Urinary incontinence (update) and pelvic organ prolapse in women: management

Consultation on draft guideline - Stakeholder comments table
09/10/18 to 19/11/18

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Abertawe Bro Morgannwg University Health Board	Guideline	1	1	**1.1 Local MDT** Addition of primary prolapse surgery creates significant increased workload for any Local MDT. The introduction of this initiative should be phased. The Local MDT should audit all local surgical work but not discuss all cases prior to surgery unless local resources allow. All Repeat same-site prolapse repairs should be discussed pre op. nb repeat posterior compartment- imaging should be discussed separately with Radiologist and reported to the regional MDT Primary prolapse surgery of another compartment The local MDT should be informed but not review.	Thank you for your comment. We consider that imaging is not done at MDT. This can be a local referral and the images would be made available to the regional MDT to be reviewed as required.
Abertawe Bro Morgannwg University Health Board	Guideline	5	55	1.1.3 Regional MDT Keep register of all 1st repeat same site prolapse repairs in their region but not discuss pre op. All 2nd repeat same compartment should be discussed pre op.	Thank you for your comment. We consider that repeat same site prolapse is a complex procedure and therefore needs pre-operative discussion.

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Abertawe Bro Morgannwg University Health Board	Guideline	5	15	1.1.4 may include…. Add Clinical psychologist Move Radiologist into this category for any cases except posterior compartment. Currently insufficient evidence that imaging significantly adds to the decision making, or justifies the expense of a radiologist attending the MDT except in redo Posterior compartment (rectal prolapse)	Thank you for your comment. The committee do not consider this list to be exhaustive.
Abertawe Bro Morgannwg University Health Board	Guideline	6	17	1.2.2 L 17 add product unique identification code	Thank you for your comment. We agree with your suggestion and have added 'manufacturer and product unique identification code' to the list of information.
Abertawe Bro Morgannwg University Health Board	Guideline	9	17	1.3.17 Bonney test- This is a test of suitability for urethral support surgery-Not urethral competence- and should be encouraged as part of clinical examination BEFORE advising upon surgical options.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
Abertawe Bro Morgannwg University Health Board	Guideline	16	1	1.4.37 re duloxetine---- this should be discussed as an option before surgery for stress UI with appropriate counselling regarding adverse effects. PATIENT CHOICE AND AWARENESS ISSUE	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.

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Abertawe Bro Morgannwg University Health Board	Guideline	20	6	1.4.58 Add …….and have failed Botulinum toxin type A therapy or unable to use this medication.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
Abertawe Bro Morgannwg University Health Board	Guideline	22	8	1.5.10 add …..urethral buttress using PDS with or without anterior repair can be considered if SUI co exists with significant urethral or bladder prolapse. Ref see Purwar et al BSUG meeting November 2018	Thank you for your comment. As there was no evidence to support this, we were unable to make such a recommendation. In addition, data from meeting presentations would not be considered as reputable evidence for this guideline.
Abertawe Bro Morgannwg University Health Board	Guideline	22	12	1.5.12 add these are permanent injectable materials without long term safety data	Thank you for your comment. The committee have redrafted the recommendations on intramural bulking agents, and we have included that these are "permanent injectable materials" and that there is "limited evidence on the long term effectiveness and adverse events".
Abertawe Bro Morgannwg University Health Board	Guideline	23	12	1.6.1 L 12 add ……..and pain	Thank you for your comment. We think that pain is not a common symptom with prolapse.
Abertawe Bro Morgannwg University Health Board	Guideline	25	8	1.7.8 L 8 add explain self management of pessaries. (removal and replacement by patient at convenient intervals to facilitate intercourse and avoidance of vaginal skin pressure problems. This group do not require 6/12ly follow up.)	Thank you for your comment. There was no evidence to suggest self-management. The committee are aware that there is a NIHR funded trial in progress investigating self management of vaginal pessaries for prolapse. In addition, the

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					recommendation does not explicitly say who should carry out the pessary removal and that this could be self-managed
Abertawe Bro Morgannwg University Health Board	Guideline	26	20	1.7.12 L 20 add …and pain.	Thank you for your comment. In light of stakeholder comments this recommendation has been amended.
Abertawe Bro Morgannwg University Health Board	Guideline	27	23	1.7.18 L 23 vaginal hysterectomy with McCall, or similar, culdoplasty.	Thank you for your comment. The committee agree that this is an interesting point and a good question; however this is prevention and was outside of the scope. We could not cover all issues which occur during hysterectomy.
Abertawe Bro Morgannwg University Health Board	Guideline	27	19	1.7. 19 L19 change "unless" to "if". Nb consider repositioning of uterosacral/cardinal ligaments without removal of any cervical tissue or the squamocolumnar junction.	Thank you for your comment. The recommendation you refer to does not use the word "unless". The committee would also like to point out that the guideline does not provide instructions on how procedures are undertaken. We would expect only trained surgeons to undertake any of these surgical procedures.
Abertawe Bro Morgannwg University Health Board	Guideline	28	5	1.7.20 L5 with mesh or autologous fascia	Thank you for your comment. We agree this is a good suggestion. We have added to a new recommendation in MDT section. "women considering pregnancy….

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				Or If the woman is considering pregnancy refer to a regional MDT before any surgical intervention.	
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	General	General	Mesh should only be used as a third line of treatment once conservative methods have failed and when non-mesh surgery has failed	Thank you for your comment. For both urinary incontinence and pelvic organ prolapse we have provided non-surgical management options. The recommendations do not say women should be offered mesh as a first line treatment. The guideline explains the limited evidence on long term complications for all surgical procedures complications, and highlights the need for clear discussion about all the risks and benefits. The recommendations provide women with a choice, and the committee believes that some women would choose mesh surgery and that that option should be available to them.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	4	4	Paragraph 1.1.1 value of a multidisciplinary team (MDT) review for all women considering native tissue surgery for primary prolapse is questionable and will require intensive resources. Instead of consuming significant MDT resources, a treatment care **pathway** and a **patient decision aid** for these women to ensure that non-surgical	Thank you for your comment. The aim of the MDT is to ensure that there is oversight of the decision-making process before proceeding to invasive procedures. This would include ensuring that women have been offered all relevant management options including both non-surgical and surgical interventions and that they have been fully informed about the benefits and risk of these options.

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				treatment options have been considered. Such pathway would include documented evidence of physiotherapy input (e.g. degree of compliance with exercises or providing reasons for declining the), an offer of a range of vaginal pessaries and addressing modifiable factors such as constipation and obesity. The pathway will identify the minority of women who may require MDT discussion. These would include: • Women with recurrent same compartment pelvic organ prolapse • Women who had previous surgery using a vaginal implant, irrespective of compartment • Women considering concurrent continence surgery • Women with neurological conditions • Women being considered for abdominal prolapse surgery • Women who request a surgical procedure that is not locally available Appropriate patient selection by an agreed local pathway and decision aid is an approach that would focus the resources where truly needed	The committee acknowledges that the MDT requires significant resource allocation but this recommendation introduces an important safeguard in the care of women which we expect will improve both the women's experience and also clinical governance. The committee is aware that in the past women were not always offered conservative options and the MDT would ensure that there is consistency in the care provided.

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All Party Parliamentary Group on Surgical Mesh Implants	Guideline	5	5	Paragraph 1.1.3 Discussing repeat continence surgery and repeat same site prolapse surgery can put unnecessary significant strain on regional MDTs. These two conditions can be effectively discussed at the local MDT meetings, which will subsequently decide whether a review by the regional MDT is required. Referral criteria can be drafted and agreed upon by the two MDTs e.g. for the rare recurrent central compartment prolapse where a regional MDT input may be required from the outset. Abdominal mesh procedures should be discussed by a regional, rather than a local MDT. The reasons are: • It involves the insertion of at least one permanent medical device (mesh) and, if laparoscopy is employed, a second device in the form of fasteners is employed too. Use of implant, rather than native tissue, requires regional MDT involvement. • The number of abdominal mesh procedures has significantly dropped due to concerns on the safety of mesh implants. Therefore, the surgical skill needs concentration in units with adequate workload. A discussion	Thank you for your comment. We think that women who are considering repeat surgery should have the benefit of the opinion of the regional MDT. We agree that women who choose surgery that is not available locally should be referred to the regional MDT. We do not agree that all abdominal mesh procedure should be discussed at the regional MDT. This will depend on the experience and practice of the local unit.

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				at regional MDT will ensure the units support each other with surgical skills. • It is likely that women and surgeons will consider abdominal mesh procedures only or mainly in recurrent central compartment prolapse, which should be an indication of a regional MDT discussion in any way. Most women considering repeat continence surgery and repeat same side prolapse surgery can be discussed at local MDT in the first instance. This will focus the resources of the regional MDT where it is truly required.	
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	9	6	Paragraph 1.3.15 For the vast majority of women, the potential benefits of urodynamics prior to surgery for pure stress urinary incontinence far outweigh the associated risks. Benefits include confirmation of diagnosis, exclusion of associated condition, appropriate counseling and for medicolegal purposes. Following the recent concerns about safety of continence surgery, obtaining urodynamics information becomes essential in counselling prior to surgery, particularly as major abdominal procedures are expected to be the most	Thank you for your comment. We have amended the recommendation to clarify that an urodynamic test should only be performed when stress urinary incontinence is not demonstrated before surgery in women with stress urinary incontinence or stress predominant mixed urinary incontinence. Moreover, the Homer (2018) study suggested that "the probability of IUT being cost-effective remains uncertain". The study found no evidence for difference in costs or benefits (see evidence review A).

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				common approach for continence surgery in the future. With regards to cost-effectiveness, a recent study suggested that urodynamics *'may be cost-saving compared to basic clinical assessment'* prior to surgery for stress urinary incontinence. *Homer T, Shen J, Vale L, McColl E, Tincello DG, Hilton P; INVESTIGATE-I studies group. Invasive urodynamic testing prior to surgical treatment for stress urinary incontinence in women: cost-effectiveness and value of information analyses in the context of a mixed methods feasibility study. Pilot Feasibility Stud. 2018 Mar 23;4:67.* The savings from reducing the number of women undergoing urodynamic testing would be offset by the cost of unnecessary intervention (and treatment of its adverse events) following an incorrect diagnosis that relied only on patient history.	
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	21	6	Para 1.5.3 NICE has highlighted the uncertainty in the research literature with regards the long-term comparative safety of mesh versus non-mesh procedures.	Thank you for your comment. We agree that long term risks are currently unknown, and consider we have made this clear. , We have ensured this is clear by including a section of text to the beginning of the "surgery for stress urinary incontinence" and

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				Evidence from patient and clinician experience, however, suggests that the incidence of mesh complications and their impact on quality of life are higher than previously reported. As mesh procedures have been in use over only two decades and in the absence of serious public concerns about long-term complications from non-mesh native tissue surgery that had been around for over six decades, a suggestion of possible equivalence is not evidence-based. It is, therefore, important that NICE highlights the current serious concerns about the long-term mesh-related adverse events in this part of the guideline. It is very likely that future research will confirm the incidence and impact on quality of life of long-term complications associated with mesh procedures is higher than those of non-mesh procedures. Until this evidence is available, NICE can choose to warn the public about such risks, rather than suggest equivalence to non-mesh surgery by highlighting the research uncertainty.	"surgery for pelvic organ prolapse" sections. This text specifically states that the evidence on long term safety is limited. The committee are very aware of the public concern over mesh procedures, and although this evidence is not directly included within the meta-analysis (as it is unpublished, non-peer reviewed evidence), the committee have made all their recommendations with these concerns in mind. Due to the concerns over mesh, we think the guideline has done all it can to balance the evidence and expert input to support clinicians to ensure women are fully informed of the potential risks and benefits, enabling informed preference and shared decision making. The committee do however think that some women will still choose to have mesh surgery, and we have amended the rationale sections which relate to surgery to provide examples of women who may still want to have mesh surgery.

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All Party Parliamentary Group on Surgical Mesh Implants	Guideline	21	15	Para 1.5.6 It is good practice for the clinician to inform the patient if there is a significant competing interest that could have influenced the choice of the (mesh) medical device/manufacturer. Recommendation from NICE in this respect would improve transparency.	Thank you for your comment. We agree that this is an important consideration and should apply across all health care decisions.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	22	1	Para 1.5.8 What new evidence did NICE rely on in issuing this recommendation regarding a transobturator tape? History of multiple previous abdominal procedures is not a contraindication to a retropubic continence procedure. Multiple previous abdominal procedures can cause surgical adhesions, however, these are intraperitoneal and are not expected to increase the risk of organ damage from the extraperitoneal retropubic mesh procedure. The classic example to be quoted of a contraindication to the retropubic mesh tape is a history of a femoro-femoral vascular graft procedure, due to the high risk of severe haemorrhage.	Thank you for your comment. The new evidence considered in this guideline is reported in Evidence Report E. The committee used a combination of trials identified and a network meta-analysis that was conducted by a group commissioned by NIHR. The recommendation gave one example which the practitioner may wish to avoid for retropubic route. It is not intended to be an exhaustive list of contra-indications.
All Party Parliamentary	Guideline	22	21	Para 1.5.14	Thank you for your comment. The 6 month follow-up appointment is for clinical practice. The

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Group on Surgical Mesh Implants				The six-month follow-up after mesh surgery sounds too short. Complication can be revealed years later. Women who had mesh procedure are best followed up yearly in order to identify, recognise and treat any long-term mesh-related adverse events and also to improve the quality of the national registry and the reporting to the MHRA.	guideline recommends that longer follow-up of over 5 years should be covered by a registry as it is important that this data is captured. The text around the difference between clinical (short term) and registry (longer term) follow-up has been amended throughout the guideline in order to make this distinction clearer. In addition we have also stated that all women who have had surgery should have access to further referral.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	24	6	Para 1.6.6 Examination under anaesthesia (EUA) is an option worth mentioning here if symptoms are not explained from examination in clinics.	Thank you for your comment. We think that this situation would not occur frequently enough to warrant a recommendation in this guideline.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	25	2	Para 1.7.2 'Preventing or treating constipation' is worthwhile adding here.	Thank you for your comment. The committee have amended this recommendation so that it now states 'preventing or treating constipation'.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	26	27	Para 1.7.14 This recommendation appears to contradict that from NICE IPG on prolapse mesh issued in December 2017. The IPG suggested that mesh can be used for women with prolapse only within the research context. The IPAC recommendation in this respect is safer than that from NICE GDG.	Thank you for your comment. We refer the stakeholder to the full evidence report (evidence review I) on this topic, in particular to the section titled "other factors the committee took into account", within this section there is a detailed discussion regarding the IPG and how the

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				In addition, biological material should not be used as an alternative to polypropylene for treatment of prolapse outside research context.	committee do not agree that mesh should only be considered for research purposes.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	27	15	Para 1.7.17 The new mesh sacrohysteropexy procedure (abdominal or laparoscopic) appears to be too invasive to be recommended as first line option. Until there is reliable research evidence on long-term outcomes, mesh sacrohysteropexy cannot be recommended if the less invasive alternatives are unsuitable or unacceptable and after discussion at a regional MDT. The alternatives are less invasive as the approach is vaginal, rather than the abdominal, and no medical device is used. Mesh sacrohysteropexy, on the other hand, adds the safety issues of abdominal entry with its inherent risks, the use of a mesh device and, if laparoscopy is employed, the use of a second medical device in the form of fasteners. This is too invasive when most women can be helped with a much less invasive and time-honoured alternatives.	Thank you for your comment. The committee have re-ordered the recommendations. The list is not an order of which procedures should be considered, simply a list of procedures which should all be considered, and the most appropriate surgery for each individual woman may differ. The committee consider that sacro-hyteropexy is an option which should be available to a small group of women who want to retain their uterus. We have added more detail to the recommendations about discussing the potential risks and benefits and lack of evidence on long term complications for all of the procedures. The guideline will be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse.
All Party Parliamentary Group on	Guideline	28	4	Para 1.7.20 The new mesh sacrohysteropexy procedure (abdominal or laparoscopic) appears to be too	Thank you for your comment. The committee have re-ordered the recommendations. The list is not an order of which procedures should be considered,

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Surgical Mesh Implants				invasive to be recommended as first line option. Until there is reliable research evidence on long-term outcomes, mesh sacrohysteropexy cannot be recommended if the less invasive alternatives are unsuitable or unacceptable and after discussion at a regional MDT. The alternatives are less invasive as the approach is vaginal, rather than the abdominal, and no medical device is used. Mesh sacrohysteropexy, on the other hand, adds the safety issues of abdominal entry with its inherent risks, the use of a mesh device and, if laparoscopy is employed, the use of a second medical device in the form of fasteners. This is too invasive when most women can be helped with a much less invasive and time-honoured alternatives.	simply a list of procedures which should all be considered, and the most appropriate surgery for each individual woman may differ. The committee think that sacro-hyteropexy is an option which should be available to a small group of women who want to retain their uterus. We have added more detail to the recommendations about discussing the potential risks and benefits and lack of evidence on long term complications for all of the procedures. In addition, the guideline will be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	28	19	Para 1.7.24 The recommendation is to consider using synthetic propylene or biological mesh in women with recurrent incontinence after MDT review. If, according to the PROSPECT study, there is no added benefit from the use of vaginal implant, over native tissues, in women with the simple condition of primary prolapse, how would implants add value to women with the complex condition of recurrent	Thank you for your comment. The two studies the stakeholder refers to may have shown no benefit for mesh as compared to native tissue; however, we conducted a comprehensive meta-analysis which included data from a total of 22 RCT for anterior prolapse (evidence review I). The two studies which the stakeholder refers to, do not separate the different data for the different compartments of prolapse; therefore the Milani

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				prolapse? Indeed, the best evidence in this respect, Milani et al 2018, confirms no added benefit in women with recurrent prolapse. *Melani et al. Long-term outcome of vaginal mesh or native tissue in recurrent prolapse: a randomized controlled trial. Int Urogynecol J (2018) 29:847–858.* In addition to lack of efficacy, there are serious safety concerns that led NICE IPAC to restrict its use only to the research context. Women with recurrent prolapse should not be exempt from such restriction, particularly their risk of developing adverse events could be even higher, compared to those with primary prolapse.	study did not meet the inclusion criteria (we could not determine which women had anterior, posterior, apical or multi-compartment surgery). However, we were provided data, separated out by compartment (for women with anterior or posterior surgery), from the authors of the PROSPECT trial. The combined data from our meta-analysis clearly showed mesh surgery was more effective, and resulted in lower recurrence rates for anterior prolapse as compared to native tissue repair. Meta-analysis is considered the highest form of evidence for clinical research as the systematic methodology reduces bias which may be more likely to occur within individual studies. Similarly, the NMA which was undertaken for this review question on the recurrence outcome indicated that mesh was more effective in reducing the risk of recurrence at the same site. It has to be noted that most RCTs included a mixed population (i.e. women undergoing primary and secondary repair). The committee was of a view that it would be reasonable to assume that the effectiveness of surgical interventions is similar in women undergoing primary and secondary repair. However, the baseline risk of recurrence may be different.

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All Party Parliamentary Group on Surgical Mesh Implants	Guideline	29	4	Para 1.7.25 This recommendation suggests that mesh is not useful for recurrent prolapse of the posterior vaginal wall but it is useful for the recurrent prolapse in the anterior vaginal wall. Milani et al study in December 2017 is the best trial with the longest follow-up in this context and is in contradiction of this recommendation.	Thank you for your comment. The Milani study was excluded as it was not possible to determine outcomes per location of prolapse i.e. we could not determine if women had anterior, apical, posterior or combined prolapse surgery (evidence review I). We conducted a meta-analysis on posterior prolapse, and the data showed no difference in effectiveness between mesh surgery and standard repair for posterior prolapse. The included studies did not provide data on recurrence; however, and with the concern over potential long term associations with mesh surgery the committee did not think it was appropriate to recommend mesh for posterior repair.
All Party Parliamentary Group on Surgical Mesh Implants	Guideline	29	7	Para 1.6.26 Reviewing all women who had prolapse surgery 6 months later is a significant use of resources that, for most women, is not required.	Thank you for your comment. The 6 month follow-up appointment is for clinical practice. The guideline recommends that longer follow-up of over 5 years should be covered by a registry as it is important that this data is captured. The text around the difference between clinical (short term) and registry (longer term) follow-up has been amended throughout the guideline in order to make this distinction clearer. In addition we have also stated that all women who have had surgery should have access to further referral.

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All Party Parliamentary Group on Surgical Mesh Implants	Guideline	29	6	Para 1.9.1, Coital bleeding as one of the adverse events worth mentioning here.	Thank you for your comment. The recommendations include "sexual function" and the committee consider that it is covered. We would expect the consultant discussing potential complications to explain these in more detail than can be provided in a guideline, which needs to be succinct as we cannot provide a text book of all possibilities.
Association of Continence Advice	Guideline	15	13	would cheaper medications be selected over most effective?	Thank you for your comment. This is outside of the scope of this guideline as the effectiveness of anticholinergic medication was not updated.
Association of Continence Advice	Guideline	16	26	agreed this is desirable, but would have a big impact on GP time – would it be feasible?	Thank you for your comment. We think that the prescriber should do a review.
Association of Continence Advice	Guideline	17	17	– should we be considering PTNS before botox?	Thank you for your comment. PTNS was outside of the scope of this guideline update. We have only reviewed the dose of Botox as part of this update. Thank you for your response. We will pass this information to the NICE surveillance team for the next update.
Association of Continence Advice	Guideline	18	13	agreed with the improved follow-up guidance re botox.	Thank you for your comment.

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Association of Continence Advice	Guideline	21	6	discussed availability of statistics on complications associated with surgery for SUI. How would practitioners access these, do surgeons provide own statistics?	Thank you for your comment. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse. For further detail on the data, please see the evidence report E
Association of Continence Advice	Guideline	21	12 &15	very good additions to guidance.	Thank you for your comment.
Association of Continence Advice	Guideline	21	22	: Follow-up should be with the surgeon. If not, guidance should be given to non-surgical practitioners.	Thank you for your comment. We have moved this recommendation to section 1.5 to make clear that follow-up should still be with the surgeon.
Association of Continence Advice	Guideline	25	2	: lifestyle advice is not enough, patients should be referred to appropriate services	Thank you for your comment. The committee think that this is up to the clinical assessment and advice on referral.
Association of Continence Advice	Guideline	25	26	including surgeons out of area. Allow patient choice.	Thank you for your comment. The committee agree, women can request to see a surgeon outside of their geographical area, thus allowing patient choice.
Association of Continence Advice	Guideline	25	29	consider the use of topical oestrogen for all women prior to pessary use (if not contraindicated).	Thank you for your comment. There was no evidence to make this a firm recommendation,

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					therefore it will remain as a 'consider treating recommendation'
Association of Continence Advice	Guideline	26	12	some considered this to be unclear.	Thank you for your comment. The committee were aware that some women would be offered surgery to prevent UI at the time of prolapse surgery. The committee reviewed the evidence and there was insufficient evidence to support offering preventative UI surgery along with prolapse surgery, therefore this recommendation was made and will remain
Association of Continence Advice	Guideline	27	15	some considered more info needed on Manchester repair. Specialist nurses/practitioners should have more knowledge of the materials used in mesh products, types of mesh surgery and of potential complications. It would be useful to have screening questions when logging complications, and awareness of when to report.	Thank you for your comment. There was only limited evidence available on Manchester repair; however this showed favourable results in comparison to vaginal hysterectomy (evidence review I). The committee agreed that despite limited evidence it should remain as an option for women. We agree that specialist nurse practitioners should have more knowledge about mesh products, and the potential complications from mesh surgery; however, it is not the remit of a guideline to provide a training manual. We hope that those health care practitioners working in this field will seek out information to ensure the women they treat receive the best clinical care.

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Astellas Pharma LTD	Guideline	14 15	26 – 29 1 -2	Guideline Point: 1.4.28 We note that the guideline lists considerations for the prescriber when offering an anticholinergic medication, these being *'coexisting conditions', 'current use of medicines affecting the total anticholinergic load'* and *'risk of adverse events including cognitive impairment'*. However, the draft guideline neither makes recommendations on action nor prescribe the scoring system for calculating total anticholinergic load. We request the inclusion in the main guideline of a reference to a published scale for the scoring of anticholinergic load to aid clinicians in the identification of medicines that contribute to Anticholinergic Burden (ACB). In addition, we request that guidance to consider an alternate class of treatment is included in section 1.4.28 should any of the considerations listed above be present, as is seen in the All Wales Medicines Strategy Group (AWMSG) 2018-19 National Prescribing Indicators document and the Polypharmacy Guidance Realistic Prescribing issued in 2018 by NHS Scotland.	Thank you for your comment. There is no validated or NICE recommended tool that is accepted for use. Although there was insufficient evidence to make a recommendation, the committee decided that it was important to highlight this issue for discussion. There are a number of different rating scores, and we cannot recommend one over the other and the validity of these differ. It is important that the prescriber considers the total anticholinergic load and to use which ever tool they believe is most useful. The guideline also cross refers to the NICE dementia guideline (please see recommendation 1.4.27), which provides more detail regarding cognitive impairment and medication.

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Astellas Pharma LTD	Guideline	15	3-6	Guideline Point: 1.4.29 We request that where in the guideline it is stated '*follow the recommendations on medicines that may cause cognitive impairment in the NICE Guideline on dementia'*, that the recommendation from the Dementia Guideline namely '*minimize the use of medicines associated with increased anticholinergic burden, and if possible look for alternatives'* be included in the body of the main guideline itself.	Thank you for your comment. The phrasing is standard signposting within NICE guidance.
Astellas Pharma LTD	Guideline	15	13-16	Guideline Points: 1.4.32 & 1.4.33 Whilst we support the initiation of an anticholinergic medication of lowest acquisition cost, we question the statement '*if the first medication for OAB or mixed UI is not-effective or well tolerated offer another of the lowest acquisition cost'*. We believe that this statement may encourage the cycling of antimuscarinic drugs, and we note that the practice of cycling up to five different OAB treatments was noted back in the full evidence guideline for CG 171 and that 'the Guideline	Thank you for your comment. This is outside of the scope of this guideline as the effectiveness of anticholinergic medication was not updated.

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				Development Group (GDG) wished to restrict this practice'.	
Astellas Pharma LTD	Evidence Review C	12	27-37	We note the committee's comments on the Richardson 2018 paper and the committee's decision to exclude it in the systematic literature review. Whilst we agree with the committee that the study has its limitations and demonstrates an association between anticholinergic drugs and increased risk of cognitive impairment, we kindly request that the committee considers the following points and re-examine the evidence on these bases: • As a case control study based on retrospective data, Richardson and colleagues included 100,856 participants examined over a long time horizon, with drug exposure period ranging from 1 to 16 years, and including a four-year gap prior to the index date (date of dementia diagnosis). • Unlike other retrospective studies of its kind performed to date, this paper has broken down and run statistical analyses on the anticholinergics by class. Moreover, this	Thank you for your comment. We discussed this publication at length within the evidence review, and the committee considered all the evidence before making the recommendations. The study, although informative did not however meet the inclusion criteria for the actual review question and was not included. Systematic reviews are conducted in a way to reduce bias and there are strict methodological methods which must be followed to ensure bias is not introduced. This study, and others were excluded as they did not meet the predefined inclusion criteria. We cannot select papers which we think are interesting simply because they are well discussed in the media – this would introduce bias. We have made a research recommendation on this topic and hope research into this area will be funded so that future updates of this guideline can provide more definitive answers to this question.

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				includes the class deemed 'urologicals' which has been classified according to the 2012 update to the Anticholinergic Burden Scale. All of the urological drugs within the 2012 update are anticholinergic medications used to treat overactive bladder. Within this group there is a statistically significant increase in the incident rate of dementia (OR: 1.18 at end of Drug Exposure period; $p<0.01$) and exposure to urological medications with an ACB score of 3. • The study has gone to significant lengths to minimize confounding factors by matching each case of dementia to controls (up to seven), considering both clinical and non-clinical factors. Whilst we agree with the committee that a well-conducted prospective cohort study exploring the long-term effects of different anticholinergic classes in specific cohorts is required, the time required for such a study, specifically examining cognitive impairment and dementia, would be substantial. In the meantime, we request that the evidence	

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				contained within the Richardson 2018 paper, specifically the association between 'urologicals' and the risk of incident dementia be examined within the context of many other studies demonstrating an association between cumulative anticholinergic use in the elderly and cognitive impairment. We further request that this weight of evidence be documented within the evidence review and used to support the recommendation for use of a non-anticholinergic medicine in at-risk patients.	

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Astellas Pharma LTD	Evidence Review C	13	16 - 17	In support of Comment 3 above, it is noted that (based on the committee's experience) there is little difference between anticholinergic drugs in terms of effectiveness. This view is further supported by real world evidence examining the utility of antimuscarinic cycling in Wet OAB patients (Chancellor et al. 2016, Limitations of anticholinergic cycling in patients with overactive bladder (OAB) with urinary incontinence (UI): results from the CONsequences of Treatment Refractory Overactive bladder (CONTROL) study), whose authors concluded that: '*UI symptom burden and adherence to therapy did not change as patients attempted more anticholinergic therapies. These results suggest that for patients who remain incontinent after attempting an anticholinergic, cycling on additional anticholinergics may not provide any additional benefit, resulting in sub-optimal care.'* Whilst it has been established that anticholinergics have different side effects and	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.

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				tolerability profiles, taking into account the views on the efficacy profiles and the evidence above, we request that consideration be given to changing 1.4.33 to suggest that if an initial antimuscarinic is ineffective in relieving the symptoms of OAB, that a change of class be considered. This would mirror recommendations by the European Association of Urologists who in section 4.2.3.3 of their guidance suggest '*If an antimuscarinic treatment proves ineffective, consider dose escalation, or offering an alternative antimuscarinic formulation, or mirabegron, or a combination'*. This draft guideline does not conclusively position B3 agonists in its current form. Alternatively, by delineating specifically where this class is to be considered, offers additional benefit by ensuring that once a patient (as per the guideline) gets to Multidisciplinary Teams (MDTs) and invasive therapies, the suggestion above will ensure that all classes of oral	

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				therapy will have been exhausted prior to more invasive and costly treatments.	
Astellas Pharma LTD	Evidence Review C	13	22 - 24	We do not agree with the representation that mirabegron is 'very expensive' and contest that this be included in the evidence review in the absence of a qualifying statement, adherence to methods guide, or economic model, where a definition as to what constitutes 'very expensive' is stated. Moreover, this statement is made in the context where anticholinergic drugs are contraindicated. In this scenario, there is no other alternative in terms of oral medication to mirabegron and therefore we do not feel cost is an appropriate argument against its use in this cohort. With reference to mirabegron being associated with 'cardiac problems', as per the SmPC, mirabegron is contraindicated in 'severe uncontrolled hypertension, defined as systolic blood pressure ≥ 180 mm Hg and/or diastolic	Thank you for your comment, as suggested, we have removed this sentence from the evidence review"

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				blood pressure ≥ 110 mm Hg'; hypertension is listed as a precaution and additionally tachycardia is a common side effect with palpitations and atrial fibrillation listed as uncommon. Stating that mirabegron is associated with 'cardiac problems' is a broad statement and implies an inferior safety profile to alternate treatments. Please kindly quote directly from the Summary of product characteristics (SmPC) if referencing any cautions or contraindications associated with mirabegron use. In light of the above, we would request that lines 22-24 be removed from the evidence review.	
Bladder Health UK	General	General	General	Following the suspension of the use of vaginal mesh, we have been contacted by a significant number of women who are asking about alternatives to surgical intervention for Stress Urinary Incontinence.	Thank you for your comment. In light of stakeholder comments, the committee have amended their recommendations from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition, the committee has recommended that the woman is told that repeat injections may be needed to

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				We advise that they consider bulking agents as a possibility and ask their urologists about the procedure. We believe that bulking agents are a potential alternative and every women should have the right to make an informed choice themselves on treatment. We find the Guidelines do not make this clear (even going as far as saying they are confusing and give mixed messages about the treatment options by not recommending bulking agents be included in early discussions with the clinician).	achieve efficacy and that efficacy is limited and diminishes with time. The committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.
Bladder Health UK	Evidence Review E	102	33	Bulking agents should be included as the fourth choice to be offered to women if non-surgical management for SUI has failed or is not considered appropriate.	Thank you for your comment. In light of stakeholder comments, the committee have amended their recommendations from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition, the committee has recommended that the woman is told that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time. The committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral

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					mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.
Bladder Health UK	Evidence Review E	104	18-20	As a patient organisation, we believe that these words leave the choice with the clinician and we feel that the patient should have the opportunity to choose.	Thank you for your comment. The guideline will be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse.
Bladder Health UK	Evidence Review E	104	27	This contradicts E1.2. If bulking agents are not included in the initial discussions with the patient as a treatment option how would a woman know what surgical procedures are suitable or acceptable?	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.
Bladder Health UK	Evidence Review E	114	9	Have the committee considered the US Study 'Efficacy and Safety of Polyacrylamide Hydrogel for the Treatment of Female Stress Incontinence: A	Thank you for your comment. The committee did not prioritise comparing different bulking agents.

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				Randomized, Prospective, Multicenter North American Study' by Eric R. Sokol, Mickey M. Karram and Roger Dmochowski?	This study compares Bulkamid with a polyacrylamide hydrogel bulking agent.
Boston Scientific	Guideline	General	General	Where the guidelines require prospective data collection on the outcomes of surgery utilising mesh, we suggest that for an effective evaluation of the change in practice that will result, this be replaced with a requirement to collect data on all recommended treatment options, whether it is a native tissue or mesh repair. This would allow data to be gathered on the efficacy and adverse events related to non-mesh surgery for a proper comparison of the outcomes from each type of surgical intervention to be made.	Thank you for your comment. The recommendation has been revised to include collecting data on women who have any surgical procedure for stress urinary incontinence or pelvic organ prolapse, or who have mesh-related complications.
Boston Scientific	Guideline	General	General	Where prospective registry data is collected on a procedure utilising a specific device, we suggest that full details of the devices utilised are recorded (including manufacturer and model). This would enable a comprehensive outcome analysis of specific devices regarding their indications, outcomes and adverse events	Thank you for your comment. We agree with your suggestion and have added 'manufacturer and product unique identification code' to the list of information to be collected.
Boston Scientific	Guideline	28	16	Regarding statement – and if:	Thank you for your comment. The committee did not prioritise any review evidence on combined

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				"Apical support is adequate", we would respectfully ask NICE to consider revising this to "Apical support is adequate or the mesh device is intended to provide anterior and apical support." There is evidence to suggest that some MESH device offers anterior and apical support, so for this we would like NICE to consider the following evidence: • Vu et.al, Minimal mesh repair for apical ad anterior prolapse: initial anatomical and subjective outcomes. Int. Urogynecol J 2012 • Letouzey et.al Utero-vaginal suspension using bilateral vaginal anterior sacrospinous fixation with mesh: intermediate results of a cohort study. Int Urogynecol J 2015 • Rakhola-Soisalo et.al. Pelvic Organ Prolapse Repair Using the Uphold Vaginal Support System: 5_year Follow up. Female Pelvic Med Reconstructive Surgery 2017	compartments, therefore are unable to make a recommendation based on this evidence. The Vu et al. study did not meet inclusion as it evaluated 'anterior and apical compartment prolapse repair'. In addition, it was not a comparative study. Letouzey et al. study did not meet inclusion as it evaluated 'treatment of the anterior vaginal wall and vault prolapse'. In addition, it was not a comparative study. Rakhola-Soisalo et al. study did not meet inclusion as it is an abstract only.
British Geriatrics Society	Guideline	General	General	The committee's work on creating a rational framework for guiding the use of and monitoring of complications from synthetic mesh for urinary incontinence and prolapse is welcomed. The current politically motivated cessation of	Thank you for your comment.

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				procedures for incontinence flies against a wealth of published evidence and disadvantages many women, particularly elderly women, who no longer receive surgical treatment for their condition and are condemned to suffer without it. The Society welcomes the positioning of conservative and pharmacotherapeutic management of incontinence prior to offering surgery.	
British Geriatrics Society	Guideline	General	General	**Recommendations for research** The Society welcomes the content of evidence review C and would support endeavours to answer this important research question.	Thank you for your comment.
British Geriatrics Society	Guideline	7	15	1.3.3 The Society notes the relevance of recommendation 1.3.3 for elderly women but feels that additional guidance on the nature of associated conditions with an impact on continence in older women might be warranted to draw attention of healthcare practitioners to the relevance of this aspect of the management of the	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.

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				multiple factors leading to incontinence in older women. The Society recognises the importance of pelvic floor muscle exercises in the treatment of all forms of incontinence, consistent with the recent Cochrane collaboration update. The Society would welcome recommendations on the nature and extent of maintenance programmes of pelvic floor muscle therapy and also recommendations for the recognition and management of elderly women who are unable to satisfactorily manage exercises. The Society feels that the place of absorbent containment products form a core of daily management for many women, despite attempts at "cure" or "resolution" of symptoms and feels that the current recommendations do not sufficiently reflect the importance of containment products to many women, including older women. For many, these containment products are adjunctive, and may be used in addition to other treatment options and not just when other options have been explored.	
British Geriatrics Society	Guideline	12	18	1.4.19-1.4.23 Recommendation 1.4.19 and 1.4.20 are however welcomed as a useful expansion on the current	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and

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				guideline and could perhaps be supplemented by a useful link to the competencies document produced by, for example the UK continence society or British society of urogynaecology. Given the relative dearth of evidence on continence care at the end of life, the Society wonders if an additional clause in recommendation 1.4.23 might be considered to include the use of catheters at the end of life, recognizing that their use in this circumstance may also be covered in the "distress' and "preference" clause. The Society welcomes the evidence informed statement on the longer term effects of antimuscarinic agents in light of the associative effects recently reported which gained considerable media hype. The Society recognises that active treatment of older women with OAB – UUI should be evidence informed and that older women should not be disadvantaged when treatment is considered. The Society supports the recommendations on the use of immediate release oxybutynin for women at risk of delirium or adverse cognitive events. The Society would appreciate an additional note regarding the high rates of discontinuation and low	cannot therefore amend the recommendations made in 2006 or 2013.

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				rates of adherence to this medication, negating its utility. The Society notes that cost is an important consideration in prescribing.	
British Geriatrics Society	Guideline	15	13	1.4.32 Recommendation 1.4.32 does however, in light of current published evidence, fly in the face of data on efficacy of antimuscarinic medication for older or medically complex older women, which currently supports the use of fesoterodine.	Thank you for your comment. This is outside of the scope of this guideline as the effectiveness of anticholinergic medication was not updated.
British Geriatrics Society	Guideline	16	26	1.4.44 The Society welcomes the additional recommendation, 1.4.44, regarding the longer term review of women on medication for OAB-UUI. The nature of this condition as a chronic medical disease should be recognised and treated as such. The society recognises the reduced efficacy of urethral bulking agents but notes that there is evidence for their use in frail older women for whom "dryness" or longer term resolution of symptoms may not be the ultimate goal. The society would appreciate an additional footnote in this regard. Older women are often offered an intravaginal pessary for incontinence despite the lack of	Thank you for your comment. We did not review incontinence pessaries as part of this guideline update. However, in light of the stakeholder comment, we have added an additional recommendation regarding women who have cognitive or physical impairment, noting they should have an appointment every 6 months (1.7.9). GPs review all patients on medication every year and is already part of current practice. In addition, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'

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				evidence regarding their use. The Society notes that there is no recommendation regarding the use of pessaries for incontinence. Given the increased risk of the "forgotten pessary" in older women, particularly those with cognitive impairment, the Society would welcome a guidance statement in this regard.	
British Geriatrics Society	Guideline	24	19	1.7.1 The Society appreciates recommendation 1.7.1, which highlights the impact of age, comorbidities and cognition on the need and extent of treatment for prolapse.	Thank you for your comment.
British Menopause Society	Evidence review D and E	General	General	I could not see a mention of the potential beneficial effects of topical oestrogens on incontinence. It would be worth suggesting adding a summary of the Cochrane review on oestrogen therapy for urinary incontinence that concluded that 'Urinary incontinence may be improved with the use of local oestrogen treatment'.	Thank you for your comment. Evidence review D is specifically relating to BoNT-A and therefore does not cover topical oestrogen and we do not think it would be warranted to be included in this section. Evidence review E examines surgery for SUI and did not review the evidence on topical oestrogen. As the Cochrane review did not meet the inclusion for either Evidence Review D or E we do not think we can reference it as the stakeholder suggests."

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				(Cody JD, Jacobs ML, Richardson K, Moehrer B, Hextall A. Oestrogen therapy for urinary incontinence in post-menopausal women. Cochrane Database of Systematic Reviews 2012, Issue 10. Art. No.: CD001405. DOI: 10.1002/14651858.CD001405)	
British Pain Society	Guideline	General		The British Pain Society welcomes the recognition of the importance of comprehensive multidisciplinary assessment and management of pain problems associated with pelvic surgery particularly where mesh has been used.	Thank you for your comment.
British Pain Society	Guideline	5	23	The pain specialist needs to have expertise in the management of pelvic pain. This should be specified here.	Thank you for your comment. We agree that this is a valid point, and have amended the recommendation to reflect this.
British Pain Society	Guideline	6	5	The arrangements for the involvement of the multidisciplinary pain management team need to be specified with clear routes of referral and assessment pathways. The multidisciplinary pain management team will need to have expertise in the management of complex pelvic pain. It could be a separate organisation or integrated as part of the regional MDT.	Thank you for your comment. Please see recommendation 1.1.5 where this is covered. Pain management services should be linked to, but not within the MDT itself.

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				A useful model is the 'multidisciplinary pain management service with expertise in pelvic pain' as specified in the service for the management of endometriosis in NG73	
British Society of Urggynaecology	Guideline	1-45		The draft guideline uses the term vaginal atrophy throughout. This is now outdated and has been replaced by GSM (genitourinary syndrome of the menopause). This should be updated in the entire document.	Thank you for your comment. To ensure consistency, this guideline has followed the terminology used in the menopause guideline.
British Society of Urggynaecology	Guideline	4	4-13	1.1.1 The inclusion of primary prolapse procedures in MDT discussions is not evidence based and will result in a large increase in workload for clinician's and MDTs. Increased workload will probably reduce quality of decision making and may reduce overall care. Please consider removing this. By setting the bar so high for MDTs there is a significant risk they will fail, better to be realistic in expectations and insist on complex cases going through MDT.	Thank you for your comment. The committee noted that the previous guideline recommended that the surgical management of stress urinary incontinence required MDT involvement. As this update included pelvic organ prolapse, this involvement needed to be extended. The committee considers that involving the MDT in the management of pelvic organ prolapse will improve standards of care, ensuring the right surgery is done for each woman. An MDT discussion avoids decisions being made by one person acting alone.
British Society of Urggynaecology	Guideline	4	9	**Section 2** - Other specific comments 1.1.1, page 4, line 9. Vague. Give examples of situations that require input from a wider range of professionals.	Thank you for your comment. The committee cannot provide examples in this case as it will depend on the individual patient's needs, and the requirement is patient dependent.

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British Society of Urggynaecology	Guideline	4	18	1.1.2, page 4, line 18. There is no need for a physiotherapist if a urogynaecology nurse specialist offers the same expertise. Please remove or combine with line 17	Thank you for your comment. The committee disagree. A physiotherapist receives specialist training which differs from the urogynaecology nurse specialist. The physiotherapist offers a different level of competency and skill set, and as such should be included in the MDT.
British Society of Urggynaecology	Guideline	5	8	1.1.3 – please make clear that repeat botox injections do not have to be discussed by the regional MDT – if this was required, the MDT would be over whelmed.	Thank you for your comment. We agree that women who simply need repeat injections do not need to have their treatment discussed at the MDT. It is however important that women who require a change in dose, or change in treatment have their care discussed at the MDT.
British Society of Urggynaecology	Guideline	5	15-28	1.1.4 More flexibility should be included in the makeup of the MDT. We are all busy clinicians. A radiologist may not always be necessary – or a pain specialist etc etc. Only members required by the cases discussed should need to attend. Nobody is going to sit in a meeting that they do not need to contribute to.	Thank you for your comment. The MDT refers to the team members who should be available if needed but they might not be required to attend every meeting. We have added recommendations to state all those listed in 1.1.2 should attend; however, those listed in 1.1.5 need only attend when their expertise is required.
British Society of Urggynaecology	Guideline	5	17	1.1.4 line 17 this should be altered; please add" or equivalent experience" to allow the MDT to be quorate with senior surgeons who trained before subspecialisation was introduced.	Thank you for your comment. The committee agreed that the regional MDT requires a clinician with sufficient skills and expertise to be recognized as a subspecialist. Given this is a guideline, the regional MDT would be able to appoint someone with equivalent experience.

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British Society of Urggynaecology	Guideline	5	28	1.1.4, page 5, line 28 Add "or an orthopaedic surgeon" or surgeon skilled at operating in the obturator region?	Thank you for your comment. We have added a 'surgeon skilled at operating in the obturator region'.
British Society of Urggynaecology	Guideline	6	23	1.2.2 line 23 – long-term follow-up, especially by outpatient visit, has resource implications. NICE should explicitly state that this needs to be supported by the CCGs. Subjective outcomes should include the use of validated patient completed questionnaires. 5 year follow up may be a research aspiration but should not be included in a guideline. Many research studies fail to achieve this eg colposuspension vs TVT trial. To date there is no scientific evidence that would support routine long term follow up. If this guideline is based on cost effectiveness of care this would be unsupported.	Thank you for your comment. We acknowledge there is a cost associated with follow up but we think this service is important and should be provided. We have amended the recommendations to make it clear that any long term follow-up (at least 5 years) would be the responsibility of the national registry of surgery for urinary incontinence and pelvic organ prolapse in women.
British Society of Urggynaecology	Guideline	6	26	1.2.2 line 26 – what is meant by *"objective measures of UI of POP"*? Objective measures means seeing and examining the patient or urodynamic investigation. These have no purpose.	Thank you for your comment. To clarify the meaning we have removed the word "objective" and replaced this with "validated". We have additionally added "adverse events to include pain".
British Society of Urggynaecology	Guideline	9	4	1.3.14 specifically recommends that pad test should not be used – it is a contradiction to, therefore, state that objective measures should be	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the

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				used – please alter to make consistent – either do use or do not use objective measures.	evidence on this, and cannot therefore amend the recommendation made in 2006 or 2013.
British Society of Urggynaecology	Guideline	14	22	1.4.27 line 22 – this is incorrect please amend. The full benefits of anticholinergic medication are not seen until 6 months. In fact 70% of the benefit is seen at 6 weeks – a review at 4 weeks is illogical when only 50% of the final effect will have been obtained.	Thank you for your comment. We did not review the effectiveness of anticholinergics as part of this update. However, we have reworded "full benefits" to "substantial" and added "at least 4 weeks". This recommendation intends to explain that the drug may not be fully working at 4 weeks, but one can expect to see some benefits by then. If there is no obvious benefit it may be appropriate to change drug or stop the drug.
British Society of Urggynaecology	Guideline	14	24.	1.4.27 line 24. This comment is unhelpful. I hope NICE has thoroughly reviewed the evidence for this. The suggestion is that anticholinergic load is associated with dementia and increased risk of death. Most anticholinergics used for incontinence increase the anticholinergic burden to unsafe levels in the elderly. Hence please justify this comment or alter it to reflect our current understanding of the risks of anticholinergics.	Thank you for your comment. We conducted a review on the risks of cognitive function for women taking anticholinergic drugs for OAB but found limited evidence (evidence review C); therefore, we were unable to make strong recommendations. In the evidence review we discuss the growing body of evidence which indicates an association between cognitive dysfunction and anticholinergic medicines, (although not specifically for treatment of OAB), and have therefore recommended that health care practitioners take this into consideration. For the population which the stakeholder specifically refers, we have cross-referenced to the NICE guideline on dementia.

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British Society of Urggynaecology	Guideline	21	1-5	**1.5.2** A general theme was dissatisfaction with the place of periurethral injections in the treatment algorithm of stress incontinence resistant to conservative therapies. An example of one such response was - "My concern is that I do not wish us to be in a situation where we offer certain surgical procedures to the patients without mentioning bulking agents as one of the options. If any surgical complication happens with the other procedures, or if they fail, in a patient who was never offered a bulking agent as an option, the surgeons will be criticised, justly, that they: - withheld information about a safer procedure - did not help the patient make an informed decision/choice - breached the Montgomery ruling" Similar comments were received from multiple respondents and we would strongly recommend that this section is rewritten and bulking agents should be part of the first line surgical treatment options. Surgeons will have great difficulty applying	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				this rule if it is medico legally unsound which it currently is. This is a contradiction – how can periurethrals be not acceptable if they are not discussed? The guideline should allow the patients to make a choice of the operation most suitable for their own circumstances. Efficacy reduces with time with all procedures – there is no need to specifically state this. Efficacy when judged by patient satisfaction is acceptable – efficacy is limited should be removed. A more appropriate term should be that "risks and complications of individual procedures should be discussed and documented" as per 1.5.1 NICE states in its document relating to care of patients that: "people have the right to be involved in discussions and make informed decisions about their care". Please apply this to this guideline	
British Society of Urggynaecology	Guideline	22	12-16	**1.5.12** There is ongoing reluctance **not** to perform urodynamics before continence surgery. Most of the research in this area relates to synthetic suburethral slings. Whilst these are "paused" in the UK, other procedures such as fascial slings and colposuspension are performed. These are major	Thank you for your comment. The committee have amended the recommendation to clarify that an urodynamic test should not be performed only when demonstrated stress urinary incontinence has already been indicated.

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				surgical procedures with risks of voiding dysfunction and long term catheterisation. Cystometry should be performed before such major procedures as there is no evidence to suggest that this investigation should not be performed. Cystometry informs part of the decision making process before these operations.	
British Society of Urggynaecology	Guideline	22	21	1.5.14 line 21 – what about long-term follow up? Earlier in the document it recommends follow-up for at least 5 years. Please make the document consistent – 6 months follow up seems acceptable in routine practise whereas 5 years does not. Please state one or the other not both.	Thank you for your comment. The 6 month follow-up appointment is for clinical practice. The longer follow-up of over 5 years is for data collection of follow up which will be recorded in the registry Unfortunately, at this stage we do not know how this longer term data will be collected, we anticipate clinicians will be contacted to provide data, but also the women themselves may be contacted to provide information. . The text around the difference between clinical and registry follow up has been amended throughout the guideline in order to make this distinction clearer. In addition we have also stated that all women who have had surgery should have access to further referral, to ensure women are clear they can go back to see either the same, or a different

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					consultant if they experience any potential complications.
British Society of Urggynaecology	Guideline	23	23-25	1.6.3 Please reconsider the routine use of POPQ; this system is not widely used and thought to be cumbersome, time-consuming, not descriptive (for staff and GPs). Ideally this should be an option but not mandated. Consider use of the more commonly used Baden Walker system.	Thank you for your comment. We consider that having a standardised examination record will improve the standard of care including choices of treatment and follow-up, and communication at MDT
British Society of Urggynaecology	Guideline	24	18-29	1.7.1 inconsistent as doesn't offer this for SUI; the document needs to be consistent for its recommendations for both prolapse and incontinence.	Thank you for your comment. The committee was of a view that pelvic organ prolapse is much more complex and there are different issues to consider. We have attempted to be consistent; however, the two conditions, pelvic organ prolapse and stress urinary incontinence cannot always mirror each other as they are different, with different pathways.
British Society of Urggynaecology	Guideline	25	7-8	1.7.8 This needs to be clarified and state that the pessary can be replaced if required	Thank you for your comment. , There was no evidence to suggest self-management. The committee are aware however that this is currently research within the NIHR pipeline. In addition, the recommendation does not explicitly say who should carry out the pessary removal and that this could be self-managed
British Society of Urggynaecology	Guideline	26	12 - 13	1.7.10 prophylactic surgery surely under choice should be discussed?	Thank you for your comment. The committee were aware that some women would be offered surgery to prevent UI at the time of prolapse surgery. The committee reviewed the evidence and there was

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					insufficient evidence to support offering preventative UI surgery along with prolapse surgery, therefore this recommendation was made and will remain
British Society of Urggynaecology	Guideline	29	7	1.7.26 line 7 – *"Offer women a review 6 months after surgery".* What about long-term follow up following mesh surgery as stated in 1.2.2 line 23? As above.	Thank you for your comment. The 6 month follow-up appointment is for clinical practice. Longer follow-up would be covered by the registry. In addition we have also stated that all women who have had surgery should have access to further referral.
British Society of Urggynaecology	Guideline	34		**Table 1** Quantitative sensory testing is a research area undertaken by one of the Centres with 2 representatives on the panel. This is biased and has no place currently. Please remove.	Thank you for your comment. We believe this was included in error and has been removed from the table.
Caesarean Birth	Guideline	General	General	My organisation receives communication from women who are suffering the effects of urinary incontinence and pelvic organ prolapse as a direct result of birth injury, and has experience supporting them in the context of management preferences for subsequent pregnancies. Caesarean Birth also works closely with other national and international organisations that support these women who are affected by these injuries in their daily lives.	Thank you for your comment. Information regarding the management of subsequent birth plans for women who have been injured during previous births is outside the scope of this guideline.

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				In this draft guideline, there is a noticeable absence of information regarding the management of subsequent birth plans for women who have been injured during previous births, and it would be very helpful for this to be included. Both directly, in information and/or recommendations, and also indirectly by referring to other relevant NICE and/or RCOG guidance. One of the most common discussions I witness by women in support groups online (Caesarean Birth has been contacted about this too) is their birth plan management for future pregnancies, as well as considering timing/space between each pregnancy (where injury has occurred during a previous birth). This is something that can be on their minds for months, and even years, before they make a final decision. There are management considerations around when or whether to have some of the treatments cited within this guideline, both before and after they have completed their family, and for those planning to have more children, there are management considerations in terms of birth plans (vaginal birth or caesarean birth),.	

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				On page 27, line number 19, there is a reference to future pregnancy considerations, in the context of a Manchester repair, and my organisation would like to see recognition of this issue extended even further as part of NICE's new recommendations here. Also, bearing in mind that many women do not even want to get pregnant unless they feel confident that they will be supported in their birth plan preferences, it would be very helpful for this guideline to refer to the recommendations contained within CG132 on maternal request caesareans. My organisation (and others, including Birthrights and the Birth Trauma Association) are aware of numerous cases where women with pelvic floor damage are unaware of recommendations including: 'For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about	

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				childbirth), a vaginal birth is still not an acceptable option, offer a planned CS. An obstetrician unwilling to perform a CS should refer the woman to an obstetrician who will carry out the CS.' Worse still, some women who are aware of these recommendations, and look forward to scheduling their caesarean birth in order to significantly reduce the risk of pelvic floor damage, are refused support by NHS Trusts that do not agree with these 2011 NICE recommendations. My organisation feels strongly that this guideline is an important opportunity for NICE to communicate and reinforce the CG132 maternal request recommendations, particularly given that this guideline is specifically for the care of a group of women who may be more likely to request a caesarean birth than those in the general maternal population.	
Caesarean Birth	Guideline	General	General	**NICE question**: What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)	Thank you for your comment. Information regarding the management of subsequent birth plans for women who have been injured during

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				Again, in the context of birth plan preferences and management, citing and/or referencing the CG132 caesarean maternal request recommendations within this guideline would help users overcome two key challenges: 1) lack of information about their birth plan choices (particularly for women who may not be aware of NICE CG132) and 2) encountering push back from health carers who are of the view that a caesarean birth plan in a subsequent pregnancy is unnecessary. Patient preferences and respect for autonomy are increasingly becoming central to NHS care, especially, as in the case of caesarean versus vaginal birth plans, there is no impact on resources and there are risks and benefits that may be weighed differently by individual women. There are certainly examples of good practice in the NHS; in particular, maternity pathways that discuss different birth plans and preferences in a balanced and unbiased manner. The NICE guideline development group may be of	previous births is outside the scope of this guideline.

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				the view that this guideline is separate from maternity care, but for women whose injuries are a direct consequence of vaginal birth, the two contexts are inextricably linked, and if they are planning to have more children, they will not only have questions about all the risks and benefits of different treatment options available to them, but also how these overlap with their considerations and challenges with planning future births. Kenyon et al. Improving the care pathway for women who request Caesarean section: an experience-based co-design study. BMC Pregnancy and Childbirth (2016) 16:348 Sharpe AN, Waring GJ, Rees J, McGarry K, Hinshaw K. Caesarean section at maternal request--the differing views of patients and healthcare professionals: a questionnaire based study. Eur J Obstet Gynecol Reprod Biol. 2015 Sep;192:54-60. SOGC COMMITTEE OPINION No. 361-Caesarean Delivery on Maternal Request. No. 361, July 2018 Keag O.E., Norman J.E., Stock S.J. (2018) Long-	

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				term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. PLoS Medicine, 15 (1). Caudwell-Hall J, Kamisan Atan I, Guzman Rojas R, Langer S, Shek KL, Dietz HP. Atraumatic normal vaginal delivery: how many women get what they want? Am J Obstet Gynecol. 2018 Oct;219(4):379.e1-379.e8.	
Caesarean Birth	Guideline	General	General	Caesarean Birth would like to thank NICE for the opportunity to comment on this guideline development.	Thank you for your comment.
Caesarean Birth	Guideline	4	2	In my organisation's experience, women can often be in a state of shock, confusion and trauma when they are diagnosed with (or first experiencing symptoms of) prolapse, and their mental health can be seriously adversely affected, in addition to their physical symptoms. It would be helpful to include relevant counselling services in the lists of local and regional multidisciplinary teams.	Thank you for this comment. We are unsure what a counselling service would add to the care of the woman at this stage in the pathway. We would like to note that this is not an exhaustive list, and if the local or regional team wishes to include a counsellor, this is at their own discretion.

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				Skinner EM, Barnett B, Dietz HP. Psychological consequences of pelvic floor trauma following vaginal birth: a qualitative study from two Australian tertiary maternity units. Arch Womens Ment Health. 2018 Jun;21(3):341-351. Williams A, Lavender T, Richmond DH, Tincello DG. Women's experiences after a third-degree obstetric anal sphincter tear: a qualitative study. Birth, 32 (2) June) (2005), pp. 129-136	
Caesarean Birth	Guideline	24	18	The section on mesh (page 34 onwards) includes: '*offer non-surgical treatments such as pain management, vaginal oestrogen, dilators, psychosexual counselling and physiotherapy*' Again, it would be helpful if the offer of counselling was also included here.	Thank you for your comment. We have amended the recommendation to include counselling (including psychosexual counselling)
Caesarean Birth	Guideline	24	22 & 27	*'Discuss management options with women who have pelvic organ prolapse, including no treatment, non-surgical treatment and all surgical options, taking into account:* *the woman's preferences…* *desire for childbearing'*	Thank you for your comment. The committee think that your point is covered within recommendation 1.7.1 by the 'desire for childbearing'.

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				This is an example of an area of the guideline where birth plan considerations could be included.	
Caesarean Birth	Guideline	26	9	*'Discuss birth plan options for subsequent pregnancies.'* This is an example of an area of the guideline where birth plan considerations could be included, with specific reference to NICE CG132.	Thank you for your comment. To make recommendations on your comments would not be within the scope of this guideline
Caesarean Birth	Guideline	41	9	'*Finding more information and resources* *To find out what NICE has said on topics related to this guideline, see our web pages on gynaecological conditions and urological conditions*' This is an example of an area of the guideline where birth plan considerations could be included. e.g. a link to CG132 Caesarean Section and also relevant RCOG Green Top publications, such as: 2015 RCOG Green-top Guideline No. 29: The Management of Third- and Fourth-Degree Perineal Tears	Thank you for your comment. This is outside of the scope of this guideline.

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				https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-29.pdf 2015 RCOG Patient Leaflet: Third- or fourth-degree tear during childbirth https://www.rcog.org.uk/en/patients/patient-leaflets/third--or-fourth-degree-tear-during-childbirth/ 2015 RCOG Patient Leaflet: Choosing to have a caesarean section https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-choosing-to-have-a-c-section.pdf	
Contura Ltd.	Guideline	4	1	The Guideline States: *"People have the right to be involved in discussions and make informed decisions about their care, as described in "your care"."* The following statement is made in "your care" – "*Your health and care professionals need to know what matters to **you** – no two people are the same and they should listen carefully to your views and concerns."* Our comments:	Thank you for your comment. In light of stakeholder comments, the committee have amended their recommendations from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension,

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				We are very concerned that the proposals set out in this draft Guideline do not honour this statement because they actually restrict the options that are currently available to women with regards to surgical treatment for stress urinary incontinence. Current clinical practice in the UK, consistent with recommendations from the National Professional Associations (British Association of Urological Surgeons https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/SUI%20options.pdf and British Society of Urogynaecologists https://bsug.org.uk/budcms/includes/kcfinder/upload/files/Urethral%20bulking%20BSUG%20Mar%202018.pdf) is to offer women a choice of urethral bulking agent (in 95% of cases this is the non-particulate polyacrylamide hydrogel Bulkamid), mid-urethral mesh sling, colposuspension and fascial sling. Many women do not want a major operation, for a whole range of reasons personal to them, and hence choose to have a urethral bulking agent even though they are told that other more invasive operations may offer a better chance of success. Based on currently available peer	retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				reviewed published evidence, as well as new data emerging, urethral bulking is achieving patient reported success rates close to those achieved with the traditional standard of care, and an increasing number of women are choosing to have a urethral bulking agent. Around 1,800 women received the urethral bulking agent Bulkamid in the UK in the first six months of 2018 (before the tape suspension was announced) and we estimate that around 4,500 women in the UK will be treated with Bulkamid in total this year, the majority as a primary surgical procedure. For reference last year there were just under 3,000 women treated with Bulkamid in the UK. The increasing uptake of urethral bulking is driven by increasing confidence from trained surgeons in performing a bulking procedure and patients achieving good outcomes with negligible risk of adverse events. Also patients are increasingly wanting less invasive, safe procedures. Patients making informed decisions about their care has in recent years been underpinned by a legal obligation. In line with the Montgomery ruling (https://www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf),	

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				choice with the associated consequences and the potential impact on the patient's life needs to be presented to patients. The ruling states "*whether a risk is material or not cannot be deduced by percentages – the significance of the risk is likely to reflect a variety of factors besides its magnitude: nature of risk, the effect of its occurrence would have on the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, **the alternatives and their risks**. The assessment is fact-sensitive and sensitive to the characteristics of the patient*". The current draft Guideline does not comply with this Supreme Court ruling. There are currently 142 NHS hospitals treating women with Bulkamid in England and Wales, plus a number of private hospitals offering it through choose and book, as well as NHS hospitals in Scotland and Northern Ireland. Under the proposals in the draft Guideline, Bulkamid (a non-particulate bulking agent) would no longer be offered to women as part of early discussions about surgical interventions, despite its effectiveness and safety profile, derived from over	

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				60,000 Bulkamid procedures having been performed worldwide over the last 15 years. Furthermore, Bulkamid is unquestionably the least invasive of the surgical options available to women. Under the draft Guideline women will only be able to choose between more invasive surgical options, each with its own risks of long term and difficult to manage adverse events such as chronic pain, pelvic organ prolapse and mesh erosion. None of these potentially life changing adverse events have ever been documented with Bulkamid. NICE rightly points out that no two people are the same, but the right to be offered a safe and effective procedure for the treatment of SUI will be taken away from the patients informed decision making process about what is important to them. Urethral bulking, and Bulkamid in particular, should therefore at the very least feature alongside the three other surgical options presented to patients following failed conservative treatment, as is current and widespread clinical practice throughout the UK. In fact, many NHS Trusts having reviewed the evidence for Bulkamid (not considered in this Draft due to the adopted methodology for Evidence Review) have even decided that Bulkamid be	

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				offered in a hierarchical manner of invasiveness, such that it is offered to patients post conservative treatment and pre the more invasive surgical options of TVT, colposuspension and fascial sling.	
Contura Ltd.	Guideline	20	22-26	The Guideline States: *"When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for stress urinary incontinence (UI). Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period."* Our comments: Under the proposals set out in this draft Guideline, women, as part of their early discussions about surgical options, will not have the opportunity to discuss with their clinician the one surgical intervention that requires no general anaesthesia, requires no stay in hospital, requires no surgical incisions and has a recovery period of 24 hours or less (as opposed to 2-6 weeks for the other surgical procedures). We feel that the patient experience of treatment with a bulking agent is	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				fundamentally different to all the other forms of surgery, and that it would be a disservice to women for them to make a surgical treatment decision, potentially affecting the rest of their life, without knowledge of this minimally invasive clinic procedure. We would therefore suggest that urethral bulking should at the very least be offered to women alongside and at the same time as the other surgical procedures as part of the fuller discussion around the risks and benefits of the different surgeries.	
Contura Ltd.	Guideline	20	24	Footnote 12 on Page 20 of the Guideline States: "*NICE is developing shared decision aids on surgery for stress urinary incontinence and pelvic organ prolapse. They will be published with the final guideline in April 2019.*" Our comments: We welcome the fact that NICE is developing shared decision aids and we would appreciate the opportunity to comment on those aids before their publication. It is our belief that such decision aids	Thank you for your comment. The guideline will be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse. The decision aids will only cover what has been reviewed as part of the guideline and you should have been invited to consult on the PDA.

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				should clearly refer to all alternative surgical procedures available for stress urinary incontinence, not be limited to the few alternatives currently set out in the draft Guideline.	
Contura Ltd.	Guideline	21	1-5	The Guideline States: *"If non-surgical management for stress UI has failed, offer the woman a choice of:* • *colposuspension (open or laparoscopic)* ***or*** • *a retropubic mid-urethral mesh sling* ***or*** • *an autologous rectus fascial sling.* ***[2019]"*** Our comments: • Given the emergence of safety concerns in the UK from patient groups and Department of Health and Social Care on the use of mid-urethral mesh sling for SUI, it is well accepted that patients need to be counselled on the options available to them (as currently stated in this Draft [page 20]). All professional societies, national and international, have developed	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence. We have reviewed the papers you mentioned. Reasons for why they were not included in the evidence for this guideline is below: Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the

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				various tools to achieve this (see BAUS and BSUG websites). Bulking has been presented by all societies in these documents as one of the options available to patients alongside synthetic tapes, colposuspension and fascial sling. This is aligned with the current NICE Guideline CG171 which states (page 28) "*Consider intramural bulking agents for the management of stress UI if conservative management has failed.*" • By not including bulking agents as a surgical option alongside mid-urethral mesh sling, colposuspension and fascial sling post failure of conservative management, surgeons will be restricting choice to their patients and therefore denying women a safe and effective treatment that has been widely used across the UK for the past decade and has indeed had a more prominent role in the past 3 years with new clinical evidence emerging. The least invasive surgical option, which has been shown to be clinically effective with a proven safety profile (Kasi et al 2015), should be presented as an option to women alongside the more invasive options that are known to cause serious adverse effects. For example, in Tables 12 and	treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. This study compared two types of bulking agents (Bulkamid vs Contigen). The committee did not prioritise comparing different types of bulking agents, but to identify if bulking agents (of any type) were effective when compared to surgery. This was with the intention that bulking agents, should they prove to have sufficient long-term effectiveness evidence could be recommended alongside surgery options. Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Robinson D, Anders K, Carozo L, Bidmead J, Dixon A, Balmforth J, Rufford J. What do women

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				13 (Evidence Review E page 48/49), the weighted average of complications indicate pain at 5+ years for TVT being 9% and for fascial sling 16.7%, and pelvic organ prolapse following colposuspension being 21%. • Given the Montgomery ruling, there is a legal obligation to offer the various options, with the associated consequences and the potential impact on the patient's life needing to be presented to patients. The current draft Guideline does not comply with this Supreme Court ruling. • Urethral bulking is the least invasive surgical option for women with SUI. Bulking with Bulkamid has consistently shown subjective efficacy above 70% in prospective multi-centred studies, and undoubtedly represents the safest of the options available post pelvic floor exercises. One could argue that Bulkamid should be considered as an invasive "procedure" rather than "surgery". When presented with the surgical options, bulking has been the preferred option above all the other procedures ("What Women Want", Robinson et al. 2003). This study in 100 women showed that when presented with a choice of either major	want? Interpretation of the Concept of Cure. Journal of Pelvic Medicine & Surgery. November/December 2003 – Volume 9 – Issue 6 – pp 273-277. This paper aimed to determine what women perceive as 'cure' and to assess treatment acceptability for UI. Whilst this paper brings valuable insight into the woman's perspective which corroborates the experience the committee had from dealing with women with stress UI throughout their career, each woman is different and their acceptability and preferences towards treatments might differ to that capture in the paper.

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				surgery with an 85% success rate but a 2% chance of a long term adverse event (colposuspension), minor surgery with an 85% success rate but a 2% chance of a long term adverse event (TVT), or a clinic procedure with a 60% chance of success but no long term adverse events (urethral bulking), the majority of women (57%) chose the latter despite the lower chance of success, with only 23% and 38% choosing the major and minor surgeries respectively. The study was recently repeated in 2018 and the same conclusion was found. This update was presented at the Annual International Urogynaecological Association Meeting in Vienna, 2018. • NICE state in the Evidence Review E introduction (page 9) that the need to update the question of what is the most effective surgical management *"has been highlighted by the reports of serious adverse events occurring in women who have received mesh or mesh sling surgery*". We are concerned that removing the surgical option with the least possibility of causing serious adverse events and only presenting the interventions with a proven record of causing serious adverse events is not	

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				in the best interests of women seeking help for this very debilitating condition. The effectiveness of the procedure should be balanced with its invasiveness and potential adverse events i.e. women should be allowed to weigh up the risk benefit profile of each treatment, not a sub-set of the treatments. Whilst stating that the reason for the need for this update to the Guideline is concerns about safety, we are extremely concerned that the draft Guideline has disconnected effectiveness from safety and inadvertently focused almost solely upon effectiveness. • We are very concerned that the treatments options proposed in the draft Guideline have been arrived at as a result of the application of an overly restrictive methodology (in that only pairwise studies, i.e. one surgery versus another form of surgery, were included and no consideration was given to randomised controlled studies which for example compared two different types of bulking agents i.e. Sokol et al 2014) of how evidence was to be reviewed. • In 2018 it is projected that about 4,500 women in the UK will choose the bulking agent	

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				Bulkamid as their treatment of choice and in the first half of 2018, prior to the tape suspension, Bulkamid represented the leading option of all "surgical" options for SUI chosen by patients. Therefore the current draft guideline means that patients are being denied their preferred treatment and one would argue that patients are therefore not central to the management of SUI which goes against one of the core values of the NHS: 'patients first'. • Importantly, an independent investigator initiated randomised controlled trial of Bulkamid versus TVT is being conducted in Helsinki. A total of 224 women with primary SUI were randomised. Baseline characteristics were similar between both groups and the median age was 49 years. Whilst the publication of the 1 year results is imminent, the data were presented at a workshop at the European Urogynaecology Association Annual Meeting on 25th October and it showed the following at 1 year: o Subjective cured or improved ▪ Bulkamid: 92% ▪ TVT: 100% o Cough stress test negative:	

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				▪ Bulkamid: 66% ▪ TVT: 95% ○ Patient Satisfaction on VAS (median): ▪ Bulkamid: 85 ▪ TVT: 99 ○ No serious safety concerns were identified with Bulkamid, whereas the complications with TVT were: ▪ Erosion: 5.0% ▪ Pain: 5.0% ▪ Dysuria: 3.0% ▪ Difficulty to empty bladder: 8.9% Given the overall benefit / risk profiles of the treatments involved, we (and the authors of the study) believe Bulkamid should at least be an option alongside TVT as 1st line surgery post physiotherapy. Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75.	

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				Robinson D, Anders K, Carozo L, Bidmead J, Dixon A, Balmforth J, Rufford J. What do women want? Interpretation of the Concept of Cure. Journal of Pelvic Medicine & Surgery. November/December 2003 – Volume 9 – Issue 6 – pp 273-277. Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9.	
Contura Ltd.	Guideline	21	6-8	The Guideline States: *"When offering surgery for stress UI, advise the woman that there are long term complications associated with all procedures and uncertainty about the proportion of women affected.* ***[2019]"*** Our comments: There have been no long term complications reported with Bulkamid, but the draft Guideline	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous

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				proposes that women are not to be offered this as a primary surgical procedure. Bulkamid's initial use in a clinical study began in 2001 and it was placed on the market in Europe in 2004. Since then more than 60 thousand women have received Bulkamid treatment and no serious safety concerns have been identified, as part of either Post Marketing Surveillance obligations of our Company or in published literature. A recent systematic literature review assessed safety (and efficacy) for two urethral bulking agents (Bulkamid® and Macroplastique) when used to treat female SUI (Siddiqui et al., 2017). Safety data in the review was based on 777 patients treated with Bulkamid®. The most frequent adverse events reported in the review for Bulkamid® were urinary tract infection (11%), implantation site pain (10%) and acute urinary retention (3%). Those are common procedure- and/or device-related adverse events for cystoscopy/bulking procedures. The other systematic literature review by Kasi et al. (2016) found results from eight studies, which enrolled a total of 767 patients who received	rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence. We have reviewed the papers you've mentioned and have given reasons as to why they are not relevant evidence for this guideline: Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. de Vries AM, Wadhwa H, Huang J, Farag F, Heesakkers JPFA, Kocjancic E. Complications of Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports. Female Pelvic Med Reconstr Surg. 2017 Sep 26 This paper was identified by our searches, and

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				treatment with Bulkamid. The most common AEs were pain at the injection site (4-14%) and urinary tract infection (3-7%) which all were transient. A comprehensive review of complications with urethral bulking agents (UBA) evaluating all recently available UBAs was published in 2017 (de Vries et al 2017) and included 14 publications on Bulkamid. The review concluded that most bulking agents have a good safety profile with low complication rates. In the author's view, Bulkamid was one of the bulking agents with the lowest complication rates. Bulkamid has demonstrated an outstanding safety profile with transient, mostly procedure related adverse events. Moreover, Bulkamid is a non-particulate soft hydrogel consisting of 97.5% water and only a 2.5% dry matter. A number of implantation studies (Christensen et al, 2012) have shown an excellent tissue biocompatibility with full integration into the host tissues and no risk of adverse tissue changes. Thus, based on the biological properties of the hydrogel and nearly two decades of usage there is	marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Siddiqui ZA, Abboudi H, Crawford R, Shah S. Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review. Int Urogynecol J. 2017 Feb 21 This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Christensen L, Nielsen J, Mouritsen L, Sorensen M, Lose G. Tissue Integration of Polyacrylamide Hydrogel: An Experimental Study of Periurethral, Perivesical, and Mammary Gland Tissue in the Pig. Dermatol Surg 2008:34:S68- S77 Whilst this study does indeed indicate the implantation of Bulkamid has good tissue biocompatibility, this study is conducted in pigs and is therefore out side of scope and cannot be considered for this guideline.

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				minimal concern of long-term serious adverse events occurring with Bulkamid treatment. Given the significant difference in the safety profile of Bulkamid compared to the other surgical procedures, which for many women may be the most important consideration when making a treatment decision, we suggest that women should be made aware of this potential treatment by its inclusion alongside synthetic mesh tape, colposuspension and fascial sling as a primary treatment option. de Vries AM, Wadhwa H, Huang J, Farag F, Heesakkers JPFA, Kocjancic E. Complications of Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports. Female Pelvic Med Reconstr Surg. 2017 Sep 26 Siddiqui ZA, Abboudi H, Crawford R, Shah S. Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review. Int Urogynecol J. 2017 Feb 21	

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Contura Ltd.	Guideline	22	12-16	The Guideline States: *"Do not offer women intramural bulking agents to manage stress UI unless alternative surgical procedures are not suitable or acceptable. Explain to women that:* • *repeat injections may be needed to achieve efficacy* • *efficacy is limited and diminishes with time.* ***[2019]*** *"*	Thank you for your comment, in light of yours and other stake holder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be need to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial

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				Our comments: In the Strengths of Recommendation section, NICE defines "do not offer" as meaning that "when we are confident that an intervention will not be of benefit for most patients". Due to methodology adopted by NICE for the evidence review, none of the evidence base for Bulkamid has been included. This has led to the exclusion of a number high quality published studies, including a Level 1 multicentre randomised clinical trial (RCT) with 345 patients, deigned and approved by the FDA to a level of regulatory rigour for a US Class 3 device, and a European multi-centred trial with 135 patients. A further study versus TVT is also ongoing and has recently reported its one year data. The majority of these studies show patient satisfaction levels at above 80%, and with no long term or serious adverse events reported, how therefore can the committee "be confident" that the bulking agent Bulkamid "will not be of benefit for most patients". The 2019 Guideline is an "Update" on the 2013 Guideline where it was stated that "surgical procedures other	sling and that there is limited long-term effectiveness and adverse events evidence. From the studies you've mentioned, reasons for why they were not includable in this guideline are given as follows: Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. This study compared two types of bulking agents (Bulkamid vs Contigen). The committee did not prioritise comparing different types of bulking agents, but to identify if bulking agents (of any type) were effective when compared to surgery. This was with the intention that bulking agents, should they prove to have sufficient long-term effectiveness evidence could be recommended alongside surgery options. Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75.

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				than single-incision sling, transobturator tape and tension-free vaginal tape for women with urinary incontinence" would not be updated. Bulking agents were thus out of scope and not reviewed in the 2013 Guideline and hence it really only reflected the 2006 Guideline. It was expected therefore, as per the "2019 Guideline Scope" that bulking agent evidence would be reviewed, as it is stated (page 7 of the Guideline Scope) that the Committee will look at evidence in the area specific to surgical procedures of stress urinary incontinence and that they "*will consider making new recommendations or updating existing recommendations in these areas only*." The Guideline Scope did not state, and nor was it expected, that it would limit the evidence review to pairwise studies only, i.e. only when one form of surgery has been compared to another form of surgery (page 9 of 812). It is interesting that mesh versus mesh studies, like tension-free vaginal tape versus secure tension-free vaginal tape, have been considered whereas an RCT comparing two bulking agents with differing modes of action have not been considered. This Level 1 evidence RCT, published in the Journal of Urology	This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012 Oct;23(10):1373-8. This study was identified by our searches and follows women who have been treated with Bulkamid for 24 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Mohr S, Marthaler C, Imboden S, Monga A, Mueller MD, Kuhn A. Bulkamid (PAHG) in mixed urinary incontinence: What is the outcome? Int Urogynecol J. 2017 Nov;28(11):1657-1661.

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				(Sokol et al 2014) compared a degradable (Contigen) vs a non-degradable (Bulkamid) bulking agent. Moreover, the study compared conventional cystoscopy with a bespoke Bulkamid injection system. We believe that the two surgical approaches used in this study are as different as different synthetic mesh techniques are to one another. In this case, it would be reasonable for the committee to consider a study showing that 77.1% of 229 women were cured or improved at one year following treatment with Bulkamid, and in turn shows that it is not the case that this intervention "will not be of benefit to most patients". Further, an independent investigator initiated randomised controlled trial of Bulkamid versus TVT is being conducted in Helsinki. A total of 224 women with primary SUI were randomised. Baseline characteristics were similar between both groups and the median age was 49 years. Whilst the publication of the 1 year results is imminent, the data were presented at the European Urogynaecology Association Annual Meeting on 25th October and it showed the following at 1 year: o Proportion of patients who were subjectively cured or improved	This study was identified by our searches and follows women who have been treated with Bulkamid for 3 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Pai, A., & Al-Singary, W. (2015). Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Central European journal of urology, 68(4), 428. This study was identified by our searches and follows women who have been treated with Bulkamid for a median of 38 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Bach et al 2017 -ASSUME TO BE: What can we learn from large data sets? When we use bulking procedures and comparison to mid urethral slings

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				▪ Bulkamid: 92% ▪ TVT: 100% ○ Proportion of patients who had a negative cough stress test: ▪ Bulkamid: 66% ▪ TVT: 95% ○ Average patient satisfaction score on a 100 point visual analogue scale (median): ▪ Bulkamid: 85 ▪ TVT: 99 ○ No serious safety concerns were identified with Bulkamid, whereas the complications with TVT were: ▪ Erosion: 5.0% ▪ Pain: 5.0% ▪ Dysuria: 3.0% ▪ Difficulty to empty bladder: 8.9% Again, it would be fair to say that an independent RCT showing that 92% of women were either cured or improved at one year following treatment with Bulkamid, is evidence that it is not the case that this intervention "will not be of benefit to most patients".	(MUS) Author(s): Bach F.; Toozs-Hobson P.; Duckett J. Source: International Urogynaecology Journal; Jun 2017; vol. 28 (no. 1) This is a conference abstract that retrospectively analysed the BSUG database. This study was not included in this guideline as a) it is a conference abstract and not a fully published paper and b) it is not prospective by design (as per protocol).

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				In addition to the evidence cited above, the evidence review process adopted has meant that further important clinical evidence for Bulkamid has been ignored. Had the 2019 Guideline followed the 2013 evidence review methodology instead of restricting its analysis to a subset of the evidence base, then in addition to Sokol et al, the following evidence would have been included: ○ Toozs-Hobson et al (2012) showed that cure and improvements rates of 67% at 1 year were maintained at 2 years in a prospective multi-centred trial with 135 patients. ○ Kasi et al (2015) published a systematic review of Bulkamid involving 8 studies and 767 patients showing that Bulkamid was a safe and effective treatment for SUI. ○ Pai et al (2015) published long term outcome data for Bulkamid showing 82% cure and improvement rates at a median follow up of 38 months and no significant decline in efficacy or quality of life scores, as measured by ICIQ and VAS, out to five years follow up. Further, no serious adverse events were	

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				reported. It also showed that with experience rates of reinjections reduce to below 10%. ○ Bach et al (2017) presented data from the BSUG Database where 1181 patients had been identified as treated with Bulkamid with positive outcomes for over 70% in a challenging cohort of patients. It concludes "**Primum non nocere**. Bulkamid is a safe option for treating incontinence. It appears equally efficacious as a primary or a secondary procedure." We therefore believe that there is a considerable body of evidence which demonstrates beyond doubt that it is not fair to say that Bulkamid "will not be of benefit to most patients". As such we suggest that urethral bulking should be included alongside synthetic mesh tape, colposuspension and fascial sling in the options presented to women who are considering a surgical intervention. Notwithstanding the evidence review methodology adopted for this draft Guideline, the collective "experience and expertise" of the Committee	

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				clinical members should be representative of their colleagues experience, expertise and practice. Given that prior to NHS England's "pause" on mesh use, bulking with Bulkamid represented the preferred "surgical" option post conservative management attempts in the UK, we hope that the Committee will acknowledge this situation and the fact that bulking with Bulkamid is presented as a 1st line option alongside the other treatments by clinicians nationally, with the full endorsement and support of the national professional societies. Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012 Oct;23(10):1373-8.	

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				Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. Mohr S, Marthaler C, Imboden S, Monga A, Mueller MD, Kuhn A. Bulkamid (PAHG) in mixed urinary incontinence: What is the outcome? Int Urogynecol J. 2017 Nov;28(11):1657-1661. Pai A, Al-Singary W. Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Cent European J Urol. 2015;68(4):428-33. Bach et al (2017) Bach F et al, Prospective cohort study of Bulkamid using the BSUG database; case mix and results: Oral presentation EUGA 2017	

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Contura Ltd.	Evidence Review E	107	27-36	The Evidence Review States: ***"Surgical procedures for treatment of stress urinary incontinence*** *The committee agreed, based on the evidence and experience and expertise, that women need to be fully informed about the all treatment options in order to facilitate shared decision making (see also the other chapters related to the treatment of stress urinary incontinence – see chapter J). Such discussions about the risks and benefits would ensure that treatments can be tailored to the individual woman taking account of her preferences and individual circumstances. Since all surgical procedures would be more invasive and would be associated with more complications than lifestyle or conservative options, these options should be considered first and surgery offered only if they have all failed."* Our comments: Recommending that clinicians do not offer urethral bulking agents to women seeking surgical intervention following the failure of lifestyle or conservative measures is not consistent with the	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				above statement, namely "that women need to be fully informed about ***all the treatment options*** in order to facilitate shared decision making" and "such discussions about the ***risks and benefits*** would ensure that treatments can be tailored to the individual woman ***taking account of her preferences and individual circumstances***". Indeed it could perhaps be argued that urethral bulking agents actually occupy a place in the treatment pathway that falls between conservative measures and invasive surgical procedures requiring incisions, and thus perhaps they too should be considered after conservative measures have failed but before more invasive surgical procedures are offered. We therefore suggest, in order to be consistent with the need statement by the Committee above to ensure that women need to be fully informed about all the treatment options, that urethral bulking is at least included alongside synthetic mesh tape, colposuspension and fascial sling in the options presented to women who are considering a surgical intervention.	

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Contura Ltd.	Evidence Review E	114	8-13	The Evidence Review States: ***"Bulking agents*** *There was no clinically important difference on any reported outcome at any time period in 1 study between Macroplastique bulking agent and autologous rectus fascial sling with the exception of a difference favouring the latter on objective cure 1 year after surgery. No studies were found for this comparison that reported continence-specific health-related quality of life and adverse events."* Our comments: Whilst restricting the review of the evidence base to a subset of the available evidence due to the pairwise analysis methodology adopted (which was not discussed at the scoping meeting or outlined in the scoping document) has meant that no studies were found that reported continence-specific health related quality of life and adverse events, a number of studies do exist which report on both of these criteria:	Thank you for your comment. NICE guideline scopes do not specify the methodology that will underpin the guideline. The methods followed can be found here: https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview. The specific details for each evidence review protocol were then prioritised and agreed with the committee during development. From the studies you mention, reasons as to why they were not suitable evidence for the guideline are given below: Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. This study compared two types of bulking agents (Bulkamid vs Contigen). The committee did not prioritise comparing different types of bulking agents, but to identify if bulking agents (of any type) were effective when compared to surgery. This was with the intention that bulking agents,

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				• Level 1 evidence of Sokol et al. published in the Journal of Urology in 2014 one the largest RCTs conducted in the field of SUI (345 patients), which was performed to the rigour of the FDA Regulatory Standards. ICIQ-UI and I-QOL results were measured for Bulkamid and demonstrated a considerable improvement which was maintained throughout the study. The average I-QOL score showed a mean increase of 31.4 points in the Bulkamid group which was maintained at 12 months. With regards to adverse events the authors reported that only 1 serious adverse event was seen with Bulkamid (transient haematuria) that was probably related to the study procedure. No long term adverse events were reported. • Toozs-Hobson et al (2012) in a prospective multi-centred trial with 135 patients showed significant improvement in ICIQ and VAS scores which were maintained for the 24 month duration of the study. No serious or long term adverse events were reported. • Kasi et al (2015) published a systematic review of Bulkamid involving 8 studies and 767 patients showing that Bulkamid was a safe and effective treatment for SUI	should they prove to have sufficient long-term effectiveness evidence could be recommended alongside surgery options. Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Pai, A., & Al-Singary, W. (2015). Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Central European journal of urology, 68(4), 428. This study was identified by our searches and follows women who have been treated with Bulkamid for a median of 38 months. This study is not comparative, and therefore we cannot know how these patients would have differed had

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				• Pai et al (2015) published long term outcome data for Bulkamid in 256 patients. ICIQ incontinence episodes per 24 hours reduced from 3.6 to 0.5 at 3 months. This reduction was maintained at 5 years. VAS QOL score was reduced from 6.4 at baseline to 1.3 at 3 months. Again the reduction was maintained at 5 years. Further, no serious or long term adverse events were reported. • Mohr et al (2017) published a study looking at Bulkamid in the treatment of women with mixed urinary incontinence in 122 women, in which the stress and urge components fell within a 60:40 ratio either way. Using the Kings Health Questionnaire, their data showed a statistically significant improvement in the domains Incontinence Impact, General Health and Role Limitations. No serious or long term adverse events were reported. • Bach et al (2017) presented data from the BSUGs Database where 1181 patients had been identified as treated with Bulkamid with positive outcomes for over 70% in a challenging cohort of patients. It concludes "**Primum non nocere**. Bulkamid is a safe option for treating	another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012 Oct;23(10):1373-8. This study was identified by our searches and follows women who have been treated with Bulkamid for 24 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Mohr S, Marthaler C, Imboden S, Monga A, Mueller MD, Kuhn A. Bulkamid (PAHG) in mixed urinary incontinence: What is the outcome? Int Urogynecol J. 2017 Nov;28(11):1657-1661. This study was identified by our searches and follows women who have been treated with Bulkamid for 3 months. This study is not

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				incontinence. It appears equally efficacious as a primary or a secondary procedure." It cannot be that the collective knowledge and experience of the Committee's clinical members find that the one study of Macroplastique Vs fascial sling (n=45) is representative of the published data for Bulkamid and further is representative of the clinical experience of their colleagues from over 140 NHS Hospitals across England and Wales, such that the committee can base their recommendation "do not offer bulking agents" on this one study alone in good faith. Given the quality of life data that exist for Bulkamid we believe that this constitutes evidence which demonstrates that it is not fair to say that Bulkamid "will not be of benefit to most patients". As such we suggest that urethral bulking should be included alongside synthetic mesh tape, colposuspension and fascial sling in the options presented to women who are considering a surgical intervention.	comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Bach et al 2017 -ASSUME TO BE: What can we learn from large data sets? When we use bulking procedures and comparison to mid urethral slings (MUS) Author(s): Bach F.; Toozs-Hobson P.; Duckett J. Source: International Urogynaecology Journal; Jun 2017; vol. 28 (no. 1) This is a conference abstract that retrospectively analysed the BSUG database. This study was not included in this guideline as a) it is a conference abstract and not a fully published paper and b) it is not prospective by design (as per protocol).

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				Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012 Oct;23(10):1373-8. Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. Mohr S, Marthaler C, Imboden S, Monga A, Mueller MD, Kuhn A. Bulkamid (PAHG) in mixed urinary incontinence: What is the outcome? Int Urogynecol J. 2017 Nov;28(11):1657-1661.	

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				Pai A, Al-Singary W. Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Cent European J Urol. 2015;68(4):428-33. Bach et al (2017)	
Contura Ltd.	Evidence Review E	114	14-16	The Evidence Review States: *"The committee recognised that there is a dearth of evidence on the use of bulking agents in the long term but agreed that, in their experience, some patients (especially the frail or elderly) find them useful."* Our comments: We agree that it is desirable that more long term data are collected for bulking agents. To date there has been a UK study (Pai et al 2015) in a cohort of 256 patients treated with Bulkamid showing 82% cure and improvement rates at a median follow up of 38 months and no significant decline in efficacy or quality of life scores, as measured by ICIQ and VAS, out to five years follow up. Further, no serious adverse events were reported. German patient	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendations from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence. Reasons as to why the studies you mentioned were not able to be used in our evidence for the guideline are given below

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				registry data in 352 women presented by Lobodasch at the International Continence Society Meeting in 2015 show an 80% cured / improved rate, with no decline out to seven years. No data exist to show a decay in the effectiveness of Bulkamid with time. It is encouraging that the committee find that some patients (especially the frail and elderly) find bulking agents useful. Interestingly, the majority of studies carried out with Bulkamid, for example (Sokol et al 2014 n=345), Toozs-Hobson et al 2012 n=135), Pai et al 2015 n=256), have been in patients where Bulkamid has been used as the woman's primary surgery. Bach et al reported on an audit of the BSUG Database and it showed that Bulkamid was equally efficacious when used as a primary or salvage procedure. In clinical practice in the UK, just under 3,000 women were treated with Bulkamid in the UK in 2017 and about 4,500 women will be treated with Bulkamid in the UK in 2018. The majority of these women are neither frail or elderly, but have received Bulkamid as their primary surgical intervention because they have chosen it, having been presented with the full range of surgical options available, in line with the	Pai, A., & Al-Singary, W. (2015). Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Central European journal of urology, 68(4), 428. This study was identified by our searches and follows women who have been treated with Bulkamid for a median of 38 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Lobodasch K & Brosche V. Long-term effectiveness and durability of Bulkamid® as primary treatment of stress urinary incontinence – a longitudinal study. ICS 2015 abstract This study is a conference abstract that reported 7 year follow-up data following Bulkamid for women with stress urinary incontinence. Data from this study could not be included in the guideline as a) it is a conference abstract and not a fully published paper (a per the protocol) and b) it is not a comparative study, therefore we cannot assess

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				Montgomery ruling. We do not think it is appropriate that the committee suggest that in future women such as these are not to be offered Bulkamid as a primary surgical treatment option. A fuller evidence review would support this. Pai A, Al-Singary W. Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Cent European J Urol. 2015;68(4):428-33. Lobodasch K & Brosche V. Long-term effectiveness and durability of Bulkamid® as primary treatment of stress urinary incontinence – a longitudinal study. ICS 2015 abstract	whether the long-term follow-up is comparable to that of other options e.g. surgery.
Contura Ltd.	Evidence Review E	114	16-20	The Evidence Review States: *"Furthermore, although there is uncertainty over the risks, any such risks are less likely to be serious compared to those associated with synthetic mesh slings. The committee therefore agreed by*	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections

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				consensus, using their knowledge and experience, that bulking agents should not be routinely offered unless other surgical procedures are not appropriate or not wanted." Our comments: We agree with the committee that any risks from Bulkamid are less likely to be serious compared to those associated with synthetic mesh slings. This has been shown in numerous studies and in clinical experience over 15 years in 60,000 women. In light of this statement we do not understand therefore, given that the need to update this Guideline has been brought about by reports of women suffering serious adverse events following treatment with mesh sling, why it is proposed in this draft Guideline to offer synthetic mesh slings as a treatment option, despite their adverse risk profile compared to bulking agents and to remove from women the opportunity to be offered bulking agents despite the evidence review stating that "any such risks are less likely to be serious compared to those associated with synthetic mesh slings". How can the woman decide what is appropriate or what	may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				is wanted when she is not informed about all the options? We would therefore suggest that urethral bulking is included alongside mid-urethral mesh tape, colposuspension and fascial sling as an option for women to choose from should they want surgery following the failure of pelvic floor exercises.	
Contura Ltd.	Evidence Review E	114	20-24	The Evidence Review States: *"The committee further agreed that it should be explained to women considering intramural bulking agents to treat SUI that repeated injection may be needed to maintain efficacy, that efficacy diminishes over time, and that retropubic midurethral mesh sling and autologous rectus fasical sling are more efficacious."* Our comments: No data have been published showing that the efficacy of Bulkamid diminishes over time with the need for repeated injection in order to maintain efficacy. Indeed, for Bulkamid, all the evidence is to	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				the contrary and has been referred to in previous comments to the draft Guideline. Not all bulking agents are the same, we are concerned that the draft Guideline fails to distinguish between bulking agents when making its recommendations. We agree that it should be explained to women considering intramural bulking agents to treat SUI that retropubic midurethral mesh sling and autologous rectus fascial sling are generally more efficacious...just as it is to explain the risks of intramural bulking agents as well as the risks of the other forms of surgery, and the nature of the surgery involved along with recovery time – and then let the woman decide what treatment she wants after she has made her own risk / benefit assessment in consultation with the treating doctor. What is important to one woman in terms of expectation of outcome and attitude towards risk will not necessarily be the same as for another woman.	

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Contura Ltd.	Evidence Review E	48 - 49	Tables 12 and 13	The following long term adverse events are listed in Table 12. Long term pain (>5 years) - retropubic synthetic sling 9.0%, transobturator synthetic sling 7.1%, fascial sling 16.7%, pelvic organ prolapse - 21.1% colposuspension Our comments: The opportunity to take a decision to avoid the risk of these serious and long lasting adverse events, other than electing to do nothing, will be denied to women if they are not made aware of the option of treatment with bulking agents. Given the importance of patient counselling and the Montgomery ruling, we would encourage the committee to include these long term AEs into the PDA. Of the 60,000 women treated with Bulkamid over the past 15 years there has not been a single reported incidence of long-term pain or pelvic organ prolapse resulting from Bulkamid treatment. Had all	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.

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				these women received colposuspension over the past 15 years then according to the draft Guideline's own figures (Tables 12 and 13), 12,660 women would have gone on to suffer from pelvic organ prolapse and had they received a sling, between 4,260 and 10,020 of them would be suffering long term pain as a result of their treatment. If women in the UK are not to be offered bulking agents following the publication of the updated Guideline, then an equivalent number of the 4,500 women who will receive Bulkamid in 2018 will instead only be offered a choice of retropubic synthetic sling, fascial sling or colposuspension. That means that there is a potential for many more serious adverse events to befall women in the future. For example if all of these 4,500 women were to choose a colposuspension in the absence of access to Bulkamid then, using the figure in Table 12, that could mean over 900 women sustaining pelvic organ prolapse over a 5+ year period. Should they all choose retropubic synthetic sling then, using the figure in Table 12 of 9% long term pain, then that could mean over 400 women	

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				suffering from long term pain over a 5+ year period, or over 750 should they all receive fascial sling.	
Contura Ltd.	Evidence Review E	153	5 Appendix A, Table 16	The Evidence Review States: *"This protocol details the pairwise analysis to be performed."* Our comments: • The 2019 Guideline is an "Update" on the 2013 Guideline where it was stated that "surgical procedures other than single-incision sling, transobturator tape and tension-free vaginal tape for women with urinary incontinence" would not be updated. Bulking agents were thus out of scope and not reviewed in the 2013 Guideline and hence it really only reflected the 2006 Guideline. • It was expected therefore, as per the "2019 Guideline Scope" that bulking agent evidence would be reviewed, as it is stated (page 7 of the Guideline Scope) that the Committee will look at evidence in the area specific to surgical procedures of stress urinary incontinence and	Thank you for your comment. NICE guideline scopes do not specify the methodology that will underpin the guideline. The methods followed can be found here: https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview. The specific details for each evidence review protocol were then prioritised and agreed with the committee during development. The committee was interested in how bulking agents compared to surgery (of any type). The different types of mesh surgery represent different surgeries entirely and could not be combined as 'mesh surgery'. From the studies you mentioned - reasons as to why their evidence was not included in this guideline are given below: Kasi AD, Pergialiotis V, Perrea DN, Khunda A, Doumouchtsis SK. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in

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				that they "*will consider making new recommendations or updating existing recommendations in these areas only*." The Guideline Scope did not state, and nor was it expected, that it would limit the evidence review to pairwise studies only, i.e. only when one form of surgery has been compared to another form of surgery (page 9 of 812). It is interesting that mesh versus mesh studies, like tension-free vaginal tape versus secure tension-free vaginal tape, have been considered whereas an RCT comparing two bulking agents with differing modes of action have not been considered. • The evidence review process adopted has meant that important clinical evidence for Bulkamid has been ignored. Had the 2019 Guideline not restricted its analysis to a subset of the evidence base, then the following references, amongst many others, would have been included. o Level 1 evidence of Sokol et al who published in the Journal of Urology in 2014 one the largest RCTs conducted in the field of SUI (345 patients), performed to the rigour of the FDA Regulatory Standards. It showed that	women: a systematic review of the literature. Int Urogynecol J. 2016 Mar;27(3):367-75. This paper was identified by our searches, and marked by our review team as a systematic review to be checked for relevant studies. This systematic review did not contain any additional relevant articles. Pai, A., & Al-Singary, W. (2015). Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid®) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Central European journal of urology, 68(4), 428. This study was identified by our searches and follows women who have been treated with Bulkamid for a median of 38 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide

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				77% of patients were satisfied with Bulkamid treatment, and a good safety profile was demonstrated. ○ Toozs-Hobson et al (2012) showed that cure and improvements rates of 67% at 1 year were maintained at 2 years in a prospective multi-centred trial with 135 patients. ○ Kasi et al (2015) published a systematic review of Bulkamid involving 8 studies and 767 patients showing that Bulkamid was a safe and effective treatment for SUI ○ Pai et al (2015) published long term outcome data for Bulkamid showing that 82% cure and improvement rates at a median follow up of 38 months and no significant decline in efficacy or quality of life scores, as measured by ICIQ and VAS, out to five years follow up. Further, no serious adverse events were reported. ○ Bach et al (2017) presented data from the BSUGs Database where 1181 patients had been identified as treated with Bulkamid with positive outcomes for	hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012 Oct;23(10):1373-8. This study was identified by our searches and follows women who have been treated with Bulkamid for 24 months. This study is not comparative, and therefore we cannot know how these patients would have differed had another treatment been given at the same time. As per our protocol, this study was excluded for being non-comparative. Bach et al 2017: What can we learn from large data sets? When we use bulking procedures and comparison to mid urethral slings (MUS) Author(s): Bach F.; Toozs-Hobson P.; Duckett J. Source: International Urogynaecology Journal; Jun 2017; vol. 28 (no. 1) This is a conference abstract that retrospectively analysed the BSUG database. This study was not included in this guideline as a) it is a conference abstract and not a fully published paper and b) it is not prospective by design (as per protocol).

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				over 70% in a challenging cohort of patients. It concludes "**Primum non nocere**. Bulkamid is a safe option for treating incontinence. It appears equally efficacious as a primary or a secondary procedure." Review of this evidence, along with the results of the Bulkamid versus TVT RCT presented at EUGA on the 25th October 2018, would have shown that between 70 – 90% of women are either cured or improved following treatment with Bulkamid, and no long term adverse events have been reported. These findings are consistent with current and widespread clinical practice across the UK. With sight of this evidence it is difficult to see how the committee would have suggested that clinicians be advised "do not offer bulking agents", the advice used "when we are confident that an intervention will not be of benefit for most patients". Four thousand five hundred women will receive Bulkamid this year in the UK. It will not benefit all of them but it will benefit many, if not most, of them. It is highly unlikely to cause any of them long term harm. We believe that women should have access	

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				to urethral bulking as one of the surgical options if and when they decide to look at a solution to their stress urinary incontinence post conservative treatment.	
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	5	3	The local multi-disciplinary team (MDT) should have access to a pain management specialist for those patients where pain is a factor. There are often pain related co-morbidities that need addressing along with the primary presentation. For those with complications of surgery and mesh managing the pain is important and often requires a multimodal approach.	Thank you for your comment. The committee believes that the management of women with pain related to mesh complications should be discussed at the regional MDT. The recommendations do not exclude pain specialists/advice at the local level. These are not exhaustive lists and each local team may have more members if that is possible and appropriate.
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	5	4 & 23	It is not clear form the document if all regional MDTs would have the expertise for complex mesh removal and if these teams are the same as those mentioned in the Mesh Oversight Group Report 2017. Nor does the document suggest the number of regional MDTs there will be. Our understanding is that some of the simpler mesh complications may have surgical remedies and could be done at the local and regional level. But there are a smaller number of more complex patients that require an MDT that specialises in mesh complications including surgical removal. The nature and composition of these teams would need to be	Thank you for your comment. We will expect that the number and regional distribution of MDT will be determined by NHS England. Our recommendations already suggest that these MDTs should have access to pain specialists. We hope that this will take notice of the recommendations we have made on the content and composition of MDTs.

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				different form the regional MDTs in order to have the breadth of experience required to manage these more complex patients. We would suggest that due to the overwhelming effect pain can have on these more complex patients that specialist pain management services with a pelvic pain expertise are core members of the MDT. It is clear from the document that a holistic approach is required with active patient participation and specialist pain management services are well placed to provide the pain focused elements of that care (medical, psychological and specialist pelvic floor physiotherapy related to pelvic pain). If the proposal for a regional MDT does not include the patients for complex mesh removal then there should be formal core membership form the local specialist pain management service. Such services should be available in many District Medical Hospitals and having them as part of the regional MDT network will allow optimal use of available skills.	
Faculty of Pain Medicine of the Royal	Guideline	6	5	The regional MDT should have a specialist pain management service formally linked into the process. This should be a service that has specific	Thank you for your comment. Please see recommendation 1.1.5 where this is covered. Pain management services should be linked to, but not within the MDT itself.

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College of Anaesthetists				experience and expertise in chronic pelvic pain for the complex mesh removal centres.	
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	30	14	Section 1.9.2. We are not clear if this is a clinician only, the local MDT or the regional MDT?	Thank you for your comment. This recommendation is to make sure women who present to any health care professional with an issue which may be related to mesh, should be referred to a specialist in mesh. The committee wish to point out that in practice people are not referred to "teams" but to a specialist with expertise, who will then refer the patient to an MDT. The committee agree it is important to highlight that women with mesh complications may be identified in any setting, i.e. in primary care, in accident and emergency. The recommendation is provided to reduce the risk of women who need care being missed.
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	31	1-3	The assessment of the pain and its impact on these patients falls within the remit of a pain management specialist at local and regional level. For the complex mesh patients, a pain management specialist with a specific chronic pelvic pain expertise is required along with the others MDT elements of a specialist pelvic pain service.	Thank you for your comment. The committee do not agree. This is a screening process where the patient is being evaluated to get an assessment of pain, (as a potential complication form mesh), it is unlikely that the woman will be referred to the pain specialist until it has discussed with the MDT.
Faculty of Pain Medicine of the Royal	Guideline	32	Table 1	Examination under anaesthesia: It is not clear what element of pain can be assessed with the patient anaesthetised.	Thank you for your comment. The recommendation is stating that the procedure to determine the cause of pain may need to be done

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College of Anaesthetists					under anaesthesia. If something is very painful to the woman, it may not be possible to investigate the underlying cause without anaesthesia.
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	32	Table 1	Laparoscopy: Pain cannot be visualised in its own right. There may be other findings that have an impact on pain such as those mentioned.	Thank you for your comment. The committee agree that this is why laparoscopy is being undertaken.
Faculty of Pain Medicine of the Royal College of Anaesthetists	Guideline	34	5	Section 1.10.1 With removal of mesh, with some exceptions you have mentioned, should this be a regional MDT or a specialist mesh removal MDT as suggested in the Mesh Oversight Group Report 2017.	Thank you for your comment. The committee decided that the regional MDT was the preferred terminology and at the time of writing the guideline the committee did not know what the plan for specialised commissioning would be.
King's College Hospital NHS trust	Guideline	5	1.1.4	Surely the regional MDT's should be tailored to suit the individual needs on the patient. For example a Urologist is not needed for a women with recurrent rectocele in the same way that a colorectal surgeon is not required for a woman with repeat cystocele. Pain specialists are generally only needed for those with mesh complications. We are concerned that having to have everyone present will not only have significant time implications on the health care professionals (HCPs) diary but also be associated with a significant cost element. Also why is an additional HCP trained in biofeedback required	Thank you for your comment. Biofeedback refers to bowel biofeedback, and we have amended the recommendation accordingly. We have also moved this to the "may include" group. MDT refers to the team members who should be available if needed but they might not be required to attend every meeting. The committee was of a view that having correctly staffed MDT will result in better and timely care for women and will result in savings to the NHS in the long-run.

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				when all women's health physiotherapists are trained in this?	
King's College Hospital NHS trust	Guideline	6	23	Who will pay for the long term follow up when clinicians are encouraged to discharge women after their first post operative review?	Thank you for your comment. We acknowledge there is a cost associated with follow up but we think this service is important and should be provided. We have amended the recommendations to make it clear that any long term follow-up (at least 5 years) would be the responsibility of the national registry of surgery for urinary incontinence and pelvic organ prolapse in women.
King's College Hospital NHS trust	Guideline	9	6	We disagree with this comment for the same reasons as we did in 2013. An audit of women presenting with 'pure stress incontinence' was performed and found that if we went by symptoms alone we would have performed inappropriate surgery in over half of the women.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
King's College Hospital NHS trust	Guideline	18	21	Where is the evidence for this?	Thank you for your comment. We reviewed the evidence but found limited data to determine how long injections work for, and the long term risks which may arise from long term use. Please see evidence review D for more information on the evidence identified and how the committee arrived at these recommendations.

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King's College Hospital NHS trust	Guideline	21	18	What about when a procedure is performed by a doctor in training and then they move on to their next rotation?	Thank you for your comment. We think that care is still under the designated consultant.
King's College Hospital NHS trust	Guideline	22	14	What about women with fixed / fibrosed urethras eg ISD or women who are unsuitable for surgery for other reasons eg co-morbidities.	Thank you for your comment. The committee think that this is covered by recommendation 1.5.10.
King's College Hospital NHS trust	Guideline	22	25	Shouldn't all women who undergo incontinence surgery have a vaginal examination as part of their post operative review?	Thank you for your comment. We agree, however with the widespread concern over mesh surgery, and the treatment of women who have mesh surgery, the committee wanted to specifically state this here.
King's College Hospital NHS trust	Guideline	25	9	What about laser therapy or osphemifene if women not suitable for or who refuse vaginal oestrogens?	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
King's College Hospital NHS trust	Guideline	27	23	What about McCall's Culdoplasty and high uterosacral ligament fixation – these have not been mentioned.	Thank you for your comment. Although these procedures were included in the review the data identified was very limited, and the committee was not able to make firm recommendations about these procedures.
King's College Hospital NHS trust	Guideline	28	3	Does this need to be discussed at a local or regional MDT. It is sometimes a first time and sometimes a recurrent prolapse	Thank you for your comment. The committee consider that this has already been addressed in the MDT section of the recommendations.

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King's College Hospital NHS trust	Guideline	28	13	We are not sure that 'intend' is the right choice of words as women can change their minds	Thank you for your comment. The committee consider that the use of 'intend' in the recommendation covers your concerns.
King's College Hospital NHS trust	Guideline	29	12	Recent BSUG's reports shows that concurrent surgery increases blood loss, length of catheterisation and readmissions and therefore is less safe than staged procedures	Thank you for your comment. The committee have amended this recommendation so that is a "consider" recommendation not "offer". The committee would however note that the BSUG's report is unpublished data and was therefore not included in our review. The only adverse event reported in the included studies for this review was bladder injury, the data showed fewer incidences with pelvic organ prolapse surgery alone as compared to combined pelvic organ prolapse and stress urinary incontinence surgery; however, the difference was not statistically significant.
King's College Hospital NHS trust	Guideline	31	1	? also add referral to neurologist as many clinicians are unable to perform a comprehensive neurological assessment.	Thank you for your comment. The committee do not agree. The committee expect those undertaking a basic assessment should have this ability. Health care professionals work within their competency, if something is out of their skill set, they should refer the woman.
King's College Hospital NHS trust	Guideline	37	9	Does this need to go to a local or regional MDT?	Thank you for your comment. This is regional MDT.

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King's College Hospital NHS trust	Guideline	38	2	Define 'long-term'	Thank you for your comment. More details are provided on each research recommendation in the corresponding evidence report. For this recommendation, please see evidence report E for further information. The committee thought it was important for future research to ascertain the success, safety and complications of mesh use over a 5-10 year period.
King's College Hospital NHS trust	Guideline	38	12	Define 'Older' – should instead it be defined by frailty?	Thank you for your comment. The evidence was based on women over 65 years (from the previous 2013 version of the guideline); risk will differ according to frailty, the number of co-morbidities and we expect the prescriber to take this into consideration.
Manchester Foundation Trust, Manchester	Guideline	General	General	In general we are supportive of the guideline. The development of Prolapse guidelines and especially the routine clinical use of POP-q is excellent. We have concerns that the consultation progress may not adequately capture the views of those who support the guidance.	Thank you for your comment.
Manchester Foundation Trust, Manchester	Guideline	4	2	Section 1.1 We are vary supportive of the concept of regional MDT meetings however there will need to be appropriate funding for this new work.	Thank you for your comment. The committee acknowledge that the MDT requires significant resource allocation but this introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance.

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					Moreover, the committee consider that having MDT ensures good decision making and the aim of clinical guidelines is to improve care.
Manchester Foundation Trust, Manchester	Guideline	6	3-4	Most centres do not have adequate access to psychology or psychosexual counselling	Thank you for your comment. We agree that most centres do not have adequate access to psychology or psychosexual counselling. The guideline is intended to consider best practice and we hope that by adding these services to the regional MDT that women's care will improve. The committee acknowledge these services are not available in all areas, and as such state that the regional MDT should have links to the services; therefore all women should be able to access them, regardless of the local circumstances.
Manchester Foundation Trust, Manchester	Guideline	6	21	To date voluntary registries run by surgical societies have failed to capture all cases and the percentage with outcome data is poor. There is no funding to support the national registry and no way to mandate use. It is not possible to record the NHS number in the BSUG database and it is difficult to extract data especially for sequential episodes of women with prolapse or mesh complications.	Thank you for your comment. We agree that this is challenging. We are recommending that providers collect data on all surgical procedures for urinary incontinence and pelvic organ prolapse, and for managing complications associated with mesh in a national registry. We understand that a national registry will be established and funded by NHS England.
Manchester Foundation	Guideline	6	23	Collecting data on outcomes at 5 years is important however it will require funding , especially objective outcome measures.	Thank you for your comment. We acknowledge there is a cost associated with obtaining outcome data at five years. We have amended the

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Trust, Manchester					recommendations to make it clear that any long term follow-up (at least 5 years) would be the responsibility of the national registry of surgery for urinary incontinence and pelvic organ prolapse in women. This is a matter which will need to resolve by those funding and running the national registry.
Manchester Foundation Trust, Manchester	Guideline	6	26	Objective POP measures in the form of POP-Q are advisable. However objective measures of UI are more time consuming i.e pad tests or urodynamics ? Perhaps PROM for UI would be preferable	Thank you for your comment. We have amended this recommendation to state validated relevant outcome measures.
Manchester Foundation Trust, Manchester	Guideline	9	6	This statement is based primarily on a large RCT from USA in which they used a positive stress test i.e SUI was seen on examination. To perform a stress test the patients bladder should have 300ml in it. The logistic of performing a stress test in an out patient appointment are difficult women often have an empty bladder.	Thank you for your comment. We have amended the recommendation to clarify that an urodynamic test should only be performed when stress urinary incontinence is not demonstrated before surgery in women with stress urinary incontinence or stress predominant mixed urinary incontinence**.**
Manchester Foundation Trust, Manchester	Guideline	14	24	The statements related to the use of anticholinergic the associated risk of dementia is not helpful for women or clinicians in practice as it doesn't quantify risk in a meaningful way .	Thank you for your comment. The committee thinks that the comment about the risk of dementia needs to remain in the guideline. We agree that it is difficult to quantify the risk, as currently no validated tools exist for this purpose. However, the committee agree it is important that health care practitioners are aware of this potential risk.
Manchester Foundation	Guideline	15	10	What age is an "older woman"	Thank you for your comment. The evidence was based on women over 65 years (from the previous

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Trust, Manchester					2013 version of the guideline); however risk will differ according to frailty, the number of co-morbidities and we expect the prescriber to take this into consideration.
Manchester Foundation Trust, Manchester	Guideline	22	16	"• efficacy is limited and diminishes with time." This statement is true of all continence surgery	Thank you for your comment.
Manchester Foundation Trust, Manchester	Guideline	22	21-25	Examining all women at 6 months is advisable however there is a risk of causing harm because a previously undiagnosed small asymptomatic vaginal exposure of polypropylene mesh may be found. This may cause anxiety to the patient unless they are counselled that there is no evidence that small asymptomatic vaginal exposure of polypropylene mesh causes harm (if not sexually active) . If clinicians excise the mesh SUI may recur. Partial excision may increase the risk of infection of the residual mesh . These are all areas of clinical uncertainty.	Thank you for your comment. We agree, but decided that it was important for the guideline to recommend a follow-up time. We would also expect the consultant to use their clinical judgement, if a woman has a small mesh exposure but no other symptoms it may not be appropriate to offer mesh excision of any type. The committee also considered that it was important for women to be examined at a post-operative follow-up visit after surgery.
Manchester Foundation Trust, Manchester	Guideline	23	16	Research opportunity does early referral of asymptomatic prolapse identified during a smear , for physio or pessary, prevent the long term progression of prolapse ?	Thank you for your comment. We agree this is a good suggestion but is outside of this guideline scope. The committee have prioritised a number of research questions, but this is not one of them. We will pass this information to the NICE surveillance team for the next update.

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Manchester Foundation Trust, Manchester	Guideline	29	25	Should there be a statement do NOT offer biological or polypropylene mesh to posterior compartment ?	Thank you for your comment. The committee consider the recommendations are clear by stating 'to offer repair without mesh'.
Manchester Foundation Trust, Manchester	Guideline	37	9 and 11	These two statements should be switched, so that statement 1.10.13 comes before statement 1.10.12	Thank you for your comment. For clarity we have reworded the recommendations, so they can now be read as stand-alone statements.
Manchester Foundation Trust, Manchester	Guideline	39	4	Research recommendation 4 does not appear to be clinically sensible question. In medicine there are hierarchies of treatment e.g pelvic floor physio prior to surgery for SUI. All women should be first offered a pessary; only if that fails should they consider surgery	Thank you for your comment. This is a suggested area for research, it is not a recommendation. The committee have developed a PICO to go along with the suggestion; however, beyond this would be for those developing the intervention to determine. We prioritised this as a research question because data is lacking.
Medtronic Ltd	Guideline	8	14-15	We suggest that a recommendation is included regarding the post-void residual volume threshold to confirm voiding dysfunction or urinary tract infection in patients with suggestive symptoms.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
Medtronic Ltd	Guideline	19	7-15	Section 1.4.54 states "after local or regional MDT review." Please clarify whether section 1.4.55 should also read "after local or regional MDT review" instead of "local MDT review."	Thank you for your comment. We have removed the recommendation 1.4.55 as it was covered by 1.4.56

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Mesh Awareness Wales	Guideline	21	6	Para 1.5.3 NICE committee is already aware of the current suspension of mesh procedures for incontinence. The best recommendation would be to restrict the use of mesh medical devices to situations where the alternative non surgical options and non-mesh surgical procedures are not suitable or acceptable. This will effectively place the mesh procedures as third line after conservative treatment.	Thank you for your comment. The committee has carefully reviewed all the evidence of the risks and benefits of all interventions for prolapse and incontinence (evidence review I and E respectively) and agreed that it is appropriate to offer some women the option of having surgery with mesh implants provided they are fully informed. For clinical, social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage some women from the most appropriate care. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
Mesh Awareness Wales	Guideline	21	15	Para 1.5.6 It is good practice for the clinician to inform the patient if there is a conflict of interest that could have influenced the choice of the (mesh) medical device/manufacturer, this would improve transparency.	Thank you for your comment. We think that this applies generally to healthcare and is outside of the remit of NICE guidelines.

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Mesh Awareness Wales	Guideline	22	21	Para 1.5.14 Six month follow up is too short, complications can arise much further down the line. Women who have had mesh implants are best followed up yearly in order to identify, recognise and treat any long-term mesh-related adverse events, this will improve the quality of the national registry and reporting to the MHRA. This souldn't replace their usual post operative check	Thank you for your comment. The 6 month follow-up appointment is for clinical practice. The guideline recommends that longer follow-up of over 5 years should be covered by a registry as it is important that this data is captured. The text around the difference between clinical (short term) and registry (longer term) follow-up has been amended throughout the guideline in order to make this distinction clearer. In addition we have also stated that all women who have had surgery should have access to further referral.
Mesh Awareness Wales	Guideline	24	6	Para 1.6.6 If symptoms are apparent in clinic then other avenues should be looked into such as translabial ultrasound and MRI	Thank you for your comment. The committee was of a view that there is no evidence that ultrasound and MRI are superior clinical examinations, but they are more costly.
Mesh Awareness Wales	Guideline	26	27	Para 1.7.14 This recommendation contradicts that of NICE IPG on prolapse mesh issued in December 2017. This suggested that mesh can be used for women with prolapse only within the research context. Biological material should not be used as an alternative to polypropylene	Thank you for your comment. We refer the stakeholder to the full evidence report (evidence review I) on this topic, in particular to the section titled "other factors the committee took into account", within this section there is a detailed discussion about the IPG and how the committee do not agree that mesh should only be considered in research for this very restricted indication.

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Mumsnet	Guideline	General	General	Explicit consideration should be given to those with connective tissue disorders (such as hypermobility or Ehlers Danlos); such disorders needs to be considered when clinicians are gathering information. People with these conditions may need a different pre-op/treatment assessment process, because they have slower skin healing and more fragile skin/tissue which may lead to worse outcomes from surgical intervention, as well as being more prone to prolapses from childbirth.	Thank you for your comment. We agree that specialist consideration would be necessary in this case; however, this population is outside the scope for this guideline.
Mumsnet	Guideline	General	General	Consider issuing further guidance to GPs, eg recording number of absorbency pads used. Many women using absorbency products for urinary incontinence will not have been referred on and will still be in primary care.	Thank you for your comment. We refer the stakeholder to recommendations on "*absorbent containment products",* where the guideline specifically states women should be offered a review at least once a year. This review would not be at a hospital clinic but carried out by a member of the primary care team. The recommendation provides details on what the assessment should cover.
Mumsnet	Guideline	7	15	Please repeat paragraph 1.3.3. (assessing urinary incontinence) in section 1.6 (Assessing pelvic organ prolapse). Both paragraphs (1.3.3 and 1.6) should state that such predisposing and precipitating factors, such as hypermobility syndromes, are documented in the patient notes.	Thank you for your comment. Your comment is outside of the scope of this guideline.

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Mumsnet	Guideline	14	24-25	Increase the emphasis on this factor. A Mumsnet user says 'My GP spent an awful lot of time talking about having a dry mouth as a result of taking Oxybutini, but she did not mention adverse effects on cognitive function at all.'	Thank you for your comment. We conducted a review on the risks of cognitive function for women taking anticholinergic drugs for OAB but found limited evidence (evidence review C); therefore, we were unable to make strong recommendations. In the evidence review we discuss the growing body of evidence which indicates an association between cognitive dysfunction and anticholinergic medicines, (although not specifically for treatment of OAB), and have therefore recommended that health care practitioners take this into consideration.
Mumsnet	Guideline	20	24-26	Discussion of risks and benefits should include discussion of possible impacts on women's capacity to experience sexual pleasure. It's important to note that positive sexual pleasure is not the same as the absence of discomfort.	Thank you for your comment. We agree that dyspareunia is an important potential complication of surgery, hence we included this in our outcomes. The guideline encourages a full discussion of all the risks and benefits of different treatments.
Mumsnet	Guideline	23	21	Examination should also take place standing up as a prolapse is gravity dependent.	Thank you for your comment. The recommendation does not state how the examination should take place. The committee consider that that this would be at the discretion of the clinician.
Mumsnet	Guideline	24	6-8	Or different time of the month, as the position of the cervix is affected by the menstrual cycle, which may exacerbate prolapse symptoms.	Thank you for your comment. We have amended this recommendation to be less specific and now reads 'or at a different time'.

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Mumsnet	Guideline	25	5	'Avoiding heavy lifting' does not have enough nuance to be applicable to many women, especially those with children who are not yet walking. This advice risks being dismissed. It would be better to teach women to evaluate the impact of different lifting activities on their prolapses.	Thank you for your comment. The committee have amended this to now read 'minimising heavy lifting'
Mumsnet	Guideline	25	18-22	Consider recommending NHS Squeezy app, which will be of more benefit than a paper handout	Thank you for your comment. The committee was unable to recommend how the delivery of information should be offered (i.e. if via app would be appropriate). In addition, the committee wanted to recommend supervised delivery of pelvic floor muscle training, which the app would not offer.
Mumsnet	Guideline	29	20-22	Discussion of risks and benefits should include discussion of possible impacts on women's capacity to experience sexual pleasure. It's important to note that positive sexual pleasure is not the same as the absence of discomfort.	Thank you for your comment. We agree that dyspareunia is an important potential complication of surgery, hence we included this in our outcomes. The committee did not prioritise sexual pleasure as this is much more subjective, and can mean different things to different people. We hope that a full discussion between the consultant and woman will take place, where this can be discussed if the woman wishes it to be.
NHS England – Specialist Women Services CRG	General	General	General	it is important the guideline is in line with service specifications the CRG is writing for commissioning services for complex incontinence and prolapse. There are some disparities at present.	Thank you for your comment. We agree, but at the time of developing the recommendations for the guideline, the committee was not aware of the service specifications.

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Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	5	3	Should all MDTs also be able to offer a patient liaison person / informed lay person?	Thank you for your comment. The committee considers that confidentiality of the patient may not be maintained should a patient liaison, or informed lay person be involved in the MDT. Therefore, it would not be appropriate to add to this recommendation.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	5	24	Should the role or type of biofeedback be clarified? We know this is not part of the 2019 changes but considering the depth of detail given of the other roles, this seems a broad statement	Thank you for your comment. The committee agree with this comment, and have amended the recommendation to specify 'bowel biofeedback'.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	5	28	We feel the role of the plastic surgeon should be clarified as to why; otherwise it could be quite intimidating for lay people accessing the guidelines	Thank you for your comment. A plastic surgeon needs to be listed, as there are occasions when a plastic surgeon is required. The committee expect that women are actually aware of this, so it is unlikely to be intimidating.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	6	7	as above (makes sense for those who have experienced mesh problems but not for your average person)	Thank you for your comment. The committee consider that confidentiality of the patient may not be maintained should a patient liaison, or informed lay person be involved in the MDT. Therefore, it would not be appropriate to add to this recommendation.
Pelvic, Obstetric &	Guideline	7	3	1.2.3 quality assured by an independent body including patient representatives	Thank you for your comment. We are recommending that providers collect data on

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Gynaecological Physiotherapy (POGP)					surgical procedures for urinary incontinence and pelvic organ prolapse. It is not however, the role of the guideline to determine how this register will be set up or who will be involved in the quality assurance procedure.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	7	12	1.3.2 perhaps reword "discuss the benefit of non-surgical management, in the context of long and short term goals"	Thank you for your comment. The committee do not agree that this re-wording is required. The committee think that the discussion of any treatment should include long and short term goals, and it is not specific to this recommendation.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	13	1	Long term management strategies – such as …. Examples should be provided to increase likelihood of compliance and understanding	Thank you for your comment. We have reflected on your comment and decided it would be clearer to delete the point 'long term management strategies'. This bullet is not adding anything to the recommendation - this bullet is covered in other bullets above.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	15	2	And offer early follow up or provide written advice	Thank you for your comment. We are not aware that this warrants written advice.
Pelvic, Obstetric & Gynaecologic	Guideline	15	10	Why may be at risk ??as previously identified? How will this be assessed, or does it need to be flagged by the GP	Thank you for your comment. There is no validated or NICE recommended tool that is accepted for use. We just wish to draw attention to

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al Physiotherapy (POGP)					this as an issue for discussion. There are a number of different rating scores, and we cannot recommend one over the other and the validity of these differ. It is important that the prescriber considers the total anticholinergic load and to use which ever tool they believe is most useful.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	15	13	**Initially** offer the cheapest	Thank you for your comment. Lowest acquisition cost is the term commonly used in NICE guidelines.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	24	2	Add **mutual** decision making	Thank you for your comment. NICE guidelines use 'shared decision-making' as the preferred term.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	24	17	This could be where sexual symptoms not explained by physical findings could be referred to psychosexual medicine services	Thank you for your comment. .

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Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	25	4	Should this be significantly overweight, or overweight and obese (appreciate not 2019)	The committee thank you for your comment. Since there was no evidence, it was decided that it would be best to use obese.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	25	7	Exercise modifications and its effects on symptoms	Thank you for your comment. The recommendation has been redrafted and there is now no reference to exercise.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	25	13	Clarify that this means vaginal pessary for oestrogen, not vaginal pessary device for support	Thank you for your comment. Recommendation 1.7.4 has been amended and now states 'impairments that might make vaginal oestrogen pessaries or creams difficult to use'.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	25	18	Why only stage 1 and stage 2? We do not think that the evidence is clear that more than stage 2 will not benefit from PFMT	Thank you for your comment. There was very little evidence for stage 3 and 4, therefore the committee were only able to make a recommendation on stage 1 and 2.
Pelvic, Obstetric &	Guideline	25	24	So this slightly contradicts the line before if PFMT alone used for grade 1 and grade 2, but pessaries	Thank you for your comment. The committee noted that pessary use remains an important

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Gynaecological Physiotherapy (POGP)				not really indicated for grade 1 certainly and often used for grade 3 and 4	alternative to surgical intervention for women with all stages of prolapse including advanced prolapse.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	26	4	Effect of pessary on sexual intercourse not known in the evidence – so this should be "discuss the possible implications of a pessary, and the choice of pessary in relation to sexual intercourse"	Thank you for your comment. The committee have amended recommendation 1.7.8 so that it now states "discuss the effect of different types of pessary on sexual intercourse".
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	34	7	Does this include immediate post-op pain – should the option for immediate removal be open if consultant and woman agree. Regional MDT would add time to the process	Thank you for your comment. The review did not include the evidence on immediate post-operative pain; the committee do not think the recommendations prevent this should it be required.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	37	22	The NICE guideline for faecal incontinence is 2007, so the work behind it is probably about 2003. This is quite old for a recommendation; might it be better to recommend latest guidelines or refer to specialist practitioner?	Thank you for your comment. This is the latest recommendation from NICE, and is still therefore the current guidance which needs to be followed.
Pelvic, Obstetric & Gynaecological	Guideline	39	1	Research recommendations: pessary use as an alternative to primary or repeat surgery would be useful. Many women opt for the surgery initially but	Thank you for your comment. This is not one of the research questions we have developed. The committee have listed a number of research priorities, and the long-term satisfaction with

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Physiotherapy (POGP)				do not want further surgery or post-operative failure or POP recurrence	pessaries compared to surgery for pelvic organ prolapse is one of these areas.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Guideline	39	21	This research could be pain in relation to any gynaecological surgery, not restricted to mesh only surgery	Thank you for your comment. The committee agree; however, the priority is to understand pain after mesh surgery.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Evidence review H	11	25	Exercise and it's effect on symptoms and recommend use of Engineered Support Garments to reduce impact on the pelvic floor and optimise it's function.	Thank you for your comment. We included V-brace in the protocol with the aim of reviewing available evidence on engineered support garments. No evidence was identified on these products and therefore, the committee were unable to make any recommendations about their use.
Pelvic, Obstetric & Gynaecological Physiotherapy (POGP)	Evidence review H	19	20	Instead of V Brace pants / underwear please consider a broader title of "Engineered Support Garments or Research Backed Support Garments"	Thank you for your comment. We included V-brace in the protocol, and this was stated in the scoping document which went out for consultation prior to the guideline being produced. We did not identify any evidence on V-brace and as such have made no recommendation on their use, or any engineered support garments.
Pelvicroar	Guideline	General	General	Connective tissue disorders such as EDS or hypermobility need particular screening	The committee agree that specialist consideration would be necessary in this case; however, this population is outside the remit of the scope for this guideline.

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Pelvicroar	Guideline	General	General	Pelvic floor education and prevention would ideally be started in schools, with reference to important age groups eg postnatal and menopause	Thank you for your comment. We agree but this is outside of the scope of the guideline.
Pelvicroar	Guideline	General	General	Can guidelines be sent to pharmacists to educate women when purchasing incontinence pads?	Thank you for your comment. This guideline applies to health care professionals, service commissioners and women with urinary incontinence, pelvic organ prolapse, or complications associated with mesh surgery for urinary incontinence or pelvic organ prolapse, their families and carers, and the public.
Pelvicroar	Guideline	General	General	Can we start to look at engineered support garments more eg EVB, which many physios recommend?	Thank you for your comment. We included V-brace in the protocol with the aim of reviewing the available evidence on engineered support garments (evidence review H). No evidence was identified on these products and so the committee was unable to make any recommendations about their use.
Poole Hospital NHS Trust	Guideline	General	General	Overall the guideline is positive and reaffirms the multi-disciplinary practice regarding the management of SUI and prolapse that many of us have been advocating for a while. However in some areas the recommendations are somewhat contradictory and in others the sheer volume of what is being recommended will make it impractical to implement without massive investment – which is unlikely.	Thank you for your comment. The committee discussions for each evidence reports were released for consultation. The rationale and impact that accompanies the recommendations will now be published with the final guideline.

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				The draft presented is only the recommendations; the detail behind some of the decision making is not presented so it's hard to understand the rationale for some of the conclusions.	
Poole Hospital NHS Trust	Guideline	4	3	Local MDT: whilst a keen supporter and innovator of MDTs recommending these be done for all women with OAB and primary prolapse seems unnecessarily burdensome. Where is the evidence that this is beneficial? Such a recommendation will take away huge resources for questionable benefit.. MDTs already exist for SUI surgery but to broaden this to such a large cohort risks deflecting time and resources from the patients who need discussion. There is only a finite time for an MDT and the more patients that need discussion the less time for each patient. Clear pathways already exist for OAB and primary prolapse and without clear evidence of a benefit for MDTs I don't see the rationale for including them in an MDT.	Thank you for your comment. The committee was of the view that the same approach should be followed for women with overactive bladder and primary prolapse as for women who require stress urinary incontinence surgery. The committee think that each condition can be equally complicated, potentially requiring input from more than one specialist; therefore women with SUI, OAB and prolapse should have their case discussed at a local MDT.
Poole Hospital NHS Trust	Guideline	5	3	The concept of a Regional MDT is welcome but realistically to function efficiently needs to have a relatively small number of complex cases. The proposed caseload is too vast and much of it is already or could be done by local MDTs, e.g. bowel	Thank you for your comment. The committee acknowledges the challenge in setting up MDTs, but MDTs are essential for good decision making for the woman. The committee acknowledge that the MDT requires significant resource allocation

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				problems. The requirements for attendees at the Regional MDT are similar to what one expect for a regional mesh centre, not necessarily the same thing. This will be very resource heavy. By setting the bar so high for MDTs there is a significant risk they will fail, better to be realistic in expectations and insist on complex cases going through the regional MDT. Some degree of flexibility would be helpful to allow for different levels of expertise in some units. For instance some "DGHs" have a very high level of specialist expertise, others less so. It would be more helpful to refer to a concept of a Regional Network of MDTs where complex problems could be shared but many of the decisions deferred to local level.	but this introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance.
Poole Hospital NHS Trust	Guideline	6-7	10	I completely support the concept of data collection although the detail of who sets up and runs the National registry is lacking. The registry should be for all treatments/procedures not just those using mesh. What is the rationale for giving women a copy of their data entered on the database? How is that going to work logistically given that it is an online process and most theatres no longer have printers.?	Thank you for your comment. We are recommending that providers collect data on surgical procedures for urinary incontinence and pelvic organ prolapse. It is not however, the role of the guideline to determine how this register will be set up. The committee agree that if the woman would like a copy of her data, she should be able to have it, as this would be in line with the General data Protection Regulation laws.

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Poole Hospital NHS Trust	Guideline	9	6	The suggestion that urodynamics should not be done before treating SUI is completely at odds with the rest of the document which aims (rightly) to emphasise the risks and concerns about surgery. Urodynamics is part of the assessment process, which includes fluid charts, questionnaires etc and in 10% of "obvious" SUI will pick up other issues. It seems a very retrograde step to suggest cutting this out whilst increasing the bureaucracy everywhere else. It actually seems to be facilitating a pathway to easier surgery while the rest of the document is pulling in the opposite direction. This recommendation is also at odds with other respected International Guidance e.g. European https://uroweb.org/wp-content/uploads/20-Urinary-Incontinence_LR.pdf	Thank you for your comment. We have amended the recommendation to clarify that an urodynamic test should only be performed when stress urinary incontinence is not demonstrated before surgery in women with stress urinary incontinence or stress predominant mixed urinary incontinence.
Poole Hospital NHS Trust	Guideline	21	5	Are the data really there to recommend autologous fascial slings as a first line treatment? The data are nowhere near as robust as for midurethral slings. To make it first line implies it is as effective with similar complication rates to colposuspension and traditional MUS. The data are not presented but the studies that I'm aware of are not as robust or with long enough follow up. The practicalities of this	Thank you for your comment. Unfortunately, the evidence was initially redacted as the data was provided in confidence until its publication. The data has now been published and can now be disclosed within the guideline.

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				option needs to be considered as very few units currently can offer this service and inevitably with a "new" technique being learned or "re-learned" there will be a learning curve. I don't feel it should be given the same weight as the other two. There is a real danger here that this guideline will create a whole group of surgeons who will start doing a new procedure with questionable benefit.	
Poole Hospital NHS Trust	Guideline	21	9	The practicalities of recommending referral to another surgeon needs to be clarified. As above for fascial slings this may mean not just out of hospital but out of region.	Thank you for your comment. We agree. This would ultimately be up to the clinician and the woman's preferences.
Poole Hospital NHS Trust	Guideline	22	12	Not recommending injectables seems paradoxical. Whilst the data on the questions asked at scoping may not be strong enough to elevate it to a first line option there needs to be a degree of pragmatism in a practical clinical guideline. There is abundant evidence that injectables are effective and relatively risk free. *e.g. Sokol ER et al Efficacy and Safety of Polyacrylamide Hydrogel for the Treatment of Female Stress Incontinence: A Randomized, Prospective, Multicenter North American Study. J Urol 2014.* Whilst injectables may not be as good as the other options they do work for many women. To rule out	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-

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				the simplest and least risky procedure when the document highlights the perils of surgery seems very paradoxical. At least I would recommend the wording should be adjusted to allow it to be offered first line if patients want on the understanding that the data are not as robust. Many of our patients have opted for this since the mesh suspension because they do not want, or cannot afford the time off, a major procedure like fascial sling or colposuspension. Mesh procedures are going to have limited uptake, despite the strong evidence they work, due to the negative publicity around them. Thus injectables offer a practical relatively safe and effective alternative. In the event they are not successful other options are not compromised.	term effectiveness and adverse events evidence. Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9. This study compared two types of bulking agents (Bulkamid vs Contigen). The committee did not prioritise comparing different types of bulking agents, but to identify if bulking agents (of any type) were effective when compared to surgery. This was with the intention that bulking agents, should they prove to have sufficient long-term effectiveness evidence could be recommended alongside surgery options.
Poole Hospital NHS Trust	Guideline	31	6	Referral of mesh related complications. I completely support the concept of regional mesh removal centres. However a degree of pragmatism is needed. For specialist uro-gynaecologists working away from a regional centre some degree of management of those complications on the minor end of the spectrum should be feasible in conjunction with local MDTs and if necessary in network with the regional centre. Volume wise	Thank you for your comment. The committee would expect the woman to be discussed at the regional level; however, if the local provider has the competencies to undertake what is necessary then the procedure can be done locally. There is no expectation that the woman has to travel for their case to be discussed at an MDT meeting.

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				these are likely to be more allowing the centres to concentrate expertise on the more complex cases. Simply referring all patients with a possible complication a) risks overloading the centres and b) disadvantages the patient as she may have to travel 100's of miles to her nearest centre. Clearly if necessary this can be done but for smaller complications this should not be necessary.	
Royal College of General Practitioners	Guideline	General	General	Community surveys consistently report that this is a common problem, often not reported to health care professionals. Like so many other problems, this appears to be because it often causes little disability or interference with daily life and therefore the women choose to put up with it. There is generally a lack of this perspective in this guideline: • There is a general assumption that all women with urinary incontinence will want treatment, rather than recommend a discussion about the degree of interference caused that might result in a shared decision to do nothing. • There are very few items in the guideline where any assessment of functional impairment is advised. See, for instance para 1.7.1	Thank you for your comment. We agree with your comment, however, the committee did not prioritise functional impairment during protocol development.

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Royal College of General Practitioners	Guideline	4	2	1.1 We do not think the recommendations should start with the role of the MDT. Female urinary incontinence is a very common issue and rarely requires the MDT. The majority of care is provided in primary and community care. we would recommend that the first section should be1.3 where we all have a role.	Thank you for your comment. Although we are aware that a proportion of women with incontinence can be managed in primary community care, there are some that their management of incontinence will require discussion at the MDT. We discussed at length where would be the best place for the MDT section. We now have an additional header to make this a section in its own right. We have the MDT section at the start of the guideline as we refer to the regional and local teams throughout the recommendations.
Royal College of General Practitioners	Guideline	4	2	1.1 Generally it is good to see the emphasis on local and regional (complex) MDT involvement to standardise and optimise treatment outcomes.	Thank you for your comment.
Royal College of General Practitioners	Guideline	6	24	It needs to be clear that it is the surgical unit who are required to maintain the register – 5 year follow-up is not usual following surgery. Will there be unnecessary costs for follow-up appointments including inconvenience for women to attend appointments or can this be managed by phone/internet/letter?	Thank you for your comment. We acknowledge there are problems and costs associated with obtaining outcome data at five years. We have amended the recommendations to make it clear that any long term follow-up (at least 5 years) would be the responsibility of the national registry of surgery for urinary incontinence and pelvic organ prolapse in women. This is a matter which will need to resolve by those funding and running the national registry.

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Royal College of General Practitioners	Guideline	7	5	Register – who is this reported to? Is this a register of problems related to MESH generally or of different providers? And who is responsible for the data collected?	Thank you for your comment. We are recommending that providers collect data on surgical procedures for urinary incontinence and pelvic organ prolapse. It is not however, the role of the guideline to determine how this register will be set up or who will be responsible for the data itself. We are providing guidance on what we believe is required to improve the quality of care and provide information on clinical practice and late adverse effects.
Royal College of General Practitioners	Guideline	12	18	1.4.19/20 It is not clear who is responsible for this review. Is this the provider of the pads – which maybe an agreement by a nursing home or residential home? Or is this the district nurse or GP responsibility? And is the information collected appropriate and would this influence future management?	Thank you for your comment. The committee consider that this should be delivered by the health care professional responsible for the care of the woman. At the time, if this is the GP, this could be devolved to a suitably trained professional. The information collected is appropriate and the committee think this will influence future management.
Royal College of General Practitioners	Guideline	14	17	Para 1.4.27 'The likelihood of the medicine being successful' Yes – this should be part of any discussion about starting treatment. But one of the regular comments from the RCGP overdiagnosis group is that the guidelines do not include the numerical detail. It would be helpful to clinicians using this guideline if the figure for absolute (not relative) improvement.	Thank you for your comment. We agree with your comment, however we did not review the effectiveness of anticholinergics as part of this update.

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				We couldn't find the relevant data in the full evidence document but think it must be there somewhere.	
Royal College of General Practitioners	Guideline	16	26	Para 1.4.44 An odd recommendation. Why is the optimum review date not to be by agreement between clinician and patient? It looks as if the guideline is using age as a proxy for severity & comorbidity.	Thank you for your comment. We are stating "offer a review", not that all women should have one.
Royal College of General Practitioners	Guideline	25	9	1.7.3 Topical oestrogen can improve SUI and OAB as well as should be included in those sections or additional information added in this section.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013. The recommendations made in 2006 (1.4.39) do however refer to oestrogens for OAB symptoms.
Royal College of General Practitioners	Guideline	25	18	1.7.5 There are far too many women with stage 1 or 2 pelvic organ prolapse to refer for 16 week supervised pelvic floor muscle training routinely.	Thank you for your comment. These are symptomatic women, not asymptomatic. The symptomatic women are likely already to be referred for assessment and treatment.
Royal College of General Practitioners	Guideline	25	29	1.7.8 There are some women who gain benefit from self-inserting pessaries for specific activities – gym, working etc	The committee thank you for your comment; however, there was no evidence to suggest self-management. The committee are aware that there is currently research within the NIHR pipeline on this topic. In addition, the recommendation does not explicitly say who should carry out the pessary removal and that this could be self-managed

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Royal College of General Practitioners	Guideline	27	13	Para 1.7.16 Editorial comment only. The phrase at the end '…preserve the uterus and hysterectomy'. We have worked out what was meant. Unusually, in this instance replacing 'and' with 'or' improves understanding & clarity, even if it is strictly ungrammatical.	Thank you for your comment. The committee have rephrased recommendation 1.8.8.
Royal College of Nursing	General	General	General	This is just to let you know that the feedback I have received from nurses caring from people with urinary incontinence and pelvic organ prolapse suggests that there is no additional comments to submit to inform on the consultation of the above draft guidelines. Thank you for the opportunity to review this document.	Thank you for your comment.
The Royal College of Obstetricians and Gynaecologists (RCOG).	General points on content, structure and approach	General	General	The RCOG welcomes NICE's updated draft guidance on the management of stress urinary incontinence and pelvic organ prolapse. This is a very comprehensive guideline that covers all aspects of urinary incontinence and prolapse treatment in women. We particularly welcome the emphasis on providing women with the support and	Thank you for your comment. Following stakeholder consultation we have reinforced the importance of promoting shared decision making and informed preference with women. The guideline will also be accompanied by decision aids which will assist decision-making for women when they are considering the non-surgical and

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				information they need about all treatment options. This is to ensure they can make informed decisions about the best treatment for their individual circumstances. Additionally, the emphasis on informed decision making and national data collection for complications is very welcome. We think there could be more emphasis on how important the woman's perspective and priorities are throughout the guidance. Furthermore, where possible, it would be helpful to include diagrams to aid women and their families' understanding of treatments and the parts of the body involved.	surgical procedures for stress UI and pelvic organ prolapse.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	General	General	We think it needs to be made clearer who is involved in a woman's ongoing care throughout the guidance. There are references to reviews on p16, line 26 and p18, line 13 but the guidance doesn't state who will be responsible for this care.	Thank you for your comment. The committee think that they should not specify who should be covering the woman's ongoing care as this is likely to depend on local arrangements. Vast majority will have care referred back to primary care (especially for OAB medication).
The Royal College of Obstetricians and	Guideline	General	General	Please include the role of Continence Advisory Nurse referral and role.	Thank you for this comment. We have added continence specialist nurse to the list of those included within the local MDT.

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Gynaecologists (RCOG).					
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	General	General	**Emotional support:** we strongly believe that women with mesh complications should be offered emotional support or referral to counselling services. Currently, there is no recognition in the guidance of the emotional trauma that women might experience as a result of mesh complications, other than a reference to psychosexual counselling for women with sexual dysfunction. Many of these other complications can have a huge impact on women's daily lives and emotional experiences too. (p29 - 31, 34 - 38).	Thank you for your comment. The committee considers that emotional support will be covered by the recommendations specifying the specialities that should be part of a regional MDT (clinical psychologist) and the access to services (psychology and psychosexual counselling) [1.1.4 and 1.1.5, respectively].
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	General	General	**Consent:** it is not clear whether women will be consenting to the collection of data as described. If consent is not required, we assume it will be anonymous. If consent is required, then this needs to be much clearer. More specifically in p18, lines 5-10 the guidance refers to starting treatment "only if the woman is willing". We strongly suggest amending this to "only if the woman has given her consent after discussion of the risks and benefits". (p6, lines 11 and 14).	Thank you for your comment. We agree that data collection should not take place without the woman's consent; this issue is not specific to this guideline, but applies to all clinical care across the NHS. In relation to this guideline and consent, the committee have made it clear that consent should be taken from the woman when collecting data on any surgical procedure which will be added to the national registry. In relation to the specific recommendation that the stakeholder refers, this is not about data

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					collection, and the committee do not think the wording requires amendment.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	General	General	**Language and structure**: an opening lay explanation of what mesh is and the different types of mesh would be helpful and make the guidance more lay friendly. More generally there are a lot of places in the text where terms could be explained. Even though NICE guidelines are primarily for healthcare professionals, it would be encouraging to see simpler language used throughout and clinical terms explained. For example, urodynamic, botulinum toxin type A and pad testing is not immediately obvious. Additionally, the table on pages 32-35 is really helpful. If possible, we think it would be very useful to have something similar included outlining the key risks/benefits for the sections describing management (Sections 1.4, 1.5, 1.7, 1.8 and 1.10).	Thank you for your comment. We acknowledge that some of the terms are technical, and there is a section called "terms used in the guideline" which provides a definition of procedures, including mesh. The guideline is required to be succinct and therefore we cannot go into detail about each term used. We have attempted to use simple language whenever possible, and have worked with the lay members on the committee to ensure the guideline is reader-friendly. We refer the stakeholder to the glossary in the full guideline where each procedure is explained in detail.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	1		"This guideline…" We feel that it would be helpful to have a general definition of what mesh is and the different types of mesh. We recommend the development of a glossary to accompany this guidance and have	Thank you for your comment. We have defined mesh in the glossary, and have also included a definition in the guideline in the section on "terms used in the guideline".

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				highlighted below suggested terms for inclusion in the proposed glossary.	
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	1		"Who is it for" We suggest adding "Women with urinary incontinence…" before "Health care professionals". This would place the emphasis on women receiving an informed choice. We appreciate that this would have implications for how the whole guidance is written (directed primarily at healthcare professionals)We feel that most women and their families will not know what "urodynamic" and "botulinum toxin type A" mean and believe it would be useful to explain both in an accompanying glossary of terms	Thank you for your comment. The order of 'who is it for' needs to remain the same as it was in the scope of the guideline. We have added the terms you mention to the glossary.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	2	7	We are concerned that this recommendation implies that every 'pelvic floor repair' operation requires discussion and agreement at either a local or a regional multidisciplinary team (MDT) meeting. Depending on the frequency that these meetings occur, we are concerned that this may result in a delay in care for women and an unmanageable workload for the MDT.	Thank you for your comment. The aim of the MDT is to ensure that there is oversight of the decision-making process prior to proceeding to invasive procedures. This would include ensuring that women have been offered all options including surgical and non-surgical and that they have been counselled about the benefits and risk of these options. The committee acknowledge that the MDT requires significant resource allocation but this

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				Further, a cystocele can be repaired by a general gynaecologist. Would discussion of a straightforward case of cystocele at an MDT result in the operation being directed to a urogynaecologist to perform?	introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance. The committee are aware that women were not always offered conservative options and the MDT would ensure that there is consistency in the care provided. The committee agree that a cyctocele can be repaired by a general gynaecologist; however, we believe there is still a requirement for the woman to be assessed according to the guideline recommendations, with the woman's case being discussed at an MDT to ensure all options have been considered and to ensure the most appropriate procedure is provided.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	4	4,5,6	This recommendation will be a challenging change in practice because most district general hospitals across the UK have only one urogynaecologist as part of a local MDT.	Thank you for your comment. The committee acknowledge that the MDT requires significant resource allocation but this introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance.
The Royal College of Obstetricians and	Guideline	4	16	This recommendation will be a challenging change in practice because most district general hospitals across the UK have only one urogynaecologist as part of a local MDT.	Thank you for your comment. The recommendation has been reworded to clarify that MDT membership can include two urogynaecologists, or an urogynaecologist and a

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Gynaecologists (RCOG).					urologist. The committee want to be clear that more than one consultant with expertise in the management of urinary incontinence and pelvic organ prolapse are needed to ensure that full discussion of care takes place. The committee wish to remove the risk of one individual making decisions without full consideration from other specialists with similar knowledge.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	4	16	This recommendation will be a challenging change in practice because in some hospital settings, in particular district general hospitals, having two urogynaecologists or two urologists with a special interest in female urology as part of the local MDT might not be possible.	Thank you for your comment. The committee was of a view that more than one urogynecologist or urologist would be necessary to satisfy the essential criteria for a MDT. The committee want to be clear that more than one consultant with expertise in the management of urinary incontinence and pelvic organ prolapse are needed to ensure that full discussion of care takes place. The committee wish to remove the risk of one individual making decisions without full consideration from other specialists.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	5	23	This recommendation will be a challenging change in practice because it would need high level agreement to alter pain medicine specialists' job plans to allow attendance at these MDTs, in addition to general pain and pelvic pain MDTs and clinics.	Thank you for your comment. The committee acknowledge the challenge in setting up MDTs, but we believe they are essential for good decision making, ensuring quality care for the woman. The committee are not stating how frequent MDTs should be, and in addition, we would not expect every member of the MDT to attend each meeting.

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					We have added recommendations to state all those listed in 1.1.2 should attend; however, those listed in 1.1.5 need only attend when their expertise is required.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	6	25	We feel it would be useful to add "improve/deteoriation/unchanged" symptoms.	Thank you for your comment. We have reconsidered the wording of this recommendation following stakeholder consultation. The committee do not think that this part of the recommendation is required - the recommendation already states to collect outcome data and it does not need an additional section to state if these outcomes are either, improved, deteriorated or unchanged; therefore, this has been removed.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	7	19	We believe that it is not necessary to include the word "routine" in this statement. The intention of the statement is the same without this word.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	7	19	1.3.4 We believe that this recommendation will be a challenging change in practice because a digital examination to assess pelvic floor contraction can be subjective.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.

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The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	7	22	This section on urine and MSU testing is clear. We suggest including: "clearer management on situations such as persistent microscopic haematuria in the absence of proven infection" and making a clear link to 1.3.2 in this case.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	8	20	We are concerned that this recommendation may be challenging in practice because it may overwhelm a patient with paperwork. We feel it would be helpful to clarify if all or some of the questionnaires listed should be completed. Lastly, the acronyms will be difficult for healthcare professionals, women and their families to understand. We suggest an explanation in an accompanying glossary of terms.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	9	26	We think women who have obstructive defecation symptoms should also be included in the indications for referral to a specialist service.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and	Guideline	10	11-14	1.3.21 We think it would be helpful to include a definition of 'Haematuria'.	Thank you for your comment. We have changed the recommendation to cross-refer to the bladder cancer section of the referral for suspected cancer guideline.

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Gynaecologists (RCOG).					
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	10	16	Consider smoking and alcohol intake in this section.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	10	21	We would suggest that the standard terms for involving dietetics in weight loss management is included here.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	12	18-20	1.4.19 We would suggest a review every six months to maintain a check on any deterioration in a patient's condition.	Thank you for your comment. There was no evidence to specific frequency, and more frequent than on a yearly basis may be appropriate for some women. We consider that the wording of the recommendation of 'at least once a year' allows for scope to reviews to be more regular and at the discretion of the health care professionals.
The Royal College of Obstetricians and	Guideline	13	10	We suggest including a section to comment on the role of long term antibiotics for SPC or indwelling catheter.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013.

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The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	13	15	We suggest explaining 'acquisition cost'. It is not currently clear what this means.	Thank you for your comment. We have added a definition to the glossary.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	14	19	We think it would be helpful to explain what "anticholinergic" means.	Thank you for your comment. We have added a definition to the glossary.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	20	22-26	1.5.1 If possible, we suggest including waiting time expectations for women and their families.	Thank you for your comment. We recognise that waiting times and expectations for the woman are important. We have added a further point to the recommendation, stating that any social or psychological factors that may influence the woman's decision should be discussed. We believe this would encompass waiting times and family expectations.
The Royal College of Obstetricians	Guideline	21	5	Has the committee considered evidence that shows the efficacy of the surgical management of fascia lata	Thank you for your comment. Only one RCT was identified that compared cadaveric fascia lata to synthetic mesh sling and no RCTs were identified

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and Gynaecologists (RCOG).					comparing autologous fascia lata (evidence review E). There were no other clinically important differences apparent between these two interventions. The committee agreed that the evidence on this intervention, consisting in a single trial on the 1-year effectiveness and safety of cadaveric fascia lata sling, did not support its use over retropubic mesh sling
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	26	7	We suggest replacing "removed" with "replaced".	Thank you for your comment. Given that replacement of pessary may be appropriate depending on the material the pessary is made from, the recommendation has not been updated
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	26	17-23	1.7.12 We suggest adding "Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period".	Thank you for your comment. This recommendation has been amended and now includes: •differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	31	14	Recommendation 1.9.5 – is this recommendation a new (2019) recommendation? If it is, need to add [2019].	Thank you for your comment. The committee have amended the recommendation so that it includes the appropriate date.

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The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	32-34	Table 1	This table is very useful and informative.	Thank you for your comment.
The Royal College of Obstetricians and Gynaecologists (RCOG).	Guideline	33	Table 1	We think it would be helpful to include explanations and definitions in an accompanying glossary.	Thank you for your comment. We have added these terms to the glossary.
Sling The Mesh	General	General	General	SLING THE MESH November 2018 FOLLOWS ARE: 1. Views of Sling The Mesh, Sling The Mesh Northern Ireland and Mesh Awareness Wales which, combined, has more than 7,800 members organised into key points. Submitted by Kath Sansom. I do not have ties to the tobacco industry. 2. Comments for each summary section	Thank you for your comment. Please see the individual responses to comments from Sling the Mesh.
Sling The Mesh	General	General	General	Views of all of our members is this: 1. Apply the precautionary principle and put all SUI and POP mesh into the category of research only	Thank you for your comment. In response to the three points: 1) The committee are aware of the public concern about mesh surgery for stress urinary incontinence and pelvic organ prolapse. The committee has carefully reviewed all the

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				2. Don't update guidelines until the outcome of the IMMDS review is known 3. Why is rectopexy mesh not included in this draft guideline. It should be. This is a grave omission.	evidence of the risks and benefits of all interventions for prolapse and incontinence (evidence reviews I and E respectively) and agreed that it is appropriate to offer some women the option of having surgery with mesh implants provided they are fully informed. In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. 2) This guideline is available for consideration by the IMMDS review. 3) Rectopexy is a procedure for rectal prolapse, which is outside of the scope of this guideline.
Sling The Mesh	General	General	General	Covering letter Dear NICE, We would like to draw the attention of NICE panel members to this: In 2003 The Health Technology Assessment programme said more long term evidence was needed into risk. See page 71 of link below. The NICE 2003 guidelines said the same yet 15 years	Thank you for your comment. The committee are aware of the public concern about mesh surgery for stress urinary incontinence and pelvic organ prolapse. The committee has carefully reviewed all the evidence of the risks and benefits of all interventions for prolapse and incontinence (evidence review I and E respectively) and agreed that it is appropriate to offer some women the option of having surgery with mesh implants provided they are fully informed. In addition, for

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				later we are stuck in the same situation with no long term evidence of risk into any mesh, least of all the most commonly used mesh, TVT, to treat SUI. Nobody gathered the data. Yet surgeons want to keep implanting into women to now try to get that long term evidence. This is ridiculous. You have had plenty of time. Enough women have been maimed. We the patients are the long term evidence and there are around 10,000 of us in UK online support groups suffering. If you look at HES data it shows 127,000 women had mesh from 2006 to 2017. Look at the number in support groups alone it makes the risk look alarming. It is clear not all women will be members of online Facebook support groups as many will not seen any media coverage, others wont have made the link, there will be older women in nursing homes and many being told they did not have a mesh operation because surgeons tell them eg they had a tape operation not a mesh or they say they had the safe mesh and not the mesh in the media. In addition, figures will be low as HES data wont show private patients or those stuck at GP surgeries for pain relief, or directed into the wrong pathways of care for their pain. Others suffering in silence. https://slingthemesh.files.wordpress.com/2018/04/h	social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. We also agree that in the first publication of this guideline in 2006 we stated that there was a need for data collection; however, NICE are not responsible for the development of this data collection. These guidelines provide details on what the committee believe to be best practice for care. In this publication we have included recommendations which state that details of all procedures (mesh and non-mesh) "*must"* be collected in a national registry. The committee agree we cannot go forward without this data and strongly support the setting up of a national registry and rolled out for use as soon as possible. In addition, we agree unbiased publications of long-term data are needed. However, the committee think that current trials, such as the PROSPECT study, (if they continue with long-term follow up data collection) can provide this. We acknowledge that studies in this review were often considered low quality when assessed by

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				ealth-technology-assessment-of-tension-free-vaginal-tape.pdf?fbclid=IwAR0BxqbnnY9sA3Ie_hMPGNCXBao7w-_VuURwIxn8dGcL12G1YfGyn1HBkE0 SEE PAGE 71 See paragraph from the HTA document in red below that we believe is wholly unacceptable as an admission. The resulting huge failing for women and patient safety, in that no long term data, databases, registries or any effort at all was made to provide robust long term evidence of ALL of the outcomes of mesh surgeries. Pain, infections, loss of sex life, auto immune conditions. We are not campaigning about whether mesh fixes or fails, we campaign and care that it has caused such horrifying post operative complications that 60% women in Sling The Mesh are suffering depression, anxiety and ptsd and many are suicidal. We are now seeing women talking of how their children are suffering from seeing their mum struggle so badly. We know of children self harming because of this. We know of women who self harm on a regular basis because of their mesh pain and they struggle to cope with it. One who took a piece of broken	the GRADE methodology. Overall the included studies ranged from moderate to very low quality and we included randomised controlled trials where available, which are generally considered robust. However due to the overall low quality of studies there is uncertainty around the effect estimates, and it is difficult to state the true benefits and harms of the interventions. During the development of this guideline we have attempted to address the concerns raised by the HTA document, for example by reviewing all available current evidence on TVT; and we are confident that the recommendations we have made support not only the included evidence from our reviews but the opinions and views of women. The recommendations provide clear guidance regarding the provision of information to women, offering non-surgical options but importantly providing women with choice about her own care.

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				glass to try to cut her mesh implant out of her vagina. She was sectioned. Almost 30% of women in Sling The Mesh have had to give up jobs and a further 20% now work reduced hours. See our survey for details on the number of women we see suffering catastrophic injuries: Sling The Mesh survey: https://slingthemesh.files.wordpress.com/2017/12/sling-the-mesh-survey.pdf HTA admits TVT was brought into widespread NHS use before its safety was known, on the basis of poor evidence, exposing "thousands of women to harm." See P71 of this document https://slingthemesh.files.wordpress.com/2018/04/health-technology-assessment-of-tension-free-vaginal-tape.pdf?fbclid=IwAR0BxqbnnY9sA3Ie_hMPGNCXBao7w-_VuURwIxn8dGcL12G1YfGyn1HBkE0 HTA said there should be unbiased trials of more than five years and called for research on long-term complications. In 2018 this has still not happened. They based mesh views on what is known as case series evidence, which is Level 4 out of 5 on the	

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				scale of evidence, 5 being the lowest quality. See this link for explanation on evidence types. https://www.orthobullets.com/basic-scie…/…/level-of-evidence For this HTA assessment they only looked at 6 months of Nilsson data, the most disliked study in mesh campaign land. Nilsson is a 17yr study that was over seen by two consultants who were paid by Ethicon. The oldest woman was 87 and the average age was 52 so having an older cohort meant pain could be blamed on age and these older women would be less sexually active so loss of sex life would not necessarily have been picked up. Additionally 22% of the cohort dropped out thus introducing a high risk of bias. Even at 5% drop out, bias is a concern. Most of the interviews were over the telephone and they concentrated on primary outcomes of the pad test – was the SUI fixed, so would not have picked up new onset of complications. Yet even basing their judgement on this flawed study HTA still said the following:	

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				A break down of key points made by HTA on P71 of its document below: ● Research is needed on possible long-term complications of TVT; this would provide either reassurance of safety or earlier warning of unanticipated adverse effects. ● If the indications for TVT are likely to be broadened to include women who are currently managed conservatively, this should be formally evaluated, ideally in an RCT, before widespread adoption. ● As new evidence about the effectiveness, safety and costs of TVT emerges, this should be incorporated in updated cost-effectiveness analyses. ● Evidence of efficacy (that TVT can be used successfully to treat incontinence) from case series led to the rapid, widespread adoption of TVT before its relative effectiveness (its place within NHS care) and long-term safety were known. Although current evidence suggests that TVT probably is effective and safe, this approach exposed thousands of women to an incompletely evaluated procedure in a poorly controlled way. ● Future research to evaluate new	

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				procedures of this type could avoid this by earlier and wider use of pragmatic RCTs and rigorously organised population-based registries. Women have been harmed for too long. Unless NICE understand that a lot of the scientific research to back up mesh use, is flawed then we will keep going round in circles using mesh, allowing more women to be harmed and be in exactly the same or very similar situation in another 15/20 years time.	
Sling The Mesh	General	General	General	15 KEY POINTS: 1a). Women suffering bowel complications after a mesh implant must not be recommended rectopexy mesh. See Mesh complications section 1b). Wny is rectopecxy mesh not covered in the draft guideline seeing as it is a rectal prolapse. This is a serious omission in our opinion.	Thank you for your comments. Our responses can be found below: 1a) This may be a misinterpretation of the recommendation (within evidence review L). We do not state anywhere in the guideline that women should be offered rectopexy. This is a procedure for rectal prolapse, which is outside of the scope of this guideline. 1b) Rectopxy is a procedure for rectal prolapse and is outside of the scope of this guideline.

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				2 The 2017 Keltie study, which uses 8yrs of NHS data to show mesh risk is AT LEAST 10%, has not been included. There are scores of pages of scientific literature links in the NICE paperwork, Three of us have checked. The Keltie study is not in there.	2) This paper was excluded because it did not meet the inclusion criteria set out in the review protocol (evidence review E). There was RCT evidence for effectiveness and complications up to 5 years. Given that RCTs give the highest level of evidence for intervention reviews, RCT data was prioritised to inform the effectiveness and complication reviews up to 5 years. Non-RCT data was considered for inclusion to inform the reviews where there was a lack of data i.e. beyond 5-years. Keltie et al., 2017 state in their title that this was an 8-year study. However, the mean follow up time was 4.2 years. As a result, this non-RCT study was excluded from our review (we only included non-randomised studies with a mean follow up time of greater than five years) see evidence review E). To finalise, Keltie et al., 2017 is a retrospective observational study and it would have been graded as of very low quality. Very low quality studies are generally not helpful/used to inform recommendations. Nevertheless, the data by Keltie et al., 2017 was considered as part of the sensitivity analysis in the ESTER study which assessed the cost-effectiveness of various surgical procedures for SUI. Unfortunately, the findings were redacted during the consultation

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					phase due to the confidentiality as the publication was going through the peer review process. However, the findings of ESTER analysis together with the committee discussion will be made available in the final guideline.
				3 NICE want to un-ban vaginal prolapse mesh that was banned10 months ago in December 2017. We vehemently oppose this.	3) We refer the stakeholder to the full evidence report (evidence review I) on this topic, in particular to the section titled "other factors the committee took into account", within this section there is a detailed discussion about how the evidence reviewed on anterior prolapse led the committee to a different recommendation than that in IPG599. The committee do not agree that mesh should only be considered in research, for some women this may be a last resort, and they should have this option available to them. As discussed in detail within Evidence review I, this will only be a very small group of women. (Evidence reviews E and I).
				4 NICE say mesh can be used as 2nd option. We want it banned. If mesh must be kept as final resort then all of it must be 3rd option, to be used only when 1. Physio has failed and 2. non mesh surgery has failed.	4) The committee has carefully reviewed all the evidence of the risks and benefits of all interventions for prolapse and incontinence and agreed that it is appropriate to offer some women the option of having surgery with mesh implants

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					provided they are fully informed (evidence review I and E respectively). In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
				5 Abdominally inserted prolapse mesh has risks that are just as grave as vaginally placed prolapse mesh. Abdominal prolapse mesh is what Eileen Baxter of Scotland had, who died in August.	5) The committee are aware that some women do experience severe complications following mesh-related procedures. After carefully considering all the evidence on the risks and benefits of the various surgical procedures for prolapse (evidence review I), the committee concluded it was important that some women were offered the option of having a mesh procedure provided they were fully informed of the possible risks and benefits. In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not

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					have this option available, would disadvantage these women from the most appropriate care. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
				6 Evidence throughout is described as low, very low, a paucity of evidence, some is at serious risk of bias. Especially when looking at mesh removals vs partial removals. How can NICE make solid and trusted decisions based on such a weak evidence base. Patient voice must be listened to very carefully in deciding the final outcomes. As must the decision of Baroness Julia Cumberlege in her IMMDSR.	6) The committee have made the recommendations on the management of mesh complications using the best available evidence (evidence review L). We agree this data is limited; however, we conducted a robust search for the evidence, and only found retrospective data. We used this evidence along with the expertise from the committee. It must be highlighted that the committee also includes lay members, who have provided invaluable insight from the women's perspective and provided crucial input to the recommendations. Throughout the entire guideline development process the committee have been aware of women's concerns and the stakeholder feedback such as yours has been immensely useful in ensuring the recommendations promote shared decision making and informed preference. This draft guideline is available for consideration by the IMMDS review (which is due for publication

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					in March 2019), and the publication of the final guidance is a requirement for lifting of the high vigilance restrictions.
				7 NICE wants to recommend oestrogen cream as a fix for mesh eroding through a vaginal wall despite no evidence! This must stop. Vaginal cream will not stop or ease a bit of harsh plastic poking through a woman's vaginal wall. It is a waste of NHS resources, gives women false hope that there is a fix and is a waste of everybody's time.	7) The committee agrees with your point about mesh extrusion, and have modified the recommendation so that it is now clear this is only for women with vaginal mesh exposure (within evidence review L). However, for mesh exposure, where the mesh is visible but is not extruding out of the epithelium, oestrogen cream may be appropriate. If a woman has mesh exposure, but no other symptoms, she may not want to have a surgical procedure, and she may wish to use a topical treatment. The committee believe that women should have a choice.
				8. Long term outcomes. NICE says all procedures have uncertain long term outcomes. Thus making out mesh and non mesh have same risks. Not true. They've lumped all complications into same pot. Mesh adds an extra layer of complications like erosion, foreign body reaction. You do not get this additional layer of risk with non mesh thus making mesh surgeries come with greater long term risk.	8) The committee would like to clarify that all of these recommendations have been made with potential complications following mesh surgery in mind. Throughout the guideline we highlight the lack of long-term evidence, and that women should be made aware of this and the potential risks and benefits of each different surgical procedure (evidence reviews E and I). The committee acknowledges that mesh surgery has

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					unique complications but believes that women should have the opportunity to choose the surgery most appropriate for them.
				9a). Database, NICE only talks of making it a mesh database but surgeons need to record ALL SUI and PO surgeries so the database has a non mesh comparator. That way they will have evidence to show risk of mesh vs non mesh.	9a) We have amended the recommendations so that all surgical procedures for stress urinary incontinence and pelvic organ prolapse (mesh and non-mesh) are documented in a national registry (evidence reviews E and I respectively). Unfortunately, we cannot reverse time and capture data on women who have already had surgery. However, the recommendations also include recording data on women who present with complications of mesh surgery. The guideline aims to ensure good practice from now on.
				9b) Database: How are they going to record this long term because they are not talking about this as if it is mandatory. Also they talk of it being 6 month follow up. It needs to be lifetime database follow up. They have not said how this will work as	9b) We are recommending that providers collect long term data beyond 6 months on all surgical procedures for urinary incontinence and pelvic organ prolapse (evidence reviews E and I respectively). Follow-up with the surgeon is

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				only a few holders of the database can access all of the data. 9c). Mesh centres need access to this database to be able to see what is occurring in real time 9d) Mesh centres need to publish their figures on complete removals, partials, outcomes 10a). Karen Ward of Manchester is clinical lead for NICE guidelines which at first seems great as she is one of our trusted removal experts BUT it is not so good for this reason. She co authored the Ward Hilton study on the Burch vs TVT and took J&J funding up to the last update in 2008 So we are concerned about a conflict of interest. Her paper "proves" TVT is better than Burch but it is a usual case of short term follow up and unknown quality of life questionnaires to capture data of true long term risk. TVT is super quick recovery and Burch can be up to 4 /5 months for pain to subside from major	recommended at 6 months. It is not however, the role of the guideline to determine how this register will work and be set up. 9c) We are recommending that providers collect long term data beyond 6 months on all surgical procedures for urinary incontinence and pelvic organ prolapse (evidence reviews E and I respectively). It is not however, the role of the guideline to determine how this register will work, be set up and how access is obtained. 9d) This would be at the discretion of the centre and not something the guideline can stipulate. 10a) All relevant conflicts of interests were declared, managed and recorded as per the NICE policy on conflicts of interest. The Ward Hilton paper specifically states how the trial was funded (Gynecare), the only additional funding was to attend conferences where the work was presented (International Continence Society meeting, Tampere Finland 2000, International urogynaecological association meeting, Rome 2000 and International Continence Society meeting, Christchurch, New Zealand 2006).

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				surgery BUT long term Burch does not have risk of mesh and long term. Whereas long term a TVT mesh can see a woman go slowly downhill from mesh complications. 10b) Ward says TVT is better than colposuspension. They should have done a 10yr follow up by now but they haven't. Why. This would give a better idea of risk comparing mesh and non mesh 10c) Without the Ward Hilton study STM believes Burch would have progressed to being done laparoscoically for the gold standard, but instead this study pushed the TVT for gold standard status.	The paper you refer to by Ward Hilton, was one of 12 RCT studies that made up all of the evidence comparing Burch to TVT. This study was quality appraised independently and its data pooled with other relevant studies. Therefore, the findings of this study were not relied upon in isolation, but in combination with other studies evaluating the same comparison (evidence review E). 10b) The Ward papers do not conclude that TVT is superior, all three papers conclude that there was no difference between the procedures, and the outcomes for incontinence were comparable. The complications reported differed, but nowhere do they state that TVT is superior. 10c) The paper you refer to by Ward Hilton, was one of 12 RCT studies that made up all of the evidence comparing Burch to TVT (evidence review E). This study was quality appraised independently and its data pooled with other relevant studies. Therefore, the findings of this study were not relied upon in isolation, but in combination with other studies evaluating the same comparison.

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				11. We If surgeons don't need to put in a medical device then why do it. If you use mesh you add another layer of complications so why take that risk when you don't have to. SUI and POP are benign conditions, not life threatening, why layer up risk with mesh .	11) The committee concluded that there is sufficient evidence to recommend the use of mesh procedures as an option in certain circumstance provided the woman is fully informed of the relative risks and benefits of all surgical procedures and of no surgery. In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care.
				12. Mesh removal must be subject to accredited training programmes and not have a go haphazard in any regional NHS or private hospital.	12) Training requirements do not fall under the remit of NICE guidelines.
				13. All outcomes & treatments to be listed with the codes in each guideline, so it's a ready reference & any un-coded needs to be given a code so everyone knows what the codes are so everybody is singing from the same hymn sheet.	13) We are unsure about what you are requesting we are unable to provide a response.
				14. THE SCIENTIFIC LITERATURE DOESNT INCLUDE KELTIE	14) The Keltie 2017 paper did not meet the inclusion criteria for the review on long term complications of stress urinary incontinence

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					surgery (evidence review E). We acknowledge the paper is described as providing 8 year follow up data; however, the mean length of follow-up of participants is actually only 4.2 years. Given that RCTs give the highest level of evidence for intervention reviews, RCT data was prioritised to inform the effectiveness and complication reviews up to 5 years. Non-RCT data was considered for inclusion to inform the reviews where there was a lack of data i.e. beyond 5-years. The Keltie study is a retrospective analysis, and is therefore is considered lower quality, with an increased risk of bias.
				15. Reversibility factor. If a woman has mesh complications she cannot be magically fixed. Even after a mesh removal there is no guarantee she will be better for this. Some women are, some same, some worse. It is Russian Roulette risk on removals, although we believe it ito be around 70% show improvements – however, we all have to accept a new normal. Some things like eg vaginal burning and allergic reactions like nose dripping are shown to stop once mesh is removed thus proving it was the mesh that caused this. Leg pains can totally go also	15) The committee are aware that complications arise from both the vaginal and abdominal insertion of mesh and from all surgical procedures for incontinence and prolapse. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.

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Sling The Mesh	Evidence Review A	p18 p19	45- 50 1 - 9	[A] Evidence review for urodynamic assessment prior to primary surgery for stress urinary incontinence Cost effectiveness and resource use https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-8 COMMENT They want to stop urodynamics testing as standard to save money for the NHS. Stopping basic tests means more women may be offered surgery who dont need it	Thank you for your comment. This recommendation says that in women where stress leakage is clinically demonstrated during the clinical examination (plus non-invasive test such as cough stress test) urodynamics testing is unnecessary. Otherwise, the urodynamics testing is left as an option. Moreover, a recent UK cost-effectiveness analysis (Homer 2018) concluded that "the probability of urodynamics testing being cost-effective remains uncertain" and the value of undertaking invasive urodynamic testing prior to surgery in all women is uncertain and further research is required to address this uncertainty. Offering cost-ineffective treatment to all women results in a cost inefficient resource allocation in the NHS. The committee have amended the recommendation to clarify that an urodynamic test should be performed if stress urinary incontinence is not demonstrated before surgery in women with stress urinary incontinence or stress predominant mixed urinary incontinence.
Sling The Mesh	EVidence Review B	p8 :	10 Recommendations	**EVIDENCE B** **(B) Treatment options for women using absorbent containment products** https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-9	Thank you for your comment. The recommendation is from the 2006 guideline and has not been reviewed in this update. The recommendation to which the stakeholder refers is stating that absorbent containment products are

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				p**8 : 10 Reccommendations** "Absorbent containment products, hand held urinals and toileting aids should not be considered as a treatment for UI. Use them only as a coping strategy pending definitive treatment an adjunct to ongoing therapy or long-term management of UI only after treatment options have been explored. Offer a review at least once a year" **COMMENT** What is wrong with women who do not want any treatment or intervention and are happy to just use Tena lady as they do not wish to have physio, medication or surgery? Women must not be made to feel pushed into a medical or surgical treatment just because of a NICE guideline	not a treatment for urinary incontinence, but a management tool. The recommendation does not state that women should have treatment if they do not want it.
Sling The Mesh	Evidence Review C	**P9 22-14 & 10 4- 23: 22**		**EVIDENCE C Evidence review on the risks to cognitive function for women taking anticholinergic drugs for overactive bladder** **P9 22-14 & 10 4- 23: 22 Cognitive function** Mostly very low quality evidence. One cannot base a guideline on this p10 **Medicines C1.1** Recommendations p10 14 Number of falls is of v low quality evidence **COMMENT**	Thank you for your comment. We agree and have developed a research recommendation on this topic: "what is the effectiveness and safety of anticholinergic medicines for overactive bladder in older women?" The committee discussed the comment regarding a 6 month check for those over 60; however, they decided that this should remain only for those over 75 years.

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				My comment is that there needs to conduct a long term trial to gather evidence on long term effects of anticholinergic drugs on cognitive function insted of relying on research with very low quality and using guess work p12:40 Women who remain on long-term medicine for OAB or UI 41 should be reviewed in primary care every 12 months, or every 6 months if they are aged over 75. **COMMENT** I like this recommendation, however we think the 6 monthly checks should apply to all women over 60.	
Sling The Mesh	Evidence Review D			**EVIDENCE D** **[D] Evidence reviews for the management of overactive bladder** https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-11 **P13 Cost effectiveness** 16-18 Having previously said in Evidence A that women with SUI dont need urodynamics they then say women with OAB considering botox should have Uro Dynamic Testing. How confusing is this in a NICE guideline as it may not be clear which type of UI a woman has until after tests	Thank you for your comment. The committee has amended the recommendation to clarify that an urodynamic test should only be indicated when stress UI has not been demonstrated on clinical examination of women with symptoms of stress UI or stress predominant mixed urinary incontinence. Given that there was no evidence available to either recommend or not recommend UDS before BoNT-A treatment the committee carried forward the recommendations from the 2013 guideline since this was in line with current clinical practice. The committee acknowledged the risk of self-

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				P22: 28 Benefits and Harm The committee was aware that there is no evidence available on the long-term effectiveness of bladder wall injection of BoNT-A, and that there is insufficient good quality evidence about the most appropriate dose, whether the duration of effect is dose dependent, or what the optimal frequency is. **COMMENT** So how can they make a guideline based on little or very low quality evidence. The guidance should be a database of outcomes must be set up to record effecitveness and any new onset of problems otherwise women are being used as human guinea pigs **P22: 47** The committee agreed that there was a lack of evidence available on the risk of adverse 48 effects associated with the two different doses of BoNT-A, particularly in relation to self49 catheterisation. The committee was aware from their own experience that there may be an 50 increased risk of self-catheterisation with 200 units BoNT-A and that patients usually wish to 51 avoid self-catheterisation if possible, and therefore may	catheterisation and that the risk may be higher with 200 units BoNT-A. The recommendation to start with 100 units BoNT-A would in fact potentially reduce the risk of self-catheterisation, and the associated costs to the NHS. 100 units BoNT-A is the licenced dosage for treatment of OAB. The committee acknowledged the relative lack of clinical evidence but when there is little or no evidence, the NICE committee may use their knowledge and experience to make consensus recommendations on the best clinical practice.

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				consent to start on the lower dose. 52 But there was no evidence to support this opinion **COMMENT** This is a huge concern. They are just using guess work to formulate women's health care that could lead to self ctherisation tha tis not only painful and humiliating ot women but also costly risk tot eh NHS as Catheter sticks cost £1 a time. **P23 : 16** The committee was also aware that at the time of the previous guidance, most BoNT-A 17 preparations had not been licensed. **COMMENT** Women have been human guinea pigs with no databases to record long term outcomes. This has to stop. We want NICE to recommend databases are set up to record outcomes over at least a year	
Sling The Mesh	Evidence Review E			**EVIDENCE E** **[E] Surgical and physical management of stress urinary incontinence** P11: 30:33 The **majority** of studies were two-arm RCT that compared 34 either the retropubic and transobturator routes of delivering a synthetic midurethral mesh 35 sling (MUS) or a single-	Thank you for your comments. Our responses can be found below: **P11: 30:33** As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and

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				incision mini-sling (SIMS) with a more traditional synthetic MUS. **COMMENT** The astounding thing about this section is the the majority of the studies upon which they base recommendations are based upon very low and lwo evidence, Every now and then a moderate evidence link pops up. So in the absesne of this the huge body of patient voice must be taken into consideration We have not been consulted in much of the guidelines for 21 years. Even new NHS pathways of care has omitted patient voice. It is time for NICe to get it right and listen to patietns We say 1. Physio first 2 Non mesh surgery 3 Mesh surgery but under special arrangements and only when 1 and 2 has failed What is the point of the majority of RCT comparing mesh to mesh. That is never going to answer the question of which is best mesh or non mesh. All these RCTs will do is say one mesh is better to another type of mesh. The key argument for	complication data was entirely based on randomised controlled trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes. This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), and incomplete outcome data (i.e. if people dropped out of the study and no reasons were given). However,

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				campaigners is trying to work out which is the most effective and with least risk. While NICE, Cochrane and surgeons keep referring back to RCTs comparing one mesh to another mesh you are never going to answer the question and all it will do is peddle the myth of mesh is best. This whole section is a ridiculous evidence base from which to work	RCTs can generally be considered relatively robust. We do not agree that the guideline ignores patient experience. The evidence included patient quality of life where it was reported, and this was considered a critical outcome for the review. The committee includes lay members on the panel, ensuring that patient experience is taken into account. The committee has been well aware that some women do experience severe and lasting adverse effects following mesh surgery. The committee has carefully reviewed all the evidence of the risks and benefits of all interventions for uterine and vaginal prolapse and agreed that it is appropriate to offer some women the option of having surgery with mesh implants provided they are fully informed. In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. The guideline will also be accompanied by decision aids which will assist decision-making for women when they are considering the non-surgical and

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				surgical procedures for stress UI and pelvic organ prolapse The NICE guideline development process is open and transparent. NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website. The guidelines recommends that non-surgical procedures should be offered first and that surgical procedures should only be offered if non-surgical treatment has not worked. The guideline aims to ensure woman are given as much information as possible in order for them to be able to make informed choices about their treatment options. As outlined in the protocol in the relevant evidence review report, the review process for this question was staged. Firstly, the committee was interested to know how mesh compared with non-mesh surgery. Secondly, if the mesh was superior the committee wanted to know which mesh type was preferred. For this reason, RCTs comparing mesh to mesh were included and provided valuable information on effectiveness and complications. Furthermore, the network meta-analysis (NMA) has advantages over the standard pairwise meta-

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					analysis in that it produced consistent estimates of the relative effects of all surgical procedures including mesh and non-mesh compared with every other mesh and non-mesh surgical procedure in a single analysis using both direct and indirect evidence. The ESTER NMA for cure and improvement included nearly 15,000 women from approximately 120 RCTs comparing various mesh and non-mesh surgical procedures including traditional sling, open and laparoscopic colposuspension, TOT, single incision, bladder neck needle, and anterior repair. In situations where more than 2 surgical procedures are being considered, synthesis of RCTs using NMA ensures that all relevant evidence, whether direct or indirect, is used to produce coherent estimates of the relative effects of every intervention compared with every other, and is the preferred method because multiple sources of evidence are used. The final estimates of effect are more robust than if only direct sources of evidence were included, because they are less likely to be influenced by the inclusion or exclusion of a single trial or a particular comparison.

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					The use of the NMA deals with the problem that you raise i.e. that the majority of RCTs compared mesh to mesh. The use of the NMA methodology allowed us to consider evidence from all available trials and not only where the mesh is compared with mesh and to estimate treatment effects between every surgical procedure compared to each other even if there was no direct RCT evidence comparing the surgical procedures of interest. From the evidence, the committee were able to make a recommendation that TOT is a treatment option that is not recommended, since the evidence does not support this type of surgery.
				ALSO WHY HAS KELTIE BEEN MISSED OUT OF THE SCIENTIFIC LITERATURE	This paper was excluded because it did not meet the inclusion criteria set out in the review protocol. There was RCT evidence for effectiveness and complications up to 5 years. Given that RCTs give the highest level of evidence RCT data was prioritised to inform the effectiveness and complication reviews up to 5 years. Non-RCT data was considered for inclusion to inform the reviews where there was a lack of data i.e. beyond 5-years. Keltie et al., 2017 state in their title that this was an 8-year study. However, the mean follow up

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					was only 4.2 years. As a result, this non-RCT study was excluded from our review. To finalise, Keltie et al., 2017 is a retrospective observational study and it would have been graded as of very low quality. Very low quality studies are generally not helpful/used to inform recommendations. Nevertheless, the data by Keltie et al., 2017 was considered as part of the sensitivity analysis in the ESTER study which assessed the cost-effectiveness of various surgical procedures for stress urinary incontinence. Unfortunately, the findings were redacted during the consultation phase due to the confidentiality as the publication was going through the peer review process. However, the findings of ESTER analysis together with the committee discussion will be made available in the final guideline.
				P12:21 Seventeen articles reporting 14 RCT were identified that compared a biological sling to a 22 synthetic mesh sling in women **COMMENT** I would like it to be noted that 4% of women suffering severe complications in STM had biological mesh. I believe there to be more but media coverage has only highlighted PP mesh so	**P12:21** We agree there is confusion among women regarding different forms of sling, and if these slings are considered mesh. We include both synthetic and biological mesh. The guideline is accompanied by a glossary where terms are explained and we have tried to ensure consistency

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				many will not make the connection that this graft also has serious risk of infection, pain, foreign body response. **P65 Clinical evidence statements** Colposuspension versus synthetic mesh sling **COMMENT** Majority is very low quality evidence. You cannot base a NICE guideline or indeed any surgeon cannot base a recommendation claiming mesh is comparable or better on this weak evidence. In this instance you must look at the huge body of patient evidence that shows the TVT has hugely terrible, life changing risk that is catastrophic in terms of pain, complications both physically, mentally and financially. There are more than 7,000 members of STM. A further 800 in STM N Ireland. A survey in our group in September 2018 shows 46% had the TVT, the most commonly used mesh sling. There are no patient groups calling to ban the Burch so one has to assume there is not the level of complications long term . Mesh adds another layer of complications to the surgical mix. In the absence of good quality evidence as written here you must	throughout the guideline in how we refer to mesh (synthetic or biological). **P65 Clinical evidence statements** We included all published and available evidence that met the inclusion criteria for this review, which included 12 RCT for the comparison of colposuspension to synthetic mesh sling. RCT evidence is considered the gold standard of evidence. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff

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				listen to the body of evidence coming from patient voice. This is seen globally not just in the UK.	may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes. This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), and incomplete outcome data (i.e. if people dropped out of the study and no reasons were given). However, RCT can generally be considered relatively robust. Our report included all the available data on complications, including patient satisfaction, pain, mesh erosion, repeat surgeries etc. and these complications were taken into account when making the recommendations. Throughout the development of this guideline the committee have taken the widespread concern over mesh complications into consideration. The committee cannot directly include this evidence into the data analysis; however, their expertise,

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					experience and judgement has shaped the recommendations as well. We think this is demonstrated by both sections on surgery where we highlight mesh complications, and the unknown risks potentially associated with mesh. We have not prioritised this for the other procedures, despite these options also having risks. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse. The NICE guideline development process is open and transparent. NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website In addition, during development of the guideline, lay members were part of the committee panel.
				P68 31 Autologous rectus fascial sling versus synthetic mesh sling **COMMENT**	**P68 31 Autologous rectus fascial sling versus synthetic mesh sling** Thank you for your comment. We included all published and available evidence that met

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				Again a raft of very low or low quality evidence. A terrible state of affairs in the evidence upon which to base a NICE guideline	inclusion criteria for this evidence review. This included 14 RCTs for the comparison of autologous rectus fascial sling to synthetic mesh sling. RCT evidence is considered the gold standard of evidence. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading

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					included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), incomplete outcome data (i.e. if people dropped out of the study and no reasons were given), selective reporting (i.e. only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling), it was unclear whether some or all participants had failed or declined conservative treatment, etc. However, RCT can generally be considered relatively robust.
				P72 14 Non-autologous biological sling versus synthetic mesh sling **COMMENT** More very low quality evidence	**P72 14 Non-autologous biological sling versus synthetic mesh sling** We included all published and available evidence that met inclusion criteria for this evidence review. This included 4 RCTs for the comparison of non-autologous biological sling to synthetic mesh sling. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was

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					often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes. This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), incomplete outcome data (i.e. if people dropped out of the study and no reasons were given), selective reporting (i.e. data reported for uneven number of participants in each group, number randomised not reported), it was unclear whether some or all participants had failed or declined conservative treatment, etc. However, RCTs can be considered as relatively robust.

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				P75 25 Transobturator mesh sling versus retropubic mesh sling **COMMENT** Majority very low quality evidence	**P75 25 Transobturator mesh sling versus retropubic mesh sling** We included all published and available evidence that met inclusion criteria for this evidence review. This included 40 RCTs for the comparison of transobturator sling with a retropubic mesh sling. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the

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					measurement of outcomes This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), incomplete outcome data (i.e. if people dropped out of the study and no reasons were given), selective reporting (i.e. study reports outcomes of interest for whole sample and not for intervention groups specifically, therefore not all available data was useable), incomplete data at 5 years follow-up etc. However, RCT can be considered as relatively robust.
				P81: 24 Single-incision mini-sling versus other synthetic mesh sling **COMMENT** Majority is very low quality and low quality evidence	**P81: 24 Single-incision mini-sling versus other synthetic mesh sling** Thank you for your comment. We included all published and available evidence that met inclusion criteria for this evidence review. This included 24 RCTs for the comparison of single-incision mini-sling to other synthetic mesh sling. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and

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					complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), incomplete outcome data (i.e. if people dropped out of the study and no reasons were given), it was unclear whether some or all participants had failed or declined

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					conservative treatment, etc. However, RCT can generally be considered relatively robust.
				P92: 33 Adjustable mesh sling versus other synthetic mesh sling **COMMENT** Majority is very low quality and low quality evidence	**P92: 33 Adjustable mesh sling versus other synthetic mesh sling** We included all published and available evidence that met inclusion criteria for this evidence review. This included 10 RCTs for the comparison of adjustable mesh sling to synthetic mesh sling. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is

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					appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes. This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred), it was unclear whether some or all participants had failed or declined conservative treatment, etc. However, RCT can generally be considered relatively robust.
				P97: 33 Autologous rectus fascial sling versus colposuspension **COMMENT** Majority is very low quality and low quality evidence	**P97: 33 Autologous rectus fascial sling versus colposuspension** We included all published and available evidence that met inclusion criteria for this evidence review. This included 4 RCTs for the comparison autologous rectus fascial sling to colposuspension. As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an

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					unclear risk of assessment bias. Participants, care staff and assessors were generally aware of treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes. This has to be acknowledged and the quality of the evidence is downgraded. Other reasons for downgrading included random sequence generation and allocation concealment (i.e. it was not always reported in the studies how the randomisation and allocation process occurred) and it was unclear whether some or all participants had failed or declined conservative treatment. However, RCT can generally be considered relatively robust.
				P100 Bulking agents versus other surgical technique 2 Continence-specific health-related quality of life 3 No evidence was identified to inform this outcome.	**P100 Bulking agents versus other surgical technique 2 Continence-specific health-related quality of life 3 No evidence was identified to inform this outcome.**

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				COMMENT No evidence, therefore you cannot make a recommendation on what is best. The list then goe son to look at very low to low quality evidence	The committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. The recommendations also make it clear that the woman should be informed that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time. The committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.
				P102 : 25 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for stress urinary incontinence (UI). Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions, and expected recovery period. **COMMENT** In that list this sentence need to be very very clear: So the line must be amended to: Include information about differences in type of anaesthesia, expected length of hospital stay,	**P102 : 25** In light of stakeholder comments, the recommendations have been amended. The committee consider the recommendations ensure all options and corresponding risks and benefits are discussed with the woman, including social or psychological factors which may influence a woman's decision.

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				surgical incisions, and expected recovery period as well as the likelihood of long term pain, the risk of loss of sex life, risk of self cathetrisation, risk of infection UTI. As it stands the focus is on short term recovery and general risks. ALL risks of mesh and none mesh surgery must be listed here E1.2 If non-surgical management for stress UI has failed, offer the woman a 34 choice of : colposuspension (open or laparoscopic) or • a retropubic mid-urethral mesh sling or • an autologous rectus fascial sling. [2019] **COMMENT** If physio and conservative methods fail then woman can be offered colposuspension or autologous sling REMOVE MESH SURGERY OPTION HERE	**E1.2** While we appreciate your concerns about the offer of mesh surgery, if we did not allow women the option of choosing it, we might be putting women at a disadvantage if after due consideration they decided that this was the best approach for them. It is important that women are given the opportunity to make an informed choice. The guideline aims to ensure all women are made aware of all risks and benefits to each option available to them. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse.

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				P102 E1.3 Advise the woman when offering surgery for stress urinary incontinence that there are long term complications associated with all procedures and uncertainty about the proportion of women affected. **COMMENT** All surgery has risk. Mesh adds an additional layer of risk on top of the usuals like anaesthesia, bleeding, . Mesh surgery must not be included as an option as second line. Remove it from this section.	**P102 E1.3** Although we appreciate your concerns about the offer of mesh surgery, it is important that women have choice about their own care, and it is clear from the experience of committee members that some women do want mesh procedures. The recommendations are providing women with all options, not just surgery. We agree that all procedures have complications associated with them and the guideline aims to ensure all women are made aware of all risks and benefits of each option available to them. We also agree mesh surgery may have different complications as compared to other procedures and we have tried to make it clear that all of these should be discussed with the woman. We have developed the guideline with the concerns of mesh procedures in mind, emphasising the risks of mesh options, and we have tried to make shared decision making a key factor.
				P103 E1.5 In women having mesh surgery for stress urinary incontinence or pelvic organ prolapse, or who have mesh-related complications,	**P103 E1.5** We agree that all surgical procedures should be included in the database. Consent is required from

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				seek consent to enter the data listed in recommendation n a national registry and give them a copy of those data. **COMMENT** Seek consent from whom? The woman? It should be entered as standard / mandatory and not with an option to back out of any kind of database as this gives scope for a pro mesh surgeon to talk a woman out of allowing her details to be put on a database just in case problems occur in the future. It must be mandatory to report ALL women and this must be part of the process. Women MUST be handed a leaflet saying they MUST be put on to this database. All women having surgery for SUI or POP should be added to this database	the woman to align with GDPR data protection laws. The committee are aware of the public concern about mesh surgery for SUI and POP, and the committee strongly support the set-up of a national registry. We have included recommendations which state that details of all procedures (mesh and non-mesh) should be collected in a national registry; however, the development of the registry is not the responsibility of NICE.
				P103 E1.6 Ensure that the following data are collected in a national registry of surgery involving mesh insertion to treat urinary incontinence (UI) or pelvic organ prolapse (POP) in women: • all surgical procedures for urinary incontinence or pelvic organ 9 prolapse that involve the insertion of synthetic polypropylene mesh **COMMENT**	**P103 E1.6** We agree that all women having surgery for stress urinary incontinence or pelvic organ prolapse should be on the list whether or not they had a procedure involving mesh. The committee are aware of the public concern about mesh surgery for SUI and POP, and the committee strongly support the set-up of a national registry. We have included recommendations

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				The database must add details of ALL women having surgery for SUI or POP regardless of it is uses mesh or not. Only by doing this will we finally obtain good quality comparable evidence of long term outcomes in the UK	which state that details of all procedures (mesh and non-mesh) should be collected in a national registry; however, the development of the registry is not the responsibility of NICE.
				E1.7 The national registry of surgery involving mesh insertion to treat 26 urinary incontinence or pelvic organ prolapse in women should report 27 annually and be quality assured. [2019] **COMMENT** The database must add details of ALL women having surgery for SUI or POP regardless of it is uses mesh or not. Only by doing this will we finally obtain good quality comparable evidence of long term outcomes in the UK	**E1.7** We agree that all women having surgery for stress urinary incontinence or pelvic organ prolapse should be on the list whether or not they had a procedure involving mesh. The committee are aware of the public concern about mesh surgery for SUI and POP, and the committee strongly support the set-up of a national registry. We have included recommendations which state that details of all procedures (mesh and non-mesh) should be collected in a national registry; however, the development of the registry is not the responsibility of NICE.
				P103 28 Mid-urethral mesh sling procedures E1.8 Advise the woman when offering a retropubic mid-urethral mesh sling 30 that this is a permanent implant and complete removal might not be possible.	**P103 28** The committee were clear in their recommendations that the woman should be fully informed of the options available to her and the risk and benefits of each procedure. A patient

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				COMMENT ALL risks of mesh must be explained and a standardised NHS leaflet given on ALL of the knowns risks as per manufacturers IFU inc long term pain, loss of use of legs, loss sex life, self cath, infection, UTI. pain in vagina, pain in pelvic region **P104 10•**consider using a retropubic mid-urethral mesh sling coloured for 11 high visibility, for ease of insertion and revision. [201 **COMMENT** If mesh is not being banned this must be made mandatory **E1.11 Do not offer a transobturator approach unless there are specific clinical circumstances (for example, multiple previous abdominal procedures) in which the retropubic approach should be avoided. [2019] 15 16 E1.12 Do not use the 'top-down' retropubic mid-urethral mesh sling approach 17 or single-incision sub-urethral short mesh sling insertion except as part of a 18 clinical trial.** **COMMENT**	decision aid will be published alongside the guideline to help the woman understand potential risks We have also added additional context at the beginning of section on surgery for stress urinary incontinence. **P104 10** Thank you for your comment, unfortunately ensuring the mesh is coloured is outside the scope of this update of the guideline. This recommendation from 2013 was based on expert opinion. **E1.11** The committee acknowledged that it was difficult for stakeholders get a sense of the entire evidence base because the ESTER analysis was redacted in the draft report. However, TVT, TOT, and SIMS do not have the same effectiveness, complications, or cost-effectiveness as indicated by the NMA, pairwise met-analyses, and review of the complications. Moreover, as discussed in the committee discussion section, the committee expressed their view based on their clinical

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				If TVTO , TOT and SIMS are effectively banned to research then why is the TVT not. It has the same grave risks as those procedures listed . The majority of women have had the TVT - our survey shows 46% compared to 24% TVT or TOT and 1% SIMS You must list in the guidelines what those cllnical circumstances are to be able to offer a transobturator approach so that patients and surgeons may comment on them. Ommitting that list is v remiss of NICE as we are now not able to make an informed judgement and informed comment on what those circumstances are	experience that TOT is much more difficult to remove if mesh complications occur. The observed risk profile in your survey may be a reflection of the frequency of the surgical procedures that women received in your sample i.e. women reporting more problems with TVT due to the fact that more of these procedures have been undertaken.
				P 104 E1.14 Do not offer women porcine dermis slings to treat stress UI. [2019] **COMMENT** Agree. Additionally NO biological mesh should be used from cow, cadaver or any other source	**P 104 E1.14** Thank you for your comment, we agree with your comment. The committee were not aware of other types of biological mesh (beyond porcine) being offered or available in the U.K.
				P104 36 Follow-up after surgery E1.17 Offer a follow-up appointment within 6 months to all women who have had a surgical procedure to treat stress UI. For women who have had retropubic mid-	**P104 36** The committee have added a new recommendation to ensure women have access to re-referral if they experience problems at any point. The committee agreed that not all women

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				urethral mesh sling surgery the follow-up appointment should include a vaginal examination to check for exposure or extrusion of the mesh 41 sling. **COMMENT** Follow up should be 6 weeks, 6 months and one year. As standard **P104/5 If the woman does not wish to have another surgical procedure, offer her advice about managing urinary symptoms and explain that if she changes her mind at a later date she can book a review appointment to discuss past tests and interventions and reconsider her treatment options.** **COMMENT** Mesh pain and complications must be mentioned within this section. **P106 Research recommendations What are the long-term risks of mesh surgery compared with non-mesh surgery for stress urinary incontinence in women? Rationale**	would need additional appointments and to recommend this as mandatory would have significant resource implications, however with this new recommendation, women should be able to get an additional appointment should they want one. **P104/5** The committee agreed that complications including pain would be discussed with the woman as described in the recommendations about each surgery. Therefore it is not necessary or appropriate to add this information to this recommendation. **P106** We apologise for the confusion which the text "*to be finalised at consultation"* has caused the stakeholder. The rationale and impact sections of the short guideline were developed during the

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				and impact To be finalised during consultation **COMMENT** What do you mean to be finalised at consultation. This section should have robust guidance on what leaflets to give to patients and advice to give on risk **P105 14 The outcomes that matter most** The committee agreed that continence-specific health-related quality of life, adverse events and (short-, medium-, and long-term) complications were the critical outcomes for this question.They were considered critical because urinary incontinence can affect a wide range of activities and impact on mental wellbeing and continence specific health-related quality of life can capture improvements in these areas. However, these improvements may be offset by complications which are therefore also critical outcomes. Change of continence status, patient	consultation period, so did not appear in the short guideline. However, all the detailed guidance which the stakeholder wanted to see was present in the discussion section of the evidence review. We should also state that these guidelines do not provide a list of relevant leaflets; however, for surgery for stress urinary incontinence we have developed decision aids which will be valuable in helping women understand the different surgical procedures and the potential different complications associated with these. **P105 14** The committee, which included lay members, agreed upon the outcome that were priorities for this evidence report. These included the complications of pain, infection (including UTIs), the health related quality of life measurement tool for sexual function and patient satisfaction. All of these outcomes were rated as critical by the committee (as opposed to important). Although data for all of these outcomes were sought by the review team, not all of the published papers reported results for all outcomes. Therefore, the summary of what the evidence found for each outcome is limited by what the studies reported.

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				satisfaction/patient reported improvement and repeat surgery were considered to be important outcomes because even though they capture important benefits and harms they could be considered to be facets of the critical outcomes (i.e. if continence status improves it would likely affect health-related quality of life and a complication may lead to repeat surgery). The majority of outcomes were reported for the majority of comparisons with the exception of continence-specific health-related quality of life for the comparisons of laparoscopic versus open colposuspension (with sutures), fascial sling versus colposuspension and bulking agents versus any other SUI surgical procedure. Repeat surgery was not reported for the comparison of laparoscopic versus open colposuspension (with sutures), and adverse events was not reported for the 33 comparison of bulking agents versus any other SUI surgical procedure **COMMENT** NICE has completely missed the point and depth of the life changing irreversible	

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				complications brought on by mesh. We are not just talking bout not being cured of SUI. In fact that is the least of ur worries, We are talking about having lives totally trashed with pain, UTIs that wont go away with women becoming abx resistant and at risk of sepsis, loss of sex life and subsequent marriage break downs Stop making this predominantly about the devastating effects of pant peeing. It is more about the new devastating effects that cam be caused by mesh implants. **P105** 34 **The quality of the evidence** The quality of the comparative evidence was assessed using GRADE. The quality ...for the majority of outcomes and comparisons was very low to low. The risk of bias for individual RCT studies was generally moderate or high due to insufficient information about randomisation method and/or allocation concealment. **COMMENT**	**P105 34** As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness and complication data was entirely based on randomised control trials, generally considered the gold standard for research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of

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				Good grief. NICE admits evidence is low to very low and risk of bias is moderate to high. In other words the studies are not worth the paper they are written on so you are basing judgements on a load of weak evidence In which case you must listen to patient voice. And patient voice says mesh is horrific with Russian Roulette risk that can cut in at any time from implantation to our latest of 20yrs later. We say ban mesh as the benefits do not outweigh the risk.	treatment allocation; the studies were not truly blind. However, in surgical research this is often not feasible due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure after care is appropriate. It is generally considered unlikely, but this lack of blinding might influence the measurement of outcomes This has to be acknowledged and the quality of the evidence is downgraded. However, RCT can generally be considered relatively robust. Based on the available evidence the committee wanted to ensure women are able to make an informed choice for their treatment from all appropriate treatment options available. Throughout the development of this guideline the committee have taken the widespread concern over mesh complications into consideration. The committee cannot directly include this evidence into the data analysis; however, their expertise, experience and judgement has shaped the recommendations as well. We think this is demonstrated by both sections on surgery where we highlight mesh complications, and the

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					unknown risks potentially associated with mesh. We have not prioritised this for the other procedures, despite these options also having risks. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
				P117: 13 **Other factors the committee took into account** The committee acknowledged that there was a recent NMA (Song 2018), which recommended TOT as the optimal regimen for SUI. **COMMENT** E1.11 says TOT should not be offered so why are you now discussing it here with this study by Song	**P117: 13** The Song NMA is a recent well-conducted analysis. The committee was of a view that it was important to acknowledge the study and explain why ESTER NMA was prioritised over the Song NMA for the transparency of process purposes.
Sling The Mesh	Evidence Review F			**EVIDENCE F** **Effectiveness of multidisciplinary teams for the assessment and management of urinary incontinence or pelvic organ prolapse**	Thank you for your comment. A clinical psychologist has been added to the list of health care professionals who may be consulted at the regional MDT and a pain specialist with expertise in management of pelvic pain has been added to

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				https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review All of page 7 **COMMENT** **No studies found to answer this question. Doh** **10 F1.1.4 Regional MDTs** **COMMENT** Needs to add a mental health practitioner **P 10: 3 The outcomes that matter most The Committee decided that 'change in management decisions' and 'health-related quality of life' (specific to urinary incontinence or pelvic organ prolapse) were critical outcomes. Patient satisfaction was considered an important outcome.** **COMMENT** Outcomes that matter to women most are feeling we are being listened to. Our pain must be taken seriously and addressed and if need be more extreme measures such as steroid injections must be offered A woman presenting with voiding dysfunction may actually have mesh erosion into the urethra. This	the list of health care professionals who should attend regional MDTs. Surgeons would be present at both local and regional MDTs. The committee wanted to ensure through their prescription of who should and who could attend local and regional MDTs that at the very minimum more than one surgeon (i.e. two view points) would discuss each case and that the mix of additional specialists attending would be dependent on a case by case basis. Based on your comments, and the addition of the clinical psychologist and requesting that pain specialist should attend a regional MDT, we hope you and the Mesh APPG panel are happy with who a suggested MDT should comprise of.

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				must be noted and addressed at surgeon and MDT level. **P10:23 There is currently no definition of what comprises an effective MDT for the assessment and management of simple and complex cases of UI or POP, including mesh complications.** **COMMENT** In which case NICE should come to the Mesh APPG with a panel of experts to ask what an MDT should comprise **P11** NICE says not every specialist (e.g. pain specialist, colorectal surgeon or neurologist) is needed at every level **COMMENT** Pain specialist is the one specialism that most definitely IS needed at every MDT level as pain is the biggest and most devastating complication of mesh implants . NICE is missing the point in a bid to save the NHS money, Sorry this is not good enough.	

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Sling The Mesh	Evidence Review G			**[G] Evidence review for assessing pelvic organ prolapse** https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-2 **P11: 13 A systematic review of the economic literature was conducted but no studies were found which were applicable to this review question.** **COMMENT** So how can NICE answer this question. They should have included patient voice at drafting stage. All it does in this entire document is list very low to low quality evidence **P15: Based on their expertise and by consensus, they emphasised the importance of the GP taking a clear history and carrying out a careful examination to inform the initial discussion and to rule out other differential diagnoses, before referring for specialist assessment if appropriate.** **COMMENT**	Thank you for your comment. No evidence was identified for the systematic review on economic studies. These studies would have looked at the costs of each strategy for assessing pelvic organ prolapse, not at how effective the assessment strategy for pelvic organ prolapse is. The committee discussed how their recommendations for assessment strategies may incur increased costs (but not significant increased costs) for the NHS, and that these increased costs at the assessment stage would be offset by the quicker and more appropriate treatment for the women, resulting in a lower overall treatment cost. The GP would not be looking to diagnose pelvic organ prolapse, but to ensure the woman is referred to the correct specialist. You are correct, women would be diagnosed with pelvic organ prolapse by a specialist in pelvic organ prolapse.

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				If surgeons and NICE are struggling to define a POP diagnosis and there is low evidence, how is a busy GP supposed to do this! **P16:25** Women must be diagnosed by a surgeon who has more skill in this matter	
Sling The Mesh	Evidence Review H			**H Lifestyle and conservative management options for pelvic organ prolapse** https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-3 **P11: 30 The outcomes that matter most The committee identified improvement in symptoms, health-related quality of life and patient satisfaction as critical outcomes as they considered these to have the greatest impact on the woman. The committee prioritised sexual function, adverse events and anatomical assessment of POP as important outcomes. No evidence was identified for any of the critical or important outcomes.** **COMMENT** Adverse events should be listed here such as mesh erosion, infection, new and ongoing pain	Thank you for your comment. Adverse events is listed as a prioritised important outcome.

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Sling The Mesh	Evidence Review I			**EVIDENCE SUMMARY I Surgical management of pelvic organ prolapse** The evidence cited throughout this section is mostly 'very low' or 'low quality data' with a 'high degree of uncertainty', with small survey numbers, with mostly short term follow up (12 or 24 months). This is not robust enough evidence upon which to base guidelines. The data ignores the patient experience (e.g. STM has 7,000 members) STM were not consulted in drafting this guidance.	Thank you for your comments. Our responses can be found below: As described in the section "quality of evidence" this review was based on data which ranged from very low quality to moderate quality, as assessed by the GRADE tool. The effectiveness data, and the short term complication data were entirely based on randomised control trials, generally considered the gold standard for clinical research. The evidence was often downgraded by GRADE because of an unclear risk of assessment bias. Participants, care staff and assessors were generally aware of the treatment allocation; the studies were not truly blind. However, in surgical research this is often due to the nature of the intervention taking place. It is not possible to blind the surgeon, it may be considered unethical to blind the participant, and occasionally care staff may need to be aware of treatment to ensure aftercare is appropriate. It is generally considered unlikely, but this lack of blinding might influence outcomes, and has to be acknowledged. This led to the formal downgrading of the quality of the evidence.

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					We do not agree with the comment that the guideline ignores patient experience. The data included patient quality of life where it was reported, and this was considered a critical outcome within the review. Additionally, the committee includes lay members on the panel, ensuring that patient experience was taken into account. The committee have always been well aware of the concern that women have about the possible adverse effects of mesh surgery and have carefully considered the patient view and patient choice when drafting the recommendations. The guideline strongly supports the provision of information on all available options to women. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse. The NICE guideline development process is open and transparent. NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website.

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				P108 "The committee noted that there are very few harms associated with treatment with pessary, physiotherapy or no treatment in comparison to surgery." **COMMENT** It is the STM view that physiotherapy, pessaries, and non- mesh surgery should always be the treatment options offered to women before mesh. The draft guidance states that NICE recommendations are not mandatory, which means that particularly data collection will continue to be inadequate and piecemeal. This will not address the under reporting and other flaws with database reporting which STM have highlighted in its submission to the IMMDS Review. No section of these guidelines should be finalised until the outcome of the IMMDS Review and its recommendations have been considered, particularly any recommendations regarding further trials, data collection in	**P108** The recommendations state that surgery for pelvic organ prolapse should be offered to women whose symptoms have not improved with, or who have declined non-surgical treatment. We are providing choice to women. The committee are aware of the public concern about mesh surgery for SUI and POP, and the committee strongly support the set-up of a national registry. We have included recommendations which state that details of all procedures (mesh and non-mesh) should be collected in a national registry; however, the development of the registry is not the responsibility of NICE. This guideline has made recommendations that will increase the information provided to women on treatment options for urinary incontinence and prolapse as well as supporting the development of a national registry to monitor success and adverse effects of surgery. This guideline is available for consideration by the IMMDS review (which is due for publication in March 2019), and the publication of this guideline is a requirement for lifting of the high vigilance restrictions.

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				order to assess the true rate of mesh complications. ***Table 4 doesn't state whether mesh WAS used?*** **Table 13** compares PP mesh with bovine mesh – not non-mesh. **Page 36** – only looks at reoccurrence risk	**Table 4** Table 4 provides a summary of studies comparing laparoscopic to abdominal sacrocolpopexy using polypropylene mesh. To clarify this, we have added this information to the table. **Table 13** Table 13 includes the comparison porcine mesh versus polypropylene mesh. The legend clearly states "clinical studies comparing porcine mesh to polypropylene mesh", it does not mention "non-mesh". **Page 36** Recurrence was the only outcome which was consistently reported across the included RCT data, and as a result this outcome was synthesised using the NMA methodology. Even though the NMA looked at the recurrence outcome the economic analysis attempted to bring together effectiveness data, complications data, and cost data in one analysis to inform the

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					recommendations on the surgical management of the anterior POP.
				Page 38 & 71 – Costs – the cost of management of mesh complications (e.g. painkillers, A&E, GP visits, removal surgeries, etc) are not mentioned. These are still unknown due to significant under reporting of complications via MHRA, and other databases. Ultimately the NICE guidelines are flawed because the true rate of complications and costs of managing complications are unknown. Cost effectiveness of mesh surgery and the costs of managing complications are impossible to calculate without a full national recall.	**Page 38 & 71** The committee acknowledged the lack of data to inform the economic analysis. Modelling is commonly undertaken to inform NICE clinical guidelines and is an established framework to inform decision making under conditions of uncertainty. The key purpose of decision modelling is to allow for the variability and uncertainty associated with decisions. Even though the true rate of complications and costs of managing complications are not known modelling can be used to incorporate this uncertainty in the decision making. So for example, since mesh complication costs are not known these were informed by the committee expert opinion. It is not uncommon where data is lacking to use committee expert opinion to inform model inputs including cost data and other assumptions for extrapolation of effects and complications from available short-term data. These are clinicians who are managing women with mesh-related complications and should be expected to provide a reasonable approximation of what resources are used to

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					manage such complications and what is the rate of mesh complications in their clinical practice, and whether the risk is increasing or not. However, given that the estimation of these parameters was uncertain this was allowed for in the model using the sensitivity analysis where the impact of this assumption on the results was tested and which showed that the findings were robust to variations in various model inputs including the rate of complications and costs of managing complications. Once full national recall data is available a further analysis can be undertaken to provide a more certain estimate of the cost-effectiveness of mesh. However, this is the best that can be done given the time constraints and the currently available clinical data in this area.
				Page 41 The modelling used to estimate long term outcomes and complications beyond 5 years is based on 'very low' and 'low' quality evidence. The assumption of no further reoccurrence of POP and no mesh erosion beyond 5 years does not equate with the STM patient experience.	**Page 41** The committee acknowledged the lack of long term outcomes and complications. However, this was the best evidence available and this was used in the economic analysis. Given the uncertainty in these model inputs an extensive sensitivity analysis was undertaken to test the robustness of the findings. Sensitivity analysis is a means of exploring uncertainty in the results of economic

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					evaluations. There may be uncertainty because data are missing, estimates are imprecise or there is controversy about methodology. The analysis is repeated using different assumptions to examine the effect of these assumptions on the results. In this particular sensitivity analysis the estimates of long term outcomes and complications were varied across ranges and the impact of these changes on the results was examined. Sensitivity analysis can also be used to see how applicable results are to other settings. The analysis is repeated using different assumptions to examine the effect of these assumptions on the results. As stated in the full evidence review this sensitivity analysis explored the impact of an extreme implausible scenario i.e. no further reoccurrence of POP and no mesh erosion beyond 5 years. However, even in this clinically implausible extreme scenario mesh was not cost-effective in women who require primary repair of anterior POP.
				Page 51 – The model inputs were informed by committee expert opinion, because of	**Page 51** It is not uncommon where data is lacking to use committee expert opinion to inform model inputs

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				the lack of data on long term mesh complications. **COMMENT** If there is a lack of data on long term complications then STM wish to know how these experts reached their opinions? Whether they have experience of undertaking non-mesh surgery OR MESH REMOVAL for POP? Any conflicts of interest? Why was patient voice not consulted as we believe that with no long term evidence patient evidence counts as lived experience of the long term outcomes.	including cost data and other assumptions for extrapolation of effects and complications from available short-term data. Please see 'The guidelines manual. Process and methods [PMG6]'. The committee are made up of health, social care and other professionals and practitioners, patients, service users, carers and members of the public, and technical experts. This particular guideline had representation from three lay members with experience of urinary incontinence and pelvic organ prolapse. The committee includes health professionals who are managing women with urinary incontinence and pelvic organ prolapse, including experts in managing surgical complications and as needed should be expected to provide a reasonable approximation of what resources are used to manage surgical complications, what is the rate of surgical complications in their clinical practice, and whether the risk of experiencing a surgical complication is constant, increasing or decreasing with time.

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					The full committee member list was provided on the NICE website together with all the consultation documents. All committee members, including the chair, and anyone else who has direct input into the guideline declare any potential conflicts of interest in line with NICE's policy on declaring and managing interest for the NICE advisory committee. Before each meeting, any potential conflicts of interest are considered by the committee chair and a senior member of the developer's team. Any decisions to exclude a person from all or part of a meeting are documented. Declarations of interest are recorded in a register for each guideline and are published on NICE's website.
				Page 64 - 1 Recommendations 2 **Collection of data on mesh surgery and mesh-related complications** **The draft guidelines only mention creating a database for mesh. Surgeons need to record ALL SUI and POP procedures (mesh and non-mesh) to enable the database to have a non mesh-comparator. That way there will be evidence to show risks of mesh versus non-mesh surgery.**	**Page 64 – 1 Recommendations** The committee agree with this statement and the recommendations have been amended to state that data from all surgical procedures should be collected. We do not agree that the term "discuss the risks and benefits" allows surgeons to be selective about procedures. We would hope that all healthcare professionals give honest, and clear

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				The draft guideline is vague on informed consent and specific risks related to mesh procedures, except to tell the patient mesh is a permanent implant and difficult to remove. STM does not agree with the term 'discuss' the risks and benefits as this allows room for surgeons to be selective in discussing risks or downplaying risks of mesh. The proportion of women affected by mesh must be defined in numbers with the scientific references. Without this information a surgeon cannot give fully informed consent. Leaving doctors to communicate risks without stating precisely what these are is likely to lead to history repeating itself i.e. lack of informed consent and a continuation of the mesh tragedy. STM believes the list of standardized mesh complications that occur immediately after mesh insertion or in the longer term should be included as part of the informed consent process, **and included as complication categories within the new database including:** □□ **Dyspareunia**	information to women about all their management options. However, in light of the stakeholders concerns we have amended the recommendations which we hope encourage shared decision making. We have stated that all procedures should be discussed, including those not provided locally. We have also stated that the NICE patient decision aid should be used to help with the process of informed consent, and shared decision making. This guideline provides recommendations on the most generally appropriate clinical care. It is not possible to describe all the potential risks and benefits which will be discussed by the woman and her heath professional. This is not a training manual; however, we expect all health care professionals who are discussing surgical options with the woman to be fully trained to do so. We have also developed recommendations on multidisciplinary teams, and suggest that a woman's care should not be determined by one person alone.

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				Partner injury or pain (penile caused by exposure of mesh in vagina)) **Loss of sex life (result of dysperuenia)** **Vaginal bleeding, discharge** **Bladder - recurrent urinary tract infections, incontinence, OAB, retention and voiding difficulties** **Neuromuscular problems – weakness in legs/pelvis, disability (caused by nerve damage/irritation)** **Acute and/or chronic pain in the inner groin, buttocks, lower back, inner thigh, leg, feet, perineum, pelvis, abdomen (caused by nerve damage/ irritation)** **Severe and chronic pelvic pain when sitting down/walking (caused by nerve damage/ irritation)** **Bowel - pain, bleeding, mucus, incontinence, constipation** **Auto immune conditions*** **Fibromyalgia** **Anxiety and depression** **PTSD** **Oedema (legs, feet)** **Swollen abdomen (bloating)** **Paresthesia (itching, pins and needles)**	

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				Skin rashes **Hair loss** *** Lupus, Sjorgren's Syndrome, Psoriasis, thyroid** There should be lifetime follow up not just the 5 years minimum suggested by NICE. **P64 1.2 – & P97** need to include make model and manufacturer of mesh device with a copy sent to the patient's GP for patient notes, as these aren't destroyed during the lifetime of patient, whilst the STM experience has been that hospital notes often are. This register is only recording mesh surgery from 2019 – this effectively continues to treat women having mesh surgery as guinea pigs taking part in an experimental procedure because the true rate of complications are unknown. This is effectively 'shutting the stable door after the horse has bolted'. Hence, why a full national recall is necessary.	**P64 1.2 – & P97** We have amended the recommendations so that all surgical procedures for SUI and POP (mesh and non-mesh) are documented in a national registry. In addition, the make, model and manufacturer of the mesh device is now recommended to be captured by the registry. Unfortunately we cannot reverse time and capture data on women who have already had surgery; however, the recommendations also include recording data on women who present with complications of mesh surgery. The guideline aims to ensure good practice from now on. The recommendations state that surgery for pelvic organ prolapse should be offered to women whose

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				Mesh should be the final surgical option for all types of POP after all other interventions have failed. **P65 11.12** The guidance specifically states the database is only for polypropylene. Yet the guidance also recommends the use of biological mesh for anterior vaginal wall prolapse. The STM patient experience is that women experience the same devastating complications including chronic pain and foreign body reaction with biological mesh implants. STM would like to know the rational for recommending biological mesh and the scientific evidence for this? We believe there is no high quality or even moderate quality evidence so it should not be recommended The database needs to include all types of mesh, as well as non-mesh so that there is a comparator. **P70** – Reporting of all mesh procedures for UI and POP and complications should be mandatory.	symptoms have not improved with, or who have declined non-surgical treatment. We are providing choice to women. **P65 11.12** We have amended the recommendation so that the registry should include all surgical procedures, not just mesh surgery. **P70** We agree with the stakeholder; however, NICE can only provide recommendations on best clinical practice, it does not develop policies. NICE does

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					not have the power to compel anybody to do anything, but we have used the strongest wording available to us ("providers must ensure the following data are collected…"), which is something we seldom do.
				P67 - Research recommendations 3. What are the long-term risks of mesh surgery compared with non-mesh surgery for pelvic organ prolapse in women? **Long term should be defined as at least 10 years. STM patient experience of 7,000 members going back years should be used as a resource.** **Where did NICE get its data on outcomes? Data from HES etc cannot be relied upon, especially for pain, because STM patient experience is that many women's complications including pain have not been recognised or reported as being mesh related. The majority of database focus on efficacy as the primary outcome which means the new onset of worse**	**P67** This is a suggested research recommendation for future work; it is not a full protocol for a research project. We would expect those developing the research itself to define the timeframe. We refer the stakeholder to the full evidence review, the section "summary of studies included in the evidence review" gives an overview of all included studies, and states which outcomes each study provided. In addition, full details of all included studies are provided in appendix D. All short term outcomes (less than 2 years) are from published randomised controlled trials, and the mid- and long- term outcomes are from published cohort studies.

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				complications are not captured in the data in the long term evidence, which has helped keep complication rates for both SUI and POP surgery low. …patient satisfaction was only recorded using non-validated scales and was therefore not included in this review. **This is yet another flaw in the data used by NICE to draft these guidelines. Other flaws are as follows: -** **P69** "The median age of women included in the studies in this review was 62 years, only two studies included women younger than 50 years (El-Nazer 2012 and Joshi 2013) and these were studies conducted in Egypt India, and therefore may not be reflective of a UK population. In addition, there are likely differences between women pre and post hysterectomy yet again the evidence in this review did not provide adequate details to answer this question." **"They were also concerned about the lack of reliable evidence on the adverse events**	We appreciate that patient satisfaction is an important outcome; however, we aimed to include data which was an acceptable standard, and so we only included outcomes reported using validated tools. Within the short-term complication data for anterior, posterior and apical prolapse we have included a range of quality of life outcomes measured, using validated tools. **P69** The committee are unsure what the stakeholder is referring to when they state, *"the evidence in this review did not provide adequate details to answer this question".* The text to which they refer on page 69 provides details about the age of the women included in the studies. In this section, we are explaining that the data may not be generalizable to younger women, as only two studies included women younger than 50 years. This is from a total of 22 randomised controlled trials, which were included in total for the review on anterior prolapse surgery.

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				following surgical interventions for UI and POP, especially those occurring after two years, despite extensive review of the existing research literature carried out for development of the guideline." With an older cohort of women pain can be blamed on other issues and they will not be as sexually active as younger so will not capture dypareunia to reflect the true scale of how mesh can affect women's sex lives. Once again lack of robust evidence. **P69** "The committee agreed that giving women a choice in which procedure she undergoes was very important, and that women should be provided with all the potential benefits and harms regarding each procedure which are relevant to her prolapse was crucial." **COMMENT** STM's position is that this statement does not stand up to scrutiny given that long term harms are not known, so a woman does not	The committee agree it would be informative to have randomised data which explicitly examines dyspareunia in women; however, we can only include and review the data which is available. **P69** Thank you for the comment. The committee think that women should be provided with a choice about their own care, and that this should not be prescribed by an individual health care practitioner. The recommendations provide non-surgical options, and these should be considered in the first instance; however, for women whose symptoms have not improved with, or women who have declined non-surgical treatment, surgery is an appropriate option. The recommendations are providing choice to women.

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				have choice as she does not know what she is signing up for. If you do not have the real figure of risk then that is not a fully informed consent under the Montgomery Ruling or Thefaut Ruling so a woman is not signing up to anything with her full consent. Also, patient experience shows us time and again that in the hands of a pro mesh surgeon the risks will be played down so that new women coming in for operations will not be given anything like the scale of problems that can potentially happen with mesh operation./ Patient literature has proved haphazard across the UK with it being a postcode lottery as to who gets what advice. Even despite a mesh suspension, NHS leaflet V12 remained online from December 2017 to circa September 2017 which promoted prolapse mesh as a treatment option with no warning whatsoever of the fact vaginal prolapse mesh was subject to a suspension. I reported this to the Dept of Health, Lord James O Shaugnessy and the media offices of RCOG yet it took 10 months to change. We cannot rely on patient literature to be the	We would expect that consultants are trained to take consent appropriately, as this would be part of standard medical training. We have attempted throughout the guideline to make shared decision making a key aspect of care, although we cannot ensure all health care practitioners follow the advice we are doing all we can to ensure women are fully informed. In-light of the stakeholders concerns we have amended the recommendations. We have stated that all procedures should be discussed, including those not provided locally. We have also stated that the NICE patient decision aid should be used to help with the process of informed consent, and shared decision making.

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				same across the UK. We cannot rely on surgeons to give a robust consent process in every single hospital. The only way you can protect women is to put all vaginal and abdominal prolapse mesh into the category of research only. **P71** – A six-month review period to identify mesh complications is not enough. The STM patient experience is that complications can occur more than 2 years after mesh implantation and for many more years after that. One woman had mesh slice her urethra after 16 years for example. Many women who present to their GPs and Consultants find that these Doctors do not understand or attribute their complications to mesh. There needs to be a standard accepted list of complications, which are publicised to GPs and mesh surgeons (as suggested above). These could be included in patient GP notes. It would be useful if all patients who have had pelvic mesh have a flag on their GP notes, to	**P71** This six-month review is to ensure short-term complications are identified. The next recommendation in this section (3.1.8) states that women who have had surgery should have access to re-referral if they have recurrent symptoms or suspected complications, and there is no time limit on this. The committee agree it can be difficult to attribute certain complications, such as pain, to mesh surgery. In an attempt to address this we have included a recommendation that states women who have had surgery for pelvic organ prolapse should have access to further referral if they have recurrent symptoms or suspected complications. In addition, the guideline includes a whole section on "assessing compilations associated with mesh surgery". The committee hope these

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				alert GPs when these patients present with any of the standard accepted complications. **P71** – "Timely identification and treatment of mesh complications may prevent the need for more resource intensive management given that delays in treatment of mesh complications exacerbate problems and may result in the overall savings to the NHS." **COMMENT** STM agree, however current NHS waiting times for the few surgeons skilled at mesh removal within the UK are unacceptable, which impacts on costs to the NHS, state benefits and social and economic costs to the patient. **P72** The committee decided that mesh to treat POP should be offered as an option. **COMMENT** **This contradicts the current IPG guidelines that mesh for POP should only be used for research purposes, effectively banning its use. However, Nice rationale is that** "The	recommendations will improve the referral system for women, ensuring women are referred in a timely manner to the most appropriate management centre. **P71** The committee cannot comment on the state of NHS waiting times and can only provide recommendations for care. **P72** The committee do not think that researchers are likely to conduct randomised controlled trials, the gold standard method for research, as this would involve randomising some women to mesh surgery. In light of current safety concerns, this would not be considered appropriate. We have

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				committee believe health care professionals would be hesitant to conduct studies due to the controversial nature of mesh surgery, and that recruitment would be difficult due potential risks of mesh surgery which have been discussed widely in the media, and the very small numbers of women meeting the inclusion criteria." STM do not understand this rationale that would allow mesh to be used as an option for POP, because research is unlikely to be conducted because of safety concerns! This puts women back into the position of being guinea pigs with only an inadequate six-month follow up to check if they have suffered complications! In the NICE literature review for the draft CG171 this U-turn is justified by stating that the committee disagrees with the prior NICE review on prolapse mesh for anterior/posterior repair (transvaginal prolapse mesh). It is not clear what scientific evidence precisely NICE has based this U-turn on! STM does not understand how NICE can put TV POP into a research only category	amended the evidence report to reflect this explanation. We also refer the stakeholder to the section on "other factors the committee took into consideration", where there is a detailed account of how the committee considered the evidence, and how this relates to the data presented in the IPG. The evidence report further explains how very few women are likely to meet the criteria for anterior prolapse surgery with mesh; however, if women do wish to have this procedure they should have the option to do so. The committee do not agree that surgeons will pressure women into any form of surgery. The recommendations aim to ensure that any decisions which are made are led by the woman herself, after she has received detailed information on the risks and benefits of all treatment options. The guideline also provides recommendations on multidisciplinary teams, which aim to ensure a woman's care is not handled by one health professional alone.

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				owing to serious concerns then 10 months later say it cannot be research only because nobody would want to do research BECAUSE OF THE RISKS! To say that health care professionals would be hesitant to conduct studies due to the controversial nature of mesh surgery, and that recruitment would be difficult due to potential risks of mesh surgery which have been discussed widely in the media is a strange comment as the media have covered all mesh not just prolapse. Plus it is recognising risk. We do not understand how it can be pretty much banned and then 10 months later outlined for general use again thus exposing women to harm. There has been no extra scientific evicence upon which to base this. We believe it will be pressure from surgeons who do not know the skills to fix women up any other way other than using mesh implants.	

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				Line 44/45 it talks of being effective with lower recurrence rates. STM wishes everybody deciding these guidelines to understand that we are not talking about efficacy. We are not talking about if mesh means less recurrence of prolapse. We are talking about mesh adding a whole layer of new and devastating complications that can and do shatter women's lives and their families lives. **46**: It is not good enough to say mesh can continue as long as women are warned of risks. We believe that is because a pro mesh surgeon can give a leading consultation whereby risks are down played. We have new members join who had POP mesh in the summer saying they knew nothing of mesh complications like pain, loss of sex lilfe, UTIs, auto immune conditions. None of these are mentioned. All that women were told and all you talk of in this guideline is recurrence and efficiency of the fix. Many are told by surgeons that they don't use the mesh in the media or they use a new mesh or it is media hype. The	**Line 44/45** The committee agree that efficacy is not the only issue when determining which procedures should be recommended. However it is important to determine efficacy of the different options; if a certain procedure is not effective, then if should not be offered at all. The recommendations have been made with thorough consideration of the potential complications of surgery, both in the short and longer term, and the committee agree that the recommendations reflect these concerns. **46** The committee do not agree. We expect all surgeons to have an unbiased discussion, ensuring that women are provided with as much information as is currently available. These recommendations clearly state that any decision should be a shared decision, and the final choice is made by the woman. The committee think that women should have all choices available to them, and that their decision should not be determined by an individual surgeon. The guideline makes it clear that a woman's care should be undertaken by a multidisciplinary group, and the woman herself

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				only way to protect women is to ban mesh implants. **STM MEMBER VIEW POINTS – 14 views from different women** 1. My thoughts are why on earth would any self respecting urogynaecologist wish to harm their patients with plastic mesh of any shape, form or description when the harm it does is immense! The costs to everyone, patients and NHS adds up too! Constant pain, hence constant pain killers and other medications (NHS cost implications), loss of sex life, losing job because of pain (pip/ government cost implications), removal by NHS (NHS costs) and possibly loss of bladder and colon!!! Surely this doesn't even justify using mesh? The paperwork if mesh was used would have to be very very precise!! How can NICE say vaginal prolapse mesh has such high risk that	should make the final decision about her care. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse. **STM MEMBER VIEW POINTS – 14 views from different women** 1) We refer the stakeholder to the section on "other factors the committee took into consideration", where there is a detailed account of how the committee considered the evidence, and how this relates to the data presented in the IPG.

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				it must only be used in research then less than a year later say it is OK. 2. This does not say under what arrangements vaginal prolapse mesh should be used. It was research only, but what will it switch to? Special or standard? Either way I disagree vehemently. how can NICE ban a type of mesh to research because of high risk then say nobody will want to do the research because of the risk. If they know it carries high risk then why does it need any more research What a joke. 3. How can it be potentially risky to trial but ok to start using again. If they know it has the possibility to harm how can they even consider using it. If they surgeons live by the rule of first do no harm. It's not Rocket science prolapse mesh has harmed many people. What will it take to make them understand. 4 How can what they are saying possibly make sense?! They acknowledge that mesh	2) We refer the stakeholder to the section on "other factors the committee took into consideration", where there is a detailed account of how the committee considered the evidence, and how this relates to the data presented in the IPG. 3) We refer the stakeholder to the section on "other factors the committee took into consideration", where there is a detailed account of how the committee considered the evidence, and how this relates to the data presented in the IPG. 4) Thank you for your comment.

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				has potentially high risks and no one would be willing to use it in a trial but then suggest that the ban should be lifted and its use continued??? Absolute madness!! After NINE years mine BROKE inside me. It didn't erode, it just snapped & coiled up under my bladder. It has cost me my quality of life, meant that I can't be a proper Mummy to my girls or have a full sexual relationship with a man I have loved for 16 years. It has caused me nerve damage, given me chronic pain & resulted in numerous & very debilitating surgeries. As a family we now have to take on £20k of debt to get me to the one surgeon who can remove the arms & anchors that the NHS specialist removal centre left me with. Oh & the prolapse they told me hadn't come back 6.By doing this NICE have shown little regard for patient safety and bring themselves under the spotlight of being corrupt. It is only a matter of time before damaged women start to demand a criminal investigation into who gets to influence their decisions and what links big pharma have in	6) The NICE guideline development process is open and transparent. NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website

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				getting rid of safety measures. Criminal Move 7. I can't believe that NICE can possibly consider using mesh now they know how women are suffering, how women with mesh have no quality of life ! It's blatant disregard of our ruined lives ! 8 Use mesh next year then in 20yrs you will need many more scanners and more surgeons	7) The committee do not agree. The committee think that women should be provided with a choice about their own care, and that this should not be prescribed by an individual health professional. The recommendations provide non-surgical options, and these should be considered in the first instance; however, for women whose symptoms have not improved with, or women who have declined non-surgical treatment these recommendations provide women with the option of surgery. The recommendations are providing choice to women. It is also important to note that the committee includes lay members on the panel, ensuring that patient experience is taken into account. The committee have always been aware of the concern that women have about mesh surgery and have always considered patient views and patient choice when drafting the recommendations. 8) Thank you for your comment.

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				to take it out, just take a look at the waiting times of the removal lists for mesh removal surgeons. It averages a year to 14 months now.	
				9. Why do they need more research and trials? They know it can cause injury which is not always seen straight away it can take years. They know they can use our own tissues as I'm soon to have done.	9) Native tissue repair is recommended as the only treatment option for posterior prolapse, and as the first choice for anterior repair; however; as detailed in the discussion section this may not always be appropriate for all women. The data demonstrates anterior repair with mesh is more effective and leads to less recurrence of prolapse than native tissue repair for anterior prolapse, and some women may wish to take this option, despite the potential risks. The guideline emphasises the importance of discussing all risks and benefits, so that women are fully informed prior to treatment.
				10. . Mesh is plastic and should not even be in the sea let alone in women's most delicate places. There are no long term records and no proof of safety ,indeed many outcomes so far are heartbreaking . Plastic mesh was designed to be permanent and so is almost impossible to remove . When it goes wrong the NHS has	10) The guideline has reviewed the available evidence on mesh surgery for SUI and POP, and these reviews have included short- mid- and long-term complication data. In addition, the guideline provides recommendations for the management of mesh complications, and we hope these improve care for women in the future.

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				few answers and pain killers for life is not acceptable answer for a problem the NHS originally caused with mesh implants.	
				11. If they say mesh surgery is so controversial, and there won't be any uptake for trial, surely the obvious conclusion is this type of surgery should not happen, especially taking into consideration the dreadful consequences both women and men are suffering	11) The committee do not believe researchers are likely to conduct randomised controlled trials, the gold standard method for research, as this would involve randomising some women to mesh surgery. In light of current safety concerns, this would not be considered appropriate. We have amended the evidence report to reflect this explanation. In addition, as explained in both the rationale section of the guideline, and the discussion section of evidence review I, some women having been informed of all benefits and risks may still choose mesh surgery as their preferred option.
				12. How can they justify injuring anymore people? Do they not care?Are they not listening or devoid of all the story's of injuries already already shared and the pain people are living with? Do they put all this before prop quality of life which they are supposed to protector is it profit and greed before quality of	12) The committee includes lay members on the panel, ensuring that patient experience is taken into account. The committee has always been aware of the concern that women have regarding mesh surgery and have always considered patient views and patient choice when drafting the recommendations.

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				live. Will they pay high compensation for injuries caused by their decisions because it's life long complications. It is also life threatening. They need to think again 13. A survey of 527 women in Sling The Mesh shows that 8.1% had a abdominal prolapse mesh while 11% had vaginal prolapse mesh. So the number in each category is not hugely different. Which shows the scale of suffering of either abdominal or vaginal POP mesh is fairly similar. Thus showing both types of POP mesh have grave and serious complications regardless of route of insertion. 14. Nice know that mesh has proved to be not fit for purpose and is causing horrific problems in an unacceptable number of people. Unfortunately no one wants to take responsibility for this and until they do many more are going to suffer. The mental health of many patients is also to be considered. Many feel no one will listen, believe, understand and help them. Trust has been destroyed. The doctors who pledge to do not harm should be	The recommendations have been made with the aim to improve care, and it is not the committees place to comment on compensation regarding previous practice. 13) The survey that the stakeholder refers to is one survey, from one particular group of women which has not been published in a peer reviewed journal. In total this review included data from 81 studies, and was developed using robust methods to identify relevant published evidence from across the globe. We refer the stakeholder to the methodology chapter for full details. 14) The committee agree that a woman's quality of life is important, and the reviews included quality of life outcomes where they were reported.

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				ashamed of themselves. The patients they see every day look to them for help. After all, where else can we go. **P 92 re: post operative SUI. "Due to the lack of suitable data, some of the cost estimates were based on the committee expert opinion."** **Robotic surgery techniques**. STM is concerned based on patient experience of the use of robotics as the heat melts mesh into the tissues and makes removal more problematic if not impossible. **P97 onwards** – re: POP surgery with mesh TVT or TOT Sling. The STM patient experience is that the TOT is more difficult to remove and risks more nerve damage especially to the transobturator nerve. Whilst the STM position is that mesh should be banned for SUI and POP, if its use is to be continued as an option for SUI, then neither TOTs nor TVOTs should be used. This section does not include any	**P 92** Thank you for your comment. Robotic surgery was not included in this review. **P97 onwards – re: POP surgery with mesh TVT or TOT Sling.** Thank you for your comment. We refer the stakeholder to evidence review E where surgery for SUI is discussed, including complications following surgery. The Keltie 2017 paper did not meet the inclusion criteria for the review on long term complications of stress urinary incontinence surgery (evidence

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				discussion about serious complications caused by mesh slings used to treat SUI which is a serious omission. The STM patient experience is that generally the more mesh that is implanted into the pelvis, the greater the complications. Therefore, implanting SUI mesh in addition to mesh for POP, increases the severity of complications, particularly pain and damage to organs such as the bowel. Using an obturator approach must be banned outright. The damage it causes it unacceptable. STM questions why TVT is still recommended to be safe to use when, for example, the recent Keltie study demonstrated a complication rate within 5 years of a mesh procedure was 9.8 per cent. This study includes acknowledgement that the true complication rate is likely to be higher. The question the related NICE scientific literature review set itself is what is the most effective surgical management for women with both SUI and prolapse.	review E). We acknowledge the paper is described as providing 8 year follow up data; however, the mean length of follow-up of participants is actually only 4.2 years. Given that RCTs give the highest level of evidence for intervention reviews, RCT data was prioritised to inform the effectiveness and complication reviews up to 5 years. Non-RCT data was considered for inclusion to inform the reviews where there was a lack of data i.e. beyond 5-years. The Keltie study is a retrospective analysis, and is therefore is considered lower quality, with an increased risk of bias.

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				So going by this table in the Nature paper https://www.nature.com/articles/s41598-017-11821-w/tables/1 STM would like clarification why this data has not been included in the literature review? STM is concerned that if a woman gets complications from one mesh implant, common sense should suggest she is more at risk of complications from a second. STM has heard the stories of women with multiple meshes in a dreadful state. **CONCLUSION** **STM would like all prolapse mesh to be put into the category of research only. If this is not taken into account then** Abdominal Prolapse mesh must only be used once conservative methods like pessaries and non mesh surgery has failed. Abdominal POP mesh must be third line and vaginal prolapse mesh must remain in research context only or better still pushed to the status of banned	**CONCLUSION** The committee think that women should be provided with a choice about their own care, this should not be prescribed by an individual health professional. The recommendations provide non-surgical options, and these should be considered in the first instance; however, for women whose symptoms have not improved with, or women who have declined non-surgical treatment surgery is an option. The recommendations are providing choice to women.

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Sling The Mesh	Evidence Review J			**[J] Surgical management of pelvic organ prolapse and stress urinary incontinence** **P11-13** The evidence cited throughout section J is mostly 'very low' or 'low quality data' with small survey numbers and short term. This is not robust enough evidence upon which to base guidelines. The data ignores the patient experience (e.g. STM has more than 7,000 members) STM were not consulted in drafting this guidance **P15: 1-13** discusses efficacy and recurrence rates. STM wishes everybody deciding these guidelines to understand that we are not talking about efficacy. We are not talking about us all being upset that mesh doesn't work, we are talking about mesh adding a whole layer of new and devastating	Thank you for your comments. Our responses can be found below: **P11-13** As registered stakeholders, Sling the Mesh have been able to provide input to the guideline at both scoping and consultation. The committee have been very aware of patients' concern about mesh and the management of mesh complications, and throughout the guideline development process the committee have listened to patient views and taken these into consideration. To highlight, we have lay members on the committee and their input and experience was instrumental in developing the recommendations. **P15: 1-13** The recommendations have been made with potential complications following mesh surgery in mind. Throughout the guideline we highlight the lack of long-term evidence, and that women should be made aware of this and the potential risks and benefits of each different surgical procedure. For example, evidence showed that

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				complications that can and do shatter women's lives and their families' lives.	mesh surgery for anterior prolapse was more effective than native repair; however, considering the widespread concern, a mesh procedure has only been recommended for use in certain cases. It is important to determine the relative effectiveness of all the different options - if a certain procedure is not effective, then if should not be offered at all. The committee acknowledges that mesh surgery has unique complications but believes that women should have the opportunity to choose the surgery most appropriate for them.
				P15: 25-33 The draft guideline is vague on informed consent and specific risks related to mesh procedures, except to tell the patient mesh is a permanent implant and difficult to remove. This allows room for surgeons to be selective in discussing risks or downplaying risks of mesh. The proportion of women affected by mesh must be defined in numbers with the scientific references. Without this information a surgeon cannot give fully informed consent. Leaving doctors to communicate risks without stating precisely	**P15: 25-33** We do not agree that the term "discuss the risks and benefits" allows surgeons to be selective about procedures. We expect all healthcare professionals to give honest, and clear information to women about all their management options. This guideline provides recommendations on the most appropriate clinical care. It is not possible to describe all the potential risks and benefits which will be discussed by the woman and her heath professional. This is not a training manual; but we expect all health care professionals who are discussing surgical options with the woman to be

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				what these are is likely to lead to history repeating itself i.e. lack of informed consent and a continuation of the mesh tragedy. STM believes the list of standardized mesh complications that occur immediately after mesh insertion or in the longer term should be included as part of the informed consent process including: **Dyspareunia** **Partner injury or pain (penile caused by exposure of mesh in vagina))** **Loss of sex life (result of dysperuenia)** **Vaginal bleeding, discharge** **Bladder - recurrent urinary tract infections, incontinence, OAB, retention and voiding difficulties** **Neuromuscular problems – weakness in legs/pelvis, disability (caused by nerve damage/irritation)** **Acute and/or chronic pain in the inner groin, buttocks, lower back, inner thigh, leg, feet, perineum, pelvis, abdomen (caused by nerve damage/ irritation)**	fully trained to do so. We have also developed recommendations on multidisciplinary teams, and suggest that a woman's care should not be determined by one person alone.

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				Severe and chronic pelvic pain when sitting down/walking (caused by nerve damage/ irritation) **Bowel - pain, bleeding, mucus, incontinence, constipation** **Auto immune conditions*** **Fibromyalgia** **Anxiety and depression** **PTSD** **Oedema (legs, feet)** **Swollen abdomen (bloating)** **Paresthesia (itching, pins and needles)** **Skin rashes** **Hair loss** • **Lupus, Sjorgren's Syndrome, Psoriasis, thyroid** • **P15 – 34-41** "It is not known whether there is a benefit to concurrent surgery or sequential surgery for these women and what the adverse effects of these approaches are. There are no long-term data to guide patients in making decisions about surgery and the committee felt that it was important to assess success	**P15 – 34-41** The recommendations have been made with potential complications following mesh surgery in mind. Throughout the guideline we highlight the lack of long-term evidence, and that women should be made aware of this and the potential

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				and complications of both approaches over a 5-year period." **COMMENT** STM's position is that this statement does not stand up to scrutiny given that long-term harms are not known so a woman does not have choice as she does not know what she is signing up for. STM patient experience is that complications can occur many years after implantation. **P15: 42- 50 P16: 1-7** It is impossible to assess the cost effectiveness of using mesh whether its one procedure for POP or two procedures for UI and POP (whether sequential or concurrent), due to years of under reporting of adverse events and complications detailed in the STM submission to the IMMDS Review – Many women who present to their GPs and Consultants find that these Doctors do not understand or attribute their complications to mesh. There needs to be a standard accepted list of complications,	risks and benefits of each different surgical procedure. For example, evidence showed that mesh surgery for anterior prolapse was more effective than native repair; however, considering the widespread concern, a mesh procedure has only been recommended for use in certain cases **P15: 42- 50 P16: 1-7** The committee agrees that there are a range of complications following mesh surgery which a woman may present with; however it is not within the scope of a guideline to list all of these or provide a training manual for general practitioners. We have provided a whole section of recommendations on assessing complications following mesh surgery and we believe these should improve care for women.

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				which are publicised to GPs and mesh surgeons (as suggested above). These could be included in patient GP notes. It would be useful if all patients who have had pelvic mesh have a flag on their GP notes, to alert GPs when these patients present with any of the standard accepted complications. Current NHS waiting times for the few surgeons skilled at mesh removal within the UK are unacceptable, which impacts on costs to the NHS, state benefits and social and economic costs to the patient. This is in addition to the costs incurred by the NHS to treat complications (pain relief, GP and A&E visits etc) The draft guidelines take non of these costs into consideration. The state has also been shielded from some costs, by the many desperate women have paid for private medical treatment, in order to save their health, careers, marriages, homes. The full extent of the economic costs of complications will be unknown until there is a full retrospective recall of all pelvic mesh patients.	The committee acknowledged that there may be wider societal costs. It is beyond the scope of this guideline to quantify such costs. The usual practice in NICE for the economic evaluation of interventions funded by the NHS and Personal Social Services (PSS) with health outcomes is to adopt NHS and PSS perspective on costs i.e. to consider only care that is funded by NHS or PSS.

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Sling The Mesh	Evidence Review K			**[K] EVIDENCE SUMMARY K Assessing mesh complications after pelvic floor mesh surgery** **P9 K1.1** For women who report new-onset symptoms after having mesh surgery for urinary incontinence (UI) or pelvic organ prolapse, evaluate whether the symptoms might be caused by a mesh-related complication. These symptoms could include: pain or sensory change in the back, abdomen, vagina, pelvis, leg, groin or perineum that is: either unprovoked, or provoked by movement or sexual activity and either generalised, or in the distribution of a specific nerve, such as the obturator nerve vaginal problems including discharge, bleeding, painful sexual intercourse, penile trauma or pain for both partners **COMMENT** Add to list UTIs that wont clear up with antibiotics, putting women are risk of sepsis. A STM survey shows 54% of women have ongoing painful UTIs and 8% are becoming antibiotic resistant.	Thank you for your comments. Our responses can be found below: **P9 K1.1** We have added "recurrent infection" to this recommendation.

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				P10: 11 K1.3 Recommendations on what to do for women eg scans and internals **COMMENT** At this stage women need to be sent for a translabial scan with a trained scanner. Only 3 of the 19 mesh NHS specialist centres have such a thing. Not good enough. Presently we know also of 2 private clinics in the UK. All innundated with mesh injured women, **P10 K1.4 res smaller than 1 cm2 31 32 see recommendation 1.10.3 i which is for partial removal or snip** **COMMENT** Women must not be given a rim or a snip or a partial mesh removal as this only helps for a few weeks or months. The mesh then fragments and pain and problems get progressively worse. All out is the only solution	**P10: 11 K1.3** The committee can only provide recommendations on good clinical care. We cannot comment on the facilities that different units do or do not have. **P10 K1.4** We acknowledge that the evidence available was limited; however, there was no evidence that partial removal made complications worse in the long term and there is no evidence that complete removal is necessarily more effective than partial removal. The effectiveness is likely to depend on the individual case, and many women may not want complete removal if partial removal has proved effective. The evidence suggested that full removal increases the risk of incontinence, additionally full removal is a more extensive procedure. The committee also acknowledge that if a woman wants a full removal, she should be supported in her decision, we think the

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					recommendations reflect that it is important each woman has a choice about her care. The committee believes that it should be the woman's choice to decide whether or not she wants partial or full removal.
				P11 39 K1.6 The responsible consultant should ensure that details of any 40 confirmed mesh-related complications are: **COMMENT** Currently only the implanting surgeon can report mesh problems to the MHRA . To report another surgeon they have to get that surgeon's permission. This arrangement needs to stop as this has kept reporting rates lower than reality.	**P11 39 K1.6** The committee do not think this is accurate. Anyone can report a complication to the MHRA.
				P17 23 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, resulting in significant impact on women's health, and lead to an overall saving ti the NHS. **COMMENT**	**P17 23** These recommendations are developed with the woman's care in mind. The committee have stated that providing "*timely access to a specialist"* may save the NHS money; but, the key point is that women are assessed and receive the care they need as soon as possible, hence improving care.

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				The NHS has caused this mess it needs to sort it out in the best way which women - the victims - deserve and need. To try to cut costs in treating these women is outrageous. Women must not be offered partial snips or trims as this makes things worse in the long term, All women must be offered a full mesh removal by a trained and accredited mesh removal surgeon. Not just a cheap fix partial removal based on no evidence that this will help them. We were used as guinea pigs for this cheap quick fix of mesh, women must now not be subjected to the same patch it up guinea pig approach for their removals. Patients should be able to self refer to named Drs with relevant experience , as their entitled to patient choice still Timely is key. Surgeons MUST send women for treatment the minute they present reporting mesh problems and surgeons must not deny it is their mesh nor blame it on another health issue as has happened for the last 20 yrs.	In response to the stakeholder's comment on 'partial snips', we acknowledge that the evidence available was limited; however, there was no evidence that partial removal made complications worse in the long term and there is no evidence that complete removal is necessarily more effective than partial removal. The effectiveness is likely to depend on the individual case, and many woman may not want complete removal if partial removal has proved effective. The evidence is clear that full removal increases the risk of incontinence and is a more extensive procedure. The committee believes it should be the woman's choice to decide whether or not she wants partial or full removal.

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Sling The Mesh	Evidence Review L			**L Management of mesh complications** **P13: 14 Due to the paucity of available evidence for each individual complication, the committee decided to consider some of the excluded studies that did not strictly meet the inclusion criteria of the individual mesh complications reviews for in order to inform the recommendations about the management of mesh complications.** **COMMENT** Good grief I am shocked to see yet more very low quality evidence. In this case a paucity which the dictionary describes as "The presence of something in only small or insufficient quantiti The key word is insufficient. In which case why has NICE even attempted to make a guideline without first consulting both women and mesh removal experts who women trust as well as talking to pain management specialists, UTI experts like Professor Malone Lee of Whittington Hospital and mental health experts.	Thank you for your comments. Our responses can be found below: **P13: 14** **The committee have made the recommendations on the management of mesh complications using the best available evidence. We agree this data is limited; however, we conducted a robust search for the evidence, and only found retrospective data. We used this evidence along with the expertise on the committee panel. The stakeholder states that experts should be consulted, and indeed we have experts (in mesh removal surgery) on the panel. The committee also includes lay members, who provided insight into the patient perspective and provided valuable input to the recommendations.** The NICE guideline development process is open and transparent. NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website.

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				P20: 20 Partial vaginal mesh removal versus complete vaginal mesh removal Continued or repeated exposure/extrusion/infection No evidence was identified to inform this outcome. **COMMENT** No Evidence / very low quality evidence from just 56 women following up for 5 weeks to 28 weeks This is not good enough to inform clinical practice. You must listen to patient voice. We know from global experience that a partial snip., trim or partial removal only makes things worse in the long run. You must not recommend this partial removal as an option esp as it relies on terrible low quality / paucity of evidence. Women have been harmed once from mesh they must not be harmed twice by a poor removal of only a section of the implant. If mesh is to be removed it must be done under the care of a trusted removal expert.	**P20: 20** We acknowledge that the evidence available was limited; however, there was no evidence that partial removal made complications worse in the long term. The committee also have no experience that partial removal is more detrimental than complete removal, and in some instances partial removal is more appropriate and the preferred option of the woman. We agree with the stakeholder that removal should be undertaken by an expert. Please note the section in the guideline on multidisciplinary teams, where recommendations make it clear that mesh should only be removed in specialist centres.

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				P33: 26 L1.2 Management of urinary complications after mesh or mesh sling surgery **COMMENT** All evidence listed in this section is very low quality or one at **P 33: 17** that admits it is at serious risk of bias. How can you make a guideline based upon this shockingly bad lack of evidence [redacted]ing with constant UTIs after mesh need to be taken seriously and need to be properly checked out by a UTI expert like Prof Malone Lee to ensure this infection is kept under control. Patient voice from CUTIC should have been employed when drawing up this guideline [redacted]	**P33: 26 L1.2** We agree that the evidence available on management of mesh complications was limited. We developed a detailed protocol and conducted a robust and thorough search for the evidence; however, to date only observational cohort studies have been published. In addition, these publications are generally retrospective in design and do not compare one treatment method to another. Nonetheless we used the best available evidence alongside experts in mesh removal, who are on the committee, to determine what we consider the best clinical care. We also have lay members on the committee and their input and experience was valuable in developing recommendations. The committee are very aware of patients concern about mesh, and the management of mesh complications, and throughout the guideline development process the committee have listened to patient views and taken these into consideration. Unfortunately CUTIC are not registered as stakeholders; however, they had the opportunity to register along with all other interested parties prior to the development of the guideline.

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				P36 L1.2 27 **COMMENT** Why put mesh in if you have to admit you cannot guarantee you can take it out. It is a permanent implant and is not designed to come out. It is grossly unfair to tell women this after problems emerge and give them the line that it is the situation that they must just put up with it. I can guarantee you no woman in any consent process understands this permanent aspect until it is too late. Most of us thought it was something semi permanent, a bit like a coil, that could easily be taken out if problems arose.	**P36 L1.2 27** The committee are aware that in the past information given to women about mesh surgery may not have been adequate. We are also aware that women were not always told about the permanency of mesh. These new recommendations have been developed to ensure that this practice does not continue. We have provided detailed recommendations on providing women with all information on potential risks and benefits about all surgical options. In particular we have stressed that women should be made aware that mesh is a permanent material, and that it may not be possible to be removed. The guideline will also be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress UI and pelvic organ prolapse.
				P36: 28 Removing only part of the mesh might be just as effective at improving symptoms as removing all of it **COMMENT**	**P36: 28** We acknowledge that the available evidence on the management of mesh complications is limited; however, there is no evidence that complete removal is necessarily more effective than partial

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				This is utter nonsense and uses no robust evidence to back it up. "might be just as effective" is a terrible sentence ot use in a NICE guideline. Nobody knows on an evidence-based basis, other than hundreds of us from patient experience which tells us partials leave women worse off in the long run. In the absence of evidence that is good quality or not at serious risk of bias then the decision on partial removals must come down to patient voice or clinical expertise from mesh removal surgeons with years of experience - neither of which NICE has asked for input until this draft guideline comment process. Patient experience shows us a partial removal is catastrophic in the long term and although may at first show signs of improvement, women who have been recommended to have this option become worse after a few weeks or months.	removal. The effectiveness is likely to depend on the individual case, and many woman may not want complete removal if partial removal has proved effective. The evidence is clear that full removal increases the risk of incontinence, is a more extensive procedure and the committee believe it should be the woman's choice to decide if she wants partial or full removal. The committee included clinical experts with extensive experience of mesh surgery and mesh removal surgery who provided their expertise on this topic. In addition we have lay members on the committee and their input and experience was valuable in developing the recommendations. The committee are very aware of patients' concern about mesh, and the management of mesh complications, and throughout the guideline development process the committee have listened to patient views, and taken these into consideration. In addition, all experts and members of the public have had the opportunity to register as stakeholders on the guideline and are invited to comment during the consultation period, to provide input with their expertise or experience.

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				P36 31 urinary incontinence or prolapse can recur after the mesh has been removed **COMMENT** Women would rather suffer SUI or POP than the devastating pain and loss of sex life of keeping the mesh implant in place **P36 32 Managing vaginal complications L2.1 Consider non-surgical treatment with topical oestrogen cream for women with a single area of vaginal mesh exposure or extrusion that is smaller than 1 cm2** **COMMENT** Please credit us with some intelligence. A bit of cream is not going to stop a sharp piece of plastic slicing through a woman's vaginal wall. Stop this lunacy. Oestrogen may well thicken vaginal walls to a degree but it will NOT stop a mesh erosion. This must be taken off the guidelines as a treatment option immediately because this is based on a "paucity" of evidence. If plastic is slicing a woman's vagina then she must have a full removal. NO snips,	**P36 31** The committee agrees that this may be the case for some women. The committee is committed to offering all woman a fully informed choice, and these recommendations have been developed with this in mind. **P36 32** The committee agree with this comment in relation to mesh extrusion, and have modified the recommendation. However for mesh exposure, where the mesh is visible but not extruding out of the epithelium, oestrogen cream may be appropriate. If a woman has mesh exposure, but no other symptoms she may not want to have a surgical procedure, and she may wish to use a topical treatment to find out if this works. The recommendations now read as follows: 1.11.3 Discuss non-surgical treatment with topical oestrogen cream with women who have a single area of vaginal mesh exposure that is smaller than 1 cm2. If accepted arrange for follow-up within 3 months [2019]

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				no trims, no cream. Patient experience shows us women who have a vaginal snip often have to go back time and again where it keeps pushing through and not only hurts her but cuts her partner. Others have gone home from clinic excited to think cream will fix them only weeks later realise it wont and then feel guilty going back to the GP to ask for yet another referral to the surgeon. For some women who are not very good at making a fuss they then put up and shut up. It is stalling tactics and relies on many women, esp older ones, just going away quietly. Stop this advice cos quite frankly it is rubbish. **P 37 L2.4 Explain to women who have vaginal complications after mesh sling surgery for stress UI that: complete removal of the vaginal portion of mesh sling is associated with a greater risk of recurrence of stress UI than partial removal partial removal is associated with a higher rate of further mesh sling extrusion**	1.11.4 Consider partial or complete surgical removal of the vaginal portion of mesh for women: • who do not wish to have treatment with topical oestrogen or • if the area of vaginal mesh sling exposure is 1 cm2 or larger or • if there is extrusion or • if there has been no response to non-surgical treatment after a period of 3 months. [2019] **P 37 L2.4** The committee agrees that there is a risk of SUI with any removal; however, the current available evidence shows that the risk of SUI is greater with complete compared to partial removal. The committee believes that a decision should be made jointly by the woman herself and her consultant, the potential risks and benefits of either partial or complete removal should be discussed, and the individual woman's specific

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				complete removal might not be possible. [2019] **COMMENT** Any removal of mesh removal may result in SUI returning. Whether it is partial or full. Only taking a bit out wont save a woman from becoming incontinent again and it only increases her chance of future erosions. It makes it more difficult to remove a second time as it is harder for the surgeon to find. **P37 11 L2.5 and L2.6 complete removal of POP mesh might not be possible** **COMMENT** So why put it in if you cannot completely take it out if it causes problems, It is admitting that it is tough luck and women just have to put up with it. It is grossly unfair to tell women this after problems emerge and give them the line that it is tough luck and they must just put up with it cos I can guarantee you no woman in any consent process understands this aspect until it is too late.	situation taken into consideration. The aim of these recommendations is to provide choice, and allow the woman to make an informed decision. **P37 11 L2.5 and L2.6** Please see the section in the guideline on surgery for POP, where there are detailed recommendations stating how the woman must be given all currently available information on the potential risks of the different surgical and non-surgical options which are available to her. The committee acknowledges that in the past women may not have been given adequate details about mesh surgery, including the fact that mesh is permanent, and that it can be difficult to remove. These recommendations aim to stop this happening in the future. It is important to note that very few surgical procedures of any type are completely reversible, and this is not an exclusive

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					issue for mesh surgery. It is not NICE's responsibility to train consultants in the consent procedure, we would expect all those discussing surgery to be adequately trained and to use GMC guidance on consent.
				P37 22 Managing pain and sexual dysfunction and pain L3.11 For women who have pain or painful sex if assessment and investigation do not show a mesh abnormality such as vaginal extrusion or exposure, or an infection, offer non-surgical treatments such as pain management, vaginal oestrogen, dilators, psychosexual counselling and physiotherapy if pain does not respond to initial management, seek advice from a regional **COMMENT** Wrong recommendation. Women suffering sexual problems should be immediately referred to the MDT for removal. Many women develop an allergic type reaction of burning or pain or terrible UTIa after sex that will not clear. Others have leg pains after sex that they never suffered pre mesh. They may not	**P37 22…. L3.11** The committee have amended the recommendation to state "consider non-surgical treatments". The committee believe it is important to consider all potential causes of dyspareunia initially. Discomfort may not always be due to mesh, and many other causes may contribute to pain during sex. The recommendation goes on to state that women should be referred if the woman does not respond to initial management. However the recommendations do clearly state that if the pain is likely to be related to mesh, then the woman should be referred to a regional MDT. The recommendations are not trying to deny access to any treatment.

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				present in clinic as mesh in wrong place or an erosion but this issue of vastly reduced or even lost sex life is a very unfair and hideous risk. It is upsetting and devastating to both the woman and her partner. To deny women access to full removals is wrong. to send them to psycho sexual counselling are you having a laugh?? If this was a man with a lost sex life from a mesh implant everybody would be aghast. Women suffering this must be given the option for full removal at the earliest opportunity.	
				P 37: 34 Managing urinary complications L4.1 Refer women who have mesh perforating the lower urinary tract to a centre for mesh complications for further assessment or management. **COMMENT** **yes**	**P 37: 34** Thank you for your comment.
				L4.2 For women with urinary symptoms after mesh surgery for stress UI or pelvic organ prolapse who are considering mesh	**L4.2** Please see the sections in the guideline for recommendations on surgical management for SUI and POP. These recommendations have

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				removal surgery, explain that: urinary symptoms might not improve and new symptoms might occur after complete or partial removal of the mesh stress UI might recur after mesh removal, and the risk of this happening is higher with complete than with partial mesh removal. C complete removal of the mesh might not be possible **COMMENT** How do you know Urinary symptoms may not clear up . Where is the evidence? Stop focusing on trying to scare women off mesh removals by saying SUI may return. Women would rather suffer that than the pain and infections. If they see a chance to maybe fix that then they should be given this as an option. PLUS all this talk of removals may not sort the problem leads to only once conclusion. If mesh is causing such devastating complications it should not be inserted in the first place.	been written with the intention that all women should be given as much information as is available, so that they can make a fully informed choice, about which option is appropriate for their particular case. In addition, for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. The committee acknowledges that the evidence on the management of mesh complications is limited; however, the evidence which is available demonstrated that complete removal of mesh is may result in the recurrence of SUI, it is important that women are given this information.

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				P38 L4.3 Consider division of mesh sling for women with voiding dysfunction caused by mesh sling surgery **COMMENT** Just no. This is utter nonsense and uses no robust evidence to back it up. In the absence of evidence that is good quality or not at serious risk of bias then the decision on partial removals must come down to patient voice or clinical expertise or mesh removal surgeons with years of experience - neither of which NICE has asked for input until this draft guideline. Patient experience shows us a partial removal is catastrophic in the long term and although will at first show signs of improvement, women who have been recommended to have this option become worse after a few weeks or months. **P38 17 Managing bowel symptoms L5.1 For women who present with functional bowel disorders after mesh surgery for pelvic organ prolapse, follow the recommendations in the NICE guideline on**	**P38 L4.3** The recommendation referred to is about division not removal (either partial or complete). The committee acknowledges that overall the evidence available on the management of mesh complications was limited; however, the data included did clearly demonstrate that division of mesh can improve urinary symptoms. Division is a simple procedure which can relieve voiding dysfunction, which may be a very difficult condition for a woman to live with. Long term voiding dysfunction can lead to catheterisation, and so a woman may choose to have division of mesh. The clinical experts on the committee have training and expertise in and experience of mesh removal. **P38 17…. L5.1** We do not state that women should be offered rectopexy, a procedure is for rectal prolapse, which this guideline does not cover. Despite a robust search, no data was available on the management of bowel complications

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				faecal incontinence in adults or locally agreed protocols for obstructed defecation. **COMMENT** Are we stuck in some kind of dystopian fiction? How is offering more mesh (rectopexy) to a woman already suffering mesh complications going to work? Just no. Bowel complicaiotns must NOT be fixed this way **L5.3 Explain to women with bowel complications directly related to mesh placement that complete removal might not be possible** **COMMENT** Why is NICE still recommending mesh if it cannot be removed. **P 38 The outcomes that matter most** **COMMENT** The NICE recommendations have not mentioned pain. Calling it all adverse events dilutes the daily nightmare of women who live in constant pain from a simple operation that was supposed to heal them but instead has harmed them.	associated with mesh surgery; however the committee agree that any management requires expertise and it is therefore important that these women are referred to an appropriate centre. **L5.3** Throughout this guideline we have developed recommendations which we believe provide women with a choice about their individual treatment, and mesh surgery is one of these options. The committee would like to point out that very few surgical procedures are reversible, and that this is not unique to mesh surgery. **P 38** All the review protocols (which are part of the published evidence) list pain in the complications section as either a critical or an important outcome. We agree that pain is a serious complication and different women suffer different levels of pain. We hope that the current recommendations will reduce the risk of women

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				P39 29 The quality of the evidence Overall the quality of the evidence from the six cohort studies included for the five reviews was very low **COMMENT** If quality of evidence is over all very low then how on earth can NICE recommend anything. My comment to this is that they msut now instead wholly listen to patient voice.	developing adverse events such as pain in the future and that, if they do, it will be managed quickly and appropriately. **P39 29** We acknowledge that the available evidence on the management of mesh complication is limited; however, recommendations are made using the evidence available and by informal consensus of the committee members. The committee included clinical experts with extensive experience of mesh surgery and mesh removal surgery who provided expertise on this topic. In addition we have lay members on the panel and their input and experience was valuable in developing the recommendations. The committee is very aware of patients' concern about mesh and the management of mesh complications, and throughout the guideline development process the committee have listened to patient views and taken these into consideration. The development of NICE guidelines is an open and transparent process and all experts and members of the public have the opportunity to register as stakeholders. These stakeholders are invited to comment during

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					the consultation period, to provide input with their expertise or experience.
				P40 1-3 Benefits and harms The limited available comparative evidence was observational in nature, mainly retrospective, of very low quality and limited to a short follow-up of one year and so could not support strong recommendations. **COMMENT** Yet again more admissions that evidence is shockingly poor.,. In which case listen to patient voice The committee based the majority of the recommendations on their expertise and experience and developed them by consensus. I am appalled by this. It should have included patient voice for the original recommendation not just guess work.	**P40 1-3** We acknowledge that the available evidence on the management of mesh complication is limited; however, recommendations are made using the evidence available and by informal consensus of the committee members. The committee included clinical experts with extensive experience of mesh surgery and mesh removal surgery who provided expertise on this topic. In addition we have lay members on the panel and their input and experience was valuable in developing the recommendations. The committee is very aware of patients' concern about mesh and the management of mesh complications, and throughout the guideline development process the committee have listened to patient views and taken these into consideration. The development of NICE guidelines is an open and transparent process and all experts and members of the public have the opportunity to register as stakeholders. These stakeholders are invited to comment during the consultation period, to provide input with their expertise or experience.

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				P40: 28 The committee recognised that although removal of synthetic mesh may be the preferred option for some women who experience mesh complications, the evidence was not enough to recommend its use as a first-line treatment as a matter of course. To support shared decision-making women need to to be informed of the possible risks and benefits of mesh removal surgery so that they can make an informed choice. **COMMENT** How can women make an informed choice when there is not the decent quality , unbiased evidence to make a fully informed decision. In the absence of this and noting that this is a permanent device not meant to be removed, NICE should recommend that all pelvic mesh is banned as there is no guaranteed fix when women suffer. Partials are not the solution either. Financially NICE may see this to be so but patient voice tells us in the long term it is more costly in financial terms and it is much worse for the woman	**P40: 28** We acknowledge that the available evidence on management of mesh complication is limited; however, the process of developing these guidelines uses robust methodology, producing systematic reviews and meta-analysis that are considered the highest form of evidence for clinical research. The recommendations in this guideline have been developed using the evidence available, expert opinion and patient views. Throughout the process the committee have been aware of patient concerns; however, the committee believe women should have a choice about their treatment. Although we acknowledge evidence is limited, the committee agree that women should be given as much information on the potential risks and benefits which is currently available to them.

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				who suffers again a few weeks or months down the line. **P41: 6 Management of vaginal complications. All the women in the included case series studies had unsuccessfully received conservative treatment before having surgery to resolve the complications.** **COMMENT** NICE must not recommend conservative treatments that don't work like oestrogen cream. Women suffering mesh complications must have the option to ask for full mesh removal at the earliest discovery of suffering mesh complications. There is a paucity of evidence to show cream works so why offer it P41: 40 **For mesh inserted to resolve prolapse or abdominally-placed mesh, the committee agreed that attempting the complete removal of mesh carries with it the inherent risk that prolapse will recur because of the lack of organ support.** **COMMENT**	**P41: 6** The committee agrees with this comment about mesh extrusion, and have modified the recommendation. However for mesh exposure, where the mesh is visible but is not extruding out of the epithelium, oestrogen cream may be appropriate. If a woman has mesh exposure, but no other symptoms, she may not want to have a surgical procedure, and she may wish to use a topical treatment. The committee believe that women should have a choice. **P41: 40** The committee agrees that some women would prefer to run the risk of having recurrent SUI or POP following mesh removal, but others may not. These guidelines have been developed to ensure women are provided with as much information as is currently available, so that they can make a fully informed choice about their own care. In addition,

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				The shocking thing is that women are prepared to put up with POP or SUI rather than the hideous pain of a mesh complications. It is very hard to get across to NICE, Cochrane, surgeons, anyone not suffering just how intense and life changingly awful this pain is. Please listen to us. The pain is so horrible women are prepared to put up with POP or SUI rather than suffer. **P42 5 Management of sexual dysfunction and/or pain complications** **COMMENT** Women should have the opportunity of a mesh removal because of loss of sex life at the earliest opportunity even if they are not presenting with a mesh erosion	for social and/or psychological reasons a woman, once fully informed on all the options available to her, may still choose to have surgery with mesh. To not have this option available, would disadvantage these women from the most appropriate care. **P42 5** The committee agrees with this comment to some extent and have amended the recommendation to state "consider non-surgical treatments". The committee believe it is important to consider all potential causes of dyspareunia or pain initially because discomfort may not always be due to mesh, and many other causes may contribute to pain. The recommendation goes on to state that women should be referred if the symptoms does not respond to initial management. However the recommendations do clearly state that if the pain is likely to be related to mesh, the woman should be referred to a regional MDT. The

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					recommendations do not state that a woman cannot have her mesh removed.
				P42 28 Management of urinary complications **COMMENT** Women should have the opportunity of a mesh full removal at the earliest opportunity. Partials are not acceptable	**P42 28** We acknowledge that the evidence available was limited; but it did not show any significant detrimental effects from partial removal. The committee believe it is important that women have a choice because in some cases partial removal is more appropriate than complete removal.
				P43: 11 Bowel complications **COMMENT** As already outlined above women with bowel complications from mesh must not be offered more mesh (rectopexy) as standard. Many women develop allergic foreign body reactions. Putting in more mesh will just make things worse. Research is just beginning into the plastic that says it can cause auto immune conditions in those already suffering allergies. http://www.cambstimes.co.uk/news/plastic-cups-mesh-sling-chris-dearmitt-jeremy-hunt-1-5525524	**P43: 11 Bowel complications** We do not state anywhere that women should be offered rectopexy, this procedure is for rectal prolapse, which this guideline does not cover. We thank the stakeholder for the interesting information on plastic research and the possible link to auto-immune disease; however, these news articles do not meet our inclusion criteria for our evidence reviews and so have not been included.

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				Other research says plastic should not be used in the human body. This body of research will only grow in time. http://www.cambstimes.co.uk/news/leading-canadian-professor-talks-on-links-between-surgical-mesh-and-auto-immune-diseases-1-5557890 It is noted the committee recognised there is a dearth of evidence . How sad then to recommend more mesh thus holding a woman up to potentially suffer more complications. **P43 37 Cost effectiveness and resource use The committee acknowledged the lack of clinical and economic evidence on the management of complications…and that the recommendations in this area may have resource implications, for example, more MDT reviews and individualised**	**P43 37** Our systematic search of evidence did not identify any relevant evidence on translabial scanning. Therefore, the committee made a research recommendation in this area.

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				treatment plans, more imaging such as CT or MRI scans **COMMENT** NICE has not recognised anywhere in this document the need for translabial scanning machines. Instead it notes an increased cost of CT or MRI scans from its recommendations, but these will not see mesh so it is a total waste of time putting women forward for CT or MRI at great expense. The only way to properly see mesh is the translabial scan. It uses the same machinery but just needs two extra transponders and some training time for staff. Currently the NHS only has translabial scanners in 2 of the 19 specialist centres. Women go to an additional private scanner in Lincolnshire and pay for their scan to save waiting in queues of up to 10 months on the NHS. I cannot believe the committee has not looked into or discussed the TL scans. They may say there is no evidence but the evidence is that you can see mesh on it whereas you cant on CT or MRI! Do you really need studies to prove this? PLUS the majority of this report is based on very low, low or a paucity of evidence so Im afraid saying no evidence to	

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				use TL scans won't wash. Patient voice says mesh can be seen on a TL scan. Why on earth has this not been recommended in this far reaching report. It is a very serious omission. In N Ireland and Wales there are no TL scanners making it even worse for women living here. TL scanners should be at all regional MDTs to cut waiting time for women. **P43 41 onwards The committee explained that timely treatment of these complications may improved outcomes and overall cost savings to the NHS, given that delays in appropriate management may result in worse problems needing more resource intensive management. Timely identification and appropriate management of mesh-related complications may reduce the overall burden of symptoms women experience and have a significant positive impact on their quality of life, especially as some mesh–related complications can last for many years and require expensive long-term management.** **COMMENT**	**P43 41** The committee reviewed available evidence identified using a systematic approach on effectiveness, risks, and cost-effectiveness and concluded that women should be given the opportunity to make a fully informed choice about their treatment. The economic analyses for UI and POP were conducted from NHS and Personal Social Service (PSS) perspective. They assessed the impact of health-related quality of life losses associated with all surgical complications using a generic EQ-5D measure which includes mobility, self-care, usual activities, pain/discomfort, and also anxiety/depression domains. The committee acknowledged that some women may experience long-term complications following all types of surgery for SUI and POP. Given the lack of long-

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				Mesh complications don't just last for many years. They last for life. They are costly to women's physical. emotional, mental and financial well being. It impacts on every area of life for the woman and her family. These are complications that may be eased with removal but all of us go back to a new normal. None of us ever go back to the women we were. It is unfair, on the basis of weak evidence, to keep offering mesh implants, that cost women and the NHS an absolute fortune in the long term.	term evidence where possible assumptions were made pertaining to the incidence of complications over the long-term follow up in order to capture the impact of such complications on costs and health-related quality of life over the long-term time horizon.
Stockport NHS FT	Guideline	4	2	MDT discussion of cases is to be applauded and we have no doubt that it enhances our patient care. However excessive discussion removes responsibility from the clinicians from planning and delivering treatment for patients that they have been trained to do and we believe that the discussions in the "local MDT" do exactly this. Surely it is more important that patients are seeing the right clinician first that is one that has experience and evidence of working in this field, who produces regular audit of their work, submits to national databases and submits their patients to national research trials in this area, subspecialty trained or not.	Thank you for your comment. The committee acknowledge that the MDT requires significant resource allocation but this introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance. In addition, referral pathways are likely to differ between trusts.

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				Organising regional MDT as well as local MDT involves job plan changes and co-ordination that most individuals will find difficult to deliver given the pressures on clinicians and managers. There is no guidance from NICE about how this is to be achieved and whether it is to be supported by administrative assistance given that most clinicians have had restriction to their sPA activity because of cost. Surely since NICE is concerned about cost-effective treatment and this financial implication this must be taken into consideration. Rather than another level of MDT discussion it would be preferable to have clear referral pathways for the tertiary management of -Prolapse repair where vaginal mesh is considered -OAB where Sacral neuromodulation is the next step -Urogenital fistulas	
Stockport NHS FT	Guideline	4	4-9	This essentially means that 'all' invasive procedures in Urogynaecology / pelvic floor surgery should first be discussed in MDT. This would mean a huge increase in the quantitative increase in MDT work, the quality of MDT is likely to suffer. Putting every prolapse through the MDT could run the risk of turning the local MDT into a mere tick box exercise.	Thank you for your comment. You are correct, as all invasive procedures would be discussed by the MDT. This is to ensure safeguarding of the woman. The committee acknowledge that the MDT requires significant resource allocation but this introduces an important safeguard in the care of women which we expect will improve women's experience and clinical governance.

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				The following suggestion may be considered instead: In primary prolapse treatment, MDT should be reserved for complex cases, such as: prolapse with concomitant incontinence / uterine prolapse where uterine conservation is necessary and procedures like Manchester repair or Sacrohysteropexy or sacrospinous-hysteropexy are being contemplated / cases that are high risk for surgery due to multiple co-morbidities where non-surgical methods have been unsuccessful, where colpocleisis is considered . It would be helpful to know if there has been any concern regarding individual practice of decision making for prolapse surgery. If so, then local clinical governance processes should be strengthened instead of increasing the work load on MDT. NICE should recommend that all units should audit surgical and non-surgical management of prolapse in their units. administrative work load and burden on the MDT. It is unlikely to improve the outcomes for the patients. By this unnecessary.	
Stockport NHS FT	Guideline	5	17	There are various Urogynaecologists in the country who have obtained adequate experience and expertise in managing complex pelvic floor	Thank you for your comment. The committee agreed that the regional MDT requires a clinician with sufficient skills and expertise to be recognized

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				problems, including recurrent incontinence / prolapse and mesh complications, but have not necessarily gone through the subspecialty training. It would be appropriate for them to be a part of a regional MDT. Hence, the recommendation should also include 'Urogynaecologist with adequate experience in managing complex problems / having skills equivalent to subspecialist'. Tools / methods can be devised to assess competencies of urogynaecologists taking part in Regional MDTs. Local (trust based) or regional models should be put in place for mentoring urogynaecologists if they are in the process of developing subspecialist equivalent skills.	as a subspecialist. Given that this is a guideline, the regional MDT would be able to appoint someone with equivalent experience.
Stockport NHS FT	Guideline	22	12-16	There are some cases like young women or women with high risk for anaesthesia, who can have other treatments but would prefer bulking agents despite the low efficacy. It may be worth re-wording the statement in the guidance and 'allow offering the Bulkamid procedure as a first line treatment with a warning of low efficacy'. Also, the results of LATITUDE are still pending. In case a woman had peri-urethral bulking as a primary treatment and was ineffective, further discussion in 'Local MDT' (and not necessarily the	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension,

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				Regional MDT) should be sufficient. Recurrence after bulking should not be treated in the same way as any case of recurrent incontinence after other procedures.	retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence. We are also only able to used published data, and so results from the pending trial LATITUDE could not be included
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	General	General	BAUS members have raised concerns regarding the composition of the guideline panel. The inclusion of only one Urological Surgeon is a shortcoming especially when there are three Gynaecologists on the panel. Members have also questioned why two gynaecologists from the same unit were included on the panel and feel that this constitutes significant risk of local bias.	Thank you for your comment. The recruitment of the committee was a transparent process whereby the proposed constituency of the committee was subject to stakeholder consultation. The recruitment process aims to bring the best clinical expertise and lay experience and in this case it happened that two gynaecologists from the same unit were the best candidates. The committee only included one urological surgeon because this guideline update included stress urinary incontinence and prolapse, and prolapse is predominantly treated by gynaecologists in the UK.
The British Association of Urological Surgeons	Guideline	4	16	1.1.2 "MDTs should include 2 urologists or urogynaecologists" – it would only be truly multi-disciplinary if at least one urologist and one urogynaecologist was present.	Thank you for your comment. The committee was of a view that 2 of either urologists or urogynaecologists would be sufficient and would satisfy the criteria for MDT.

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(BAUS) - FNUU					The committee want to be clear that more than one consultant with expertise in the management of urinary incontinence and pelvic organ prolapse are needed to ensure that full discussion of care takes place. The committee wish to remove the risk of one individual making decisions without full consideration from other specialists.
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	6	8	1.2 Data entry for all SUI / POP procedures should be mandated, not just those with mesh complications.	Thank you for your comment. We agree and have amended the recommendation to include data entry on all surgical procedures for stress urinary incontinence and pelvic organ prolapse.
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	8	20	1.3.12 Some of these questionnaires detailed towards the end have been absorbed by the ICIQ format; eg KHQ is essentially the ICIQ LUTS QoL and likewise the BFLUTS is now the ICIQ-FLUTS.	Thank you for your comment. We have amended this recommendation, the different questionnaires have been removed and replace with the term "*validated urinary incontinence-specific symptom and quality of life questionnaire".*
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	9	6-8	1.3.15 Agree - UDS does not need to be performed in SUI (based on RCT) but it does need to be performed in stress-predominant mixed UI – this seems to be based on poorly informed 'expert decision making' (page 18 evidence review A) which largely	Thank you for your comment. We have amended the recommendation to clarify that an urodynamic test should only be performed when stress urinary incontinence is not demonstrated before surgery in women with stress urinary incontinence or stress predominant mixed urinary incontinence.

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				discusses the value of UDS in SUI only (and does not adequately discuss stress-predominate SUI).	
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	10	11-14	1.3.21 This line needs amending as it suggests a woman with recurrent or persistent unexplained UTI should be referred as per the bladder cancer guidelines – the advice from those guidelines is to consider referral in those aged 60 and over.	Thank you for your comment. The recommendation you mention has been revised.
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	12	18-27	1.4.19 Review of all women using containment products in hospital clinics is not consistent with review recommendations for other patient groups. It would not be practical and would overwhelm most services. Perhaps these patients should be reviewed in primary care (similar to the recommendation for women on long term medications as recommended in 1.4.44) or opt-in to specialist review as per the recommendation for women with failed primary SUI surgery in 1.5.15.	Thank you for your comment. We have not specified where the review should take place. The committee were of the view that this would normally take place in primary care, but ultimately this would be up to local arrangements.
The British Association of Urological Surgeons	Guideline	15	19-20	1.4.35 The statement on Mirabegron appears out of date – we have been using this medication for some years now and the recommendation for its use,	Thank you for your comment. The use of Mirabegron was not in the scope of this guideline. Its use is covered by the NICE technology

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(BAUS) - FNUU				particularly in those unsuitable for anticholinergics or who have failed or not tolerated this class of drug, should be stronger.	appraisal referred to in the guideline. Please see recommendation 1.4.35.
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	21-22	22	All lines on page 22 1.5.2 – 1.5.8 Strongly disagree with differentiation of promoting retropubic over transobturator tape procedures. Song P, Wen Y, Huang C et al. The efficacy and safety comparison of surgical treatments for stress urinary incontinence: A network meta-analysis. Neurourol Urodyn. 2018 Apr;37(4):1199-1211. This is a network meta-analysis of 45 RCTs and 7925 patients which has assessed efficacy and safety of TVT, TOT, TVT-O, TVT-S, and Ajust (I recognise the limitations of including TVT-Secur data). • There were 44 studies which reported objective cure rate (7117 patients). Compared to TVT, TOT (and Adjust) had no significant difference in objective cure rate (whist TVTO and TVT-S had lower objective cure rates) • There were 18 studies that described subjective cure rate (2490 patients).	Thank you for your comment. The Song NMA is a recent well-conducted analysis and is discussed in the discussion section of evidence review E. The committee was of a view that it was important to acknowledge the study and explain why ESTER NMA was prioritised over the Song NMA for the transparency of process purposes. Thank you for highlighting the Gurol-Urganci paper, unfortunately as it is such a recent publication (late October 2018), it was not published in time to be considered as evidence in this review.

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				There were no significant differences between TVT, TOT, and TVT-O. • There were 20 studies (3200 patients) reporting the number of postoperative complication. Results from NMA suggested that there were no statistically significant differences existed between TVT and TOT (TVTO, Adjust and TVT-S) • A total of 16 studies had described the adverse event of the bladder perforation. TOT (TVTO and TVT-S) had a statistically lower bladder perforation rate compared with TVT. • 13 studies reported the adverse event of tape erosion - there were no significant differences between TVT and TOT (Adjust, TVT-S and TVTO). • In total of 22 studies were analyzed the postoperative urinary retention. The method of TVT-O appeared to exhibit a less postoperative retention compared with TVT (TVT-O: OR = 0.35, 95%CI	

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				[0.16, 0.74]). The other surgeries of TVT-S, TOT, and Ajust had no significant difference with each other. • There were 22 studies describing postoperative pain. No significant difference was observed concerning TVT and TOT. (TVT-S had the lowest pain risk) TOT had a superior efficacy and ranking the first place in both objective cure rate and subjective cure rate. Gurol-Urganci I, Geary RS, Mamza JB, et al. Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence. JAMA. 2018;320(16):1659–1669 • In this retrospective cohort study that included 95 057 women who underwent midurethral mesh sling insertion for stress urinary incontinence, the rate of sling removal was 3.3% at 9 years. • The 9-year removal risk after transobturator insertion (2.7% [95% CI, 2.4%-2.9%]) was	

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				lower than the risk after retropubic insertion (3.6% [95% CI, 3.5%-3.8%]; subdistribution hazard ratio, 0.72 [95% CI, 0.62-0.84]).	
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	22	12-16	1.5.12 Bulking agent should not have such a lowly place on the agenda- women should be offered all options plus the evidence and make their own decisions. In addition there has been recent presentation of a Finnish study (https://clinicaltrials.gov/ct2/show/NCT02538991) comparing Bulkamid to TVT with favourable results.	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence. TVT Versus Bulkamid®-Injections in Treatment of Stress Urinary Incontinence – NCT02538991. Data from this study has not been published and therefore was not accessible to be used in the guideline.

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The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	22	17-19	1.5.13 There is no evidence that lifelong follow-up after artificial urinary sphincter surgery is necessary in women. We do not offer lifelong follow-up for male AUS patients.	Thank you for your comment. We agree and have removed "life-long".
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	24	4-5	1.6.5 Pelvic imaging is important in the assessment of prolapse especially prior to vault surgery as size of uterus not always best assessed clinically and is an important factor in the decision making process.	Thank you for your comment. We agreed that it would not be necessary to routinely perform imaging to see if there is a prolapse. We were however aware that imaging would be useful in women with suspected pelvic mass. The committee did not feel any amendments to the recommendation would be necessary.
The British Association of Urological Surgeons (BAUS) - FNUU	Guideline	35	5-6	What is the evidence base for stating that partial mesh removal may be just as effective as total removal? This should be a research priority – a trial to answer this question is urgently needed.	Thank you for your comment. The committee acknowledges that the evidence on management of mesh complications was limited (evidence review L). The data generally showed little difference in pain between the procedures; however there was a possible benefit on some complications, for example stress urinary incontinence. We have made it clear the evidence was limited, and that this should be discussed with the woman. We agree with stakeholder that research into this is urgently required.
The British Association of	Evidence Review E	General	General	There seem to be a large amount of data redacted so it seems unfair that stakeholders and public are	Thank you for your comment. The redactions in the consultation version of Evidence Report E

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Urological Surgeons (BAUS) - FNUU				expected to make statements with missing information.	were due to the need to respect the confidentiality of some unpublished results. As per the NICE guideline manual, they were kept to an absolute minimum. The redactions will be removed in the final published version of the guideline.
The British Association of Urological Surgeons (BAUS) - FNUU	Evidence Review E	75-81 and 579 - 595		Pages 75 to 81 and Forest plots P579 to P595 do not adequately indicate difference between retropubic and transobturator in Continence-specific health-related quality of life, Adverse events, Complications, Change in continence status, Patient satisfaction/patient-reported improvement or Repeat surgery.	Thank you for your comment. In addition to the evidence and forest plots you've highlighted, the committee also used the results from the NMA when it came to comparing between different treatment options. So whilst it might not look like there are adequate differences between the retropubic and transobturator surgery, the NMA indicated there were.
The British Association of Urological Surgeons (BAUS) - FNUU	Evidence Review E	110 – 111	26-33 27-42	Large amount of redacted statements, especially as retropubic favoured by committee due to network meta-analysis (NMA) that is not visible. Also it is not clear why NICE has placed emphasis on NMA, and not followed GRADE recommendations on interpreting quality of NMAs. Confidence in effect of differences likely to be low based on NMA as there appear to be no consistent differences in the tables and FPs outlined above. "The committee agreed that the increased risk of perioperative bladder injury from the use of a retropubic mesh sling, compared to a transobturator mesh sling, does not provide a	Thank you for your comment. The committee acknowledged the difficulty posed to stakeholders due to the redacted text. However, due to the confidentiality issues, NIHR HTA could not be fully disclosed to the stakeholders during the consultation phase. However, the findings will be fully disclosed in the final NICE guideline and will make it clearer to the stakeholders how NICE guideline committee reached their recommendations in this area. There are a number of approaches for assessing the quality, or confidence in outputs derived from NMA that have been proposed. The strengths of these

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				substantive reason to prefer the transobturator route because the injury is usually straightforward to manage clinically and does not cause long-term problems." We do not know this. We do not know if bladder erosions are more common in patients who have had a bladder perforation during retropubic insertion – this seems to be a biased statement.	approaches and their application to guideline development are currently being assessed by NICE.
The British Association of Urological Surgeons (BAUS) - FNUU	Evidence Review E	111	6-13	"It is standard practice to perform cystoscopy to look for bladder injury during the insertion of a retropubic synthetic mesh sling (but not during insertion of transobturator mesh slings) and that its increased risk may be partly due to detection bias." Cystoscopy post TOT is standard practice nowadays – the increased risk is unlikely to be due to selection bias and more likely to be due to route of placement. "The committee also discussed the difficulties in completely removing transobturator mesh sling and agreed on the basis of their knowledge and experience that it was much harder to remove than synthetic mesh inserted via the retropubic route (especially if the vaginal portion of the transobturator mesh sling has been removed)."	Thank you for your comment. We are sorry that you find the statement biased. The statement you highlight reflects the discussion that the committee had and represents one side of the argument. We hope that you found the concluding remarks of this section and the recommendations that were made unbiased. 'Taking this and the evidence in to account, the committee acknowledged that there are clinical situations in which surgery via the retropubic space should be avoided and therefore agreed that provision for this should be made in the recommendations.'

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				This seems to be a biased statement also – there is no evidence to support this assertion.	
The Pelvic Partnership	Guideline	General	General	Thank you for inviting us to review this guideline. Overall this looks like a well thought through and woman-centred guideline.	Thank you for your comment.
The Pelvic Partnership	Guideline	17	13	Recs 1.4.46, 1.4.47, 1.4.48	Thank you for your comment. We are not clear about your comment.
The Pelvic Partnership	Guideline	21	6	1.5.3 This is vague – what are the complications? Suggest a short bulleted list of the key complications would be helpful here	Thank you for your comment. The recommendations state that the risks and benefits, long-term adverse events, differences in procedures and social and psychological factors should be discussed with the woman. In addition, the recommendations specifically state that the discussion of all procedures, whether available locally or not should be discussed using the NICE patient decision aids, which will assist shared decision-making.
The Pelvic Partnership	Guideline	26	12	1.7.10 This seems an odd recommendation – why would these women be offered surgery for something they don't have?	Thank you for your comment. The committee were aware that some women would be offered surgery to prevent UI at the time of prolapse surgery. The committee reviewed the evidence and there was insufficient evidence to support offering preventative UI surgery along with prolapse

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					surgery, therefore this recommendation was made and will remain
The Pelvic Partnership	Guideline	26	25	1.7.13 This is not very clear. How could the woman be offered a procedure that is not available. Is this because a woman might have heard about a procedure and requested it from a surgeon who doesn't do the procedure, or because the surgeon might be aware of a different surgery that they do not undertake. In this case are they able to assess appropriately that a woman's condition is suitable for the alternative intervention?	Thank you for your comment. The committee were aware that it may be the case that women are not offered alternative treatments if the consulting surgeon cannot perform them. Therefore, this recommendation was made to ensure women are able to access all procedures. We do not agree that a consultant cannot provide information on a procedure they do not undertake themselves. A trained individual should still be aware of the other treatment options available for the woman, even if they themselves do not undertake the surgery.
The Pelvic Partnership	Guideline	26	27	1.7.14 Should this list include discussion of the benefits, risks and alternatives to the mesh surgery?	Thank you for your comment. This recommendation is specifically about what to do if mesh is used.
The Pelvic Partnership	Guideline	27	4	1.7.15 Should this explicitly include discussion of benefits, risks and alternatives to the surgery?	Thank you for your comment. The committee agree and have added the need to discuss risks and benefits.
The Pelvic Partnership	Guideline	28	12	1.7.22 It is not clear to the lay reader what this procedure is	Thank you for your comment. We refer the reader to "terms used in this guideline" and the glossary where there is an explanation of this procedure.
The Pelvic Partnership	Guideline	29	15	1.8.2 It seems odd to be offering surgery with such uncertianlty of its efficacy beyond a year. Is this	Thank you for your comment. The committee have amended this recommendation so that is a "consider" recommendation not "offer". The committee would like to draw the stakeholders'

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				really both cost effective and acceptable to women?	attention to the evidence review J on this topic. Pelvic organ prolapse surgery on its own was favoured over concurrent pelvic organ prolapse and stress urinary incontinence surgery on only one outcome, the resolution of storage symptoms. There was one RCT which reported outcomes longer than 5 years after surgery, which showed no difference between any outcomes for concurrent pelvic organ prolapse and stress urinary incontinence surgery, as compared to pelvic organ prolapse surgery alone. The committee noted that this combined approach may be preferred by women as they would only undergo one rather than two surgical procedures. Given the limited quality and quantity of evidence the recommendations are not prescriptive as to what surgery should be offered. Unfortunately, there was no evidence on the cost-effectiveness. However, the committee was of a view that performing both surgeries at the same time will result cost savings to the NHS i.e. only one preoperative assessment, one anaesthetic procedure, one recovery period, one admission, etc. There may also be benefits to women in terms of quality of life if they want to avoid the inconvenience of another surgical procedure.

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					Overall, concurrent pelvic organ prolapse and stress urinary incontinence repair may present a cost-effective strategy.
The Pelvic Partnership	Guideline	34	5	1.10.1 This sounds like it will be someone else's decision to undertake the surgery. Should it not be the woman who makes the final decision?	Thank you for your comment. The committee have reworded this recommendation to ensure it is clear that it is the woman who is making the decision.
The Pelvic Partnership	Guideline	35	13	1.10.4 After surgery would you offer the options that would have been offered before resporting to surgery ie physio etc? what is the post-operative support/care/treatment for women in this situation?	Thank you for your comment. The guideline recommends that women with recurrent symptoms are discussed at regional MDT before a decision is made.
The Pelvic Partnership	Guideline	37	25	1.10.16 This doesn't read well - -suggest "discus bowel complciations that are directly related to…..formulate an individualised treatment plan with women with bowel symptoms"	Thank you for your comment. We have reworded the recommendation.
University College London Hospitals NHS Foundation Trust	Guideline	General		Our stakeholder group would like to congratulate the whole committee on the production of a superb draft guideline. We would like to raise the following points for consideration:	Thank you for your comment.
University College London	Guideline	7	26	The draft guidance states 'If women have symptoms of urinary tract infection (UTI) and their urine tests positive for both leucocytes and nitrites,	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and

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Hospitals NHS Foundation Trust				send a midstream urine specimen for culture and analysis of antibiotic sensitivities. Prescribe an appropriate course of antibiotic treatment pending culture results'. The Public Health England 'Management of infection guidance for primary care for consultation and local adaptation 2017' states that patients can be treated with antibiotics on acute symptoms of UTI alone, in the face of three or more acute symptoms. We would suggest that the guidance should reflect the option of symptom-based treatment alone, in line with PHE recommendations.	cannot therefore amend the recommendations made in 2006 or 2013.
University College London Hospitals NHS Foundation Trust	Guideline	16	1-6	The recommendations in section 1.4 'Non-surgical management of urinary incontinence' do not reflect NHS England (NHSE) recommendations that all conservative and surgical options should be discussed with women. Thus, there is a lack of consistency between the NICE draft guidance and NHSE recommendations. The NICE draft guidance states that duloxetine should not be routinely offered as a first- or second-line therapy. We are concerned that by not offering all options, we will not demonstrate compliance with Montgomery principles with respect to consent.	Thank you for your comment. This relates to a recommendation which has not been updated. We have not reviewed the evidence on this, and cannot therefore amend the recommendations made in 2006 or 2013. Please note that the guideline will be accompanied by decision aids that will assist decision-making for women when they are considering the non-surgical and surgical procedures for stress urinary incontinence and pelvic organ prolapse.

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University College London Hospitals NHS Foundation Trust	Guideline	22	12-16	The recommendations in section 1.5 'Surgical management of stress urinary incontinence' do not reflect NHS England recommendations that all conservative and surgical options should be discussed with women. Thus, there is a lack of consistency between the NICE draft guidance and NHSE recommendations. We refer specifically to the recommendation that intramural bulking agents should not be routinely offered to women with stress urinary incontinence. We are concerned that by not offering all surgical options, we will not demonstrate compliance with Montgomery principles with respect to consent.	Thank you for your comment. In light of stakeholder comments, the committee have amended the recommendation from a 'do not offer intramural bulking agents' to a 'consider intramural bulking agents'. In addition to ensuring the woman has had explained to her that repeat injections may be needed to achieve efficacy and that efficacy is limited and diminishes with time, the committee added that the woman should know that the injectable materials are permanent, that efficacy is inferior to that of colposuspension, retropubic mid-urethral mesh sling and autologous rectus fascial sling and that there is limited long-term effectiveness and adverse events evidence.
University College London Hospitals NHS Foundation Trust	Guideline	27	15-26	The option of abdominal hysteropexy (open or preferably laparoscopic) using non-absorbable sutures is not noted as one of the options in the draft guidance. This is of particularly relevance to women who wish to conserve their uterus but are mesh-averse or wish to conceive. There are data supporting the short- and medium-term efficacy of numerous variants of this procedure in the literature, using uterosacral and sacral anchor points.	Thank you for your comment. The committee did not prioritise a review to look at the different type of sutures used across procedures.

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University College London Hospitals NHS Foundation Trust	Guideline	27	23	Vaginal hysterectomy (VH) is included as an option for the treatment of uterine prolapse but total laparoscopic hysterectomy (TLH) is not included in the draft guidance. Complete removal of the adnexae may be required or there may be a need for the assessment and treatment of other pelvic pathology. There are some cases where a vaginal approach may be hazardous (e.g. in the presence of large fibroids or if there is a high risk of significant adhesive disease). The draft guidance describes the need to provide adequate vaginal vault support at hysterectomy. Total laparoscopic hysterectomy with high uterosacral ligament suspension is another option for achieving adequate vaginal vault support after hysterectomy. Better ureteric visualisation at laparoscopy may reduce the risk of ureteric injury at the time of high uterosacral suspension. We would suggest that laparoscopic or abdominal hysterectomy with vaginal vault support should be included as options in the management of uterine prolapse. 'Vaginal hysterectomy' might be replaced by 'hysterectomy' with vaginal vault support to accommodate these surgical approaches.	Thank you for your comment. We did not look at different routes for hysterectomy and our evidence reviews only identified evidence or vaginal hysterectomy. Clearly there will be clinical situations where it is not possible to do vaginal hysterectomy and we would expect the clinician to choose the most appropriate route.

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University College London Hospitals NHS Foundation Trust	Guideline	28	19-25	We found this section a little difficult to understand and would welcome some clarifications. Line 24 highlights the importance of apical support, which confers the greatest influence on anterior prolapse dimensions, and is a critical part any assessment of anterior wall prolapse. This important part of the assessment is outlined in the section relating only to vaginal mesh insertion. We would welcome this recommendation being highlighted in the assessment of any anterior vaginal wall prolapse prior to surgery. Line 25 suggests that mesh repair should only be considered if an abdominal approach is contraindicated. We are unclear as to what this means. Paravaginal repair is an abdominal approach to anterior vaginal wall prolapse although this is not specifically referred to and not included as an option in the draft guidance or in the evidence review.	Thank you for your comment. The recommendation incudes a standardised method of assessment, and we would expect any trained professional undertaking this to understand the recommendation. We found limited data on paravaginal repair and therefore the committee did not think the evidence warranted a recommendation on this procedure.
University of Southampton	Guideline	12-13	11-27, 1-9	The guidance on absorbent containment products covers when products should be used and who should do the product assessment. However, little detail is provided on how the products should be selected. There is a wide range of products to choose from; each product group offers different advantages and potential harms for different users.	Thank you for your comment. We agree, but comparing the different products was outside of the scope of the guideline.

Urinary incontinence (update) and pelvic organ prolapse in women: management

Consultation on draft guideline - Stakeholder comments table
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				Product choice should be based on best available evidence. Women should be signposted to independent evidence based comprehensive advice. Although information is available on many websites, only the Continence Product Advisor (www.continenceproductadvisor.org) fulfils all those criteria. Women whose incontinence meets the threshold for NHS product supply should be referred to the appropriate community service.	
University of Southampton	Guideline	12-13	11-27, 1-9	The guidance does not give any indication on the range and number of containment products that should be offered in different circumstances. It is not clear whether or not all women experiencing long-term urinary incontinence should be provided with suitable containment products. Clarification of provision expectations are needed. If products are not being provided, advice on choosing between the wide range of products commercially available should be provided (as described above). Women should have access to more than one product type if required to meet their physical and lifestyle needs. Evidence-based tools should be used where available to guide women to their optimum product selection such as is available in the above website.	Thank you for your comment. We agree, but comparing the different products was outside of the scope of the guideline. A registered provider would have this detail available.

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University of Southampton	Evidence review H	11	25	Exercise and its effect on symptoms and consider use of support garments to reduce impact on the pelvic floor.	Thank you for your comment. We included V-brace in the protocol with the aim of reviewing available evidence on engineered support garments. No evidence was identified on these products and therefore, the committee were unable to make any recommendations about their use.
University of Southampton	Evidence Review H	19	20	V- brace (pants/underwear). We are concerned that this recommendation does not give companies incentives to create better improved support garments if there is only one named Brand on the guidelines. For example EVB Sport Garments are recommended by leading WH Physio's and Surgeons in Ireland and UK and across the world, are research backed, customer focused and keen to improve the lives of millions of women. The guidelines should read Engineered Support Garments or Research Backed Support Garments.	Thank you for your comment. We included V-brace in the protocol, and this was stated in the scoping document which went out for consultation prior to the guideline being produced. We did not identify any evidence on V-brace and as such have made no recommendation on their use, or any engineered support garments.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*