GID-HTE10049 Intermittent urethral catheters for long-term urinary management in adults – Addendum 1

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Contents

1. Aim

The EAG completed a report for the late-stage assessment of urethral catheters for long-term urinary management in adults, which was discussed at MTAC in January 2025. Within that original report the External Assessment Group (EAG) attributed the presence of 8 catheter features defined in the NICE Final Scope (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) to intermittent catheter product lines using information provided by 12 companies who responded to NICE, company websites and published literature. However, catheter design and features were often poorly described, missing or open to interpretation and the EAG acknowledged that this may have resulted in cases of mis-categorisation. Additionally, there was no consensus on the definition or importance of intermittent catheter features among Clinical and Lay Experts. The EAG previously conducted component network meta-analysis (CNMA) for 5 outcomes which were prioritised by Clinical and Lay Experts (UTI, haematuria, residual volume, comfort and ease of use). However, there was a low number of studies and small samples of 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). Therefore, the EAG concluded that there was large uncertainty associated with the effectiveness of individual intermittent catheter features. The committee therefore decided there was not enough evidence to justify the pricing variation between intermittent catheters available on the NHS Drug Tariff.

The aim of this addendum is to: a) apply an alternative, independent categorisation of intermittent catheter lubrication types and features, supplied by one of the Specialist Committee Members supporting the late-stage assessment, and b) repeat the component network meta-analysis using the alternative categories. The EAG have considered this as an additional sensitivity analysis.

2. Methods

The categorisation of the intermittent catheters used in this addendum was developed by Prof Mandy Fader and team based on their previous extensive work where they requested samples of all the catheters listed on the Drug tariff, and

reviewed company websites. Prof Fader and team amended the categorisation of features (of catheters included in the original EAG report) to broadly align with their separate categorisation (Table 1). Regarding the categorisation process conducted by Prof Fader and team:

- Samples were obtained for some but not all catheters; an additional column was added to the table to make this distinction.
- Six groupings were applied to capture all the main differences between the type of lubricant and the method of application:
    - P1 - Plain (needs lubricant gel not supplied)
    - G1 – Gel (pre-lubricated)
    - G2 – Gel (integral sachet or reservoir)
    - H1 – Hydrophilic/coated (pre-lubricated)
    - H2 – Hydrophilic/coated (integral water/saline sachet)
    - H3 – Hydrophilic/coated (needs water not supplied)
- Five key features were assigned:
    - F1 – Integrated bag
    - F2 – Tip protector (separate)
    - F3 – Insertion aid/sleeve (gripper/handle combined)
    - F4 – Hard case
    - F5 – Micro-holes (noting that this is only available for 1 catheter).
- The team advised against including “no touch” as a feature, as this was considered hard to define with potential overlap with the “insertion aid/sleeve” feature.
- The team advised how they would have categorised catheters considered to have an integrated amphiphilic surfactant. GentleCath Air (Female) and GentleCath Air (Male) would have fallen into the H1 – Hydrophilic/coated (pre-lubricated) and H2 – Hydrophilic/coated (integral water/saline sachet) categories respectively. No evidence was available for these catheters, therefore they do not feature in the update component network meta-analysis (CNMA).

It is important to note that the description of lubrication methods applied by the EAG in the original EAG report directly corresponded to the separate categorisation conducted by Prof Fader and team, Table 2.

Table 2: Summary of lubrication methods between EAG and Prof Fader and team categorisation methods

Original categorisation of lubrication method (applied by EAG in original EAG report)	Updated categorisation of lubrication method (applied by Prof Fader and team)
U1 - Uncoated (non-lubricated)	P1 - Plain (needs lubricant gel not supplied)
U3 - Uncoated (pre-lubricated)	G1 – Gel (pre-lubricated)
U2 - Uncoated (self-lubricated)	G2 – Gel (integral sachet or reservoir)
H3 – Hydrophilic/coated (pre-activated)	H1 – Hydrophilic/coated (pre-lubricated)
H2 – Hydrophilic/coated (needs activation; water integrated into packaging)	H2 – Hydrophilic/coated (integral water/saline sachet)
H1 – Hydrophilic/coated (needs activation; water not provided)	H3 – Hydrophilic/coated (needs water not supplied)

The definitions of features included in the independent categorisation provided by Prof. Fader may have varied from those which are listed in the NICE Final Scope and has prevented a mapping between EAG categorisation in the EAR and the Prof Fader categories.

The EAG then applied the coded categorisation of lubrication method and features (described above), to the evidence included in the original EAG report, and re-ran the CNMA for the 5 outcomes where there was sufficient data: urinary tract infection (UTI), haematuria, discomfort, comfort, pain.

The EAG did not repeat CNMA for residual volume or ease of use outcomes. As described in the original EAG report:

- the EAG determined that it was inappropriate to perform a CNMA for this residual volume because of strong evidence of skewed data.
- the EAG considered it was not possible to conduct a CNMA for these outcomes because of 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 were available.

Table 1: Amended categorisation of intermittent catheters (for the studies in the included evidence)

Device	Comparative studies reporting use of the device (included in the original EAG report)	Samples reviewed (if N then website or comment)	Plain (needs lubricant gel – not supplied) (P1)	Gel - pre-lubricated (G1)	Gel – Integral sachet or reservoir (G2)	Hydrophilic/ coated - pre-lubricated (H1)	Hydrophilic/ coated - integral water/saline sachet (H2)	Hydrophilic/ coated - needs water - not supplied (H3)	Integrated bag (F1)	Tip Protection (Separate) (F2)	Insertion aid/sleeve (Gripper/Handle) (F3)	Hard Case (F4)	Micro-holes (F5)
Actreen Glys	Greghi (ESTIMA, 2022; e2522); Brazil	Y	-	Y	-	-	-	-	-	-	Y	-	-
Actreen Lite	Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321); Brazil	Y	-	Y	-	-	-	-	-	-	Y	-	-
Conveen	Cardenas (PM&R, 2011; 408-417); US, Canada De Ridder (Eur Urol, 2005; 991-995); Spain, Belgium	N – not available	Y	-	-	-	-	-	-	-	-	-	-
EasiCath	Biering-Sørensen (Spinal Cord, 1999; 299-300);Denmark Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]; the Netherlands Waller (Spinal Cord, 1997; 229-233); Sweden	Y	-	-	-	-	-	Y	-	-	-	-	-
Flocath Hydro Gel	Sarica (Eur J Phys Rehab Med, 2010; 473-480); Turkey	Y	-	-	-	-	-	Y	-	-	Y	-	-
Flocath Intro Gel	Sarica (Eur J Phys Rehab Med, 2010; 473-480); Turkey	N	-	Y	-	-	-	-	Y	Y	Y	-	-
LoFric	Biering-Sørensen (Spinal Cord, 1999; 299-300); Denmark Cardenas (Arch Phys Med Rehab, 2009; 1668-1671) Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]; the Netherlands Pascoe (Br J Nurs, 2001; 325-329); UK Waller (Spinal Cord, 1997; 229-233) Sweden	Y	-	-	-	-	-	Y	-	-	-	-	-

Device	Comparative studies reporting use of the device (included in the original EAG report)	Samples reviewed (if N then website or comment)	Plain (needs lubricant gel – not supplied) (P1)	Gel - pre-lubricated (G1)	Gel – Integral sachet or reservoir (G2)	Hydrophilic/ coated - pre-lubricated (H1)	Hydrophilic/ coated - integral water/saline sachet (H2)	Hydrophilic/ coated - needs water - not supplied (H3)	Integrated bag (F1)	Tip Protection (Separate) (F2)	Insertion aid/sleeve (Gripper/Handle) (F3)	Hard Case (F4)	Micro-holes (F5)
LoFric Primo	Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321); Brazil	Y	-	-	-	-	Y	-	-	-	Y	-	-
Luja	Athanasiadou (Nephrology Dialysis Transplantation, 2023; i250); Abstract/Poster, Denmark Landauro (J Wound Ostomy Continence, 2023; 504-511), Denmark Landauro (J Clin Med, 2023a; 5266); Denmark Thiruchelvam (Br J Nursing, 2024a; 834-843); Denmark, UK, France Thiruchelvam (Neurourology Urodynamics, 2024; 464-478); Denmark, France, Germany, UK	Y	-	-	-	Y	-	-	-	Y	Y	-	Y
Self-Cath with lubrication jelly	Gopalakrishnan (Continence Reports, 2022; 100010); Canada	Y	Y	-	-	-	-	-	-	-	-	-	-
SpeediCath	Athanasiadou (Nephrology Dialysis Transplantation, 2023; i250); Abstract/Poster; Denmark Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321); Brazil Cardenas (PM&R, 2011; 408-417); US, Canada Chartier-Kastler (Spinal Cord, 2011; 844-850) France, Denmark De Ridder (Eur Urol, 2005; 991-995); Spain, Belgium Domurath (Spinal Cord, 2011; 817-821); Germany Gopalakrishnan (Continence Reports, 2022; 100010); Canada	Y	-	-	-	Y	-	-	-	-	-	-	-

Device	Comparative studies reporting use of the device (included in the original EAG report)	Samples reviewed (if N then website or comment)	Plain (needs lubricant gel – not supplied) (P1)	Gel - pre-lubricated (G1)	Gel – Integral sachet or reservoir (G2)	Hydrophilic/ coated - pre-lubricated (H1)	Hydrophilic/ coated - integral water/saline sachet (H2)	Hydrophilic/ coated - needs water - not supplied (H3)	Integrated bag (F1)	Tip Protection (Separate) (F2)	Insertion aid/sleeve (Gripper/Handle) (F3)	Hard Case (F4)	Micro-holes (F5)
	Koenen (Proceedings Int Spinal Cord Soc, 2004) [Poster]; the Netherlands Pascoe (Br J Nurs, 2001; 325-329); UK												
SpeediCath Compact	Greghi (ESTIMA, 2022; e2522); Brazil	Y	-	-	-	Y	-	-	-	-	-	Y	-
SpeediCath Compact Eve	Thiruchelvam (Br J Nursing, 2024; 834-843); Denmark, UK, France	Y	-	-	-	Y	-	-	-	-	-	Y	-
SpeediCath Compact Male	Chartier-Kastler (Spinal Cord, 2011; 844-850) France, Denmark Domurath (Spinal Cord, 2011; 817-821); Germany	Y	-	-	-	Y	-	-	-	-	Y	Y	-
SpeediCath Flex	Landauro (J Wound Ostomy Continence, 2023; 504-511), Denmark Thiruchelvam (Neurourology Urodynamics, 2024; 464-478); Denmark, France, Germany, UK	Y	-	-	-	Y	-	-	-	Y	Y	-	-
Conventional uncoated PVC catheter	Bonello (ESTIMA Braz J Enterostomal Ther, 2021; e2321); Brazil Cardenas (Arch Phys Med Rehab, 2009; 1668-1671) Sarica (Eur J Phys Rehab Med, 2010; 473-480)	N	Y	-	-	-	-	-	-	-	-	-	-
VaPro	Landauro (J Clin Med, 2023; 5266); Denmark	Y	-	-	-	Y	-	-	-	Y	Y	-	-

Abbreviations: NR, Not Reported

3. Results

For the raw data for urinary tract infection (UTI), haematuria, discomfort, comfort and pain outcomes for the included studies with the categorisation of lubrication method and features see Appendix.

3.1 Urinary Tract Infection (UTI)

Table 2 summarizes the CNMA independent effects model for UTI. The initial model included all features identified in the included studies. However, 3 features were associated with a lack of convergence (because of very sparse data). Therefore, three features were retained in the final model:

- Hydrophilic/coated-pre-lubricated (H1)
- Hydrophilic/coated- needs water – not supplied (H3)
- Insertion aid/sleeve (Gripper/Handle) (F3)

Total residual deviance (mean=6.23 from 7 datapoints) suggested a reasonable goodness of fit for the model. The hydrophilic/coated – pre-lubricated feature was associated with a reduced risk of UTI with relative risk (RR) 0.60, 95% credible interval (CrI) 0.31 to 0.94. No further statistically significant risks were observed (Table 2). An independent effects model was used, which assumes the impact of each individual feature is independent (that is, no interaction effects between features). Total residual deviance suggests a reasonable goodness of fit (mean=6.23, from 7 datapoints). There were insufficient data to assess the goodness of fit of models with different assumptions.

Consistent with the previous EAG analysis of UTI outcomes, data for all features had wide 95% credible intervals and were judged to be of very low certainty. Only 3 studies could be included in the revised CNMA (using Prof Fader's categorisations), compared with 4 studies in the previous EAG analysis, as the 2 catheters compared in Waller et al. 1997 had effectively the same features under the alternative categorisation and therefore did not contribute substantially to effect estimates.

Table 2: Summary of CNMA results for UTI risk (k=3 studies)

	Hydrophilic/coated – pre-lubricated (H1) RR (95% CrI)	**Hydrophilic/coated – pre-lubricated** (H1) CINeMA rating	**Hydrophilic/coated - needs water - not supplied)** (H3) RR (95% CrI)	**Hydrophilic/coated - needs water - not supplied)** (H3) CINeMA rating	**Insertion aid/sleeve (Gripper/ Handle)** (F3) RR (95% CrI)	**Insertion aid/sleeve (Gripper/ Handle)** (F3) CINeMA rating
Independent (additive) effects model: compared with P1	0.60 (0.31 to 0.94)	Very Low[1,2,4]	0.91 (0.46 to 1.31)	Very Low[1,2,3]	0.40 (0.05 to 1.11)	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: one trial 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; CrI, Credible interval; RR, relative risk; UTI, Urinary tract infection; P1, uncoated plain catheter

3.2 Haematuria

The initial model included all features identified in the included studies. All features showed convergence within this model. Therefore, the features included in the final model were:

- Hydrophilic/coated-pre-lubricated (H1)
- Hydrophilic/coated- needs water – not supplied (H3)
- Tip protection (separate; F2)
- Insertion aid/sleeve (gripper/handle; F3)
- Hard case (F4)
- Micro-holes (F5)

In contrast with the previous EAG analyses, the fixed-effect model and random-effect model were similar, as the fixed-effect model is simpler, this was preferred:

- Random-effects model: lower deviance information criteria (DIC)=9.724, total residual deviance=5.46 from 6 datapoints

- Fixed effect model: DIC=8.15, total residual deviance=5.06 from 6 datapoint.

The hydrophilic/coated - needs water - not supplied feature showed statistically significant associated decrease of risk haematuria (RR 0.75, 95% CrI 0.64 to 0.86). No further statistically significant risks were observed (Table 3). Consistent with the previous EAG analysis of haematuria outcomes, data for all features were judged to be of very low certainty.

An independent effects model was used, which assumes the impact of each individual feature is independent (that is, no interaction effects between features).

The EAG highlight that only 2 of the studies incorporated in the CNMA reported on visible bleeding (which the clinical experts highlighted previously reported was relevant clinically):

- Chartier-Kastler et al. 2011 (non-inferiority RCT): reporting more visible bleeding over 2 weeks (2/36) with SpeediCath Compact Male (hydrophilic pre-lubricated catheter with insertion aid/sleeve and hard case) compared with SpeediCath Male (0/36) which is a hydrophilic pre-lubricated catheter with no additional features as per the amended categorisation.

- De Ridder et al. 2005 (RCT); reporting more bleeding over 12 months with SpeediCath (hydrophilic pre-lubricated catheter with no additional features; 38/55) compared with a plain catheter (no additional features; 32/59).

The EAG acknowledge that these findings may be confounded by the population or setting or the studies where increased bleeding was reported.

Table 3: Summary of CNMA results for haematuria risk (k=6 studies)

	Hydrophilic/coated – pre-lubricated (H1) RR (95% CrI)	**Hydrophilic/coated – pre-lubricated** (H1) CINeMA rating	**Hydrophilic/coated - needs water - not supplied** (H3) RR (95% CrI)	**Hydrophilic/coated - needs water - not supplied** (H3) CINeMA rating	**Tip protector** (F2) RR (95% CrI)	**Tip protector** (F2) CINeMA rating	**Insertion aid/sleeve** (F3) RR (95% CrI)	**Insertion aid/sleeve** (F3) CINeMA rating	**Hard case** (F4) RR (95% CrI)	**Hard case** (F4) CINeMA rating	**Micro-holes** (F5) RR (95% CrI)	**Micro-holes** (F5) CINeMA rating
Independent (additive) model (fixed effect): compared with P1	1.27 (0.94 to 1.60)	Very Low[1,2,3,4]	0.75 (0.64 to 0.86)	Very Low[1,2,3,4]	1.66 (0.09 to 2.27)	Very Low[1,2,3,4]	0.29 (0.02 to 1.45)	Very Low[1,2,3,4]	0.91 (0.00 to 2.29)	Very Low[1,2,3,4]	1.20 (0.00 to 2.29)	Very Low[1,2,3,4]

Key: [1] Major concerns due to heterogeneity: between-study SD=2.04 (95% CrI 0.14 to 8.00) [2] Some concerns due to risk of bias: most studies did not report sufficient information on allocation concealment or random sequence generation methods, [3]Major concerns due to imprecision: wide 95% CrI and limited weight in the CNMA, [4]Some concerns due to indirectness: two out of four studies used dipstick measures, clinical expert opinion judged these outcomes as unlikely to be clinically meaningful.

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis; CrI, Credible interval; RR, relative risk; P1, uncoated plain catheter

3.3 Discomfort

It was not possible to construct a network diagram for discomfort as the three included studies assessed for this outcome had two types of comparisons that did not form a network. However, as there are overlapping features in these studies, the EAG were able to conduct component network meta-analyses (CNMA) on individual features and explored random and fixed effect model approaches.

The initial model included all features identified in the included studies. However, the model failed to converge (because of very sparse data). Therefore, 2 features with more available data were retained in the final model (and compared with Hydrophilic/coated (pre-lubricated) (H1)):

- Insertion aid/sleeve (gripper/handle) (F3)
- Hard case (F4)

In common with the previous EAG analyses, the random-effects model was preferred because it fitted the data better:

- Random-effects model: lower DIC=0.79, total residual deviance=3.11 from 3 datapoints
- Fixed effect model: DIC=6.04, total residual deviance=9.45 from 3 datapoints

Table 4: Summary of CNMA results for discomfort (k=3 studies)

	Insertion aid/sleeve (gripper/handle) (F3) Mean difference (95% CrI)	**Insertion aid/sleeve (gripper/handle)** (F3) CINeMA rating	**Hard case** (F4) Mean difference (95% CrI)	**Hard case** (F4) CINeMA rating
Independent (additive) model (random effects): compared with H1	-0.83 (-3.98 to 2.39)	Very Low[1,2]	0.80 (-3.11 to 4.64)	Very Low[1,2]

Key:, [1] Major concerns due to risk of bias: most studies did not report sufficient information on allocation concealment or random sequence generation methods; lack of adjustment for cross-over [2]Major concerns due to imprecision: very wide 95% CrI

Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis; CrI, Credible interval; RR, relative risk; H1, hydrophilic/coated – pre-lubricated

In the previous EAG report, CNMA was judged infeasible due to a lack of convergence for all models. However, with the different categorisation, it was possible to estimate effects of insertion aid/sleeve (gripper/handle) (F3) and hard case (F4) features on the Visual Analogue Scale (VAS) compared with the hydrophilic/coated – pre-lubricated (H1) feature. Both features were associated with negligible differences in pain/discomfort compared with H1, but the 95% CrI was very wide indicating substantial uncertainty regarding estimates of the true level of pain/discomfort in an average patient.

3.4 Comfort

The initial model included all features identified in the included studies (except for the Hydrophilic/coated (needs water not supplied) (H3) vs Plain (needs lubricant gel not supplied) (P1) features as data from this study (Cardenas et al., 2011) did not connect to the rest of the network as noted above). There was a lack of convergence for all features in the CNMA.

Because there was only one trial (Cardenas et al. 2011) comparing H3 with Plain (needs lubricant gel not supplied) (P1) features, no meta-analyses were possible. Cardenas et al. found that a hydrophilic/coated - needs water - not supplied (H3) catheter was associated with a small improvement in comfort (SMD: 0.26, 95% CrI -0.21 to 0.73) compared with a plain catheter (P1) but with a wide 95% confidence interval indicating substantial uncertainty about the effectiveness of this feature. Therefore, in common with the previous EAG analysis, these data were rated as very low certainty because of major concerns with imprecision and risk of bias.

3.5 Pain

In common with the discomfort outcome above, it was not possible to construct a network diagram as the three included studies assessed two types of comparisons (Hydrophilic/coated (pre-lubricated) (H1) + Insertion aid/sleeve (gripper/handle) (F3) + Hard case (F4) vs H1 and Hydrophilic/coated (pre-lubricated) (H1) + Tip protector (separate) (F2) + Insertion aid/sleeve (gripper/handle) (F3) vs Hydrophilic/coated (pre-lubricated) (H1) + Hard case (F4)) that did not form a network. However, as there are overlapping features in these studies, the EAG were able to conduct component network meta-analyses (CNMA) on individual features and explored alternative model approaches.

The initial model included all features identified in the included studies. However, the model failed to converge (because of very sparse data). Therefore, 2 features with more available data were retained in the final model (and compared with Hydrophilic/ coated (pre-lubricated) (H1)):

- Insertion aid/sleeve (gripper/handle) (F3)
- Hard case (F4)

Goodness of fit statistics were similar for the random-effects and fixed effect models. Therefore, the simpler model (fixed effect) was preferred:

- Random-effects model: lower DIC=33.37, total residual deviance=6.10 from 6 datapoints
- Fixed effect model: DIC=31.56, total residual deviance=5.50 from 6 datapoints.

Table 5: Summary of CNMA results for pain risk (k=3 studies)

	Insertion aid/sleeve (gripper/handle) (F3) RR (95% CrI)	**Insertion aid/sleeve (gripper/handle)** (F3) CINeMA rating	**Hard case** (F4) RR (95% CrI)	**Hard case** (F4) CINeMA rating
Independent (additive) model (fixed effect): compared with H1	0.61 (0.33 to 0.90)	Very Low[1,2]	1.30 (1.06 to 1.63)	Very Low[1,2]

Key: [1] Major concerns due to risk of bias: most studies did not report sufficient information on allocation concealment or random sequence generation methods; most studies did not adjust for clustering [2]Some concerns due to imprecision: three small studies, insufficient number of events for valid estimation. Abbreviations: CINeMA: Confidence in Network Meta-analysis, CNMA, component network meta-analysis; CrI, Credible interval; RR, relative risk; H1, hydrophilic/coated – pre-lubricated

Insertion aid/sleeve features were associated with reduced risk of pain/discomfort (RR 0.61, 95% CrI 0.33 to 0.90) compared with a catheter with only hydrophilic/coated - pre-lubricated feature. However, this evidence was rated very low certainty due to high risk of bias and a very limited evidence base (3 small studies). There was evidence that a hard case was associated with a small increased risk of pain (RR 1.30, 95% CrI 1.06 to 1.63) compared with a catheter with

only hydrophilic/coated - pre-lubricated feature. However, this result lacks clinical plausibility as the case is for carrying the catheter and not used during insertion and may be related to population or setting of the trials included in this report. Therefore, while the feature converged within the model, it is likely the result is driven by the sparsity of the data. Additionally, evidence for this feature was also rated as very low certainty for the same reasons as above.

4. Conclusions

The updated component network meta-analysis (CNMA) based on an alternate definition and categorisation of intermittent catheter lubrication method and features by an independent team (Prof Fader and colleagues at University of Southampton) did not change the overall conclusions for the original EAG report and large uncertainty remains. In common with the previous EAG report and categorisation of features, all evidence was rated as very low certainty. Additional evidence demonstrating the effectiveness of features is still required.

A key strength of this work is the application of an independent categorisation of lubrication methods and features by an independent team who had physical samples for the majority of intermittent catheters to enable to support their categorisation. This is important given that there is a lack of description on the NHS Drug Tariff and inconsistent terminology on company websites, impacting those prescribing the intermittent catheters and informed patient selection of a catheter that will meet their needs and preferences.

A key limitation is the lack of comparative evidence for intermittent catheters and their features. Re-categorisation of features has not increased the level of certainty associated with the effectiveness of individual intermittent catheter features; therefore, future evidence generation recommendations listed in the original EAG report remain. Even where CNMA was possible, it did not seek to establish the causal mechanisms by which features influence outcomes (for example hard case and pain) and the CNMA may be confounded by the population or setting of the studies included in analysis.

The use of an alternative categorisation method led to some minor differences compared with the previous EAG report. In this addendum we were able to provide CNMA results for discomfort and pain outcomes, whereas these models failed to converge in the EAG previous analyses. However, it should be noted that these new results were based on sparse data, and as noted above, very low certainty evidence. Therefore, these new analyses do not substantially change the EAG's conclusions. Models for the comfort outcome, using the new categorisation, failed to converge. Whereas CNMA models converged using the EAG's original categorisation. As above, these minor differences make little impact on the EAG's conclusions since all evidence was judged to be very low certainty.

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6. Appendix - summary of included studies

UTI

Study	Study design	Intervention features (refer to Table 1)	Comparator features (refer to Table 1)	Intervention: UTI/30 days	Comparator: UTI/30 days
De Ridder (Eur Urol, 2005; 991-995)	RCT	H1	P1	≥1 UTIs: 39/61 (64%) in 12 months	≥1 UTIs: 51/62 (82%) in 12 months
Sarica (Eur J Phys Rehab Med, 2010; 473-480)	Crossover RCT	*Intervention 1:* G1, F1, F2, F3 *Intervention 2:* H3, F3	P1	Intervention 1: 1/25 in 6 weeks; Intervention 2: 1/25 in 6 weeks	4/25 in 6 weeks
Cardenas (Arch Phys Med Rehabil, 2009; 1668-1671)	RCT (n=56)	H3	P1	12/22 (54%) in 12 months	14/23 (61%) in 12 months
Waller (Spinal Cord, 1997; 229-233)	Crossover RCT (n=14)	H3	H3	2/14 patients within 10 days	3/14 patients within 10 days

Haematuria

Study	Study design	Intervention features (refer to Table 1)	Comparator features (refer to Table 1)	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	H1, F2, F3, F5	H1, F2, F3	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	H1, F2, F3, F5	H1, F2, F3	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	H1, F2, F3, F5	H1, F2, F3	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	H3	P1	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)	H1, F3, F4	H1	Visible bleeding	5.6% (2/36) over 2 weeks	0% (0/36) over 2 weeks	-
De Ridder (Eur Urol, 2005; 991-995)	RCT	H1	P1	Visible bleeding	69% (38/55) over 12 months	54% (32/59) over 12 months	-

Discomfort, comfort or pain

Study	Study design	Intervention features (refer to Table 1)	Comparator features (refer to Table 1)	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)	H1, F3, F4	H1	Discomfort (VAS)	10.1 (16.65) mm	6.8 (9.77) mm	p=0.30
Greghi (ESTIMA, 2022; e2522);	Prospective cohort (n=50)	G1, F3	H1, F3, F4	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)	H1, F3, F4	H1	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	H1, F2, F3, F5	H1, F4	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	H1, F2, F3, F5	H1, F4	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	H1, F2, F3, F5	H1, F4	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	H1, F2, F3, F5	H1, F4	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	H1, F2, F3, F5	H1, F4	Gentle to empty	55 strongly agree 16 agree 3 neither 1 disagree 0 strongly disagree 0 don't know 3 not applicable	32 strongly agree 30 agree 3 neither 6 disagree 4 strongly disagree 0 don't know 2 not applicable	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)	H1, F3, F4	H1	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	H3	P1	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	H1, F2, F3, F5	H1, F4	Gentle to insert	51 strongly agree 19 agree 1 neither 2 disagree 2 strongly disagree 0 don't know 3 not applicable	29 strongly agree 32 agree 3 neither 5 disagree 5 strongly disagree 0 don't know 3 not applicable	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)	H1, F3, F4	H1	No pain	80.0% (24/36)	73.3% (22/36)	p=0.6675
Domurath (Spinal Cord, 2011; 817-821)	Cross-over RCT (non-inferiority)	H1, F3, F4	H1	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	H1, F2, F3, F5	H1, F4	Pinching or stinging	1 strongly agree 3 agree 2 neither 27 disagree 42 strongly disagree 0 don't know 3 not applicable	7 strongly agree 11 agree 5 neither 24 disagree 26 strongly disagree 0 don't know 4 not applicable	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)	H1, F3, F4	H1	No stinging	80% (24/36)	76.6% (23/36)	p=0.6831

Study	Study design	Intervention features (refer to Table 1)	Comparator features (refer to Table 1)	Outcome measure	Outcome in intervention arm	Outcome in comparator arm	Difference (intervention-comparator): mean (SD)
Thiruchelvam (Neurourology Urodynamics, 2024b; 464-478)	Cross-over RCT	H1, F2, F3, F5	H1, F2, F3	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)	H1, F3, F4	H1	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)	H1, F3, F4	H1	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	H3	P1	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	H1, F2, F3, F5	H1, F4	Gentle to withdraw	54 strongly agree 18 agree 1 neither 3 disagree 0 strongly disagree 0 don't know 2 not applicable	26 strongly agree 28 agree 5 neither 7 disagree 7 strongly disagree 0 don't know 4 not applicable	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)	H1	P1	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)	H1	P1	Did not feel pain (Likert scale: 1 strongly disagree to 5 strongly agree)	4 [4, 5]	4 [3, 5]	p=0.173
Greghi (ESTIMA, 2022; e2522);	Prospective cohort (n=50)	G1, F3	H1, F3, F4	Feeling while using the catheter [scale unclear]	Median: 3	Median 3	p=0.272