

Urinary incontinence and pelvic organ prolapse in women: management

[K] Evidence review for assessing mesh complications after pelvic floor mesh surgery

NICE guideline NG123

Evidence reviews

April 2019

Final

These evidence reviews were developed by the National Guideline Alliance hosted by the Royal College of Obstetricians and Gynaecologists

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#). All NICE guidance is subject to regular review and may be updated or withdrawn.

Copyright

© NICE 2019. All rights reserved. Subject to [Notice of rights](#).

ISBN: 978-1-4731-3319-8

Contents

Assessment of mesh complications following pelvic floor mesh surgery	6
Review question	6
Introduction	6
Summary of the protocol	6
For further details see the review protocol in appendix A.....	8
Methods and process	8
Clinical evidence	8
Summary of clinical studies included in the evidence review	9
Quality assessment of clinical studies included in the evidence review	9
Economic evidence	9
Summary of studies included in the economic evidence review.....	9
Economic model.....	9
Clinical evidence statements	9
Economic evidence statements	9
Table 1 Investigations for assessing suspected mesh-related complications. Error! Bookmark not defined.	
Research recommendations.....	13
The committee’s discussion of the evidence.....	13
References.....	15
Appendices.....	16
Appendix A – Review protocols	16
Review protocol for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	16
Appendix B – Literature search strategies	23
Literature search strategies for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?.....	23
Appendix C – Clinical evidence study selection	27
Clinical evidence study selection for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?.....	27
Appendix D – Clinical evidence tables	28
Clinical evidence tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?.....	28
Appendix E – Forest plots.....	29
Forest plots for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	29

Appendix F – GRADE tables	30
GRADE tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	30
Appendix G – Economic evidence study selection.....	31
Economic evidence study selection for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	31
Appendix H – Economic evidence tables.....	32
Economic evidence tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	32
Appendix I – Health economic evidence profiles.....	33
Economic evidence profiles for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	33
Appendix J – Health economic analysis.....	34
Economic evidence analysis for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	34
Appendix K – Excluded studies	35
Excluded studies for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	35
Clinical studies	35
Economic studies	43
Appendix L – Research recommendations	44
Research recommendations for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?	44

Assessment of mesh complications following pelvic floor mesh surgery

Review question

What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

Introduction

Complications from pelvic floor mesh surgery can cause significant morbidity for women. Clinical assessment of women suffering from these complications can vary in clinical practice. A standardised approach to care would help to guide clinicians when assessing such complex cases and ensure women receive appropriate care. The Mesh Oversight Group Report, July 2017, advised that women with mesh complications should be seen in a specialised mesh centre offering a multidisciplinary team approach consisting of urogynaecology, urology, specialist radiology, specialist pain management and specialist diagnostic medical / allied health professional team members. This review aims to determine the most effective clinical framework for assessing mesh complications to inform clinical management decisions.

Summary of the protocol

Please see Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO Table)

Population	<p>Women who have undergone surgery using any type of mesh for UI or POP and who have suspected mesh complications of any stage or severity.</p> <ul style="list-style-type: none"> • Vaginal complications (mesh extruding into the vagina, called exposure or erosion, and infection) • Urinary complications (mesh extruding into urinary tract, fistula, voiding difficulties) • Bowel complications (mesh extruding into bowel, fistula, bowel obstruction) • Pain (can be pelvic, vaginal, buttock, thigh) • Sexual dysfunction <p>Studies with indirect populations (such as women with vaginal, urinary or bowel symptoms, pain or sexual dysfunction that is not considered related to their previous mesh surgery) will not be considered.</p> <p>Exclusions</p> <ul style="list-style-type: none"> • Women with chronic pelvic pain, sexual dysfunction, vaginal, urinary or bowel symptoms which were known to be due to pre-existing conditions and not due to mesh complication
-------------------	--

	<ul style="list-style-type: none"> • Studies with mixed populations of women with pain, sexual dysfunction, vaginal urinary or bowel symptoms of which less than 66% have a confirmed diagnosis of mesh complication
Intervention	<p>We will include any of the following assessment strategies (alone or in combination) prior to treatment:</p> <ul style="list-style-type: none"> • Clinical history and examination • Imaging <ul style="list-style-type: none"> ○ Translabial or transperineal ultrasound (for vaginally inserted mesh) ○ MRI ○ CT • Examination under anaesthetic (EUA) and direct visual examination <ul style="list-style-type: none"> ○ EUA and Cystoscopy (for vaginal, urinary complications, pain and sexual dysfunction) ○ EUA and Sigmoidoscopy (for bowel complications) • Validated sexual health questionnaire (for sexual dysfunction) <ul style="list-style-type: none"> ○ ePAQ, PISQ, Female Sexual Function Index (FSFI) • Validated pain score (for pain) <ul style="list-style-type: none"> ○ such as Brief Pain Inventory • Urodynamic tests (for urinary complications)
Comparison	<p>Head to head comparisons of assessment strategies prior to treatment (alone or in combination).</p> <p>We anticipate women to receive treatment following assessment; however the comparisons of interest will only relate to assessment methods.</p> <p>Assessments will only be compared in situations when the intervention is consistent; i.e. we will compare assessment X to Assessment Y, only when the treatment the women have received is the same.</p>
Outcomes	<p>Critical</p> <ul style="list-style-type: none"> • Patient satisfaction <ul style="list-style-type: none"> ○ PGI-I ○ PGI-S ○ Self-reported • Symptoms and Quality of life <ul style="list-style-type: none"> ○ Self-reported symptoms (all complications) ○ ePAQ (all complications) ○ PIS-Q (sexual dysfunction) ○ For UI <ul style="list-style-type: none"> - ICIQ - BFLUTS - I-QOL - SUIQQ - UISS - SEAPI-QMM

- ISI
- KHQ
 - o For POP
- POP-SS
- ICIQ-VS
- PFIQ-7/PFDI-20
 - o Pain relief (measured using validated scales specific to UI and/or POP; in their absence, we will consider the use of VAS or the number of women experiencing – or not- improvement of their pain (i.e., a dichotomous outcome)
- Adverse events associated with testing

Important

- Change in clinical management

BFLUTS: Bristol Female Lower Urinary Tract Symptoms; CT: Computed Tomography; ePAQ: Electronic Personal Assessment Questionnaire; EUA: Examination Under Anaesthetic; FSFI: Female Sexual Function Index; ICIQ: International Consultation Incontinence Questionnaire; ICIQ-VS: International Consultation Incontinence Questionnaire – Vaginal Symptoms; IQOL: Urinary Incontinence Quality of Life Scale; IQOL: Urinary Incontinence Quality of Life Scale; ISI: Incontinence Quality of Life Scale; KHQ: Kings Health Questionnaire; MRI: Magnetic Resonance Imaging; PFDI-20: Pelvic Floor Dysfunction Index – short form; PFIQ-7: Pelvic Floor Impact Questionnaire – short form; PGI-I: Patient Global Impression of Severity; PSIQ: Pelvic Organ Prolapse/Incontinence Sexual Questionnaire; POP: Pelvic Organ Prolapse; POP-SS: Pelvic Organ Prolapse Symptom Score; SEAPI-QMM: Stress-Related Leak, Emptying, Anatomy, Protection, Inhibition, Quality of Life, Mobility and Mental Status Incontinence Classification System; SUIQQ: Stress and Urgency Incontinence and Quality of Life Questionnaire; UI: Urinary Incontinence

For further details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in [Developing NICE guidelines: the manual 2014](#). Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary material C.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to NICE's 2018 [conflicts of interest policy](#). Those interests declared until April 2018 were reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

A systematic review of the clinical literature was conducted but no studies were found which were applicable to this review question.

See the literature search strategy in appendix B and the study selection flow chart in appendix C.

Excluded studies

Studies excluded from the review and reasons for their exclusion are provided in appendix K.

Summary of clinical studies included in the evidence review

No studies were found which were applicable to this review question.

Quality assessment of clinical studies included in the evidence review

No clinical evidence was found for this review (and so no quality assessment was undertaken and there are no GRADE tables in appendix F).

Economic evidence**Included studies**

A systematic review of the economic literature was conducted but no studies were identified which were applicable to this review question. See supplementary material D for further information.

Excluded studies

No studies were found which were applicable to this review question.

Summary of studies included in the economic evidence review

No economic evaluations were found which were applicable to this review question.

Economic model

This question was not prioritised for economic modelling because the evidence to base this on was anticipated to be limited.

Clinical evidence statements

No clinical evidence was found which was applicable to this review question.

Economic evidence statements

No studies were found which were applicable to this review question.

Table 2: Investigations for assessing suspected mesh-related complications¹

Individualised investigation plans may include, but are not limited to, one or more of these investigations.			
Investigation	Type of mesh	Indications	Benefits and risks
Examination under anaesthesia	All types of mesh	Pain or suspected: <ul style="list-style-type: none"> • Vaginal or rectal exposure or extrusion. • Sinus tract, urinary or bowel fistula. 	Benefits Allows diagnosis when not revealed by awake examination or when an awake examination is not tolerated.
			Risks Anaesthetic risk.
Cystourethroscopy	All types of mesh	Suspected: <ul style="list-style-type: none"> • Urethral perforation. • Bladder perforation. • Fistula. • Calculus on suture or mesh material. 	Benefits <ul style="list-style-type: none"> • Allows diagnosis by direct visualisation. • Aids management planning.
			Risks Anaesthetic risk and risk of urinary tract infection.
Sigmoidoscopy	Abdominally, laparoscopically or vaginally placed mesh for pelvic organ prolapse	Suspected bowel perforation by mesh	Benefits <ul style="list-style-type: none"> • Allows diagnosis by direct visualisation. • Aids management planning.
			Risks <ul style="list-style-type: none"> • Anaesthetic risk if carried out under anaesthetic. • Risk of bowel perforation.
Laparoscopy	Abdominally or laparoscopically placed mesh for pelvic organ prolapse	<ul style="list-style-type: none"> • Pain. • Suspected bowel entrapment around mesh. • Suspected adhesions 	Benefits <ul style="list-style-type: none"> • Allows diagnosis by direct visualisation. • Aids management planning.

¹ This table is based on committee consensus on the range of investigation's that may be helpful in the assessment mesh-related complications.

		secondary to mesh placement.	<p>Risks</p> <ul style="list-style-type: none"> • Anaesthetic risk. • Risks of laparoscopy, including bowel injury.
MRI. protocolled and reported by a clinician with experience in interpreting mesh complications	All types of mesh	<ul style="list-style-type: none"> • Suspected mesh infection. • Anatomical mapping of suspected fistula. • Anatomical mapping and mesh localisation to guide further surgery. • Back pain following abdominal mesh placement with mesh attachment to sacral promontory. • Identification of discitis or osteomyelitis. 	<p>Benefits</p> <ul style="list-style-type: none"> • Shows implanted material and complications nearby. • Shows location of mesh in relation to the vaginal wall and sacrum.
			<p>Risks</p> <p>Generally regarded as safe, with a low risk of short- and long-term harms. Risk of contrast media injection.</p>
Ultrasound scan (transperineal, transvaginal or translabial, or 3D), performed and reported by a clinician with experience in interpreting mesh complications	Vaginally placed mesh to treat incontinence	<ul style="list-style-type: none"> • Pain. • Voiding dysfunction. • Suspected infection. • Suspected urethral mesh perforation. • Anatomical mapping to guide excision surgery. 	<p>Benefits</p> <ul style="list-style-type: none"> • Shows implanted material and local complications. • Identifies mid-urethral slings. • Shows location of mesh in relation to the vaginal wall and urethra.
			<p>Risks</p> <p>Discomfort</p>
CT	All types of mesh, although CT is not commonly used to show	<p>Suspected:</p> <ul style="list-style-type: none"> • Urinary tract injury. • Bowel injury. • Bowel obstruction. 	<p>Benefits</p> <p>May be useful in assessing for urinary fistulae or bowel injury.</p>

	implanted material		Risks Potential radiation-related harms and risk of contrast media injection.
Fluoroscopic studies (cystography or contrast enema)* *Perform with water-soluble contrast media. Fluoroscopic studies and CT may be used according to local preference and expertise.	All types of mesh	Suspected: • Urinary or bowel fistula.	Benefits Aids management planning.
			Risks Potential radiation-related harms.
Urinary flow studies and post-void residual volume assessment or cystometry	All types of mesh	• Voiding dysfunction. • Urinary incontinence.	Benefits Aids management planning.
			Risks Urinary tract infection and radiation risks if fluoroscopy is used.
Neurophysiology, including nerve conduction studies *	All types of mesh	Suspected: • Nerve injury.	Benefits Allows diagnosis of impaired nerve function.
			Risks Nerve conduction studies are difficult to perform and can induce more pain.

Research recommendations

What is the effectiveness of ultrasound-guided visualisation compared with clinical assessment to identify complications after mesh surgery for stress urinary incontinence or pelvic organ prolapse in women?

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee prioritised patient satisfaction, symptoms and quality of life scales and adverse events as critical outcomes. Change in clinical management was prioritised as an important outcome by the committee.

The quality of the evidence

No clinical evidence on the assessment of mesh complications was found for this review.

Benefits and harms

No clinical evidence on the assessment of mesh complications was found for this review and therefore all the recommendations are based on the committee's expertise and experience and developed by consensus.

Women presenting with new symptoms after mesh surgery for urinary incontinence or prolapse which are thought to be caused by a mesh-related complication may present with a variety of symptoms which may not appear to be obviously related to the previous surgery but need to be fully evaluated. Women report that there is often a delay between them presenting with symptoms and having a mesh complication diagnosed and managed. The committee agreed that greater awareness of the possibility of a mesh complication was needed in both primary and secondary care to facilitate prompt referral and treatment.

The committee agreed that it was important for women with a suspected mesh-related complication to be referred to a specialist for assessment and to determine the likelihood of mesh being the underlying cause of the symptoms.

The committee agreed that women with a confirmed mesh-related complication should be referred to a centre specialising in the diagnosis and management of mesh-related complications. The committee was aware that small asymptomatic exposures may heal with no treatment or treatment with oestrogen and that this could be done locally by a specialist urologist or urogynaecologist, before referring to the more specialist centre.

No evidence was found to guide these recommendations and the committee agreed that due to the complexity of the clinical problems encountered, each patient would need an individual plan for assessment by the specialist mesh centre, the committee was clear that women should be referred for specialist evaluation when mesh complications are suspected.

The committee was aware that the procedures used to assess and investigate mesh complications will depend on the nature of the initial surgical procedure, the type of material that was implanted, and the type of complication(s) experienced by women. Each assessment procedure will have specific benefits and harms associated with it,

and the committee outlined these based on their expertise and experience in a table to aid discussion and shared decision making. The committee agreed that the specialist should take a detailed history of the woman's surgical procedures, to determine a full clinical picture. The history should include, type of mesh used, site of mesh placement, and date of mesh placement. Validated tools should be used to aid assessment, which may include a pelvic floor symptom questionnaire and a pain questionnaire. Vaginal examinations will be required to determine whether the mesh is exposed or extruding, it may also be necessary to conduct rectal and neurological examinations. Individualised investigation plans may include, but are not limited to, one or more of the investigations detailed in the table above (Investigations for assessing suspected mesh-related complications).

They noted that these need to be considered when developing individualised investigation plans for women with suspected mesh complications.

Due to the limited evidence for assessing complications of mesh surgery via ultrasound-guided visualisation the committee made a research recommendation. This is important because ultrasound can be used to evaluate the position of mid-urethral tapes. Many women request an ultrasound as they have been advised by other women that ultrasound can diagnose and guide management of mesh complications. However, there is no data available to support this and providing this investigation to all women presenting with problems following insertion of mid-urethral tape has significant resource implications for the NHS. The committee considered it was important for further research to ascertain whether ultrasound has a benefit in the management of mesh complications.

Cost effectiveness and resource use

No economic evidence on the most effective strategy for assessing women with mesh complications was available.

The committee was aware that some diagnostic and management procedures could safely be carried out locally in secondary care clinics.

The committee explained that there could be resource implications in:

- referring women who are suspected of having a mesh complication to a urogynaecologist or urologist for assessment,
- referring women with a confirmed mesh complication or unexplained symptoms following a mesh procedure to a centre specialising in the diagnosis and management of mesh complications
- planning an individualised investigation.

However, they believed that the use of the resources to set up and provide such services are justifiable since it is essential to ensure that women with such complications get appropriate care.

The committee acknowledged that the management of mesh complications can require expensive surgical management. For example, mesh revision is a complicated procedure that may involve a series of costly operations and relatively few surgeons have the skills and experience needed to ensure a successful outcome. Therefore it is very important that such care is provided by qualified specialist services that have expertise in dealing with such problems.

The committee felt that if such assessment and individualised specialist care led to the timely identification and appropriate treatment of mesh complications then the additional costs associated with providing this care would probably be outweighed

by the long-term improvements in health outcomes, health-related quality of life, and the potential cost savings to the NHS, given that delays in appropriate care exacerbate the symptoms and may lead to permanent serious problems.

Overall, the committee believed that providing timely access to specialist assessment and management may prevent the need for expensive secondary care at a later stage, result in significant impact on women's health, and lead to an overall saving to the NHS.

Other factors the committee took into account

The Mesh Oversight Group Report suggested that awareness of mesh complications and appropriate care pathways in primary care was a problem. In response NHS England have created a [resource](#) for health professionals and patients describing some of the signs and symptoms of mesh complications, as well as where to refer women.

References

No studies were found which were applicable to this review question

Appendices

Appendix A – Review protocols

Review protocol for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

Table 3: Review protocol for what is the most effective strategy for assessing mesh complications of sexual dysfunction, pain, vaginal, urinary and bowel complications after mesh surgery?

Field (based on PRISMA-P)	Content
Review question	What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?
Type of review question	Intervention
Objective of the review	<p>The recent Mesh Oversight Group Report, July 2017 states that all women with mesh complications should be seen in a specialised mesh centre offering a multi-disciplinary team approach (consisting of urogynaecology, urology, specialist radiology, colorectal surgeon, specialist pain management and specialist diagnostic medical / allied health professional team members).</p> <p>The aim of this review is to determine the most effective framework for assessing mesh complications to inform management decisions.</p>
Eligibility criteria – population/disease/condition/issue/domain	<p>Women who have undergone surgery using any type of mesh for UI or POP and who have suspected mesh complications of any stage or severity.</p> <ul style="list-style-type: none"> • Vaginal complications (mesh extruding into the vagina, called exposure or erosion, and infection) • Urinary complications (mesh extruding into urinary tract, fistula, voiding difficulties) • Bowel complications (mesh extruding into bowel, fistula, bowel obstruction) • Pain (can be pelvic, vaginal, buttock, thigh) • Sexual dysfunction

Field (based on PRISMA-P)	Content
	<p>Studies with indirect populations (such as women with vaginal, urinary or bowel symptoms, pain or sexual dysfunction that is not considered related to their previous mesh surgery) will not be considered.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Women with chronic pelvic pain, sexual dysfunction, vaginal, urinary or bowel symptoms which were known to be due to pre-existing conditions and not due to mesh complication. • Studies with mixed populations of women with pain, sexual dysfunction, vaginal urinary or bowel symptoms of which less than 66% have a confirmed diagnosis of mesh complication
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	<p>We will include any of the following assessment strategies (alone or in combination) prior to treatment:</p> <ul style="list-style-type: none"> • Clinical history and examination • Imaging <ul style="list-style-type: none"> ○ Translabial or transperineal ultrasound (for vaginally inserted mesh) ○ MRI ○ CT • Examination under anaesthetic (EUA) and direct visual examination <ul style="list-style-type: none"> ○ EUA and Cystoscopy (for vaginal, urinary complications, pain and sexual dysfunction) ○ EUA and Sigmoidoscopy (for bowel complications) • Validated sexual health questionnaire (for sexual dysfunction) <ul style="list-style-type: none"> ○ ePAQ, PISQ, Female Sexual Function Index (FSFI) • Validated pain score (for pain) <ul style="list-style-type: none"> ○ such as Brief Pain Inventory • Urodynamic tests (for urinary complications)

Field (based on PRISMA-P)	Content
Eligibility criteria – comparator(s)/control or reference (gold) standard	<p>Head to head comparisons of assessment strategies prior to treatment (alone or in combination).</p> <p>We anticipate women to receive treatment following assessment; however the comparisons of interest will only relate to assessment methods.</p> <p>Assessments will only be compared in situations when the intervention is consistent; i.e. we will compare assessment X to Assessment Y, only when the treatment the women have received is the same.</p>
Outcomes and prioritisation	<p>Critical</p> <ul style="list-style-type: none"> • Patient satisfaction <ul style="list-style-type: none"> ○ PGI-I ○ PGI-S ○ Self-reported • Symptoms and Quality of life <ul style="list-style-type: none"> ○ Self-reported symptoms (all complications) ○ ePAQ (all complications) ○ PIS-Q (sexual dysfunction) ○ For UI <ul style="list-style-type: none"> - ICIQ - BFLUTS - I-QOL - SUIQQ - UISS - SEAPI-QMM - ISI - KHQ ○ For POP <ul style="list-style-type: none"> - POP-SS - ICIQ-VS - PFIQ-7/PFDI-20

Field (based on PRISMA-P)	Content
	<ul style="list-style-type: none"> ○ Pain relief (measured using validated scales specific to UI and/or POP; in their absence, we will consider the use of VAS or the number of women experiencing – or not- improvement of their pain (i.e., a dichotomous outcome)) ● Adverse events associated with testing <p>Important Change in clinical management</p>
Eligibility criteria – study design	Systematic reviews of RCTs RCTs Comparative cohort studies will be included in the absence of evidence from RCT's.
Other inclusion exclusion criteria	<p>Exclusions Patients with neurological disease will be excluded. No restriction on number of participants. No date restriction.</p>
Proposed sensitivity/sub-group analysis, or meta-regression	<p>Groups that will be reviewed and analysed separately:</p> <p>Pre-specified sub-group analyses:</p> <ul style="list-style-type: none"> ● Surgery for UI and surgery for POP ● Site of mesh insertion <ul style="list-style-type: none"> ○ Vaginally inserted mesh – for incontinence or prolapse ○ Abdominally inserted mesh ● Type of complication <ul style="list-style-type: none"> ○ Vaginal symptoms ○ Urinary symptoms ○ Bowel symptoms ○ Pain ○ Sexual dysfunction ● Type of mesh <ul style="list-style-type: none"> ○ Synthetic

Field (based on PRISMA-P)	Content
	<ul style="list-style-type: none"> ○ Biological <p>Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available:</p> <ul style="list-style-type: none"> ● older women ● women with physical disabilities ● women with cognitive impairment <p>Special consideration of women who are considering future pregnancy was not prioritised for this question.</p> <p>Important confounders (when comparative observational studies are included for interventional reviews):</p> <ul style="list-style-type: none"> ● Age ● Severity ● Prior interventions
Selection process – duplicate screening/selection/analysis	Duplicate screening will be performed using STAR - minimum sample size is 10% of the total for <1000 titles and abstracts, and 5% of the total for ≥1000 titles and abstracts. All discrepancies are discussed and resolved between 2 screeners. Any disputes will be resolved in discussion with the Senior Systematic Reviewer. Data extraction will be supervised by a senior reviewer. Draft excluded studies and evidence tables will be discussed with the Topic Advisor, prior to circulation to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	<p>Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5).</p> <p>'GRADEpro' will be used to assess the quality of evidence for each outcome.</p> <p>STAR will be used for:</p> <ul style="list-style-type: none"> ● bibliographies/citations, text mining, and study sifting ● Data extraction and quality assessment/critical appraisal

Field (based on PRISMA-P)	Content
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Apply standard animal/non-English language exclusion Limit to RCTs and systematic reviews in first instance but download all results Dates from 1995. Studies published post 1995 will be considered for this review question as the GC believed that this was an appropriate threshold for studies representing current practice For details please see appendix B of the full guideline.
Identify if an update	New area of the guideline.
Author contacts	Developer: The National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10035 .
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014 .
Search strategy – for one database	For details please see appendix B of the full guideline.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014 The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the ‘Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox’ developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014 .

Field (based on PRISMA-P)	Content
Methods for analysis – combining studies and exploring (in)consistency	For details please see the methods chapter of the full guideline.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014 . If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	The GRADE approach was used. For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014 .
Rationale/context – Current management	For details please see the introduction to the evidence review in the full guideline.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual 2014 . Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter of the full guideline.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

Appendix B – Literature search strategies

Literature search strategies for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

Database: Medline & Embase (Multifile)

Last searched on Embase Classic+Embase 1947 to 2017 August 04, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present,

Date of last search: 8th August 2017.

#	Searches
1	exp Pelvic Organ Prolapse/ use ppez
2	exp pelvic organ prolapse/ use emczd
3	(pelvic\$ adj3 organ\$ adj3 prolaps\$).tw.
4	(urinary adj3 bladder adj3 prolaps\$).tw.
5	((vagin\$ or urogenital\$ or genit\$ or uter\$ or viscer\$ or anterior\$ or posterior\$ or apical or pelvi\$ or vault\$ or urethr\$ or bladder\$) adj3 prolaps\$).tw.
6	(splachnoptos\$ or visceroptos\$).tw.
7	Rectocele/ use ppez
8	rectocele/ use emczd
9	(hernia\$ adj3 (pelvi\$ or vagin\$ or urogenital\$ or uter\$ or bladder\$ or urethr\$ or viscer\$)).tw.
10	(urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$).tw.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	Urinary Incontinence/ use ppez
13	urine incontinence/ use emczd
14	Urinary Incontinence, Stress/ use ppez
15	stress incontinence/ use emczd
16	mixed incontinence/ use emczd
17	((mix\$ or urin\$ or stress\$) adj5 incontinen\$).tw.
18	(UI or SUI).tw.
19	(urine adj2 (loss or leak\$)).tw.
20	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	Cystoscopy/ use ppez
22	Cystography/ use ppez
23	cystoscopy/ use emczd
24	cystography/ use emczd
25	Proctoscopy/ use ppez
26	exp Colonoscopy/ use ppez
27	rectoscopy/ use emczd
28	colonoscopy/ use emczd
29	sigmoidoscopy/ use emczd
30	Colonography, Computed Tomographic/ use ppez
31	computed tomographic colonography/ use emczd
32	defecography/ use emczd
33	(cystoscop\$ or cystograph\$ or cystogram\$ or cystourethroscop\$ or cystourethrograph\$ or cystourethrogram\$ or proctoscop\$ or proctograph\$ or proctogram\$ or rectoscop\$ or rectograph\$ or rectogram\$ or colonoscopy\$ or colonograph\$ or colonogram\$ or sigmoidoscop\$ or sigmoidograph\$ or sigmoidogram\$ or defecoscop\$ or defecograph\$ or defecogram\$).tw.
34	exp Magnetic Resonance Imaging/ use ppez
35	exp nuclear magnetic resonance imaging/ use emczd
36	magnet\$ resonance.mp.
37	(MRI or MRI\$1 or NMR\$1).tw.
38	(MR adj (imag\$ or scan\$)).tw.
39	(magnet\$ adj (imag\$ or scan\$)).tw.
40	(magneti?ation adj3 imaging).tw.
41	exp Ultrasonography/ use ppez
42	exp echography/ use emczd
43	exp ultrasound/ use emczd
44	(ultrasound\$ or ultrasonograph\$ or sonogra\$ or endosonogra\$).mp.

#	Searches
45	((translabial or transperineal) adj3 (US or MRI)).tw.
46	Laparoscopy/ use ppez
47	Laparotomy/ use ppez
48	Laparoscopes/ use ppez
49	laparoscopy/ use emczd
50	laparotomy/ use emczd
51	laparoscope/ use emczd
52	((laparoscop\$ or laparot\$) adj3 (diagnos\$ or assess\$)).tw.
53	Fluoroscopy/ use ppez
54	Enema/ use ppez
55	fluoroscopy/ use emczd
56	enema/ use emczd
57	enema\$.tw.
58	Pain Measurement/ use ppez
59	exp pain assessment/ use emczd
60	(pain adj3 (scale\$ or assess\$ or question\$ or index\$ or inventor\$ or measure\$)).tw.
61	exp Physical Examination/ use ppez
62	exp physical examination/ use emczd
63	clinical examination/ use emczd
64	exp medical history/ use emczd
65	((physical or clinical) adj examination).tw.
66	((medical or clinical or patient) adj history).tw.
67	palpat\$.tw.
68	(exam\$ adj5 (anaesthes\$ or anesthes\$)).tw.
69	EUA.tw.
70	**"Surveys and Questionnaires"/ use ppez
71	*questionnaire/ use emczd
72	((assessment or activity or symptom\$ or sexual\$) adj (question\$ or scale\$ or index\$ or inventor\$ or measure\$)).tw.
73	(sexual\$ adj function\$ adj (question\$ or scale\$ or index\$ or inventor\$ or measure\$)).tw.
74	(EPAQ\$ or e-PAQ\$ or PISQ\$ or FSFI\$ or FISF\$ or PFDI\$).tw.
75	or/21-74
76	exp Surgical Mesh/ use ppez
77	exp surgical mesh/ use emczd
78	mesh\$.tw.
79	**"Prostheses and Implants"/ use ppez
80	*implant/ use emczd
81	*Biocompatible Materials/ use ppez
82	*biomaterial/ use emczd
83	((biolog\$ or synthetic\$) adj implant\$).tw.
84	76 or 77 or 78 or 79 or 80 or 81 or 82 or 83
85	11 and 75 and 84
86	20 and 75 and 84
87	85 or 86
88	Clinical Coding/ use ppez
89	classification/ use emczd
90	(complication\$ adj3 (classif\$ or diagnos\$ or assess\$)).tw.
91	88 or 89 or 90
92	11 and 84 and 91
93	20 and 84 and 91
94	87 or 92 or 93
95	URODYNAMICS/ use ppez
96	*URODYNAMICS/ use emczd
97	*CYSTOMETRY/ use emczd
98	*URETHRA PRESSURE/ use emczd
99	*UROFLOWMETRY/ use emczd
100	(urodynamic\$ or cystometr\$ or uroflowmet\$).tw.
101	(urethr\$ adj3 pressure\$ adj3 (study or studies or profile\$)).tw.
102	(void\$ adj3 pressure\$ adj3 (study or studies or profile\$)).tw.
103	(pressure\$ adj3 flow).tw.
104	(videourodynamic\$ or video urodynamic\$).tw.
105	(ambulatory adj3 urodynamic\$).tw.
106	(videocystometr\$ or video cystometr\$).tw.
107	(ambulatory adj3 cystometr\$).tw.
108	((video\$ or void\$) adj3 cystourethrogra\$).tw.
109	VCUG.tw.

#	Searches
110	profilometr\$.tw.
111	leak point pressure\$.tw.
112	95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111
113	11 and 84 and 112
114	20 and 84 and 112
115	94 or 113 or 114
116	remove duplicates from 115
117	limit 116 to english language [general exclusions filter applied]

Database: Cochrane Library via Wiley Online

Date of last search: 8th August 2017.

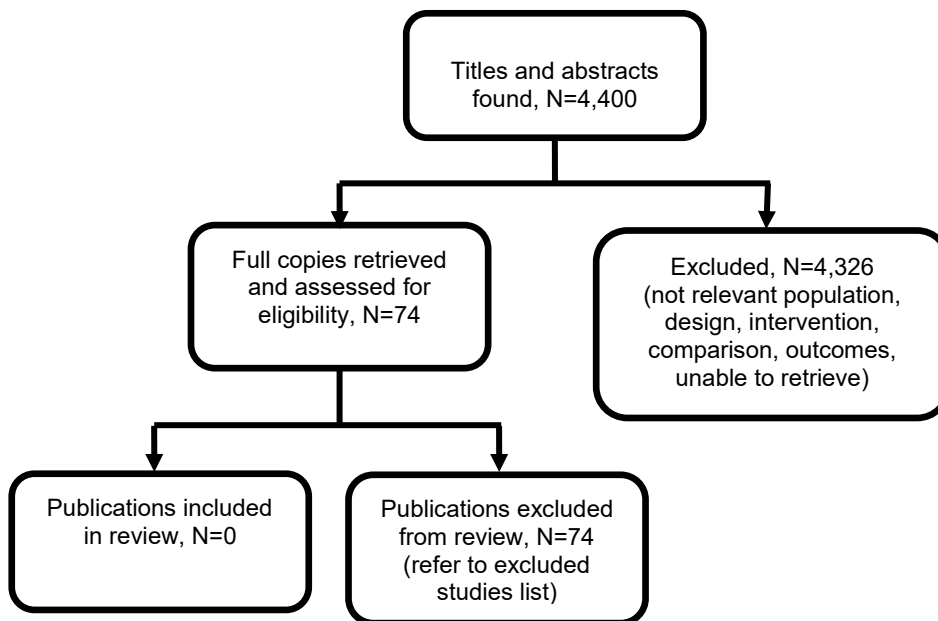
#	Searches
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splachnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrocoele* or enterocele* or enterococele* or sigmoidococele* or sigmoidocele* or proctococele* or proctococele* or rectocele* or rectococele* or cystocele* or cystococele* or rectoenterocele* or rectoenterococele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#9	MeSH descriptor: [Urinary Incontinence, Stress] explode all trees
#10	MeSH descriptor: [Urinary Incontinence] this term only
#11	((mix* or urin* or stress*) near/5 incontinen*):ti,ab,kw (Word variations have been searched)
#12	(UI or SUI):ti,ab,kw (Word variations have been searched)
#13	(urine near/2 (loss or leak*)):ti,ab,kw (Word variations have been searched)
#14	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
#15	MeSH descriptor: [Cystoscopy] this term only
#16	MeSH descriptor: [Cystography] explode all trees
#17	MeSH descriptor: [Proctoscopy] explode all trees
#18	MeSH descriptor: [Colonoscopy] explode all trees
#19	MeSH descriptor: [Colonography, Computed Tomographic] this term only
#20	(cystoscop* or cystograph* or cystogram* or cystourethroscop* or cystourethrograph* or cystourethrogram* or proctoscop* or proctograph* or proctogram* or rectoscop* or rectograph* or rectogram* or colonoscopy* or colonograph* or colonogram* or sigmoidoscop* or sigmoidograph* or sigmoidogram* or defecograph* or defecogram*):ti,ab,kw (Word variations have been searched)
#21	MeSH descriptor: [Magnetic Resonance Imaging] explode all trees
#22	magnet* resonance:ti,ab,kw (Word variations have been searched)
#23	(MRI or MRI*1 or NMR*1):ti,ab,kw (Word variations have been searched)
#24	(MR next (imag*\$ or scan*)):ti,ab,kw (Word variations have been searched)
#25	(magnet* next (imag* or scan*)):ti,ab,kw (Word variations have been searched)
#26	((magnetisation or magnetization) near/3 imaging):ti,ab,kw (Word variations have been searched)
#27	MeSH descriptor: [Ultrasonography] explode all trees
#28	(ultrasound* or ultrasonograph* or sonogra* or endosonogra*):ti,ab,kw (Word variations have been searched)
#29	((translabial or transperineal) near/3 (US or MRI)):ti,ab,kw (Word variations have been searched)
#30	MeSH descriptor: [Laparoscopy] explode all trees
#31	MeSH descriptor: [Laparotomy] this term only
#32	MeSH descriptor: [Laparoscopes] this term only
#33	((laparoscop* or laparot*) near/3 (diagnos* or assess*)):ti,ab,kw (Word variations have been searched)
#34	MeSH descriptor: [Fluoroscopy] explode all trees
#35	MeSH descriptor: [Enema] this term only
#36	enema*:ti,ab,kw (Word variations have been searched)
#37	MeSH descriptor: [Pain Measurement] this term only
#38	(pain near/3 (scale* or assess* or question* or index* or inventor* or measure*)):ti,ab,kw (Word variations have been searched)
#39	MeSH descriptor: [Physical Examination] explode all trees
#40	((physical or clinical) next examination):ti,ab,kw (Word variations have been searched)
#41	((medical or clinical or patient) next history):ti,ab,kw (Word variations have been searched)
#42	palpat*:ti,ab,kw (Word variations have been searched)
#43	(exam* near/5 (anaesthes* or anesthes*)):ti,ab,kw (Word variations have been searched)

#	Searches
#44	EUA:ti,ab,kw (Word variations have been searched)
#45	MeSH descriptor: [Surveys and Questionnaires] this term only
#46	((assessment or activity or symptom* or sexual*) next (question* or scale* or index* or inventor* or measure*)):ti,ab,kw (Word variations have been searched)
#47	(sexual* next function* next (question* or scale* or index* or inventor* or measure*)):ti,ab,kw (Word variations have been searched)
#48	(EPAQ* or e-PAQ* or PISQ* or FSFI* or FISF* or PFDI*):ti,ab,kw (Word variations have been searched)
#49	#15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48
#50	#14 and #49
#51	MeSH descriptor: [Surgical Mesh] explode all trees
#52	mesh*:ti,ab,kw (Word variations have been searched)
#53	MeSH descriptor: [Prostheses and Implants] this term only
#54	MeSH descriptor: [Biocompatible Materials] this term only
#55	((biolog* or synthetic*) next implant*):ti,ab,kw (Word variations have been searched)
#56	#51 or #52 or #53 or #54 or #55
#57	#50 and #56
#58	MeSH descriptor: [Clinical Coding] explode all trees
#59	(complication* near/3 (classif* or diagnos* or assess*)):ti,ab,kw (Word variations have been searched)
#60	#58 or #59
#61	#14 and #56 and #60
#62	#57 or #61
#63	MeSH descriptor: [Urodynamics] this term only
#64	(urodynamic* or cystometr* or uroflowmet*):ti,ab,kw (Word variations have been searched)
#65	(urethr* near/3 pressure* near/3 (study or studies or profile*)):ti,ab,kw (Word variations have been searched)
#66	(void* near/3 pressure* near/3 (study or studies or profile*)):ti,ab,kw (Word variations have been searched)
#67	(pressure* near/3 flow):ti,ab,kw (Word variations have been searched)
#68	(videourodynamic* or video urodynamic*):ti,ab,kw (Word variations have been searched)
#69	(ambulatory near/3 urodynamic*):ti,ab,kw (Word variations have been searched)
#70	(ambulatory near/3 cystometr*):ti,ab,kw (Word variations have been searched)
#71	((video* or void*) near/3 cystourethrogra*):ti,ab,kw (Word variations have been searched)
#72	VCUG:ti,ab,kw (Word variations have been searched)
#73	profilometr*:ti,ab,kw (Word variations have been searched)
#74	leak point pressure*:ti,ab,kw (Word variations have been searched)
#75	#63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72 or #73 or #74
#76	#14 and #56 and #75
#77	#62 or #76

Appendix C – Clinical evidence study selection

Clinical evidence study selection for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

Figure 1: PRISMA flow chart for what is the most effective strategy for assessing mesh complications of sexual dysfunction, pain, vaginal, urinary and bowel complications after mesh surgery?



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No studies were identified which were applicable to this review question

Appendix E – Forest plots

Forest plots for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No studies were identified which were applicable to this review question.

Appendix F – GRADE tables

GRADE tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No studies were identified which were applicable to this review question.

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

One global search for economic evidence was conducted for the review question. See appendix D for further information.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No economic studies were identified which were applicable to this review question.

Appendix I – Health economic evidence profiles

Economic evidence profiles for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No economic studies were identified which were applicable to this review question.

Appendix J – Health economic analysis

Economic evidence analysis for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

Clinical studies

Table 4: Excluded studies with reasons for exclusion

Excluded studies	
Study	Reason for Exclusion
Abbott, S., Unger, C. A., Evans, J. M., Jallad, K., Mishra, K., Karram, M. M., Iglesia, C. B., Rardin, C. R., Barber, M. D., Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study, American Journal of Obstetrics & Gynecology, 210, 163.e1-8, 2014	Outcomes not relevant - the paper describes the evaluation and management of synthetic mesh complications after surgery but does not compare assessment strategies prior to treatment
Abdel-Fattah, M., Sivanesan, K., Ramsay, I., Pringle, S., Bjornsson, S., How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure, BJU International, 98, 594-8, 2006	Outcomes not relevant - the study compares vaginal/urethral erosion rates
Abraham, N., Vasavada, S., Urgency after a sling: review of the management, Current urology reports, 15, 400, 2014	Narrative literature review - regarding the causes, evaluation, and treatment for urinary urgency after synthetic midurethral sling surgery
Agarwala, N., Hasiak, N., Shade, M., Graft interposition colpocleisis, perineorrhaphy, and tension-free sling for pelvic organ prolapse and stress urinary incontinence in elderly patients, Journal of Minimally Invasive Gynecology, 14, 740-745, 2007	No relevant comparison of assessment strategies for the identification of mesh complications
Agnew, G., Dwyer, P. L., Rosamilia, A., Lim, Y., Edwards, G., Lee, J. K., Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence, International Urogynecology Journal, 25, 235-9, 2014	No relevant comparison of assessment strategies for the identification of mesh complications

Excluded studies	
Aigmuller,T., Trutnovsky,G., Tamussino,K., Kargl,J., Wittmann,A., Surtov,M., Kern,P., Frudinger,A., Riss,P., Bjelic-Radiscic,V., Ten-year follow-up after the tension-free vaginal tape procedure, American journal of obstetrics and gynecology, 205, 496-5, 2011	No relevant comparison of assessment strategies for the identification of mesh complications
Amundsen,C.L., Flynn,B.J., Webster,G.D., Urethral erosion after synthetic and nonsynthetic pubovaginal slings: differences in management and continence outcome, Journal of Urology, 170, 134-137, 2003	No relevant comparison of assessment strategies for the identification of mesh complications
Andonian,S., St-Denis,B., Lemieux,M.C., Corcos,J., Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results, European Urology, 52, 245-251, 2007	No relevant comparison of assessment strategies for the identification of mesh complications
Anger,J.T., Litwin,M.S., Wang,Q., Pashos,C.L., Rodriguez,L.V., Complications of sling surgery among female Medicare beneficiaries, Obstetrics and Gynecology, 109, 707-714, 2007	No relevant comparison of assessment strategies for the identification of mesh complications
Anonymous., Committee Opinion No. 694 Summary: Management of Mesh and Graft Complications in Gynecologic Surgery, Obstetrics & Gynecology, 129, 773-774, 2017	Summary paper - on the management of complications related to mesh for stress urinary incontinence or pelvic organ prolapse
Argirovic,R.B., Gudovic,A.M., Babovic,I.R., Berisavac,M.V., Transvaginal repair of genital prolapse with polypropylene mesh using a tension-free technique, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 153, 104-107, 2010	No relevant comparison of assessment strategies for the identification of mesh complications
Aungst,M.J., Friedman,E.B., von Pechmann,W.S., Horbach,N.S., Welgoss,J.A., De novo stress incontinence and pelvic muscle symptoms after transvaginal mesh repair, American Journal of Obstetrics and Gynecology, 201, 73-77, 2009	Outcomes not relevant - the study describes the rate of stress incontinence related outcomes after transvaginal mesh repair
Azais, H., Charles, C. J., Delporte, P., Debodinance, P., Prolapse repair using the Elevate™ kit: prospective study on 70 patients, International Urogynecology Journal, 23, 1421-8, 2012	Outcomes not relevant - the study assesses the outcomes and complications after prolapse repair
Badrek-Al Amoudi, A. H., Greenslade, G. L., Dixon, A. R., How to deal with complications after laparoscopic ventral mesh rectopexy: lessons learnt from a tertiary referral centre, Colorectal Disease, 15, 707-12, 2013	No relevant comparison of assessment strategies for the identification of mesh complications - the article describes tertiary referral practice of patients who have failed or developed late complications after laparoscopic ventral mesh rectopexy
Baessler,K., Hewson,A.D., Tunn,R., Schuessler,B., Maher,C.F., Severe mesh complications following intravaginal slingplasty, Obstetrics and Gynecology, 106, 713-716, 2005	No relevant comparison of assessment strategies for the identification of mesh complications -case series of

Excluded studies	
	complications following anterior and/or posterior intravaginal slingplasty
Bafghi,A., Benizri,E.I., Trastour,C., Benizri,E.J., Michiels,J.F., Bongain,A., Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 376-378, 2005	Outcomes not relevant - data on purulent collections in the retropubic space related to the use of a multifilament polypropylene mesh sling
Balakrishnan, S, Lim, Yn, Barry, C, Corstiaans, A, Kannan, K, Rane, A, Sling distress: a subanalysis of the IVS tapes from the SUSPEND trial, Australian & New Zealand Journal of Obstetrics & Gynaecology Aust N Z J Obstet Gynaecol, 47, 496-498, 2007	No relevant outcomes - data on the incidence of erosions and infections following the use of intravaginal slingplasty treatment for stress urinary incontinence
Barski, D., Otto, T., Gerullis, H., Systematic Review and Classification of Complications after Anterior, Posterior, Apical, and Total Vaginal Mesh Implantation for Prolapse Repair, Surgical Technology International. XXIV, 6, 6, 2014	Systematic review - references checked for inclusion
Blaivas, J. G., Mekel, G., Management of urinary fistulas due to midurethral sling surgery, Journal of Urology, 192, 1137-42, 2014	No relevant comparison of assessment strategies for the identification of mesh complications - data is on the diagnosis and management of women with urinary fistula after mid-urethral sling surgery
Bontje, H. F., van de Pol, G., van der Zaag-Loonen, H. J., Spaans, W. A., Follow-up of mesh complications using the IUGA/ICS category-time-site coding classification, International Urogynecology Journal, 25, 817-22, 2014	No relevant comparison of assessment strategies for the identification of mesh complications
Bozkurt, M., Yumru, A. E., Salman, S., Assessment of perioperative, early, and late postoperative complications of the inside-out transobturator tape procedure in the treatment of stress urinary incontinence, Clinical & Experimental Obstetrics & Gynecology, 42, 82-9, 2015	Outcomes not relevant - the study describes perioperative, early and late complications associated with transobturator sling
Brown, E. T., Cohn, J., Kaufman, M., Dmochowski, R., Reynolds, W. S., Evaluation and Management of Mid-Urethral Sling Complications, Current Bladder Dysfunction Reports, 11, 160-168, 2016	Narrative literature review
Brucker, B. M., Malacarne, D. R., Bladder Outlet Obstruction After Incontinence Surgery, Current Bladder Dysfunction Reports, 11, 45-52, 2016	Narrative literature review
Cardenas-Trowers, O. O., Malekzadeh, P., Nix, D. E., Hatch, K. D., Vaginal Mesh Removal Outcomes: Eight Years of Experience at an Academic Hospital, Female Pelvic Medicine & Reconstructive Surgery Female pelvic med, 20, 20, 2017	No relevant comparison of assessment strategies for the identification of mesh complications - descriptive study of clinical history and outcomes of mesh removal surgery

Excluded studies	
Castellani, D., Galica, V., Saldutto, P., Biferi, D., Paradiso Galatioto, G., Vicentini, C., Unilateral sling transection for patients with postoperative voiding dysfunction after transobturator sling surgery, <i>International Journal of Gynecology and Obstetrics</i> , 131, 313-314, 2015	No relevant comparison of assessment strategies for the identification of mesh complications - study assesses the efficacy of unilateral sling transection to treat post-operative bladder outlet obstruction
Chan, G., Mamut, A., Martin, P., Welk, B., Holmium:YAG Laser Ablation for the Management of Lower Urinary Tract Foreign Bodies Following Incontinence Surgery: A Case Series and Systematic Review, <i>Journal of Endourology</i> , 6, 6, 2016	Outcomes not relevant - data on outcomes associated with the endoscopic removal of foreign bodies in the lower urinary tract after female stress incontinence surgery with the Holmium:YAG laser
Choi, J. M., Nguyen, V., Khavari, R., Reeves, K., Snyder, M., Fletcher, S. G., Complex rectovaginal fistulas after pelvic organ prolapse repair with synthetic mesh: a multidisciplinary approach to evaluation and management, <i>Female Pelvic Medicine & Reconstructive Surgery</i> Female pelvic med, 18, 366-71, 2012	Study design not relevant - case series data on complex rectovaginal fistulas after synthetic mesh-augmented pelvic organ prolapse repair
Clemens, J. Q., Delancey, J. O., Faerber, G. J., Westney, O. L., McGuire, E. J., Urinary tract erosions after synthetic pubovaginal slings: Diagnosis and management strategy, <i>Urology</i> , 56, 589-594, 2000	Outcomes not relevant - data on diagnosis and management of genitourinary tract erosion
Cornu, J. N., Peyrat, L., Haab, F., Update in management of vaginal mesh erosion, <i>Current Urology Reports</i> , 14, 471-5, 2013	Narrative literature review
Curti, P., Cerruto, M.A., Fabrello, M., D'Amico, A., Zattoni, F., Perineal ultrasound assessment of vesico-urethral mobility before and after TVT-O, <i>Urologica</i> , 18, 19-, 2008	Narrative literature review - on the pelvic floor ultrasound procedure to investigate vesico-urethral morphological and functional changes in the management of stress urinary incontinence and pelvic organ prolapse
Davis, N. F., Smyth, L. G., Giri, S. K., Flood, H. D., Evaluation of endoscopic laser excision of polypropylene mesh/sutures following anti-incontinence procedures, <i>Journal of Urology</i> , 188, 1828-32, 2012	Outcomes not relevant - data on outcomes of patients who underwent endoscopic laser excision of eroded polypropylene mesh or sutures as a complication of previous anti-incontinence procedures
Deval, B., Haab, F., Management of the complications of the synthetic slings, <i>Current Opinion in Urology</i> , 16, 240-243, 2006	Narrative literature review - on frequency, pathogenesis, diagnosis and management of vaginal erosion and pelvic abscess in women with urinary incontinence
Dietz, H. P., Mesh in prolapse surgery: an imaging perspective, <i>Ultrasound in Obstetrics & Gynecology</i> Ultrasound Obstet Gynecol, 40, 495-503, 2012	Descriptive paper - applications of pelvic floor ultrasound during pelvic reconstructive surgery

Excluded studies	
Dietz, H. P., Pelvic floor ultrasound: a review, American Journal of Obstetrics & Gynecology, 202, 321-34, 2010	Narrative literature review - on translabial/ transperineal ultrasound and its use in clinical assessment
Diwadkar, G. B., Barber, M. D., Feiner, B., Maher, C., Jelovsek, J. E., Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review, Obstetrics & Gynecology, 113, 367-73, 2009	Systematic review - references checked for inclusion
Domingo,S., Alama,P., Ruiz,N., Perales,A., Pellicer,A., Diagnosis, management and prognosis of vaginal erosion after transobturator suburethral tape procedure using a nonwoven thermally bonded polypropylene mesh, Journal of Urology, 173, 1627-1630, 2005	No relevant comparison of assessment strategies for the identification of mesh complications - data on the prognosis of vaginal erosion
Eisenberg, V. H., Steinberg, M., Weiner, Z., Schiff, E., Lowenstein, L., Long-term follow-up of sacrocolpopexy mesh implants at two time intervals at least 1 year apart using 4D transperineal ultrasound, Ultrasound in Obstetrics & GynecologyUltrasound Obstet Gynecol, 49, 398-403, 2017	Outcomes not relevant - data on follow-up of sacrocolpopexy mesh implants using 4D transperineal ultrasound
Elzevier, H. W., Venema, P. L., Lycklama a Nijeholt, A. A. B., Sexual function after tension-free vaginal tape (TVT) for stress incontinence: Results of a mailed questionnaire, International Urogynecology Journal, 15, 313-318, 2004	Outcomes not relevant - data on sexual function following tension-free vaginal tape procedures for stress urinary incontinence
Fayyad, A. M., North, C., Reid, F. M., Smith, A. R. B., Prospective study of anterior transobturator mesh kit (ProliftTM) for the management of recurrent anterior vaginal wall prolapse, International Urogynecology Journal, 22, 157-163, 2011	Outcomes not relevant - data on anatomical and functional outcomes following Anterior Prolift for recurrent anterior vaginal wall prolapse
Fleischer, A. C., Harvey, S. M., Kurita, S. C., Andreotti, R. F., Zimmerman, C. W., Two-/three-dimensional transperineal sonography of complicated tape and mesh implants, Ultrasound QuarterlyUltrasound Q, 28, 243-9, 2012	Narrative literature review - application of the transperineal sonography for the assessment of the postoperative complications in dynamic pelvic floor disorders
Flock,F., Kohorst,F., Kreienberg,R., Reich,A., Ultrasound assessment of tension-free vaginal tape (TVT), Ultraschall in der Medizin, 32 Suppl 1, S35-S40, 2011	Unable to obtain full text article
Huang, W. C., Yang, S. H., Yang, J. M., Pelvic floor muscle functions are improved after successful transobturator vaginal mesh procedures, Neurourology & UrodynamicsNeurourol Urodyn, 36, 380-384, 2017	Intervention not relevant - comparison of preoperative and postoperative pelvic floor muscle functions assessed by 4D ultrasound after successful transobturator vaginal mesh procedures

Excluded studies	
Husch, T., Mager, R., Ober, E., Bentler, R., Ulm, K., Haferkamp, A., Quality of life in women of non-reproductive age with transvaginal mesh repair for pelvic organ prolapse: A cohort study, <i>International Journal Of Surgery</i> Int J Surg, 33 Pt A, 36-41, 2016	Outcomes not relevant - data on quality of life and peri- and postoperative complication rates after transvaginal mesh repair for pelvic organ prolapse
Illiano, E., Manasse, G., Maglia, D., Orcidi, D., Zucchi, A., Balsamo, R., Carbone, A., Costantini, E., Are there predictive sonographic parameters of the trans-obturator midurethral sling failure? role of transperineal ultrasound, <i>Neurourology and urodynamics</i> , 36, S17-S18, 2017	Conference abstract
Ingber, M. S., Krlin, R. M., Vasavada, S. P., Firoozi, F., Goldman, H. B., Outcomes of midurethral slings in women with concomitant preoperative severe lower urinary tract voiding symptoms, <i>Ochsner Journal</i> , 15, 223-227, 2015	Population not relevant to protocol - women did not have complications after mesh surgery
Jellison, F., Nakamura, L., Hartshorn, T., Rogo-Gupta, L., Chow, D., Kim, J. H., Rodriguez, L., Raz, S., Translabial ultrasound (TLUS) detection in urethral mesh sling revision and urethral reconstruction, <i>Neurourology and Urodynamics</i> , 32 (2), 191, 2013	Conference abstract
Jellison, F., Nakamura, L., Rogo-Gupta, L., Chow, D., Baxter, C., Kim, J. H., Rodriguez, L., Raz, S., Translabial ultrasound (TLUS) detection in urethral mesh sling revision: Factors associated with the need for interpositional tissue flap or urethral reconstruction, <i>Journal of urology</i> , 1), e231, 2013	Conference abstract
Jung, B. C., Tran, N. A., Verma, S., Dutta, R., Tung, P., Mousa, M., Hernandez-Rangel, E., Nayyar, M., Lall, C., Cross-sectional imaging following surgical interventions for stress urinary incontinence in females, <i>Abdominal Radiology</i> , 41, 1178-1186, 2016	Narrative literature review - CT and MRI for the identification of changes following surgical (including mesh) and non-surgical treatment of stress urinary incontinence
Kociszewski, J., Kolben, S., Barski, D., Viereck, V., Barcz, E., Complications following Tension-Free Vaginal Tapes: Accurate Diagnosis and Complications Management, <i>BioMed Research International</i> , 2015, 538391, 2015	Narrative literature review
Manonai, J., Rostaminia, G., Denson, L., Shobeiri, S. A., Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications, <i>Neurourology & Urodynamics</i> <i>Neurourol Urodyn</i> , 35, 407-11, 2016	Outcomes not relevant to the protocol
Mouracade, P., El Abiad, S., Roy, C., Lang, H., Jacqmin, D., Saussine, C., Correlation of introital ultrasound with LUTS after sling surgery, <i>International urogynecology journal</i> , 21, 1261-1264, 2010	Outcomes not relevant to the protocol

Excluded studies	
Mousty, E., Huberlant, S., Pouget, O., Mares, P., De Tayrac, R., Letouzey, V., Prospective ultrasonographic follow-up of synthetic mesh in cohort of patients after vaginal repair of cystocele, <i>Progres en Urologie</i> , 23, 530-537, 2013	No relevant comparison of assessment strategies for the identification of mesh complications - validation study of a sequence of ultrasonographic mesh measurements
Petri, E., Ashok, K., Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification, <i>European Journal of Obstetrics, Gynecology, & Reproductive Biology</i> , 165, 347-51, 2012	No relevant comparison of assessment strategies for the identification of mesh complications - analysis of the complications of tension-free vaginal sling managed in a tertiary centre
Ram, R., Oliphant, S. S., Barr, S. A., Pandey, T., Imaging of Pelvic Floor Reconstruction, <i>Seminars in Ultrasound, CT & MR</i> <i>Semin Ultrasound CT MR</i> , 38, 200-212, 2017	Narrative literature review
Reisenauer, C., Viereck, V., Mesh-related complications in urogynecology - A multidisciplinary challenge, <i>Acta Obstetrica et Gynecologica Scandinavica</i> , 91, 869-872, 2012	Study design not relevant - case series of women who experienced mesh complications
Ridgeway, B., Walters, M. D., Paraiso, M. F. R., Barber, M. D., McAchrans, S. E., Goldman, H. B., Jelovsek, J. E., Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits, <i>American Journal of Obstetrics and Gynecology</i> , 199, 703.e1-703.e7, 2008	Study design not relevant - retrospective review of women who underwent mesh removal
Rogo-Gupta, L., Huynh, L., Hartshorn, T. G., Rodriguez, L. V., Raz, S., Long-term symptom improvement and overall satisfaction after prolapse and incontinence graft removal, <i>Female Pelvic Medicine and Reconstructive Surgery</i> , 19, 352-355, 2013	Intervention not relevant - data on long-term subjective symptom improvements and overall satisfaction outcomes in patients after removal of grafts used in pelvic reconstruction
Rousset, P., Deval, B., Chaillot, P. F., Amara, N., Buy, J. N., Hoeffel, C., MRI and CT of sacrocolpopexy, <i>American Journal of Roentgenology</i> , 200, W383-W394, 2013	Descriptive paper - on the surgical procedure of sacrocolpopexy
Sajadi, K.P., Vasavada, S.P., Overactive bladder after sling surgery, <i>Current Urology Reports</i> , 11, 366-371, 2010	Narrative literature review - on overactive bladder after sling surgery, its epidemiology and management
Sakalis, V.I., Gkotsi, A.C., Triantafyllidis, A., Giouris, A., Charalambous, S., Transurethral holmium laser intravesical tape excision following TVT procedure: Results from seven patients in a 12-month follow-up, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 23, 769-777, 2012	No relevant comparison of assessment strategies for the identification of mesh complications - describes the efficacy and the safety of the holmium:YAG laser for intravesical mesh excision
Shek, K. L., Dietz, H. P., Imaging of slings and meshes, <i>Australasian Journal of Ultrasound in Medicine</i> <i>Australas J Ultrasound Med</i> , 17, 61-71, 2014	Narrative literature review - on the role of translabial ultrasound in the evaluation of synthetic implants used in

Excluded studies	
	the treatment of urinary incontinence and pelvic organ prolapse
Shek, K. L., Dietz, H. P., Pelvic floor ultrasonography: An update, <i>Minerva Ginecologica</i> , 65, 1-20, 2013	Narrative literature review - on pelvic floor ultrasonography
Shek, K. L., Dietz, H. P., Rane, A., Balakrishnan, S., Transobturator mesh for cystocele repair: A short- to medium-term follow-up using 3D/4D ultrasound, <i>Ultrasound in Obstetrics and Gynecology</i> , 32, 82-86, 2008	Outcomes not relevant - data on the outcomes of an external surgical audit using 3- and 4-dimensional pelvic floor ultrasound to study the short- to medium-term safety and efficacy of transobturator mesh placement
Siracusano, S., Ciciliato, S., Lampropoulou, N., Cucchi, A., Visalli, F., Talamini, R., Porcine small intestinal submucosa implant in pubovaginal sling procedure on 48 consecutive patients: Long-term results, <i>European Journal of Obstetrics Gynecology and Reproductive Biology</i> , 158, 350-353, 2011	Outcomes not relevant - data on the long-term efficacy, safety and reliability of pubovaginal sling procedure with porcine small intestinal submucosa implant in women affected by stress urinary incontinence
Spelzini, F., Cesana, M. C., Verri, D., Polizzi, S., Frigerio, M., Milani, R., Three-dimensional ultrasound assessment and middle term efficacy of a single-incision sling, <i>International Urogynecology Journal</i> , 24, 1391-7, 2013	Outcomes not relevant - data on the functional outcome of a single-incision sling procedure for the treatment of female stress urinary incontinence and its correlation with the cure rate when using a pelvic floor ultrasound examination
Staack, A., Vitale, J., Ragavendra, N., Rodriguez, L. V., Translabial ultrasonography for evaluation of synthetic mesh in the vagina, <i>Urology</i> , 83, 68-74, 2014	Outcomes not relevant to the protocol
Starkman, J.S., Wolter, C., Gomelsky, A., Scarpero, H.M., Dmochowski, R.R., Voiding dysfunction following removal of eroded synthetic mid urethral slings, <i>Journal of Urology</i> , 176, 1040-1044, 2006	Outcomes not relevant to the protocol
Svabik, K., Martan, A., Masata, J., El-Haddad, R., Hubka, P., Pavlikova, M., Ultrasound appearances after mesh implantation - Evidence of mesh contraction or folding?, <i>International Urogynecology Journal</i> , 22, 529-533, 2011	Intervention not relevant - assessment of ultrasound appearance of mesh implants over time
Tse, V., Chan, L., Outlet obstruction after sling surgery, <i>BJU International</i> , 108, 24-28, 2011	Narrative literature review - on outlet obstruction after sling surgery

Excluded studies	
Tunitsky-Bitton, E., Unger, C. A., Barber, M. D., Goldman, H. B., Walters, M. D., Ultrasound Evaluation of Midurethral Sling Position and Correlation to Physical Examination and Patient Symptoms, Female pelvic medicine & reconstructive surgery, 21, 263-8, 2015	Study design not relevant - cross sectional study, which evaluated the position and angle variation between 3 midurethral slings (retropubic, out-to-in transobturator, and in-to-out transobturator) using 3D ultrasound
Velemir, L., Amblard, J., Fatton, B., Savary, D., Jacquetin, B., Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study, Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 35, 474-480, 2010	No relevant comparison of assessment strategy for mesh complications - study uses ultrasound to quantify mesh retraction and prolapse recurrence
Velemir, L., Amblard, J., Jacquetin, B., Fatton, B., Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management, International Urogynecology Journal, 19, 999-1006, 2008	Study design not relevant - case series data on risk factors and diagnostic modalities of urethral erosion
Wohlrab, K. J., Erekson, E. A., Myers, D. L., Postoperative erosions of the Mersilene suburethral sling mesh for antiincontinence surgery, International Urogynecology Journal, 20, 417-420, 2009	Study design not relevant - retrospective review which describes the presentation of vaginal mesh erosion following Mersilene suburethral slings for urinary incontinence
Zambon, J. P., Badlani, G. H., Vaginal Mesh Exposure Presentation, Evaluation, and Management, Current Urology Reports, 17 (9) (no pagination), 2016	Narrative literature review - on vaginal mesh exposure

Economic studies

No economic evidence was identified which was applicable to this review question. See supplementary material D for further information.

Appendix L – Research recommendations

Research recommendations for review question: What is the most effective strategy for assessing mesh complications of sexual dysfunction; pain; vaginal, urinary and bowel complications after mesh surgery?

What is the effectiveness of ultrasound-guided visualisation compared with clinical assessment to identify complications after mesh surgery for stress urinary incontinence or pelvic organ prolapse in women?

Why this is important?

Ultrasound can be used to evaluate the position of mid-urethral tapes. Many women request an ultrasound as they have been advised by other women that an ultrasound can diagnose and guide management of mesh complications. However, there is no data available to support this and providing this investigation to all women presenting with problems following insertion of mid-urethral tape has significant resource implications for the NHS. The Committee considered it was important for further research to ascertain whether ultrasound has a benefit in the management of mesh complications.

Table 5: Research recommendation rationale

Research question	What is the value of ultrasound guided visualisation to assess complications compared to clinical assessment, following mesh surgery?
Importance to 'patients' or the population	Many women consider that ultrasound can help evaluate for a mesh complication.
Relevance to NICE guidance	Relevant to management of mesh complications
Relevance to the NHS	Has large resource implication
National priorities	High because increasing demand for unproven investigation.
Current evidence base	There is none
Equality	Currently access is limited to a few centres

Table 6: Research recommendation modified PICO table

Criterion	Explanation
Population	Women who have had a mesh sling and are presenting with suspected complications.
Intervention	Clinical assessment + transperineal ultrasound,
Comparator	Clinical assessment alone,
Outcome	Change in MDT decision making. Secondary: symptom improvement; use of US information in surgical decision making; need for diagnostic cystourethroscopy.
Study design	Diagnostic RCT ideal
Timeframe	12 months

Criterion	Explanation
Additional information	Additional analysis: MDT blinded to outcome and then decision made; then MDT given report and see if they make a different decision. This study might inform for which group of patients is it more informative