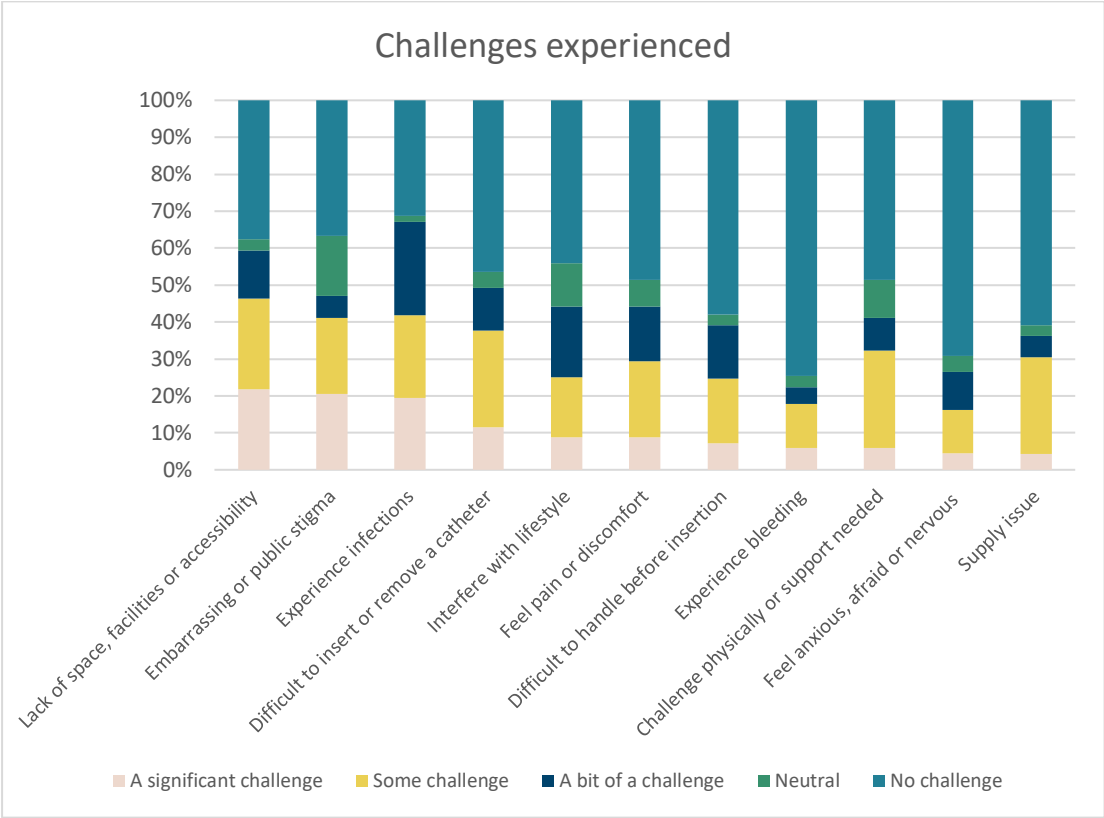
Challenges

Based on people's experience of doing IC, they identified and ranked the challenges they faced from 'no challenge' to 'significant challenge' (figure 1).

The top 3 significant challenges they encountered were 'lack of appropriate

space, facilities or accessibility for doing catheterisation' (22%), 'embarrassing or public stigma' (21%) and 'experience infections' (19%). When combining 'significant challenge' with 'some challenge', the top 3 challenges remained the same and followed the same order.

Figure 1 challenges people faced



Twenty-six people provided explanation of the challenges they faced. Some people reiterated the difficulties caused by the lack of space, facilities or accessibility when doing IC and disposing the used devices outside the home environment. This challenged further in people who used a wheelchair or was paraplegia due to a different positioning needed when performing IC, such as “due to my paraplegia positioning has been a very big issue for me when anywhere but home.”

A few people restated the challenge relating to ‘embarrassing or public stigma’ as they were concerned about public understanding of IC and worried about embarrassment. In addition, two people mentioned about the potential pressures when doing IC outside the home and chose to do IC at home only. A few people described that they preferred ‘ready to use’ or short catheters

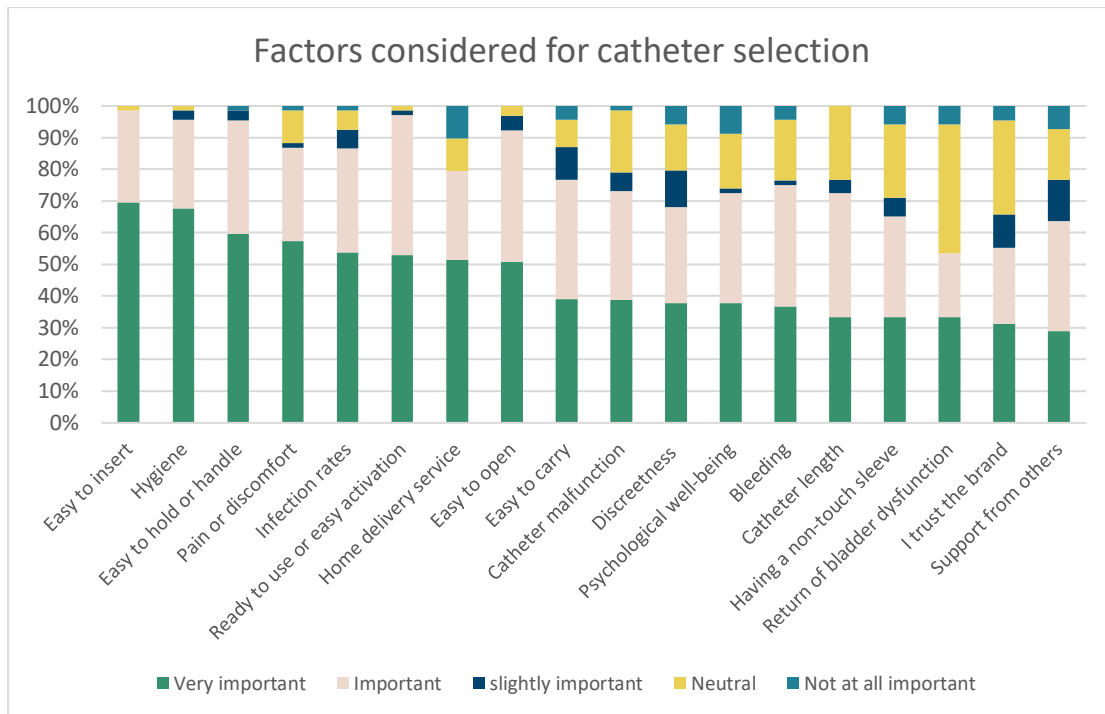
due to issues with hands, and would like to have 'a wet bag, filled with all essentials'. Two people were concerned about storage capacity when travelling aboard or not having enough catheters prescribed when going for holidays. A few people also pointed out the need for more training and for emergency access if no catheters available. Lastly, two people stated the usefulness of training and support from others and acknowledged the learning curve.

Due to the difficulties people faced and their personal needs, nearly two-thirds of people used 2 or more types of catheters (Table 2). The reasons for changing to different catheters were stated by 42 people. The main reasons consisted of 4 categories, including personal preference (e.g. easy to use and insert, discreetness), clinical needs (e.g. reduce infection, dexterity issues, pain and bleeding, urethral damage), trial and error to find a suitable one, and supply issues or low quality.

Preferences

People ranked the factors that they would consider when choosing one type over another, based on the level of importance to themselves from 'not at all important' to 'very important' (figure 2). The top 5 very important factors were 'easy to insert' (70%), 'hygiene' (68%), 'easy to hold or handle' (60%), 'pain or discomfort' (57%), and 'ready to use or easy activation' (53%). When emerging 'important' and 'very important' together, the top 5 factors that were considered 'important' or 'very important' were 'easy to insert' (99%), 'ready to use or easy activation' (97%), 'easy to hold or handle' (96%), 'hygiene' (96%), and 'easy to open' (92%). As indicated, 'easy to open' replaced 'pain or discomfort' and 'ready to use or easy activation' moved up to the second place, whilst 'easy to insert' remained at the top of the order. Figure 2 shows how important each factor people thought when selecting catheters to use.

Figure 2 preferences for catheter selection



Twenty-four people also provided further details about their preferences. Some people repeated the importance of some factors that were described previously, such as ease of use, easy of insertion, risk of infection, and discreetness. Additionally, some people highlighted the significance of choice and felt that catheter selection “should be the user’s choice” as choice was not available or they were not aware of it. A few people also pointed out the need for easy ordering, professional support and the availability of different catheters for a range of settings. More importantly, when choosing a catheter to use, two people considered factors beyond personal needs but instead took into account their social responsibilities and preferred catheters that could be recyclable.

Seeking help or support

If people had questions or concerns about the intermittent catheters or the IC procedure, they often sought help from ‘specialised nurse/doctor’ (63%) or ‘they figured it out themselves (searching the internet, instruction that come with catheter, etc.)’ (50%). Some people went for help from ‘general (non-specialised) nurse/doctor’ (9%), ‘other users’ (9%), or ‘charity’ (4%). A small proportion of people did not have any questions or concerns (13%). When people looked for support, 24% of people used 2 or more sources.

Satisfaction

Based on the intermittent catheters people used the most, the majority of people were satisfied (38%) or very satisfied (41%), and the minority were dissatisfied (1%) or very dissatisfied (4%). Sixteen percent of people gave a neutral view on this.

Overall experience

Fifty-eight people shared their overall experience of using intermittent catheters in managing their incomplete bladder emptying and how IC affected their daily life, socially and emotionally. The themes emerged from the data were 'positive impact', 'negative impact', 'acceptance and adaptation', and 'support and regular review'.

Positive impact

There was a strong sense of positivity towards using intermittent catheters and the impact of IC on people's experiences. Although it might be 'anxious' or 'tricky' to begin with, it would get easier 'with the right catheter and practice'. A learning curve to IC was recognised, "it's hard at first but you get better at it ..."

After the initial learning stage, most people described a positive experience, including improvement in symptoms (e.g. emptying, leakage), reduce the risk of UTIs, maintaining active life, and 'boost confidence' as people had control of their bladder. This certainly led to 'improved QOL [quality of life]'.

"It has been life changing for me. Emptying my bladder completely means I can go out and about and not fear desperately needing the toilet with urgency or leaking."

"It has improved it significantly. I used to get UTI's regularly, which would cause relapses. It has reduced these significantly."

"It has changed my life for the better. It gives me confidence to do what I need to do and live a near normal lifestyle. Socially and confidently...it enhances it [my daily life] totally."

Negative impact

Inevitably, some people expressed a sense of negativity. They felt that “it is very challenging” and had negative experience of using intermittent catheters, such as “pain, interferes with daily routine, infection, bleeding.” The negative feelings could be impactful, “it’s horrible...”. The challenge could be escalated further when people were feeling unwell, as shared by a person: “It’s inconvenient and very hard to do when you don’t feel well.”

Some people also stressed the challenges they faced when out and about, such as “difficult finding somewhere clean when out” and “not being able to find suitable places to go”. Consequently, IC limited activities and restricted social participation, as shared by a person as an illustration: “Certain activities I can’t take part in. Restricted to places I can do it. Have to have toilet access”.

Some people explained the emotional impact of IC on themselves, consisting of anxiety, embarrassment and loneliness. One person expressed the feeling of being anxious, “it makes me anxious to go anywhere that I don’t know”. Another person worried that the constant use of catheters would damage the urethra. A few people felt embarrassed and were concerned about judgement and stigma from others.

“Even after self-catheterising for over 20 years, I don’t like doing it in some people’s homes, I suppose I feel embarrassed.”

“Judgement and stigma from many people are difficult to live with...”

Two people expressed a sense of loneliness, such as “it’s a lonely journey...”

Acceptance and adaptation

People’s attitude towards IC affected how they coped with it and a sense of acceptance was required as part of their coping strategy. A few people expressed their acceptance of IC, even though they felt that there were no other choices.

“It’s just something I have to do....”

“I have no choice and have to do ISC number of times daily ...”

Acceptance often required adaptation which could not happen without efforts and better planning, “I have to fit it into everything I do, planning where I can use the catheter to go about daily life.”

Consequently, ‘acceptation and adaptation’ could lead to a new form of normality over time. As evident, some people transformed to a new ‘normality’ status and perceived IC as part of their normal life despite their initial views of IC.

“Been doing it so long now it has become a way of life.”

“It doesn’t affect me anymore as it is just part of who I am.”

This could be one of the reasons why some people reported that they had ‘no issues’ with using intermittent catheter or felt ‘no difference’ to their daily life.

Support and regular review

People’s journey of IC was sometimes a challenge and could be ‘lonely’, and as such, support from others was crucial. People valued the ongoing support from their healthcare professionals at both an emotional and practical level.

“... Emotionally it has been a journey that I had to start, I was very lucky that my nurse was so kind and talked through the doing before we even did a practice together ... I have formed a bond with after our appointments and chats about how I was coping with ISC.”

“I was very fortunate with the urology department with how understanding and helpful ... Stipulated how many catheters I would require each month writing to my doctor twice as they would only issue 30 to start with and that’s now been changed to 90 a month”.

When support was unavailable, such as “general lack of support from GP & Urology for long-term patients ...” the need for it was required.

Support from a family member was also important, “As my dexterity deteriorates it is proving more difficult to self-care so depending more on my partner.”

Regular review of catheterisation was considered good practice. However, this might not always occur in practice. For example, one person shared her experience and how it affected her IC practice:

“As I have not had a review for over 4 years, I am not sure how many times I should be using them. But when feeling really uncomfortable and at times in pain.”

Discussion

This cross-sectional survey assessed the experience, needs and preferences of using intermittent urethral catheters from 69 people. Of these people, 75% had been using intermittent catheters for more than 3 years and 91% were doing IC themselves. Most people had training before doing IC and were generally satisfied with the training session.

When they initially started using catheters, only one-third of people were provided with the option to choose, although they had chances to change to other types of catheters later on. For the majority of people, the number of IC performed daily generally matched the prescribed schedule.

When doing IC, people inevitably encountered various challenges. The top 3 significant challenges were ‘lack of appropriate space, facilities or accessibility for doing catheterisation’, ‘embarrassing or public stigma’ and ‘experience infections’. This finding is consistent with the published literature. The finding relating to ‘embarrassing or public stigma’ echoes the work by Yilmax (2014) and Seth (2014). Yilmax (2014) found that, when starting IC, people feared embarrassment (43%). Seth (2014) stated that a stigma exists in society towards urinary problems in general, which could lead to reluctance to catheterise. Some people reported a feeling of shame when having to perform IC. The importance given to secrecy and discretion results in some people avoiding IC in public toilets or at other people’s homes. This claim could explain why two-thirds of people considered ‘discreetness’ important or very

important in this survey. The finding of 'experience infection' also mirrors the published evidence that the risk of infection (UTI and recurrent UTI) is a common but crucial factor in people's experiences with IC (Goldstine 2019, Zacharia 2024) and it was considered one of the reasons for discontinuing IC (McClurg 2019; Zacharia 2024).

In terms of people's preference of catheters, the top 5 very important factors they considered were 'easy to insert', 'hygiene', 'easy to hold or handle', 'pain or discomfort', and 'ready to use or easy activation'. Catheter preference sometimes went beyond personal needs, and social responsibility came into play. This gave rise to sustainability and so recyclability was identified as an important preference for some people. Kelly (2014) found that people were concerned about the environmental impact of disposable IC products, and in this survey, people preferred catheters that were recyclable, as described in the 'preference' section of the report. The increasing interest in sustainability could lead to the further improvement in catheter designs to meet societal needs and personal preference to reduce waste.

If people had questions or concerns about the intermittent catheters or the IC procedure, they often sought help from 'specialised nurse/doctor' or 'they figured it out themselves'. Nearly a quarter of people used 2 or more sources. The implication of this could be that people wanted to double check for reassurance or that one source of support or information was not sufficient in answering their questions or to resolve their problems.

Despite the challenges people encountered, the majority were satisfied (38%) or very satisfied (41%) with the catheters they commonly used.

In respect of people's overall experiences of doing IC and its impact on their daily lives, there were 4 emergent themes: 'positive impact', 'negative impact', 'acceptance and adaptation', and 'support and regular review'. There was a strong sense of positivity towards using intermittent catheters and the impact of IC on daily life.

However, the feeling of negativity was also expressed and could be impactful in some cases. Some people felt that performing IC was challenging and was a negative experience, particularly when doing it outside the home

environment. Challenges to IC due to a lack of appropriate space, facilities or accessibility in public spaces were well documented in the literature (Balhi 2021; Bolinger 2013; Cobussen-Boekhorst 2016; Herberts 2023; Joshi 2022; Logan 2024; Seth 2014), even though the continued efforts were given to make public space accessible to all. The finding of this survey echoes the current literature.

Some people illustrated their acceptance of IC, even though it required efforts and adaptation. People also raised the importance of support from others and the need for regular review of IC by healthcare professionals in terms of their IC journey and continuation. The significance of support echoes McClurg (2019) claim that professional support and support at home were crucial to continuation of IC.

We recognised several limitations of this online survey. First, this study was a cross-sectional survey which is susceptible to biases, such as self-selection bias and recall bias. Second, an online survey was used for data collection, which might have restricted access to the questionnaire for some people. Third, the number of respondents was small and did not reflect the wider population. Hence, further research with a larger sample would be beneficial. Despite these limitations, the open-ended questions included in the survey allowed people to provide context-risk information and enabled them to detail their views so that rich insights into their experience of using IC were gained.

Conclusion

This survey study investigated people's needs and preferences of using IC and gained insights into their experiences. Several important conclusions could be drawn. Choice was not offered to the majority of people; so, there is a need for choice to be made available for all. The significant challenge people faced was performing IC outside the home environment. This suggests the necessity to improve facilities and accessibility in the public space and to increase awareness and understanding of IC in the general public. Although people's preference of catheters varied, 'easy to insert' was perceived as the most important factor. Based on people's overall experience, there appears to be a need for support and regular review of catheterisation frequency. Lastly,

this survey provides valuable insights into people's preferences around catheter selection which pave the way for catheter improvement while encompassing the sustainability aspect in its design.

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Appendices

Appendix A: Challenges

	No challenge	Neutral	A bit of a challenge	Some challenge	A significant challenge
Lack of space, facilities or accessibility	38%	3%	13%	25%	22%
Embarrassing or public stigma	37%	16%	6%	21%	21%
Experience infections	31%	1%	25%	22%	19%
Difficult to insert or remove a catheter	46%	4%	12%	26%	12%
Interfere with lifestyle	44%	12%	19%	16%	9%
Feel pain or discomfort	49%	7%	15%	21%	9%
Difficult to handle before insertion	58%	3%	14%	17%	7%
Experience bleeding	75%	3%	4%	12%	6%
Challenge physically or support needed	49%	10%	9%	26%	6%
Feel anxious, afraid or nervous	69%	4%	10%	12%	4%
Supply issue	61%	3%	6%	26%	4%

Appendix B: Preferences

	Not at all important	Neutral	slightly important	Important	Very important
Easy to insert	0%	1%	0%	29%	70%
Hygiene	0%	1%	3%	28%	68%
Easy to hold or handle	1%	0%	3%	36%	60%
Pain or discomfort	1%	10%	1%	29%	57%
Infection rates	1%	6%	6%	33%	54%
Ready to use or easy activation	0%	1%	1%	44%	53%
Home delivery service	10%	10%	0%	28%	51%
Easy to open	0%	3%	5%	42%	51%
Easy to carry	4%	9%	10%	38%	39%
Catheter malfunction	1%	19%	6%	34%	39%
Discreetness	6%	14%	12%	30%	38%
Psychological well-being	9%	17%	1%	35%	38%
Bleeding	4%	19%	1%	38%	37%
Catheter length	0%	23%	4%	39%	33%
Having a non-touch sleeve	6%	23%	6%	32%	33%
Return of bladder dysfunction	6%	41%	0%	20%	33%
I trust the brand	4%	30%	10%	24%	31%
Support from others	7%	16%	13%	35%	29%

Appendix C: Exploratory statistical analysis

Mann Whitney U test was performed to explore if there were statistically significant differences in challenges, preference and satisfaction by gender, as the data was not normally distributed. A p-value of less than 0.05 was considered statistically significant.

Challenges and preferences

People ranked the challenged they faced from 'no challenges' to 'significant challenge'. When comparing people who identified as female with people who identified as male, there was a statistically significant difference in 'difficult to insert or remove a catheter from the urethra' ($z=-2.20$, $p=0.028$) but not in other challenges.

People also ranked the factors that they would consider when choosing one type of catheter over another, based on the level of importance to themselves from 'not at all important' to 'very important'. The analysis showed that there were statistically significant differences in 'easy to open' ($z=-3.73$, $p=0.0002$), 'easy to hold or handle' ($z=-2.91$, $p=0.003$), 'ready to use or easy activation' ($z=-3.70$; $p=0.0002$), 'catheter length' ($z=-2.60$; $p=0.009$), 'psychological well-being' ($z=-2.31$, $p=0.020$) when comparing people who identified as female with people who identified as male.

Satisfaction

Based on the reported level of satisfaction or dissatisfaction, a comparison analysis was made by gender. The analysis showed that there was a statistically significant difference in their level of satisfaction (Mann Whitney U test, $z=-1.98$, $p=0.048$), with people who identified as female being less satisfied with the catheters they commonly used than those who identified as male.

Limitations

The sample size was small, in particular subgroups. Also, this statistical method was not written a priori. Hence, this analysis was carried out using an exploratory approach but not for hypothesis testing.

Appendix D: Survey – main questions

1. What is the main reason why you use intermittent catheters to empty your bladder?
 - Brain and/or spinal cord disease (e.g. multiple sclerosis, myelitis, tumour, cyst)
 - Neural tube defects, e.g. Spinal Bifida
 - Spinal cord injury, paraplegia or tetraplegia
 - Bladder dysfunction, e.g. overactive bladder
 - Bladder outlet obstruction, e.g. prostate hyperplasia/enlargement
 - Post-surgical condition, e.g. neobladder, orthotopic bladder substitutes
 - Other, please specify:
 - I do not know
2. How long have you been using intermittent catheters?
 - Less than 3 months
 - 3 months to 1 year
 - 1 to 3 years
 - More than 3 years
 - I am not sure
3. Did you receive training from a nurse before you started using intermittent catheters to empty your bladder?
 - Yes
 - No, please explain why
 - I am not sure
4. How satisfied or dissatisfied were you with the training you received? [5-point Likert scale, from 'very dissatisfied' to 'very satisfied' and 'not applicable']
5. Did you have choice to select a suitable catheter to use when you first started doing intermittent catheterisation?
 - Yes, please explain your choice:
 - No
 - I'm not sure
6. When catheterising, do you do it yourself?
 - Yes, all of the time
 - Yes, but sometimes I need support from a carer or a family member when catheterising
 - No, my carer or family member does it for me
7. How many times have you been advised to catheterise per day?
 - 2 or less
 - 3 to 4
 - 5 to 6
 - More than 6

- I do not know
8. How often do you actually catheterise per day? (please specify the average number of catheterisations per day)
- 2 or less
 - 3 to 4
 - 5 to 6
 - More than 6
 - I do not know
9. What is your usual body position during catheterisation?
- Sitting
 - Standing
 - Lying down
 - Other, please explain
10. Based on your experience, how challenging have you found each of the following aspects when doing intermittent catheterisation? [5-point Likert scale from 'no challenge' to 'a significant challenge']
- It's hard with my schedule or interferes with my lifestyle
 - Embarrassing or public stigma
 - It's physically a challenge, or I need a caregiver to support
 - Feel physical pain or discomfort
 - Risk of bleeding
 - Risk of infection
 - Difficult to insert or remove a catheter from the urethra (the tube through which urine leaves the body)
 - Difficult to handle the catheter before it is inserted into the urethra
 - Supply issue
 - Feel anxious, afraid or nervous
 - Lack of appropriate space, facilities or accessibility for doing catheterisation
- If there are other aspects of using an intermittent catheter which presents a challenge to you, please explain:
11. How many different types of intermittent catheters have you used?
- 1
 - 2 to 5
 - More than 5
12. What were the reasons for you changing to different catheters?
13. How important are the following factors that you would consider when choosing one type of intermittent catheter over another? [5-point Likert scale from 'not at all important' to 'very important']
- Easy to carry
 - Easy to open
 - Easy to hold or handle

- Ready to use or easy activation
- Easy to insert
- Catheter length
- Pain or discomfort
- Having a non-touch sleeve
- Infection rates
- Bleeding
- Hygiene
- Discreetness (e.g. discreet design, discreet disposal)
- Catheter malfunction
- I trust the brand
- Psychological well-being
- Support from a company, for example specialist nurse or literature
- Home delivery service
- Return of bladder dysfunction

If there are other factors which are important to you when choosing one type of intermittent catheter over another, please explain:

14. Please provide any additional information that you feel is relevant to the above and include any other factors that have affected you to select one type of catheter over another in the box below:

15. If you have questions or concerns about the intermittent catheters or the procedure (intermittent catheterisation), where would you go for help?

- I figure it out myself (searching the internet, instructions that come with catheter, etc.)
- Specialised nurse/doctor
- General (non-specialised) nurse/doctor
- Charity
- Family/friends
- Other users
- I haven't had any questions or concerns so far
- Other, please specify:

16. How satisfied or dissatisfied are you with the intermittent catheter you use the most? [5-point Likert scale from 'very dissatisfied' to 'very satisfied']

17. Please state the name of the catheter(s) you mainly use and explain your reasons why you are satisfied or dissatisfied with it in the box below:

18. Please describe your experience of using intermittent catheters in managing your incomplete bladder emptying:

19. How does intermittent catheterisation affect your daily life, socially and emotionally?

20. What is your gender identity?

- ☐ Male
- ☐ Female
- ☐ Other, please say
- ☐ Prefer not to say

21. What is your age range?

- ☐ 18-24
- ☐ 25-39
- ☐ 40-44
- ☐ 45-49
- ☐ 50-54
- ☐ 55-59
- ☐ 60-69
- ☐ 70-79
- ☐ 80 and above

Appendix E: Abbreviations

IC	Intermittent catheterisation
ISC	Intermittent self-catheterisation
LSA	Late-stage assessment
NICE	National Institute for Health and Care Excellence
QOL	Quality of life
UTI	Urinary tract infection

Late-stage assessment

Intermittent urethral catheters for chronic incomplete bladder emptying in adults

User experience, need and preference report summary page

This summary page outlines a suite of user-centred work that has been done by NICE during the late-stage assessment of intermittent urethral catheters for chronic incomplete bladder emptying in adults.

User preference in late-stage assessment

Alongside the assessment of a technology's value based on costs and effectiveness, the committee will consider user preferences that influence decision making when selecting which technology to use.

The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. Users are defined as those who will use the technology and are directly involved in the decision to choose one technology over another.

Background for this late-stage assessment

Intermittent catheterisation (IC) is considered the preferred option to indwelling urethral or suprapubic catheterisation for emptying the bladder in people with incomplete bladder emptying caused by a range of conditions. The IC procedure requires the use of urethral catheters. When deciding on which catheter to use, it is important to consider the person's clinical needs and preference.

Given the large number of intermittent catheters available in the market and the different needs of a diverse population, one size does not fit all. It is necessary to understand user experience, need and preference of the technology, as outlined in the [final scope](#). Hence, 3 pieces of user-centred work were done to explore this, including:

- A thematic review of the literature: to capture the experiences and needs of people using intermittent catheters for catheterisation, and their preferences of the catheter features. The knowledge gained from the review would contextualise people's preferences and explain why varying needs exist as well as facilitating their choice in practice.
- A user preference assessment: to identify criteria that people consider important when deciding which intermittent catheter to choose.
- An online survey: to explore people's needs, preferences and experiences of using intermittent catheters for their own bladder emptying.

Thematic review

The thematic review included 19 articles, and 5 themes emerged: 'general experience of IC', 'technology and procedure', 'internal influential factors', 'external influential factors', and 'facilitation or enablement'. These 5 themes were supported by 15 sub-themes. Please see the thematic review of the literature for full details.

User preference assessment

A group of 9 people participated in the user preference assessment to identify what is important to them when choosing a catheter. Please see the user preference assessment report for full details.

Online survey

The survey was shared with 23 patient and carer organisations. A total of 73 people completed the survey, but 69 people were eligible and gave their consent. So, 69 responses were included in the analysis. Please see the online survey report for full details.

Key messages from user-centred work

- People's needs, preferences and experiences of using intermittent catheters varied.
- When choosing a catheter to use, shared decision making was considered important. Choice was not always available in practice.

- When choosing a catheter to use, the most common factors that people considered important were ease and comfort of insertion, and risk of infection.
- People faced various challenges, and they were more likely to experience difficulties when doing IC outside the home environment.
- Different catheters need to be available to meet individual's lifestyles and needs across a range of situations and settings.
- Sustainability could be better incorporated in the range of available catheters. Also, where components of a catheter are recyclable, information about catheter sustainability needs to be made available and accessible.

Table 1 User preference criteria, definitions and supporting information from the survey findings

Criteria	Definition	Supported by the survey findings (n=69)
Comfortable to insert	Can be inserted with minimal difficulty, pain or discomfort.	One challenge people faced was 'difficult to insert or remove a catheter' 'Easy to insert' was considered important or very important by 99% of people 'Pain or discomfort' was rated as important or very important by 96% of people
Comfortable to remove	Can be removed with minimal difficulty, pain or discomfort.	
Full bladder drainage	Drains the bladder fully, as quickly as possible and without the need for repositioning the catheter.	Not reported
Risk of infection	A low risk of developing an infection.	One challenge faced by people using catheters was experiencing infections and 'infection rates' was considered important or very important by 87% of people
Options to suit individual needs and lifestyles	Available in various options (such as different sizes, designs or styles) that are as convenient and discreet as possible, suitable for various activities (such as travelling) and have options that create minimal mess (such as less liquid).	One challenge people faced was that it was hard with their schedule or interfered with their lifestyles
Easy to remove from packaging	Can be removed from the packaging and prepared for use easily (for example, with	'Ready to use or easy activation' was considered

and prepare for use	minimal spillage of lubrication [for pre-lubricated catheters], minimal handling, or a self-adhesive tab that remains stuck to a hard surface during catheter preparation).	important or very important by 97% of people and 'easy to open' by 93%
Level of catheter flexibility	Appropriate flexibility for a person's individual and situational needs to enable insertion and removal with minimal pain or discomfort.	'Pain or discomfort' was rated as important or very important by 96% of people
Ease of disposal	Can be disposed of at a person's earliest convenience without leakages.	One challenge people faced was a lack of space, facilities or accessibility when doing IC and disposing the used devices outside the home environment.
Reduced environmental impact	Minimal packaging, with components that can be recycled. A catheter that can be recycled (where appropriate) that is manufactured using sustainable practices and materials, with the option for a reusable catheter.	Recyclable catheters were preferred by 2 people

NICE - HealthTech Programme

Intermittent urethral catheters for chronic incomplete bladder emptying in adults: Late-stage assessment

User Preference comments

Comment no	Organisation	Page no / section no	Comment	NICE response
General				
1	Consultee 2 B. Braun Medical	N/A General comment	While the EAG have clearly taken great care to review the available literature and have conducted their user preference assessments in much the same way as in other LSAs, the above comments would have been much more cohesive if manufacturers and other stakeholders were able to comment on the UPR and EAGR at the same time. Many of the comments on the EAGR may now be rendered redundant as they were provided without the context of the UPR. Given that there was only one week between the release of the two documents, it is unclear why the EAGR publication could not have been delayed by a week to coincide with the release of the UPR. Any future LSAs should have simultaneous release of both sets of documents to ensure the most useful and accurate possible comments from stakeholders.	Thank you for your comment. The rationale for the different factual accuracy check periods was due to the delay for the user preference workshops (low number of confirmed attendees). This was communicated to the companies.
2	Consultee 4 Coloplast	General	Coloplast thanks the EAG for their thorough work and the opportunity to comment on the user preference documents. In the spirit of constructive engagement, we have reviewed and added detailed responses. However, the release of this suite of documents further reinforces Coloplast's anxieties regarding the LSA programme.	Thank you for your comment. The assessment has been conducted in line with NICE's interim statement on late-stage assessment, including topic selection.

Comment no	Organisation	Page no / section no	Comment	NICE response
			While we understand that this process step is designed to be limited to comments on factual accuracy, we are placing on record, in addition, significant concerns about the process, methods, and technical content of the documents. The overall impression given by the documents is of work which has not been adequately planned for or researched and has been rushed in execution (as evidenced by errors and omissions beyond simple matters of factual accuracy). Coloplast therefore believes that, in their current form, the documents are not fit for purpose to comprise part of the evidence base, and that any resulting guidance will not be in the interests of patients or the NHS. Coloplast applauds the efforts of NICE to incorporate patient preference into the LSA process, and appreciates the attempt to augment the typical, limited User Preferences Report with additional research into existing literature and the use of a survey to capture a greater variety of patient preferences. However, we believe that a more robust process should have been used when developing these additional methods, which we will outline below. The core issue with the Intermittent Catheterisation LSA, which runs deeper than even the methods and processes used, is that it lacks an appreciation for the degree of personalisation that is required for patients using intermittent catheters. Starting with a product group and using that as the defining characteristic of a patient group means that intimate continence needs of a wide and varied group of patients has been considered through a lens of cost instead of clinical and anatomical	Patient surveys and thematic reviews of literature are a standard part of NICE's guidance development programmes and have been conducted alongside the user preference assessment for this topic to provide additional context for the committee.

Comment no	Organisation	Page no / section no	Comment	NICE response
			need. Indeed, even if the LSA had started with a more narrowly defined patient group, i.e. spinal cord injury patients, NICE would still discover wide, clinically significant variation of individual patient needs alongside various anatomical challenges for which it would be very difficult to provide general recommendations. It is this overgeneralisation which is of greatest concern to Coloplast. As a company which has for 60 years created quality, personalised products which align to individual patient needs and aim to tackle some of the anatomical challenges many patients face when voiding their bladders, we are dismayed to see such a small and poorly defined sample of patients used to prioritise the needs and preferences of all intermittent catheter users. Considering the already alarming amount of health inequalities present within the NHS, we feel that the recommendations drawn from this analysis will only deepen the discrimination faced by the UK's most vulnerable patients, i.e. those with significant disabilities and/or are bed-bound by their condition. In light of this feedback, we ask NICE to appreciate where this LSA pilot has succeeded – namely in highlighting the need for greater evidence and a new paradigm for evaluating highly-personalised technologies – and to reconsider both the pace and methodology of the current LSA process. The LSA process overall, and this LSA in particular, have shown that it is difficult to evaluate individual products in an environment of highly personalised care which requires a significant degree of user input. We hope that this experience with the Intermittent Catheter LSA pilot will prompt NICE to work with industry to create an agenda for MedTech in the UK which fosters appropriate evidence generation and	

Comment no	Organisation	Page no / section no	Comment	NICE response
			sufficiently evaluates patient needs, preferences, and rights to be a part of their own health journey. Moreover, this should ensure patients dignity and individualised continence needs are respected aligned to “excellence in continence care guidance - Practical guidance for commissioners, and leaders in health and social care, June 2018.	
3	Consultee 4 Coloplast	General	It is procedurally unfair to stakeholders who were, on the basis of experience with other LSA topics, expecting one user preference report, to only allow one week for a suite of documents, particularly when – without prior warning from NICE – the release of the documents was delayed by 9 days. This has compromised the effectiveness of the review for those documents requiring specialist resource not planned by stakeholders to be available for the delayed review window. It is also procedurally unfair to not allow stakeholders to review the user preference and EAG reports simultaneously. We request that NICE explain why the delay was needed when the date of completion of the User Preference report is 4 December, a week prior to its release on 11th December. Stakeholders have been prevented from an effective review of the user preference evidence. Because of the way that it has been presented, in three different documents with an additional summary document, it is unclear what conclusions will be drawn as a whole from the findings of the different research methodologies. Notwithstanding the comments below on the individual reports, and notwithstanding that a short executive summary has been prepared, the topic timeline should	Thank you for your comment. For late-stage assessment, NICE usually gives 7 calendar days for factual accuracy comment periods. Factual inaccuracies are cases in which there is an objective error of material fact in the report. It does not include disagreements about scientific or clinical interpretation or judgement, whether this refers to the appropriateness of an analysis or the report itself. NICE felt that the usual 7 calendar days was appropriate for the user preference work factual accuracy comment period for this assessment. You will have the opportunity to review and comment on the draft guidance and related documentation during the public consultation period. The executive summary included the key findings/messages from across 3 pieces of user-centred work. This summary has been shared with the stakeholders for factual accuracy review. The assessment has been conducted in line with NICE's interim statement on late-stage

Comment no	Organisation	Page no / section no	Comment	NICE response
			be revised to allow the user preference evidence to be synthesised in a single report which should then be subject to stakeholder factual accuracy review. Coloplast welcomes the additional user preference work carried out by NICE for this topic. On page 1, the Executive Summary states: “The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose.” However, the approach taken has not been transparent because new user preference testing methodologies (the User Survey and Thematic Review) were used which are in the published interim methods for LSA and there is without inadequate explanation of whether they are based on, or compliant with, the published methods for qualitative research in either NICE’s Health Technology Evaluations manual or in the Guidelines Manual. In view of the approach taken with this topic in contrast to other LSAs, please can NICE explain: - whether consideration was given to commissioning methods support from the Decision Support Unit and if not, why not? - whether NICE has, through this or any other method, assessed the impact of applying user preference, methods inconsistently across different LSAs, when the decision-making scenarios (limited evidence of low quality, and an acknowledged importance of user preference and patient-reported outcomes) are comparable?	assessment. Patient surveys and thematic reviews of literature are a standard part of NICE’s guidance development programmes and have been conducted alongside the user preference assessment for this topic to provide additional context for the committee.

Comment no	Organisation	Page no / section no	Comment	NICE response
4	Consultee 4 Coloplast	Page 24 Conclusion	The report notes that NICE's own guideline on Shared Decision Making (NG197) says that patients should have the right to make their own informed choices for their care. This is reinforced by the EAUN intermittent catheterisation guideline which states, 'It is important that healthcare professionals enable patients to make an informed choice when choosing the best method and product for their individual need' (Vahr 2024). However, despite this appeal from national and international guidelines, the User Survey reports that only 32% of surveyed people had a choice in their catheter selection. Can NICE please explain how recommendations regarding patient choice as part of this LSA will be supported via healthcare professional training, financial incentivisation, improved service commissioning, ongoing monitoring and follow-up in the community, etc to ensure that these recommendations will be adopted in practice?	Thank you for your comment. Please note that at this stage, NICE cannot speculate on the outcome of this assessment. The process needs to proceed to the next step of the committee deliberation before being able to comment on the outcome.
5	Consultee 5 Hollister	Not specified	Limitations seems to be a general theme emerging across the different parts of the whole IC Late Stage Assessment (similarly to the Colostomy LSA) and must surely call into question whether LSAs and the NICE methodology is even appropriate for IC. Manufacturers in this sector have generally not had to work to NICE requirements before, unlike Pharma. To expect manufacturers to have NICE level evidence/data etc is unrealistic when it has never been required for reimbursement. Such evidence can be gained but will take a number of years.	Thank you for your comment. The assessment was done in line with NICE's interim statement on late-stage assessment , including topic selection.

Comment no	Organisation	Page no / section no	Comment	NICE response
Patient survey				
6	Consultee 2 B. Braun Medical	Page 4 Table 1	The title of this report is “People’s needs, preferences and experiences of using intermittent urethral catheters for urinary management: a cross-sectional survey”. The demographics of the respondents should therefore be reflective of the ISC population as a whole, yet within the survey some patient ISC groups are overrepresented, and others underrepresented. The demographics information included in table 1 shows that: The majority of survey respondents (N=69) were female (77%). In reality, more men than women use intermittent catheters. Patient groups segmented by ‘Reasons for using IC’ are unbalanced. There is an overrepresentation of respondents using intermittent catheters due to brain and/or spinal cord disease (e.g. multiple sclerosis, myelitis, tumour, cyst) within the survey at 66%. Conversely, there is an underrepresentation of patients responding to the survey with a bladder outlet obstruction, e.g. prostate hyperplasia/enlargement. Only 1 patient responded from this important cohort. User perspectives are an integral part of this Late Stage Assessment but should be reflective of the entire patient group requiring IC to manage a bladder condition. Imbalances in patient groups introduce bias to the report as the views of some groups are not accurately reflected. Important insights from the underrepresented group may have been missed and may lead to gaps in the data	Thank you for your comment. This has been addressed as part of the limitations, please see the discussion section of the report.

Comment no	Organisation	Page no / section no	Comment	NICE response
			overall, raising questions about the validity and reliability of the survey results.	
7	Consultee 4 Coloplast	Page 1 Methods	The LSA interim process and methods statement does not describe methods for user surveys as part of assessing user preference. Please can NICE explain what qualitative methods research was done to inform the design of the user survey, with specific reference to section 3.3.18 of the NICE Health Technology Evaluations Manual (PMG36)? Please can NICE explain why this work was not carried out by an External Assessment Group which would, as is standard practice, have provided independence and assurance of access to relevant expertise)?	Thank you for your comment. All user-centred work was done by NICE and was considered a standard part of NICE guidance development. The literature review contributed to the design of the questionnaire. Also, as described in the survey report, the questionnaire was developed and tested with a person with experience of using intermittent catheters for their own bladder management and Bladder Health UK. This was to ensure that the questions were appropriate for, and ease to understand by, the target population.
8	Consultee 4 Coloplast	Page 4 Table 1	The 69 survey respondents do not match the general population in UK doing intermittent catheterisation: - Women are overrepresented: 77%, would expect >50% male. [REDACTED] - Spinal cord injury patients appear underrepresented: 6%, would expect ~40% - Brain/spinal cord disease (e.g. MS) appears overrepresented: 62%, would expect <40% - Benign Prostatic Hyperplasia (BPH) appears underrepresented: 1.4%, would expect >5% Not matching the general population doing IC, may impact conclusions regarding:	Thank you for your comment. This has been addressed as part of the limitations, please see the discussion section of the report.

Comment no	Organisation	Page no / section no	Comment	NICE response
			- Importance of having an integrated bag - Importance of sensation, as this depends on pathology - Importance on handling due to poor hand dexterity - Importance of ease of opening due to poor hand dexterity - Importance of handling due to poor mobility - Stigma, which may be less important for SCI patients, compared to MS and other diseases that are not necessarily visible	
9	Consultee 4 Coloplast	Page 7 Challenges and preferences	Could NICE please clarify the following statement? "This challenged further in people who used a wheelchair or was paraplegia due to a different positioning needed when performing IC."	Thank you for your comment. Extra wording has been added in response to this comment.
10	Consultee 5 Hollister		Low number of respondents makes it difficult to draw any meaningful conclusions.	Thank you for your comment. The small number of respondents was highlighted as one of the limitations in the survey report.
11	Consultee 6 Convatec	Page 6 Results	Catheterisation frequency – table 3 would suggest that the HE model of 5 catheters per day being an over estimation and thus the factual accuracy of patient population is questionable.	Thank you for your comment. The limitations of the survey were detailed in the discussion section of the report. Different numbers of catheter used per day were considered in the sensitivity analysis.
12	Consultee 6 Convatec	Page 10 Satisfaction	Unnecessary inclusion of brand names without correlation. With such a small user sample this information becomes irrelevant.	Thank you for your comment. The information relating to the brand names has been removed.

Comment no	Organisation	Page no / section no	Comment	NICE response
13	Consultee 6	Page 4 Respondent demographics	The age split is not representative of demographic, population is much older. Thus excluding a large cohort making some of the findings inaccurate of 2,000 ISC patients in Amcare DAC 50% are currently over 70 years of age, this group with different preferences have been excluded. Also the female to male split does not reflect the market, more male products are prescribed and females favour compacts.	Thank you for your comment. This has been addressed as part of the limitations, please see the discussion section of the report.
Thematic review				
14	Consultee 1 CliniMed Ltd	Thematic Report	Only 5 of the 19 studies were conducted in the UK. The UK has a very different health service compared to other countries and is unique in many ways.	Thank you for your comment. The small number of studies conducted in the UK and the difference in healthcare systems were acknowledged in the report.
15	Consultee 1 CliniMed Ltd	Thematic Report	Some of the studies included in the review were funded or sponsored by catheter manufacturers and therefore findings will be in favour of their particular products or attributes of their product. This will skew any assumptions/findings.	Thank you for your comment. The report stated that 6 studies were funded or sponsored by manufacturers.
16	Consultee 4 Coloplast	Page 3 Methods	LSA interim process and methods statement does not describe methods for thematic review of the qualitative research literature as part of user preference assessment. Coloplast notes that the evidence critique was based on methods described in the NICE Guidelines Manual (PMG20). Please can NICE explain what qualitative methods research was done to inform the design of the thematic review, and please can the relevant expertise and experience in this type of work be added to the report? Please can NICE explain why, in common with other evidence identification, assessment and syntheses, this	Thank you for your comment. The report described the method and its rationale, please see the methods section. All user-centred work was done by NICE and was considered a standard part of NICE guidance development.

Comment no	Organisation	Page no / section no	Comment	NICE response
			work was not carried out by an External Assessment Group which would, as is standard practice, have provided independence and assurance of access to relevant expertise?	
17	Consultee 4 Coloplast	Page 6 Table 1	Please can the relevant quality assessment tool scoring be added to the table to improve transparency, with specific reference to the relevant section of the NICE guidelines manual (PMG20), as described in the methods section of the main text?	Thank you for your comment. Extra wording has been added to the methods section of the report.

Comment no	Organisation	Page no / section no	Comment	NICE response
18	Consultee 4 Coloplast	Page 32 References	Please consider including the following references: Publication Study Participants Key message van Achterberg 2007 Interview 30 Assessing dropout, short term (n=10) and long term (n=20). Main reasons for drop-out: knowledge, complexity, misconceptions, fear etc + quality and continuity of professional care Bagi 2011 RCT non blinded randomized 28 Compact catheter was preferred over non-compact by nurses for 87% of the participants (p<0.0001) Bonello 2021 Descriptive exploratory cross-sectional study 32 Most respondents (73%) preferred SpeediCath over LoFric, Actreen and PVC Domurath 2011 Prospective, randomized, crossover study 37 More subjects preferred the compact catheter over the standard catheter (61.1%, 22/36) Lane 2017 Survey (retrospective) 100 Long term study. Most common reasons to stop IC included inconvenience, physician recommended, patient dislike. 50% of people on indwelling started on IC Motavasseli 2018 Questionnaire 164 Adherence correlated with higher frequency of CIC. Drop-out was related to end of treatment with botox Zanollo 2015 Questionnaire after 1 year with CIC 400 The "IC training program" used in multiple hospital settings proved to increase adherence to CIC and reduce the impact on daily life for SCI patients	Thank you for your comment. van Achterberg (2008) was included in the review (Balhi 2021) and the other studies did not meet the inclusion criteria.

Comment no	Organisation	Page no / section no	Comment	NICE response
19	Consultee 5 Hollister		P30 states there are several limitations to the Thematic review.	Thank you for your comment.
User preference report				
20	Consultee 1 CliniMed Ltd	UPR	The user preference assessment involved only 10 participants (4 with lived experience and 6 with prescribing experience although only 5 HCPs were named at the end). This small sample size may not fully represent the diverse experiences and preferences of all catheter users. Due to the small and specific sample, the findings may not be generalisable to the wider population of catheter users.	Thank you for your comment. We have amended the report to confirm that 9 people (4 with lived experience and 5 with experience of prescribing) took part in the user preference assessment. NICE acknowledged that the findings from the user preference report may not be generalisable to the wider population due to the difficulty of recruiting people with lived experience and the varied experiences and needs of the population in section 6 of the user preference report. To address this limitation, NICE also completed a thematic review of the published literature and an online survey to help the committee understand people's experiences and what is important to users when choosing which catheter to use. NICE publicly advertises its specialist committee member roles and shares the adverts with relevant professional organisations and patient organisations to. In addition to this stakeholder comment period, NICE holds public consultation on the draft recommendations and associated documents. So, other healthcare

Comment no	Organisation	Page no / section no	Comment	NICE response
				professionals and users can provide additional comments.
21	Consultee 2 B. Braun Medical	Page 9 4.1 Identifying and defining criteria	Users identified that pain/discomfort may lead to avoidance/low adherence or incorrect use, which in turn may lead to infection. While pain/discomfort is included in the economic model, this is only from a patient QoL perspective and is not modelled to relate to infection in any way. The EAG could seek published literature on this to allow these potential causal links to be accounted for in the model, or seek expert consensus if no such evidence currently exists.	Thank you for your comment. The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. This is likely to include the important factors related to characteristics or features of the technology that may not be captured elsewhere in the evidence base. The user preference assessment is intended to compliment the clinical and economic evaluation, where appropriate.
22	Consultee 2 B. Braun Medical	Page 8-9 4.1 Identifying and defining criteria	Ease of opening packaging is identified as an attribute which is important to patients, particularly from a health equality perspective considering patients with manual dexterity difficulties or cognitive impairments. This is not fully reflected in the economic model, and while NICE argues that following the publication of this LSA, patients (alongside HCPs) will still have choice, NICE should take extreme caution in their roll-out of the resulting guidance to ensure that attributes such as ease of opening – which are not easily quantified economically or clinically – are not unduly disregarded by virtue of the difficulty in	Thank you for your comment. The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. This is likely to include the important factors related to characteristics or features of the technology that may not be captured elsewhere in the evidence base. The user preference assessment is intended

Comment no	Organisation	Page no / section no	Comment	NICE response
			assigning an incremental benefit to them, thereby potentially exacerbating health inequalities for these patient subgroups. Similarly, catheter discretion is also not easily quantifiable but is nevertheless clearly important to patients. The UPR (page 8) notes that this is of greater importance to patients when they are out of the house, and as above, if this attribute is disregarded in the economic model this may disincentivise the NHS to offer a full range of catheters for patients to choose from. At worst, this could lead to patients withdrawing socially or professionally if they have impeded access to discreet catheters. It is important to note that discretion ranks higher in importance than risk of infection (Table 3, page 11), which is the primary focus of the economic model.	to compliment the clinical and economic evaluation, where appropriate. Please note that at this stage, NICE cannot speculate on the outcome of this assessment. The process needs to proceed to the next step of the committee deliberation before being able to comment on the outcome. NICE recognises that having a range of products available is important to accommodate patient choice and to stimulate innovation within a category. The aim of late-stage assessment is to assess if the value added by incremental innovation justifies the price variation to help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.
23	Consultee 2 B. Braun Medical	Page 7-10 4.1 Identifying and defining criteria	The broad range of criteria that are important to patients, and the diverse range of indications for ISC, highlight that user choice is crucial in catheter care. Thematic review finds that certain attributes such as pain can have a significant impact on patient QoL and catheterisation experience (p23, UPR), yet only 32% of patients are offered choice (p24, UPR). The results of this LSA cannot be considered in isolation, as in practice they will be intrinsically linked to the DHSC MedTech Part IX Tariff Assessment Framework. It must be stressed that patient choice should not be hindered by the outcomes of this LSA, and should instead be informed by it, ideally	Thank you for your comment. Please see the response to comment 22.

Comment no	Organisation	Page no / section no	Comment	NICE response
			increasing the proportion of patients who are offered choice to much higher than 32% in the future.	
24	Consultee 2 B. Braun Medical	Page 13 Creating performance rules	It is unclear whether manufacturers are expected to provide evidence on difficulty to insert or remove catheters, and if so, by which scale. These are clearly very important attributes to consider, therefore NICE should provide guidance on how they wish manufacturers to produce evidence of this. The EAGR demonstrates that some manufacturers had attempted to provide evidence of this in their RFIs but the scale used had been described as “unclear” (e.g. Table 10, p70, EAG Report).	Thank you for your comment. Please note that at this stage, NICE cannot speculate on the outcome of this assessment. The process needs to proceed to the next step of the committee deliberation before being able to comment on the outcome.
25	Consultee 3 BD	Page 29	How will NICE align the features that have been awarded NMB in the LSA report, for example, an integrated handle to the criteria (benefits) captured in the User Group? Having a handle will make a catheter easier to be removed from the packaging, but it could also make the catheter more comfortable to insert and remove? Please also advise if Manufacturers will be allowed to comment on these matches.	Thank you for your comment. The aim of the user preference assessment was to identify factors related to preferences that influence the decision of choosing which catheter to use. Alongside the assessment of the technology’s value based on costs and effectiveness, the committee will consider user preferences that influence decision making. Stakeholders will have the opportunity to review and comment on the draft guidance and related documentation during the public consultation period.

Comment no	Organisation	Page no / section no	Comment	NICE response
26	Consultee 4 Coloplast	Page 3 Section 2	Consider adding that IC users are of higher risk of hospitalisation than non-IC users when acquiring a UTI (Butcher et al., 2022), [REDACTED]	Thank you for your comment. As the manuscript is not publicly available and the journal article is not open access, this has not been added to section 2, which is intended to be a short background summary only.
27	Consultee 4 Coloplast	Page 7 Table 1	Please can additional information be added to the table to show – if not 100% - the user attendance rate at each of the workshops?	Thank you for your comment. No amendment has been made as the total number of participants for each stage is considered sufficient.
28	Consultee 4 Coloplast	Page 7 Section 4	A short description of the patient panel is missing, to better understand if they are representative for IC users in UK (gender / pathology / wheelchair bound? Etc.)	Thank you for your comment. Demographic information is not routinely collected as part of the user preference assessment process to ensure that private information is kept confidential for users in the assessment.
29	Consultee 4 Coloplast	Page 7 Section 4	Any discussion on importance of having a bag attached to the catheter has been neglected by the panel. Having a bag is essential for patients confined to a wheelchair, or those who are bed bound and unable to transfer to a toilet themselves.	Thank you for your comment. The outcome of the user preference assessment is intended to reflect the views of the sample of users who took part and what is important to them. We are unable to ascertain what our participants do not know. However, all those who took part had access to the project scope were all aware of the features under evaluation in this LSA. Section 6 of the user preference report also states the potential benefit of an external collection bag highlighted in the external assessment report. Additional detail has been added to this section to highlight that the importance of this

Comment no	Organisation	Page no / section no	Comment	NICE response
				feature for some people may not be fully captured in the user preference report.
30	Consultee 4 Coloplast	Page 7-9 Section 4.1	Coloplast questions the lack of bias mitigation techniques detailed in the User Preference Report, referring to the accepted best practices, and cautions the omission of otherwise important decision criteria. The MCDA decision criteria were identified and defined by clinical and lived experience stakeholders. Discussions revealed some lived experience users were unaware of the availability of catheter options. These experiences aligned with the User Survey findings, where only 32% of lived experience users reported having a choice when selecting a suitable catheter. · “One person with lived experience explained that it took them a number of years before they were aware of any other choices over the catheter that they had been prescribed. Another user stated that they had never been involved in the decision to choose which catheter was most appropriate for them.” [User Preference Report, Page 22]. These findings are acknowledged by NICE, and we agree with the need for improved communication during decision-making. We note, however, the potential influence of availability bias when prompting stakeholders for decision criteria. Lived experience users may have omitted otherwise important criteria they were unaware were available. Bias among stakeholders is acknowledged in the ISPOR Task Force Report (cited in	Thank you for your comment. Please see the response to comment 29. Please note, NICE’s methods for collecting user preferences are informed, where appropriate, by MCDA best practices. It does not follow the MCDA process. Please see the LSA interim methods and process document for more information.

Comment no	Organisation	Page no / section no	Comment	NICE response
			the NICE Interim Methods and Process Statement for LSA). Specifically, the authors recommend reviewing varied sources, cautioning the risk of bias during stakeholder consultation. “Consultations with decision makers, stakeholders, and experts will usually form part of criteria identification. The analysts should be aware of the potential bias that may invalidate such consultation, and techniques that can be used to mitigate the impact of these biases (see Montibeller and von Winterfeldt).” (Marsh 2016).	
31	Consultee 4 Coloplast	Pages 9, 31 Page 21 Pages 17-21 Section 4, Appendix D Appendix C Theme 3: internal influential factors	Coloplast appreciates the challenges experienced while engaging lived experience from users. However, we would question the representativeness of the findings across the document suite given the limited sample sizes and caution against drawing meaningful conclusions from this analysis to inform policy decision-making. Limited information is provided about the sample characteristics for the multi-criteria decision analysis (MCDA) in the User Preferences report. Four lived experience users participated, and their names are stated in Appendix D. No information is provided about their sociodemographic and clinical characteristics. Accordingly, we cannot verify the generalisability of the findings beyond acknowledging the limited sample size. Given the scope considers all intermittent self-catheter populations, we would assert that a representative sample of catheter users should have been included. Similar concerns were raised about the External Assessment Group’s (EAG) analyses and the potential	Thank you for your comment. NICE acknowledged that the findings from the user preference report and patient survey may not be generalisable to the wider population due to the difficulty of recruiting people with lived experience and the varied experiences and needs of the population. Demographic information is not routinely collected as part of the user preference assessment process to ensure that private information is kept confidential for users in the assessment. NICE recognises that having a range of products available is important to accommodate patient choice and to stimulate innovation within a category.

Comment no	Organisation	Page no / section no	Comment	NICE response
			overrepresentation of spinal cord injury populations. Coloplast also appreciates the User Survey as a supplemental exercise; however, as acknowledged by NICE, the small sample size limits meaningful inferential subgroup comparisons (Appendix C). For instance, assessing preference differences between male (n = 16) and female (n = 53) users (exploratory analyses are presented in Appendix C). Anatomical differences for each sex are a clinically meaningful subgroup and was identified as an internal influential factor in the Thematic Review due to challenges associated with urethral length and location, noting considerations for women with neurogenic lower urinary tract dysfunction and overweight or obese women. Other identified considerations include the reason for catheter use, age, and physical, psychological and cognitive function. Acknowledging individual needs, preferences and limitations surrounding generalisability, and in the absence of a representative, large preference study to justify prioritising discrete treatment features, Coloplast argues that maintaining a wide range of product choices is appropriate. This position, concerning the importance of choice and shared decision-making, is consistent with sentiments expressed throughout the User Preference Report, User Survey and Thematic Review. Once again, we emphasise that by drawing conclusions for all users on the basis of small and non-representative sample, NICE runs the risk of marginalising the most vulnerable patients deepening the well-recognised health inequalities crisis in the UK.	The aim of late-stage assessment is to assess if the value added by incremental innovation justifies the price variation to help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.

Comment no	Organisation	Page no / section no	Comment	NICE response
			As an illustrative example of the potential impact of not appreciating the individual preferences of all patient groups, selecting a catheter that does not satisfy preferences, and clinical need may contribute to non-adherence, which, alongside incorrect use, stakeholders associated with infections. “Users with lived experience explained that using catheters that cause pain or discomfort on insertion or removal may impact how they use their catheter and could lead to avoidance or incorrect use. They stated that incorrect use or lack of adherence may lead to infection, which can negatively impact their quality of life.” [User Preference Report, Page 9].	
32	Consultee 4 Coloplast	Page 11 Table 3	The miscalculated mean scores from Table 5 in Appendix A (see comment 15) have been carried over into the rankings of criteria in Table 3.	Thank you for your comment. This inaccuracy has been corrected throughout the report.
33	Consultee 4 Coloplast	Pages 12-21 Page 8 4.3 Preferences section	Coloplast notes the impact of potentially overlapping decision criteria and cautions against the underweighting of otherwise important criteria. The ‘Comfortable to insert’, ‘Comfortable to remove’ and ‘Level of catheter flexibility’ decision criteria display overlap. Specifically, the definitions and performance rules attributed to these criteria concern: • The level of difficulty experienced. • The level and impact of pain experienced. • The level and impact of discomfort experienced. • The presence of blood. Including overlapping criteria can, per the ISPOR Task	Thank you for your comment. NICE’s methods for collecting user preferences are informed, where appropriate, by MCDA best practices. It does not follow the full MCDA process. Please see the LSA interim methods and process document for more information. This work is based on consensus opinion of the group of users consulted. Users did acknowledge that there is overlap in the

Comment no	Organisation	Page no / section no	Comment	NICE response
			Force Report, lead to overattributing weight to a value dimension. Consequently, otherwise important criteria may be underweighted. For instance, 'ready to use or easy activation' and 'easy to open' were considered 'Very Important' or 'Important' by User Survey participants (97% and 92%, respectively). Despite this, 'Easy to remove from packaging and prepare for use' only comprised 6.5% of the weighting. Criteria overlap may explain why the 'Comfortable to insert' and 'Comfortable to remove' criteria occupied 44.8% of the weighting (50.4% including 'Level of catheter flexibility'). The Company suggests further scoping, refinement and validation of the decision criteria (and the definitions) was required, potentially decomposing the listed outcomes into individual criteria (e.g. reducing bleeding during insertion, removal and draining).	criteria but agreed to these criteria based on what was important to them.
34	Consultee 4 Coloplast	Pages 12-21 4.3	Coloplast questions whether appropriate scoping and validation procedures have been conducted to generate criteria definitions and performance rules, limiting the usefulness of the performance matrix to assess alternative interventions. The 'options to suit individual needs and lifestyles' criterion considered multiple treatment features, including the catheter's size, design, style, convenience and discreteness. The User Survey participants also consider catheter size, length and discreteness were also considered important when choosing a catheter. As no qualitative rationales are reported for the MCDA, it is impossible for Coloplast to discern which treatment features were considered important and, therefore, informed stakeholders' responses to the ranking and weighting tasks for this criterion.	Thank you for your comment. Please see the response to comment 33.

Comment no	Organisation	Page no / section no	Comment	NICE response
			The criterion definition does not satisfy the recommendations presented in the ISPOR Task Force Report. The consequences of implementing an alternative that does not possess the cited features (e.g. suited to individual needs) are not clearly defined. “Once criteria have been identified, they should be defined. Individual criteria should have the following properties: unambiguous (clear relationship between the impact of an alternative and the description of the impact), comprehensive (covering the full range of possible consequences), direct (describe as directly as possible the consequence of implementing an alternative), operational (the information required by the criterion is available and it is possible to make value trade-offs), and understandable (consequences of the criterion are clearly understood by decision-makers).” (Marsh 2016). The performance rules for this criterion were also not associated with (specified) measurable outcomes, limiting the usefulness of these data as they do not enable comparison between alternative interventions. For example, NICE does not detail how ‘quality of life’ (impact on a person’s lifestyle) should be assessed, and what aspects of quality of life this entails (e.g. activities of daily living, generic domains of health-related quality of life). Similar limitations apply to the other criteria (e.g. ‘Level of force needed or difficulty experienced when inserting the catheter’). Consensus was not reached for six of the nine decision criteria. These limitations may reflect	

Comment no	Organisation	Page no / section no	Comment	NICE response
			insufficient validation measures. The Company appreciates that the timelines allocated within the Late-Stage Assessment (LSA) process may not have allowed iterative validation – at each MCDA stage – as per the ISPOR Task Force Report recommendations. • “The key role of validation is to confirm that the MCDA design, input, and outputs are plausible and consistent with decision maker objectives and stakeholder preferences. This is especially important given the subjective nature of many of the inputs into an MCDA... Validation should be built into each step of the MCDA, and the steps taken to validate the MCDA should be reported.” (Marsh 2016). In this case, we suggest that decomposing the feature-related decision criteria and refining the definitions to satisfy the properties listed in the ISPOR Task Force Report (2b) may have aided stakeholders in conceptualising (and agreeing upon) measurable performance rules.	
35	Consultee 4 Coloplast	Page 22 6	The report should explore how products which do not meet user requirements may impact compliance to prescribed treatment regimen (catheterisations/day and or drop off treatment)	Thank you for your comment. This work is based on consensus opinion of the group of users consulted. The opinion and discussion captured in the report was that of the users involved in the assessment at the time, it cannot be changed retrospectively.

Comment no	Organisation	Page no / section no	Comment	NICE response
36	Consultee 4 Coloplast	Page 23 6	While acknowledging that the working group pointed out both insertion and removal as important categories, having them as two separate groups might result in overrepresentation of that criteria (50%).	Thank you for your comment. This work is based on consensus opinion of the group of users consulted. Users did acknowledge that there is overlap in the criteria but agreed to these criteria based on what was important to them.
37	Consultee 4 Coloplast	Page 26 Appendix A, Table 5	There appears to be a critical factual error in calculating mean ranking, which impacts overall ranking of the criteria by 1-2 ranks. This critical flaw significantly impacts conclusions and calls into question the findings in this document. User 1 has been excluded from analysis (except on the 'Reduced Environmental Impact' criterion), which leads to undervaluing 'Full Bladder Drainage' and 'Risk of Infection', Whereas 'Options to suit individual needs and lifestyles' is overvalued. Furthermore 'Reduced environmental impact' and 'Ease of disposal' switches places.	Thank you for your comment. This inaccuracy has been corrected throughout the report.
38	Consultee 4 Coloplast	Page 31 Appendix D	Coloplast is concerned with the potential undeclared interest concerning the team at Southampton University's involvement with the EAG and the User Preference analysis given the involvement of Southampton in the MultiCath trial alongside involvement with the Cochrane collaborations work in this area – including what appears to be some crossover involvement with the entirely separate Part IX modernisation project	Thank you for your comment. Users were recruited in line with NICE's Interim methods and process statement for late-stage assessment . NICE's policy on declaring and managing interests for NICE advisory committees was considered during the recruitment process. Users who were directly employed by a company whose technologies are being evaluated were excluded from the process. A declarations of interest register will be published alongside the guidance document on NICE's topic page .

Comment no	Organisation	Page no / section no	Comment	NICE response
39	Consultee 5 Hollister	Page 4 Section 2	A wide choice of products is essential as individual needs can vary so much, there is never any 'one size fits all' for Intermittent Catheters	Thank you for your comment. NICE recognises that having a range of products available is important to accommodate patient choice and to stimulate innovation within a category. The aim of late-stage assessment is to assess if the value added by incremental innovation justifies the price variation to help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.
40	Consultee 5 Hollister	Page 4 Section 2	Reference is made to users not always being made aware of options. Feedback from many clinicians over many years is that they will assess the patient needs and then explain the benefits of the two or three most relevant options. To provide more choice is potentially both confusing and daunting - often the patient, who typically will not have had any prior experience of IC, will therefore ask the clinician to recommend "the best one".	Thank you for your comment. This work is based on consensus opinion of the group of users consulted. The opinion and discussion captured in the report was that of the users involved in the assessment at the time.
41	Consultee 5 Hollister	Page 7 Section 3	Both numbers of users with lived experience and number of prescribers seem exceptionally low to be able to draw any meaningful conclusions at all. For Stage 1, the number of users with lived experience is as low as 2!	Thank you for your comment. NICE acknowledged that the findings from the user preference report may not be generalisable to the wider population due to the difficulty of recruiting people with lived experience and the varied experiences and needs of the population in section 6 of the user preference report. To address this limitation, NICE also completed a thematic review of the published literature and an online survey to help the committee

Comment no	Organisation	Page no / section no	Comment	NICE response
				understand people's experiences and what is important to users when choosing which catheter to use.
42	Consultee 5 Hollister	Page 7 Section 3	Given only 4 users with lived experience were involved, this would indicate a likely maximum of four different products being mainly used. Given the huge number of products available, this again would suggest it would be very difficult to make robust conclusions that could be applied across all IC users. (It is also noted the online survey had a small sample size and was potentially limited in variety of products used).	Thank you for your comment. Please see the response to comment 41.
43	Consultee 5 Hollister	Page 9 Section 4	Had more users with lived experience of undertaking IC taken part this would have been more representative of the broader IC population, and there may have been additions/deletions to the criteria together with changes in weighting.	Thank you for your comment. Please see the response to comment 41.
44	Consultee 5 Hollister	Page 25 Section 6	Given the very low number of users and the fact there appears to be links with certain manufacturers it is very difficult to see how the findings in this report can be applicable to the wider population with any degree of certainty at all. This appears to be acknowledged by the comment: "As a result, the findings from this user preference may not be generalisable to the wider population".	Thank you for your comment. Please see the response to comment 41.

Comment no	Organisation	Page no / section no	Comment	NICE response
45	Consultee 6 Convatec	Page 19 Performance matrix	The table notes: No resistance, pain, discomfort or blood present when removing a catheter is considered acceptable. No sticking and minimal gripping is considered acceptable. However the word 'sticking' what does this mean as a performance rule. The catheter being completely stuck? Studies show there is resistance and sticking of urethral cells, and this causes micro trauma but this cannot be seen by a user.	Thank you for your comment. This work is based on consensus opinion of the group of users consulted. The opinion and discussion captured in the report was that of the users involved in the assessment at the time and cannot be changed retrospectively.
46	Consultee 6 Convatec	Page 7	Sample sizes are much too small to be used (users n=4). This is creating bias towards features which may be important to those users, but the number is much too small for this to be relevant. This study should be discounted	Thank you for your comment. Please see the response to comment 41.

Medical Technologies Advisory Committee Interests Register

Topic: Intermittent urethral catheters for chronic incomplete bladder emptying in adults: late stage assessment
NICE's declaration of interest policy can be accessed [here](#)

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Thomas Clutton-Brock	Committee member	Nil	-	-	-	-	-
Jacob Brown	Committee member	Nil	-	-	-	-	-
Teik Goh	Committee member	Nil	-	-	-	-	-
Funminiye Adenle	Committee member	Nil	-	-	-	-	-
Kiran Bali	Committee member	Nil	-	-	-	-	-
Katherine Boylan	Committee member	Nil	-	-	-	-	-
Stacey Chang-Douglass	Committee member	Financial	I am a part-time employee of Evidera, a health economic and outcome research consultancy. Evidera is part of PPD, which is a business entity of Thermo Fisher Scientific. However, research and consulting activities conducted by Evidera are independent of its parent organisations and other entities within the business. My company provides research and consulting support to pharmaceutical companies at various stages of their product development, including NICE submissions. However, I am not involved in any work associated with medical or diagnostic devices or medical technologies.	January 2023	April 2024	31 July 2024	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Stacey Chang-Douglass	Committee member	Indirect	I am the founding director of a charitable organisation, Pro Bono Health Economist Network, which provides research and training support to other health charities, which could be patient groups directly or indirectly involved in NICE recommendations. However, currently we are not involved in any work with any patient group. Additionally, we do not receive funding from any pharmaceutical or medical device manufacturers.	December 2021			Declare and participate
Stacey Chang-Douglass	Committee member	Indirect	I have been a professional reviewer (health economist) for National Institute for Health Research (NIHR) since August 2015. I provide independent comments on NIHR funding proposals and Health Technology Assessment reports, which may include research associated with pharmaceutical products or medical devices. However, I am not involved directly in any of the funding decisions.	August 2015			Declare and participate
Donna Cowan	Committee member	Nil	-	-	-	-	-
Philip Crilly	Committee member	Financial	Work full time at Kingston University and work one day per month for Boots the Chemist as a community pharmacist.		April 2024	Ongoing	Declare and participate
Neil Hawkins	Committee member	Financial	I am a director of a consultancy that provided health technology assessment (HTA) services to pharmaceutical and biotech companies.		April 2024	Ongoing	Declare and participate
Neil Hawkins	Committee member	Financial	I am a Professor of Health Technology Assessment at the University of Glasgow, UK. From time to time this role may involve the provision of support for evaluations of technologies developed by academic and commercial entities.		April 2024	Ongoing	Declare and participate
Devavrata Joshi	Committee member	Financial	Senior Clinical Lecturer, Brunel Medical School, Brunel University	November 2023	April 2024	Ongoing	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Devavrata Joshi	Committee member	Financial	Salaried GP, Parkbury House Surgery	December 2022	April 2024	Ongoing	Declare and participate
Devavrata Joshi	Committee member	Financial	Shield Therapeutics – shareholdings (Pharmaceutical company – a commercial stage specialty pharmaceutical company with a focus on addressing iron deficiency with one compound, ferric maltol)	January 2021	April 2024	Ongoing	Declare and participate
Devavrata Joshi	Committee member	Financial	GP Fellow, Hertfordshire & West Essex ICB Part of the ICB team involved in the delivery and commissioning of diabetes care within the ICB	March 2023	April 2024	March 2024	Declare and participate
Devavrata Joshi	Committee member	Financial	AstraZeneca - shareholdings	July 2023	April 2024	April 2024	Declare and participate
Devavrata Joshi	Committee member	Non-Financial Professional and Personal Interest	NICE Guidance Committee Member – Otitis media with effusion in under 12s guideline Dates: 25.05.2022 - 30.08.2023	May 2022	April 2024	August 2023	Declare and participate
Michael Kolovetsios	Committee member	Financial & Indirect	I'm a Medtronic employee since November 2019. Medtronic is a large med-tech company with a comprehensive portfolio of products used in various clinical therapies, that at times are considered direct (or indirect) comparators in NICE med-tech evaluations.	November 2019	April 2024	Ongoing	Declare and participate
Jihad Malasi	Committee member	Nil	-	-	-	-	-
Avril McCarthy	Committee member	Nil	-	-	-	-	-
Naomi McVey	Committee member	Nil	-	-	-	-	-
Richard Packer	Committee member	Nil	-	-	-	-	-
Abdullah Pandor	Committee member	Financial	I have delivered online workshops on rapid reviews at international conferences (ISPOR) for	November 2021	April 2024	August 2023	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			which I received an honorarium. November 2021 and August 2023				
Abdullah Pandor	Committee member	Financial	I am an expert evaluator for Horizon Europe (EU Research and Innovation programme grant). I received payment for this role. May/June 2022 and May/June 2023	May 2022	April 2024	June 2023	Declare and participate
Abdullah Pandor	Committee member	Non-Financial Professional and Personal Interest	I am a standing member of the NIHR Health Technology Assessment General Funding Committee. 2022 (ongoing)		April 2024	Ongoing	Declare and participate
Abdullah Pandor	Committee member	Non-Financial Professional and Personal Interest	I am currently employed by the University of Sheffield whose job description includes bringing in research grant income primarily from sources such as the NIHR, Industry, Charitable Institutions, and other agencies (NICE and the Ministry of Health in Singapore).		April 2024	Ongoing	Declare and participate
Abdullah Pandor	Committee member	Non-Financial Professional and Personal Interest	I am also engaged in major academic research collaborations with various organisations (see https://www.fundingawards.nihr.ac.uk/ for detailed list of academic collaborators).		April 2024	Ongoing	Declare and participate
Abdullah Pandor	Committee member	Indirect	My spouse is an academic at the University of Sheffield. She has a similar research profile to mine and is also tasked with generating research grant income from sources such as the NIHR, Industry, Charitable Institutions, and other government agencies.		April 2024	Ongoing	Declare and participate
Jai Patel	Committee member	-	-	-	-	-	-
Elizabeth Schroeder	Committee member	-	-	-	-	-	-

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Jennie Walker	Committee member	-	-	-	-	-	-
Noemi Muszbek	Committee member	-	-	-	-	-	-
Paddy Storrie	Committee member	Indirect	My wife works for manufacturer Clinisupplies.		April 2024	Ongoing	Part 1 only

Medical Technologies Advisory Committee Interests Register

Topic: Intermittent urethral catheters for chronic incomplete bladder emptying in adults: late stage assessment
NICE's declaration of interest policy can be accessed [here](#)

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Daphne Colpman	Specialist Committee Member	Non-Financial Professional and Personal Interest	Multicath Study steering committee member - this study sought to examine the reuse of intermittent catheters. The steering committee met on an annual basis to discuss the strategic direction and governance of the study.	2013	July 2024	2024	Declare and Participate
Faizan Awan	Specialist Committee Member	None	-	-	-	-	-
Laura Rose	Specialist Committee Member	None	-	-	-	-	-
Mandy Fader	Specialist Committee Member	Financial Interest	Employed as an academic in the University of Southampton (lead for Bladder and Bowel research group)	2004	July 2024	Ongoing	Declare and Participate
Mandy Fader	Specialist Committee Member	Non-Financial Professional and Personal Interest	Chief Investigator of NIHR funded programme grant on the development and testing of a cleaning method for reusable intermittent catheters	2013	July 2024	Ongoing	Declare and Participate
Mandy Fader	Specialist Committee Member	Non-Financial Professional and Personal Interest	Author of Cochrane review of designs, strategies and techniques for intermittent catheterisation	2021	July 2024	Ongoing	Declare and Participate
Mandy Fader	Specialist Committee Member	Non-Financial Professional and Personal Interest	Board member of Health Innovation Wessex	2018	July 2024	Ongoing	Declare and Participate
Mandy Fader	Specialist Committee Member	Non-Financial Professional and Personal Interest	Governor, University Hospitals Southampton	2020	July 2024	Ongoing	Declare and Participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Marcus John Drake	Specialist Committee Member	Financial Interest	Director of "Dr MJ Drake Limited" for medicolegal and expert witness work	Prior to 2023	July 2024	Ongoing	Declare and Participate
Marcus John Drake	Specialist Committee Member	Non-Financial Professional and Personal Interest	Trustee of the International Continence Society (UK charity)	Before 2023	July 2024	Ongoing	Declare and Participate
Sarah Markham	Specialist Committee Member	None	-	-	-	-	-
Ann Yates	Professional Expert	Financial Interest	I sit on the Coloplast advisory Board for LUJA ISC catheter and contributed to a patient experience article recently published	2022	02/10/202	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Financial Interest	I sit on the BD advisory board for Purewick and development of patient outcome measures and patient experience forms	2021	02/10/202	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Financial Interest	Unplanned Admissions Consensus Committee (sponsored by BD) (member and now Chair) a multi-disciplinary national group that looks at preventing admission into hospital due to continence issues.	2018	02/10/2024	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Non-Financial Professional and Personal Interest	Chair of All Wales Continence Forum – a forum that represents all bladder and bowel specialists in Wales and reports directly to the Office of the Chief Nursing Officer for Wales	2006	02/10/202	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Non-Financial Professional and Personal Interest	Member of the Welsh Government task and finish for continence care – a task group that identified specific continence care issues across Wales and advised on how to improve.	2023	02/10/202	June 2024	Declare and Participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Ann Yates	Professional Expert	Non-Financial Professional and Personal Interest	Contributor to publications with regards to coloplast LUJA ISC catheters.	2022	02/10/2022	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Non-Financial Professional and Personal Interest	Have authored a number of published articles with regards to ISC which may have contributed to NICE information	2016	02/10/2022	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Indirect Interest	Chair of All Wales Continence Forum – a forum that represents all bladder and bowel specialists in Wales and reports directly to the Office of the Chief Nursing Officer for Wales	2006	02/10/2022	Ongoing	Declare and Participate
Ann Yates	Professional Expert	Indirect Interest	Have previously sat on the Hollister sponsored Consensus guidance for MS patients and contributed to the MS pathway		December 2024		Declare and Participate
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	Trustee Bladder Health UK Charity	2015	July 2024	2024	Declare and Participate
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	Chapple C, Abrams P, Lam T, Mangera A, Belal M, Curtis C, Emkes J, Hillery S, Irwin K, Logan K, Weston P, Yates A. A consensus statement on when to start clean intermittent self-catheterization: An untapped resource? Neurourol Urodyn. 2024 Feb;43(2):459-463. doi: 10.1002/nau.25353. Epub 2023 Dec 11. PMID: 38078751.	2023	July 2024	2024	Declare and Participate
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	University of Southampton with Professor Mandy Fader Margaret Macauley advisor for the website known as https://www.continenceproductadvisor.org/	2017	July 2024	Ongoing	Declare and Participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	Yates A, Weston P. Product evaluation of the Luja Micro-hole Zone Technology in clean intermittent self-catheterisation. Br J Nurs. 2024 May 9;33(9):S10-S15. doi: 10.12968/bjon.2024.33.9.S10. PMID: 38722003	2024	July 2024	Ongoing	Declare and Participate
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	Patient observer for MultiCath Trial whether mixed intermittent catheter use (using reusable catheters sometimes and single use catheters at other times) is no more likely to cause urinary tract infection than using single-use catheters only.	2019	July 2024	Ongoing	Declare and Participate
Jacqueline Emkes	Professional Expert	Non-Financial Professional and Personal Interest	I use Coloplast catheters. As previously declared spoke at two conferences funded by Coloplast in 2024. Conferences were about CISC in general. UTIs. No further events planned. Honoraria paid.	2024	November 2024	Ongoing	Declare and Participate
Keith Ford	Professional Expert	Non-Financial Professional and Personal Interest	I am an Ambassador for Coloplast and this has previously been declared.	May 2023	October 2024	Ongoing	Declare and Participate
Robin Ward	Professional Expert	Non-Financial Professional and Personal Interest	Publicly-elected Governor of the NCA Foundation Trust	July 2023	2024	Ongoing	Declare and Participate
Robin Ward	Professional Expert	Non-Financial Professional and Personal Interest	Lay member Greater Manchester Primary Care Digital Board	2022	2024	Ongoing	Declare and Participate
Sam Davison	Professional Expert	Financial Interest	Urinary catheterisation Best practice statement Funded by Becton Dickinson (BD)	2022	October 2024	2022	Declare and Participate
Sam Davison	Professional Expert	Financial Interest	Purewick Advisory Board Becton Dickinson (BD)	September 2023	October 2024	September 2023	Declare and Participate
Sam Davison	Professional Expert	Non-Financial Professional and Personal Interest	Infection Prevention Society (IPS) Indwelling device- related infection prevention practice (DRIPP)	2018	October 2024	Ongoing	Declare and Participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Sam Davison	Professional Expert	Indirect interest	I work as a Clinical Procurement Lead Nurse working with clinicians, NHS Supply Chain, Direct contact with suppliers and manufacturers. I promote a fair and standardized non-bias professional approach to advise and challenge all areas to source the best products for patient care at an affordable cost to the South Tees Hospitals NHSFT.	December 2020	October 2024	Ongoing	Declare and Participate
Soosie Cole	Professional expert	Non-Financial Professional and Personal Interest	I have 2 sponsored nursing posts in my team and I manage these positions, sponsored by B Braun, however this does not impact on my own professional judgement	2018	December 2024	Ongoing	Declare and Participate