

National Institute for Health and Care Excellence
IP 660/2 Transvaginal mesh repair of anterior or posterior vaginal wall

IPAC date: July 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	1.1	<p>My main point would be that surgeons need to stop looking at anatomical outcomes and instead look at quality of life outcomes. They used to say mesh implants had a stronger, longer lasting anatomical fix - but PROSPECT has shown this to not be the case - see below - In addition we are not debating efficacy of outcome. We are debating the fact that this mesh can leave women in such debilitating pain that it is almost pointless them having had their prolapse fixed because what they are left with is something way worse.</p> <p>If a native tissue repair of a prolapse fails the woman is back to square one - if a mesh fails they could be left with severe ongoing pain, erosion, lost sex life, and difficulty walking. These risks are high and life changing . And no woman is warned properly of these risks.</p> <p>My concern is that even if POP mesh remains as a treatment option for the so called worse case scenario or last resort cases - even if you have a mandatory patient information leaflet with the risks on - a mesh proponent could still carry out a leading consent process where the risks are down played and thus a woman is unwittingly talked into having a mesh not truly knowing the risk. It would appear to be Russian roulette as to who suffers. After 2.5 years of running Sling The Mesh I can't point my finger at why certain women suffer and others don't.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee discussed evidence from the PROSPECT study as part of their deliberations. Section 1.1 of the guidance states that there are serious but well-recognised safety concerns and that evidence of long-term efficacy is inadequate in quality and quantity.</p> <p>Quality of life has been added to the list of research outcomes in section 1.3 of the guidance.</p>

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2	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	1.1	PROSPECT said of POP mesh surgeries "Augmentation of a vaginal repair with mesh or graft material did not improve women's outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term, but more than one in ten women had a mesh complication. Therefore, follow-up is vital to identify any longer-term potential benefits and serious adverse effects of mesh or graft reinforcement in vaginal prolapse surgery." Why is it Ok to admit mesh does not have any advantages over native tissue repairs long term then say - carry on with them but audit them - would it not be better to apply the precautionary principle and simply stop it - it is clear there are no advantages but only disadvantages in the long term.	Please respond to all comments Thank you for your comment. The Committee discussed evidence from the PROSPECT study as part of their deliberations. Section 1.1 of the guidance states that there are serious but well-recognised safety concerns and that evidence of long-term efficacy is inadequate in quality and quantity. Section 1.3 of the guidance states that further research should include long-term outcomes.
3	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	1	Mesh problems hit women of all ages, sizes, races, fitness levels - there is no clear reason as to why some suffer and others don't. The talk of obesity or smoking certainly does not ring true in my support group. So why would it be appropriate to allow a women with a severe prolapse to potentially fall victim to high risks when none of us can say for sure who or why some have problems.	Thank you for your comment. Section 1.2 of the guidance states that further research should include details of patient selection, long-term outcomes including complications, type of mesh used and method of fixation. Section 1.3 of the guidance states that further research should include long-term outcomes.
4	Consultee 1 NHS Professional	General	I have no concerns about the revision, process, or conclusions. However, with an update to CG171 planned to include prolapse, I'm a little surprised that this IPG went ahead - or at least that it didn't make reference to the update (albeit that it's not planned to publish until 2019)	Thank you for your comment. The committee are aware of the guideline update and this IP guidance will be taken into account by the guideline committee. The planned update to the clinical guideline will be referred to in the overview. A committee comment has been added to section 6 of the guidance, noting the planned update to CG171.

5	<p>Consultee 2 Specialist Adviser British Society of Urogynaecology</p>	General	<p>"The BSUG advisors for this document have reviewed the document and have 2 concerns:</p> <ol style="list-style-type: none"> 1. We feel that NICE should question a large cohort of "unselected"™ patients who have had mesh procedures as in other guidance. 2. We are concerned regards the comment "œœ Therefore, this procedure should only be used in the context of research"œœ. <p>Although there is much public debate currently and some of the Nice medical advisors on this guidance maybe involved in these aspects and hence have strong feelings, this is an established procedure and guidance exists in the Schenir report and the Scottish review. Indeed the NHS England review is about to be produced (July).</p> <p>This statement appears at odds with the current European and Scottish advice and it will be rather awkward if it also contradicts NHS England advice.</p>	<p>Thank you for your comment.</p> <p>If this comment refers to the patient commentaries, then NICE's Public Involvement Programme has followed the usual process for the Interventional Procedures programme, in line with the programme manual. Questionnaires were sent to NHS trusts for distribution to patients who had the procedure. When NICE received the completed questionnaires, these were discussed by the committee.</p> <p>The NICE Interventional Procedures programme is not able to identify and question a large cohort of patients who have had this procedure. This could be done as part of the research suggested in the guidance.</p> <p>The committee were aware of the report from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) when they agreed this guidance. The SCENIHR recommendations are summarised in the 'Existing assessments of this procedure' section of the overview.</p> <p>The committee were also aware of the 2017 Scottish review findings, which stated: 'In the surgical treatment of POP, current evidence does not indicate any additional benefit from the use of transvaginal implants (polypropylene mesh or biological graft) over native tissue repair. Transvaginal mesh procedures must not be offered routinely.'</p> <p>The committee were also aware of the NHS England review, and the NHS England advice is summarised in the 'Existing assessments of this procedure' section of the overview.</p> <p>The review of this guidance was in part initiated by these reports and the NHS England working group.</p>
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6	<p>Consultee 3</p> <p>Lead Urogynaecologist and Honorary Senior Clinical Lecturer</p> <p>NHS Professional</p>	General	<p>Conclusions: At 7 years follow-up the composite success rate of trocar-guided mesh insertion appeared to be equal to native tissue repair in this group of patients with a history of recurrent POP. Although the mesh exposure rate was extremely high, we found no difference in pain rate or dyspareunia between the two groups. Since the composite success is considered the most relevant clinical outcome and since it appears equal at 7 years follow up in either group of patients with recurrent POP (around 60%), we consider the harm/benefit ratio unbalanced. Alternative (non-mesh) treatments, including non surgical, should seriously be considered.</p> <p>Clinical trial registration: NCT 00372190</p> <p>Important to mention that the vast majority of the evidence relied upon in this IPG relate to devices that no longer exists due to relabeling by the manufacturer (e.g. Johnson & Johnson Gynemesh), collapse of the manufacturer (e.g. AMS Perigee, Apogee and Elevate), withdrawal by the manufacturer (e.g. Prolift, Prolift M and Prosima) or alert/recall by a regulatory body (e.g. Boston Scientific Pinnacle).</p> <p>Important to clearly state that, in general, there may be no benefit from prolapse mesh or, at best, the risks outweigh the benefit, at least currently while awaiting long-term results.</p> <p>Please note the long-term results of the largest RCT in patients with recurrent prolapse is now published as abstract (attached). The complication rate was quite high and the use of mesh did not offer any additional benefit over native tissue surgery. The full publication is underway.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview, unless they contain important safety data. The committee noted that the full publication is underway. A published peer-reviewed study will be considered for inclusion in any future update of this guidance.</p> <p>Section 6.4 of the guidance already states that 'Randomised controlled trial data showed no added benefit of using mesh compared with native tissue repair.'</p>

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7	Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer NHS Professional	General	"â€¢ Reiterate the importance of following the IDEAL collaboration guidance. Due to serious risks associated with these medical devices, suggest no further research into new devices or materials until there is proof of concept that insertion of vaginal implants (as a class of devices) reduces the risk of recurrence of vaginal wall prolapse in primary and/or secondary prolapse. Such information will be available with the publication of 5 year results of PROSPECT."	Please respond to all comments Thank you for your comment. The 2-year results of the PROSPECT study have recently been published, and the 5-year results are not yet available. The Committee discussed evidence from the PROSPECT study as part of their deliberations.
8	Consultee 4 on behalf of the Guidelines Committee RCOG	General	It would be important to note that a thorough review on tapes and meshes was published in Scotland a couple of months ago (http://www.gov.scot/Resource/0051/00515856.pdf). It would be helpful if the document could clarify from the outset that it refers to mesh inserted vaginally and that it excludes management of vault prolapse. The current title and introductory notes are unclear in that respect.	Thank you for your comment. The committee took the Scottish review into account and the conclusions of the final report are summarised in the 'Existing assessments of this procedure' section of the overview. The title has been changed to 'Transvaginal mesh repair of anterior or posterior vaginal wall prolapse.'
9	Consultee 4 on behalf of the Guidelines Committee RCOG	1.2	National databases should be established to record this information	Thank you for your comment. The recent NHS England review recommended 'Strengthening clinical leadership and, in doing so, improving rates of reporting of adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA), and submissions to the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) databases.' The recommendation in this guidance is for research only, so the procedure should only be done under research governance. The committee could not make a specific recommendation about submission of routine clinical data to a registry.

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10	Consultee 4 on behalf of the Guidelines Committee RCOG	2.1	Great to start with description of condition but would welcome clearer definitions of: Urethrocele, cystocele, rectocele and enterocele	Thank you for your comment. Section 2.1 of the guidance has been changed.
11	Consultee 4 on behalf of the Guidelines Committee RCOG	2.2	Would welcome clearer description of what the following are: - ring - shelf pessaries - colporrhaphy (explained later in 3.1, so would be good to move description up to 2.2) - paravaginal	Thank you for your comment. Section 2 is intended to be a brief description of the current treatments. Colporrhaphy is described in detail in section 3 of the guidance.
12	Consultee 4 on behalf of the Guidelines Committee RCOG	2.3	Clear and helpful; and good to see reference to Ehlers Danlos Syndrome	Thank you for your comment.
13	Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer NHS Professional	3.1	"3.1 Surgical repair with mesh involves removing some of the stretched tissue if needed". Factually incorrect statement. No tissues should be removed if mesh is to be inserted. Removal of tissues can lead to tension on suture line which, in turn, can cause complications e.g. erosion."	Thank you for your comment. The Committee was advised that tissue is removed in some patients.
14	Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer NHS Professional	3.2	"3.2 The procedure is usually done with the patient under general anaesthesia. Replace 'usually' with 'mostly'. In fact, mesh repair is very rarely done under local anaesthesia."	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
15	Consultee 4 on behalf of the Guidelines Committee RCOG	3.2	Would welcome definition of: - fascia - levator ani	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

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16	<p>Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer</p> <p>NHS Professional</p>	3.3	<p>"3.3 'although trocar introducers can also be used without direct visualisation'.</p> <p>Remove the sentence as trocar "guided mesh kits are not available any more.</p> <p>'or the whole vagina may be surrounded by mesh ('total mesh' technique)'.</p> <p>Remove the sentence as "total mesh"™ technique is not done anymore as the total mesh devices are not available any more.</p> <p>"</p> <p>"Mesh repair is theoretically suitable for any degree of symptomatic anterior or posterior vaginal wall prolapse'.</p> <p>Factually incorrect statement as mesh should not be used in Stage I (mild) as it is unnecessary. It should not be used in Stage IV (advanced) as too risky (erosion due to unhealthy skin) and less efficacious in addressing the central compartment prolapse that is invariably present in advanced vaginal wall prolapse.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Section 3.3 of the guidance has been changed.</p>
17	<p>Consultee 4 on behalf of the Guidelines Committee RCOG</p>	3.3	<p>Would welcome definition of:</p> <ul style="list-style-type: none"> - trocar introducers 	<p>Thank you for your comment.</p> <p>The Committee considered this comment but decided not to change the guidance.</p>

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18	Consultee 4 on behalf of the Guidelines Committee RCOG	4	There are no references for the articles quoted. Does this information include the most up to date studies on mesh procedures? Glazener, C. M. et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel group, multicentre, randomised, controlled trials (PROSPECT). Lancet 389, 381–392 (2017) Morling, J. R. et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study. Lancet 389, 629–640 (2017)	Thank you for your comment. All the references are cited in the overview. The guidance states in both the safety and efficacy sections ‘For more detailed information on the evidence, see the interventional procedure overview.’ The studies cited by the consultee are both included in table 2 of the overview.
19	Consultee 4 on behalf of the Guidelines Committee RCOG	4.1	I think the reference to ‘something coming down’ is helpful	Thank you for your comment.
20	Consultee 4 on behalf of the Guidelines Committee RCOG	4. Efficacy whole section	I would have to spend some time looking at the data and remembering my stats training to figure out the research findings! Is there a way to present the findings with the same statistical rigour but summarise data in simple terms?	Thank you for your comment. The guidance document provides a summary of the research evidence, a more detailed presentation of the data from each included study is provided in the overview document.
21	Consultee 4 on behalf of the Guidelines Committee	5	Again citation of references required	Thank you for your comment. All the references are cited in the overview. The guidance states in both the safety and efficacy sections ‘For more detailed information on the evidence, see the interventional procedure overview.’
22	Consultee 4 on behalf of the Guidelines Committee RCOG	5. Safety	The description of the findings was much easier to read than section 4 above. I think it’s because they seem to summarise the findings in a sentence at the beginning of the paragraph.	Thank you for your comment.

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23	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	5	<p>From 2006 to 2016 only 380 adverse POP events were reported to the MHRA that does not mean there were only 380 problems in 10 years - it means surgeons are NOT reporting adverse events. A study by Duckett et al shows only 27% surgeons report all their complications to the MHRA database https://link.springer.com/article/10.1007/s00192-016-3217-z</p> <p>PLUS There are no prolapse removal codes so there is no audit of POP mesh removals anyway - the code is being introduced October 2017 - talk about shutting the door after the horse has bolted</p> <p>FDA has raised POP mesh to high risk in America</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Section 5 of the guidance reports the rate of mesh complications from several large randomised controlled trials and cohort studies.</p> <p>A recommendation to report adverse events to the MHRA has been added to section 1 of the guidance.</p>
24	Consultee 4 on behalf of the Guidelines Committee RCOG	6.1	<p>Interesting, but what is the relevance of this for women making decisions on whether they go for mesh implants or not?</p>	<p>Thank you for your comment.</p> <p>The committee comments section aims to highlight any important issues with regard to safety and efficacy that have not been addressed elsewhere in the guidance.</p> <p>The committee considered that it was helpful for health professionals using this guidance to note that different materials are in use and that newer ones have been developed.</p>
25	Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer NHS Professional	6.3	<p>"6.3 'Removal of mesh can be technically difficult, should it be needed'.</p> <p>Would add "it is very difficult or impossible to safely remove the mesh device in its entirety"TM.</p> <p>It could be even more difficult to remove than the Single-Incision Short Mesh Sling (recommendation 1.1 in the relevant recent NICE IPG)."</p>	<p>Thank you for your comment.</p> <p>Section 6.3 of the guidance has been changed.</p>

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26	Consultee 3 Lead Urogynaecologist and Honorary Senior Clinical Lecturer NHS Professional	6.4	"6.4 'Randomised controlled trial data showed no added benefit of using mesh compared with native tissue repair'. I would add "in both in primary or secondary/recurrent prolapse".	Please respond to all comments Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

27	Consultee 5 Patient	General	<p>Re Surgical Repair of Vaginal Wall using Mesh</p> <p>Dear Sirs, Having pulled out the previous correspondence on this topic in 2008, I can find no reference number but I have letters from [REDACTED] and [REDACTED].</p> <p>The latest versions of NICE GUIDANCE reflects more of the uncertainty and risks of this procedure. None of the studies follow up over a long enough period of time. It is known that, over time, some synthetic meshes break down into fragments [my mesh, removed in 2008, was in about 5 pieces]. The only study that proposed to follow patients over a reasonable period was one outlined by the French -- clinical trials identifier NCT00153257. None of the studies that you mention do any follow up to 5 years or even 3 years.</p> <p>My experience --- Mesh was inserted in 2004 at [REDACTED] Hospital. Trimmed in 2005 and 2006 " " " " Removed at [REDACTED] Hospital in 2008.</p> <p>You should have the earlier history on record. However the day that I was due to be admitted at [REDACTED], no bed was immediately available, so I lay on the floor of the reception area because it was the least painful position, all the pain relief I was allowed having little effect.</p> <p>I would like more stress put on having time to absorb written and verbal information BEFORE signing a consent form inserted into 'Your Responsibility' section AND THAT ALTERNATIVE NON MESH SHOULD BE OPTION OFFERED.</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. They note your statement that mesh has had a devastating effect on your life, and in particular that you had to have the mesh removed and that you have experienced extreme pain over a long period.</p> <p>This guidance recommends that this procedure should only be used in the context of a research study. This should include a detailed fully informed consent process.</p>
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			<p>Audit should also be stressed more -- and record kept of those who are re-referred with problems</p> <p>It seems likely that only lawyers have information on frequency of some problems -- studies do not include relevant questions.</p> <p>Mesh has had a devastating effect on my life -- The only effective pain relief is cortico steroid injected into the focus of pain in the vaginal wall. It is not easy to do effectively and has to be spaced at 16 week intervals [and I yell]. Other medication has to be used as effect wears off and I also wear a TENS machine [not at night since I burnt one out].</p> <p>In 2011 I moved into supported sheltered accommodation.</p> <p>The past 3 months have been particularly difficult as the syringe came apart and I did not get full dose of cortico-steroid -- I do not like being reduced to tears in public but it has happened -- and I have had to cancel even the activities I can still manage when injection works.</p> <p>My current consultant has told me it is getting more difficult to treat me and has arranged for a colleague consultant to join him when I am seen on 18th.</p> <p>Closing date for this submission is 17th!</p> <p>Apologies if this is not set out well -- But if you have questions please ask.</p> <p>Regards [REDACTED].</p>	

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28	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	<p>Finally I would like to ask NICE how did the NHS allow Prosima to be implanted / was there any robust audit with this? Prosima included a Vaginal Support Device which was a triangular piece of plastic stitched into place once the Prosima mesh was fitted . It was left in the vagina for 4 weeks. Then a balloon was inflated and inserted into the vagina for 2 days - in theory to help hold the prolapse mesh in place. The VSD remained for 4 weeks - all this against a freshly stitched wound. Leaving a device in the vagina for 4 weeks with the risk of infection is insane.</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2253712/pdf/bjo0115-0391.pdf</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The NICE Interventional Procedures programme produces guidance on procedures rather than specific devices. It does not regulate device use in the NHS. The cited study was not included in the overview because it is a case series with fewer than 100 patients.</p>
29	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	<p>Sling The Mesh Survey:</p> <p>153 out of 175 women were told their mesh had nothing to do with their pain (SUI and POP mesh women took part) I include this as there will be many women suffering POP mesh pain and complications who have been fobbed off who wont show up in any stats or databases</p> <p>The rest of my submission follows with case studies of women who remain anonymous. They give a clear indication of the impact that prolapse mesh complications have on a woman's quality of life.</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure and note the findings of your survey.</p> <p>A committee comment has been added to section 6 of the guidance, in response to the submitted case studies.</p>

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30	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	<p>CASE STUDIES</p> <p>Case study one</p> <p>I had surgery in 2009 - for vaginal prolapse, rectocele and mild bladder issues. I had the Ethicon Prolift mesh. Severe issues from day one. I live in chronic pain. I have paralysis of the lower bowel, rectum, severe digestive/motility issues, I have to use the Peristeen kit every day as I no longer have the use of my bowel/rectum. My vaginal prolapse is now severe. The scar tissue pain is debilitating. Vulval, pubis, clitoral, chronic pain - every day, all day. The rectal prolapse is severe. My incontinence issues are much, much worse now. I have severe nerve damage, fluctuating shooting pains, stabbing pain, razor type pain and recently, my left side is becoming much worse, to the point where I have had days of only being able to drag my leg along due to frozen areas and chronic pain. My immune system has been severely affected, with more issues arising with each year that goes by. Mobility has been severely affected, and my life now revolves around my home, sitting, standing, sleeping - all a huge challenge for me now.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.</p>

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31	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	<p>Case study two</p> <p>I had prolapse mesh surgery for both vaginal and rectal issues in April 2009, with serious signs of damage and pain beginning while still in hospital. I have been left with far worse levels of prolapse, 24/7 chronic pain, paralysis of my lower bowel, rectum, no gut motility, am no longer able to consume solid food, new ongoing immune issues, severe nerve damage and have serious difficulty with movement, sitting and sleeping. This surgery has destroyed so much of my life. My relationships, who I was. What I was able to do and my plans for my later years. I live like a recluse now, seeing very few people. I have to reduce my food down to babyhood now. At nearly 55 years of age, no longer able to walk for lovely long stretches of time as I once did, no more hours of yoga in the mornings, no more joy in cooking. No intimacy anymore. I think i've gone past most of my initial anger somehow, somehow. The surgeon told me that in no way could my issues be anything to do with the mesh, making me feel as though I was insane - it all comes together to affect you on every level of who you are. I have days where I just try to hold onto the 'me' I was and keep going. Keep telling myself that one day in the future this will be all on record as another global scandal of our time. That the daughters of our future will be spared from suffering from these procedures. One day at a time really. That's my life now.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.</p>
32	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	<p>Case study three</p> <p>The surgeon cut the mesh to fit as there were no kits in 2005. I now have an erosion and part of the mesh expelled itself. Now waiting for the rest to be removed. I wasn't aware of all the side effects but I have been left with numbness following the operation in 2005. I also now know that the recurring BV infection is down to the mesh eroding my vagina wall.</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.</p>

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33	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study four I had mesh, that I was unaware of, for vaginal wall prolapse and my notes say 'mesh used as repair needed to large to do otherwise' and that is what caused the erosions that [REDACTED] had to repair the best she could.	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
34	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study five Had vaginal wall prolapse caused by rectocele as well as cystocele in 2008. The Avaulta Plus Mesh used for the back vaginal wall almost immediately Eroded. Initially oozed so much pus that consultant thought it was urine !! . Consultant did not have a clue what to do about it at the time - telephoned his mate to ask for advice whilst I was in his office !	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
35	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study six I had the Mesh in 2011 it was successful but has now been giving me lots of UTI and pain had scan and referring to a consultant I constantly feel ill and like there is something wrong	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
36	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study seven I had posterior vaginal repair with Mesh. Also hammock to hold up Bowel! Mine lasted 5 yrs and over last year the symptoms are back, bloated beyond belief, pain in inner pelvis, hips, down legs, lower back and hammock Site! Recently hospitalised for non Bowel/Colon Evac for 13 days!! Pain was immense!	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
37	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study eight Pop sacrocolpopexy - sling fitted 2002. Trouble from start. Agony No one listened. Mesh pushed out through vaginal wall 2003. Despite several major removal ops between 2005 and 20013 still having major problems 15 years later and advised to have colostomy. Staged management process Peristeen colonic irrigation. When this fails to work they will fit ACE and after this eventually fails, colostomy. I had Ethicon Mercilene Mesh Sling	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

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38	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study nine I had mesh for anterior and posterior prolapses. Both done 2011. Went off work with hip pain in November 2013. Long story short, anterior mesh causing nerve pain, both groin areas. Removal (tho 5cm each side remains) a year ago yesterday. Now medically retired from nursing profession. Was senior theatre nurse for 23 years. Have moved house twice. Previous house had 2 sets of stairs which I struggled with, sold that and moved to flat. Now registered disabled and use crutches for walking. Living the life of timing painkillers	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
39	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study ten At 69 yrs bladder prolapse, cystocele fixed with MESH. 7 years excruciating pain and immobility in legs and pubis. Arm crutches now. I have help with pain management .At 76 awaiting long haul removal date - will I make it?	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
40	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study eleven Had mine for prolapse in December 2012, was told it would improve my quality of life. It has ruined my life. Not able to walk very far , in constant pain, now have fibro.	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
41	Consultee 6 On behalf of 'Sling the Mesh' Patient support group	General	Case study twelve I had mesh for prolapse in 1998 at the same time as a hysterectomy. The specialist told me he'd recently trained in this brilliant new technique using mesh and recommended it saying I would benefit from not needing further surgery in future. He predicted that I would develop bladder prolapse problems within a couple of years if he did not do something then to help. I had a procidentia and think I had a rectocele at the time. When [REDACTED] removed the mesh in 2015 she said it looked as if he had tried to achieve several things at the same time with the mesh. My mesh symptoms - Leg, foot and groin pain/cramp abdominal cramps and bloating vaginal pain/burning Pelvic/hip pain buttock pain Kidney/low back pain Feeling low and frequently needing to empty bladder. UTI's but always told specimen negative when tested bowel - either constipated or the opposite and have to rush Pain - sitting, standing & walking for long Difficulty walking up or down an incline and on uneven ground Pain walking up/down stairs Difficulty getting to sleep and staying asleep due to pain Now diagnosed with fibromyalgia - generalised pain, brain fog, numbness and tingling in my hands and feet, sensitivity to pain, touch, smells, clothing - feels heavy like things are weighing me down, weakness in wrists & knees, mood swings, irritability, fatigue Eczema Jaw stiffness & clicking Low mood, depression and anxiety.	Please respond to all comments Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

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