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**Public Petitions Committee**  
**Comataidh nan Athchuingean Poblach**

**PE1517 - Polypropylene Mesh Medical  
Devices**



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# Public Petitions Committee

The remit of the Public Petitions Committee is to consider and report on - whether a public petition is admissible; and what action is to be taken upon the petition.



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# Committee Membership



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**Deputy Convener**  
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Scottish Conservative  
and Unionist Party



**Rona Mackay**  
Scottish National Party



**Brian Whittle**  
Scottish Conservative  
and Unionist Party

# Membership changes

1. There have been two occasions where the membership of the Committee has changed during the consideration of this petition during Session 5 (from 12 May 2016 - to date):
  - Michelle Ballantyne MSP replaced Maurice Corry MSP on 28 June 2017 and;
  - Rachael Hamilton MSP replaced Michelle Ballantyne MSP on 17 May 2018.

# Introduction

2. Petition PE1517 was lodged in April 2014, when transvaginal mesh was being used in procedures to treat pelvic organ prolapse, and transvaginal tapes were being used in the treatment of stress urinary incontinence.
3. For both conditions there are non-surgical interventions, though it may be necessary to consider surgery in certain cases. Mesh procedures have also been used for treating hernias in men.
4. PE1517 was lodged in April 2014 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors “Hear Our Voice” campaign. The petition was brought forward in light of a number of women experiencing severe and debilitating complications from having undergone the procedure. The petition called on the Scottish Government to—
  - suspend the use of polypropylene transvaginal Mesh (TVM) procedures
  - initiate a public inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world
  - introduce mandatory reporting of all adverse incidents by health professionals
  - set up a Scottish Transvaginal Mesh implant register with a view to linking this up with national and international registers
  - introduce fully informed consent with uniformity throughout Scotland's Health Boards
  - write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.
5. The petition stated that the “wholesale use of polypropylene mesh medical implants to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) has been described as one of the biggest medical disasters of all time”.
6. On 3 June 2014, the Session 4 Committee took evidence from the petitioners. At that meeting, the petitioners expanded on their experiences and concerns which had led to their petition.
7. The petitioners summarised their concerns around informed consent. For example, Elaine Holmes stated:

” We were not told that as many as one in five mesh implants can go wrong. When you consider that 11,000 women in Scotland have had the procedure, one in five suddenly becomes an alarming statistic. Further, as complications often take years to develop, we fear that we may just be the tip of the iceberg.”<sup>i</sup>

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<sup>i</sup> Public Petitions Committee (Session 4), [Official Report](#), 3 June 2014, col 2325.

8. The petitioners explained their understanding that no action had been taken on the issue because it was considered that the benefits of a mesh procedure outweighed the risks, and argued that the system in place had failed because it was voluntary. They referred to official figures which showed that 328 women had "endured multiple surgeries", but that "only 12 doctor-reported incidents have been received from Scotland by the MHRA". They asked:

” "Why did those doctors not report the complications in 328 women? Because they did not have to."<sup>ii</sup>

9. The petitioners highlighted significant concerns about the role of the MHRA as the regulatory body, numbers, missing or non-existent data and under-reporting. These issues are discussed further below.

10. Following the petitioners' evidence, the then Cabinet Secretary, Alex Neil appeared before the Committee. In his opening statement he set out the steps that the Scottish Government had taken to address the issues. This included the development of 'patient guidance booklets' and correspondence to all general practitioners "to alert them to the possibility that women may suffer complications following insertion of the mesh implants, and that all adverse events must be reported to the MHRA".<sup>iii</sup>

11. The Cabinet Secretary outlined other steps that he had taken, including holding discussions with the chief executive of the MHRA and writing to the European Commission. Despite these steps, he was "convinced that more needs to be done by us in Scotland".<sup>iv</sup>

12. The Cabinet Secretary announced that he would set up an independent review "to report on all the issues that have been raised, including complication rates and under-reporting of adverse events". He went on:

” "In addition, I have asked the acting chief medical officer this week to write to all health boards to request them to suspend immediately the POP and transvaginal tape procedures until further evidence becomes available..."<sup>v</sup>

13. The Committee noted that some health boards, including Dumfries and Galloway had already suspended the use of mesh for POP procedures, and sought the Cabinet Secretary's response to this. The Cabinet Secretary said:

” "By rolling out the suspension throughout Scotland, we can ensure that every health board takes exactly the same position."<sup>vi</sup>

14. The Cabinet Secretary acknowledged that the regulatory regime was not straightforward, given that in Scotland health boards make the decisions but expressed his confidence that boards would act on his request.

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ii Public Petitions Committee (Session 4), [Official Report](#), 3 June 2014, col 2326.

iii Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2363.

iv Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2364.

v Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2364.

vi Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2364.



15. When asked how health boards might implement the recommendations, the Cabinet Secretary said:
  - ” “If the health boards receive a letter from the acting chief medical officer with the backing of the Cabinet Secretary for Health and Wellbeing, it would be highly unlikely - and highly unacceptable - if they did not agree to the request.”<sup>vii</sup>
16. In response to the Committee's request for further detail of the remit of the independent review, the Cabinet Secretary acknowledged the concerns expressed previously by the petitioners and noted the discrepancy between official reporting of adverse events compared to the number of women who had come forward to the petitioners.
  - ” “That indicates that the percentages that have been officially reported by the MHRA represent significant under-reporting of the number of adverse events. [...] I would like the independent review to at least have a stab at getting a percentage that is of the right order of magnitude for the number of adverse events.”<sup>viii</sup>
17. To address concerns about whether the review would be fully independent and without any suggestion of vested interests, the Cabinet Secretary stated that it was essential that the review had the confidence of the petitioners and other women who had been affected by mesh, and that he had made it clear that the chair of the review would be “totally independent of any manufacturer or other vested interest”.<sup>ix</sup>
18. The Independent Review was established in the summer of 2014. Its formal title was *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women*.
19. Its remit was “to evaluate both the efficacy and the extent and causes of adverse incidents and complication rates associated with stress urinary incontinence and for pelvic organ prolapse”.
20. The group that undertook the Review comprised of patients (including the petitioners), clinicians, professional bodies, the MHRA and senior health officials. It was chaired by Dr Leslie Wilkie, former Director of Public Health at NHS Grampian.

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vii Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2370.

viii Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2366-2367

ix Public Petitions Committee (Session 4), [Official Report](#), 17 June 2014, col 2371.

# Context of mesh issues

## Role of the MHRA

21. The Scottish Government does not have the power to regulate what medical devices are licensed for use in the UK. The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medical devices in the UK and works closely with similar agencies across the EU.

22. The Scottish Government does, however, have the power to recommend whether or not products approved by MHRA for use in the UK should be used in Scotland. The Committee understands that the Cabinet Secretary thought this was possible, when he announced the moratorium in June 2014. Alex Neil stated in the Committee's meeting on 28 September 2017:

” "When I issued the suspension, I made it absolutely clear to every chief executive and chair that I expected the wishes to be carried out by every health board, not just some of them. You can issue a formal directive, but nine times out of 10 that is not necessary. Clearly, there were forces at work here, as became apparent later, that allowed some health boards effectively to ignore the suspension."<sup>x</sup>

23. The MHRA monitors reports of adverse incidents and the current scientific evidence and makes judgements on risks based upon that information. The Session 4 Committee explored the MHRA's role in more detail.

24. In their evidence to the Committee, the petitioners were asked for their views on how effective the agency was as a regulatory body. Their response was damning. Elaine Holmes said:

” "The agency is not an effective watchdog. It does not take our concerns seriously. We have written to it a number of times and telephoned it, but we get standard copy-and-paste replies. The agency does not listen to us."<sup>xi</sup>

25. Olive McIlroy added:

” "The agency's work is subject to European Union medical directives and most of it depends on the evaluation of reported incidents. As reporting is not mandatory, the incidents are not getting to where they have to be evaluated. The agency is not getting reports because nothing is mandatory - it is all voluntary."<sup>xii</sup>

26. At the time, the MHRA's view was that the evidence available to it did not support removing these devices from the market. The MHRA noted that, in its view, clinicians should improve their reporting of adverse incidents but it did not support mandatory reporting on the basis that making something mandatory may not be the best approach to ensuring adverse incidents are reported by clinicians.

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<sup>x</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 38.

<sup>xi</sup> Public Petitions Committee (Session 4), [Official Report](#), 3 June 2014, col 2329.

<sup>xii</sup> Public Petitions Committee (Session 4), [Official Report](#), 3 June 2014, col 2329.

27. The MHRA gave evidence to the Committee in February 2015. When asked to explain why it continued to promote the benefits, rather than the risks of mesh, particularly given a growing body of evidence from, for example, America and Australia, Dr Neil McGuire stated:
- ” "...we are not seeing the level of complications that we would expect from the information that we have been given by various groups who tell us that hundreds and thousands of women have serious complications."<sup>xiii</sup>
28. He added that MHRA's role once a device is on the market is to "monitor it through adverse incident reporting".<sup>xiv</sup>
29. Dr McGuire stated that regulation was about "judging risk". He explained this as balancing the question of whether a device is inherently safe and then whether it is being used "in accordance with the manufacturer's instructions".<sup>xv</sup>
30. The Committee was concerned that Dr McGuire was focusing more on the mesh procedure rather than the product itself. He repeated that there was no evidence that there was an issue with the product:
- ” "If we had thousands upon thousands of reports to say that this was an issue and that complication rates were not within limits deemed acceptable by the clinical community, we would change our stance, but we cannot act without information, and that information does not appear to be out there."<sup>xvi</sup>
31. The Committee raised the concerns about under-reporting, and asked for the MHRA's view on mandatory reporting. Dr McGuire acknowledged:
- ” "We know that there is underreporting. We know that healthcare professionals have not been as good as they could be and, in our view, should be. That is why we have had to consider evidence from all different areas."<sup>xvii</sup>
32. Dr McGuire considered mandatory reporting from a regulatory perspective, suggesting that reporting should be set within a collaborative system which incentivised reporting:
- ” "This is going to sound a bit foolish, but we believe that mandatory voluntary reporting within a professional set of circumstances and with incentives to do that would produce results."<sup>xviii</sup>
33. Despite its best efforts, the Committee was unable to establish under what, if any, set of circumstances MHRA would take action to stop the use of mesh implant surgery and the use of the device. Dr McGuire simply referred to the lack of evidence before the MHRA:

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xiii Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 5.

xiv Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 1.

xv Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 5.

xvi Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 7.

xvii Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 13.

xviii Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 14.

” It is absolutely vital that the difference in the numbers that are bandied about by various groups is reconciled. I do not mean that flippantly; I mean that we get lots of numbers thrown at us, but we cannot work without evidence, and there is no evidence about it from anywhere else in the world.”<sup>xix</sup>

34. The Session 4 Committee was deeply concerned that the MHRA did not seem willing to accept that there was any issue with the use of mesh and instead inferred that the issue was with clinicians carrying out procedures or, incredibly, that the women who were experiencing such severe adverse effects were simply imagining it.

35. Whilst not an issue directly explored in evidence with the MHRA in 2015, this Committee also notes reports and claims that some mesh products contained counterfeit material. These concerns began to emerge towards the end of 2016. The Committee considers that this casts further doubt on the efficacy of the MHRA as a watchdog, and raises questions about the transparency of its testing and verification process with regard to mesh products, particularly in terms of the reporting of adverse events in contrast to regulatory bodies elsewhere. For example, in evidence to the Committee on 28 September 2017, Dr Wael Agur said:

” I believe that the MHRA could have done a lot more. On the point about transparency, the MHRA proposed years ago the publication of a transparent database of reported adverse events for all medical devices. That would bring it into line with Australia. The Therapeutic Goods Administration in Australia—the equivalent of the MHRA down under—appears to have done a lot more work on the publication of adverse events.”<sup>xx</sup>

## Litigation and global concerns

36. On 24 February 2015 the Committee also heard evidence via video-conference from Adam Slater, a lawyer working on litigation cases in New Jersey. In a clear contradiction to the evidence presented by the MHRA, Mr Slater explained the number of cases that he was involved with and that, in his view, mesh devices are not safe.

37. At that time, Mr Slater stated that 7000 women had filed cases against mesh manufacturers in New Jersey alone. He added that, in West Virginia, there were “about 70,000 or more cases filed in the federal courts”.<sup>xxi</sup>

38. When asked about the level of data that was available to show adverse events and the number of women affected, Mr Slater said that as part of his work in litigation he was able to access internal documents from manufacturers:

” We are talking about millions of women, according to the data from the manufacturers themselves.”<sup>xxii</sup>

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<sup>xix</sup> Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 24.

<sup>xx</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 20.

<sup>xxi</sup> Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 26.

<sup>xxii</sup> Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 26.

39. He explained that there were two types of claims: one on the basis that mesh devices were defective and one relating to a failure to warn, which he suggested was due to doctors (and patients) not having full information about potential complications:
- ” ”First, the women are not warned and their doctors, especially, are not told the truth about how serious the complications are and how untreatable they are for so many women. Secondly, the products are defective and it is unsafe to put polypropylene mesh in so many women.”<sup>xxiii</sup>
40. The Committee discussed with Mr Slater the role of the Food and Drug Administration (the FDA), the US equivalent of MHRA as the body responsible for regulating medical devices.
41. It was noted that in April 2014 the FDA gave notice that it was considering upgrading the risk classification of surgical mesh for pelvic organ prolapse from class two, a moderate risk, to class one, high risk. It was anticipated that, in addition to reclassification, manufacturers would be required to seek pre-market approval from the FDA, to allow it to evaluate safety and effectiveness. When the Committee asked what the effect of the proposed reclassification had been, Mr Slater said that the reclassification had not come into effect.
42. According to Mr Slater there were three reasons for the delay in reclassification. One was that "many of the manufacturers pulled their products off the market instead of having them studied by those robust randomised controlled trials".<sup>xxiv</sup>
43. The other two reasons, in Mr Slater's opinion, were essentially due to the relationship between the FDA and manufacturers, which he referred to as "collaboration":
- ” ”For example, before the FDA issues pronouncements about mesh it consults the medical device manufacturers, and it is being lobbied. There is a close relationship there, which is unfortunate and takes the FDA away from the neutral, objective position that it should hold.”<sup>xxv</sup>
44. Despite the delay in reclassification, Mr Slater did note that due to the growing profile and concern about mesh some doctors were taking the decision to treat the products as high-risk and refusing to use them.
45. The Committee asked Mr Slater what advice, based on his experience of the relationship between the manufacturers and the regulatory body in the US, he would offer to the MHRA. He suggested that wherever possible the MHRA should seek to review studies used by the manufacturers themselves, rather than low-budget options such as the York report. He also suggested that any 'independent' studies which might be regarded as offering evidence could be subject to a conflict of interests. He referred to the study on TVT conducted in the late 1990s:

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xxiii Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 27.

xxiv Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 28.

xxv Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 28.

” “The bedrock studies are therefore not reliable, and safety is never their end-point. They did not study safety in a robust and objective way, as they should have; rather, they looked at whether there would be less leakage and whether the organs would stay in the right place better. Modern concepts about such types of surgery recognise that the most important thing is how the woman feels, because it is elective surgery that nobody needs.”<sup>xxvi</sup>

46. The Committee asked Mr Slater for his views on MHRA's position that there was no evidence to support the argument that the mesh products were defective. He advised the Committee that in cases that had gone to trial in the US, the majority had resulted in the jury finding the product to be defective, adding that the verdicts had "uniformly awarded compensation in seven figures, and in several cases punitive damages [were] awarded".<sup>xxvii</sup>

47. It was suggested to Mr Slater that there was a significant conflict of interests throughout the world on the use of mesh, involving the regulatory bodies, manufacturers, and clinicians. Mr Slater said "I agree 100 per cent" and provided examples of such conflicts.

48. The Committee has received submissions from across the world, including America, Ireland, Australia and New Zealand, with women describing the distress and debilitating effects that they have suffered. The Committee considers that this reflects the global nature of this scandal.

49. The Committee recognises action that has been taken by the Therapeutic Goods Administration (TGA), the regulatory body in Australia, and its counterpart in New Zealand, the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

50. In November 2017, the TGA decided to "remove transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG)". The Committee in particular notes the comments in the TGA's press release of 22 December 2017, which stated:

” "...the TGA is of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients."<sup>xxviii</sup>

51. The TGA also considered there was insufficient evidence for it to be satisfied with regard to the safety of another mesh product - single incision mini-slings - for the treatment of stress urinary incontinence, and removed them from the ARTG. This regulatory action came into effect on 4 January 2018.

52. On 31 January 2018, Medsafe followed suit and announced that the same products will no longer be supplied in New Zealand. It added that in line with the regulatory approach in Australia, manufacturers had also been notified of changes they were

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<sup>xxvi</sup> Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 30.

<sup>xxvii</sup> Public Petitions Committee (Session 4), [Official Report](#), 24 February 2015, col 34.

<sup>xxviii</sup> Australian Government, Department of Health, Therapeutic Goods Administration. [TGA actions after review into urogynaecological surgical mesh implants](#). [Accessed 2 July 2018]

expected to make to warnings in their Instructions for Use, and it continued to work with the companies to ensure these changes are delivered as soon as possible. Medsafe referred to this as "the strongest action possible under current legislation".<sup>xxix</sup>

53. On 10 July 2018, the UK Government Department of Health and Social Care accepted the recommendation of the Independent Medicines and Medical Devices Safety Devices for an immediate halt to the use of surgical mesh for stress urinary incontinence. The Chair of the Review, Baroness Cumberlege, said:

” “We strongly believe that mesh must not be used to treat women with stress urinary incontinence until we can manage the risk of complications much more effectively. We have not seen evidence on the benefits of mesh that outweighs the severity of human suffering caused by mesh complications.”<sup>xxx</sup>

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<sup>xxix</sup> New Zealand Medicines and Medical Devices Safety Authority. *Regulatory action on surgical mesh products*. [Accessed 2 July 2018]

<sup>xxx</sup> The Independent Medicines and Medical Devices Safety Review. *Independent Review calls for immediate halt of the use of surgical mesh for stress urinary incontinence*. [Accessed 23 July 2018]

## Publication of the interim report

54. On 2 October 2015 the Independent Review published an [interim report](#). The Executive Summary explained that the Independent Review was awaiting the publication of findings from two studies: final opinion of the European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the use of mesh implants, and the Prolapse Surgery: Pragmatic Evaluation and randomised Controlled Trials, known as the PROSPECT study [[link](#)], discussed later in this report. However, the Executive Summary stated:

” ...as the main programme of work has been completed the IR has been able to draw conclusions and make recommendations.”

55. The conclusions and recommendations of the Interim Report are included at annex (TBC). The preface of the report summarises the Review’s findings:

” We found some concerning features about how new techniques are introduced into routine practice, how and for how long they are followed up, how women are informed of the risks and benefits so that they can give true informed consent and also how adverse events are reported and to what extent.

“Our conclusions focus on the need for improved governance around both the introduction of new procedures or techniques and also of how women are assessed and treated, both initially and in the event of any side effects following surgery. Reporting of adverse events is another area where we feel that a tighter, more explicit practice is required and we suggest ways the government should consider to ensure this area is improved. We differentiate between the use of mesh in the treatment of stress urinary incontinence and when it is used in the repair of pelvic organ prolapse. We see the need for an Expert Group to oversee the implementation of an improved way of working, and of organising services. We are aware that some of our conclusions have wider implications and see the need to embed this in the Patient Safety and Clinical Governance strands of the NHS.”

56. While generally the interim report was welcomed, the petitioners produced a minority report and the Scottish mesh survivors group considered that, rather than waiting for publication of the final report, the recommendations should be actioned immediately with a clearer monitoring process in place before any further mesh procedures took place.
57. The Cabinet Secretary for Health, Wellbeing and Sport, Shona Robison, accepted all of the conclusions of the interim report. The Cabinet Secretary stated that in line with the conclusions of the interim report safeguards would be put in place. She also stated that she wanted to be in possession of the final report before implementing permanent changes.

## Evidence from chair of the Independent Review

58. Following publication of the interim report, the Committee heard evidence from Dr Lesley Wilkie, the chair of the Independent Review, alongside Dr Rachael Wood of



Information Services Division and Dr Phil Mackie of the Scottish public health network.

59. In her statement to the Committee, Dr Wilkie appeared confident that action on the interim recommendations could go ahead:
- ” “We have published an interim report because we have carried out an extensive body of work that already lets us make recommendations on actions to improve patient care in the area. We hope that it will be possible, with certain provisos, to begin to take those proposed actions as soon as possible.”<sup>xxxix</sup>
60. The chair of the Independent Review summarised some of the key points arising from the group's work. This included the experiences of women, set out in chapter 3. That chapter included some reports of women who had had "positive outcomes" as a result of mesh surgery but, in the main, contained details of women who had experienced serious and debilitating complications and in the chair's words "distressingly, at times [those women] have not been believed when they sought help". She noted:
- ” “However, in the absence of specific qualitative research, the largest proportion of women who have had mesh surgery have not shared their personal experiences.”<sup>xxxix</sup>
61. Chapter 4 of the interim report contained high level health data covering a 15 year period which the chair said revealed "the complex decisions that clinicians are presented with when considering the best treatment options for women".
62. Chapter 5 highlighted concerns about the lack of research literature, particularly with regard to long-term follow-up. Dr Wilkie said:
- ” “The lack of research studies on the long-term outcomes, including quality of life and daily living activities, is concerning and we conclude that research on that basis is a priority.”<sup>xxxix</sup>
63. The interim report reflected the balance that needed to be struck between the benefit and risk of a mesh procedure. Reflecting on the figure of one in five women who had undergone the procedure going on to experience some form of difficulty or complication thereafter, the Committee asked the witnesses if they could provide an example of any other procedures which might affect such a significant number of patients, but which would continue to be performed regardless. Dr Wood observed that "no surgical procedure is without risk", going on to note:
- ” “We are always on shifting sands, because there is always innovation in medical practice. As new medical devices come in, it is important that we understand the associated balance of risks and benefits.”<sup>xxxix</sup>
64. The Committee asked what difficulties the review faced in reaching its interim conclusions and recommendations due to the lack of research evidence. Dr Wilkie

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<sup>xxxix</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 2.

<sup>xxxix</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 3.

<sup>xxxix</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 4.

<sup>xxxix</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 6.

said the two main issues on research related to the need for "longer-term follow-up, including routine surveillance, and the need to look at not just clinical outcomes, such as whether the operation worked, but the impact on quality of life". Dr Mackie expanded on this point:

” There is a tendency in the research literature to look at the formal indicators of quality of life, which are somewhat abstracted from the day-to-day lives that we all lead. We recognised that that is a major gap in understanding people's lived experience. The surgery might well have consequences for the type of day-to-day activities that we accept as straightforward, such as dressing, bathing and being able to get out of the house when you choose rather than when it is arranged for you.”<sup>xxxv</sup>

65. Dr Wood provided an explanation of concerns about the use, or lack, of coding, noting that "there can be a considerable lag between an operation becoming available and a specific code that describes it becoming available". She provided examples of no code being available to record the provision of mini-slings and that, while codes were available for the removal of tapes, there were no codes for the removal of prolapse mesh.<sup>xxxvi</sup>
66. The Committee turned to the recurring theme of women not being believed and being treated in a prejudicial manner. Dr Wilkie stated her strong personal feeling that "there is an issue with listening to women and valuing what they say", and that she was "seized by the fact" that there was a prejudicial attitude. She referred to the recommendation on education:
- ” Education is obviously not just about knowledge of the side effects; it is a balance. People must have the knowledge of how many and what percentage of patients are affected - the majority have not reported poor outcomes, but a significant number have had very poor outcomes - but education is also about empathy and appreciation and the ability to listen actively. We must involve women.”<sup>xxxvii</sup>
67. The Committee queried whether, if prejudice still pervaded, the chair of the review was confident that the recommendations would not be ignored or pushed aside by clinicians or a body with a vested interest in the product and procedure. The chair considered that this would not happen.
68. The Committee was not convinced that the recommendations were sufficiently robust or that there was a culture among clinicians to accept them. The Committee was concerned that the recommendations could be circumvented under the guise of participating in trials, such as the single-incision mini-slings trials, which were exempt from the suspension on the use of mesh.
69. The Committee discussed this further with Dr Wilkie, for her thoughts on what the expectation was of the so-called moratorium:

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<sup>xxxv</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 7.

<sup>xxxvi</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 7.

<sup>xxxvii</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 9.

” "When we started the review, we were under the impression that the procedures would be suspended but some would take place in the context of clinical trials."<sup>xxxviii</sup>

70. The Committee asked, whether, in light of the concerns about the product, the procedure, the lack of data, and the fact that procedures were continuing even when a 'moratorium' was in place, the review had considered whether the "precautionary principle" should be applied. In other words, stop everything until more was known about the safety or otherwise of mesh products and procedures. Dr Wilkie said that the review was not asked to consider that approach:

” "Our remit was to find and look at the information that was available, not to consider whether the procedure should be suspended."<sup>xxxix</sup>

## Minority report

71. The petitioners and the Scottish Mesh Survivors group produced a [minority report](#), submitted to the Committee on 7 October 2015, making clear their opinion that until such time as the recommendations "in the interim and final reports are all agreed, actioned and able to be monitored", mesh should not be used at all.

72. They noted how the interim report set out the concerns about prolapse mesh and obturator mesh tapes and recommended that the retropubic approach be the default procedure "as it carries the least mesh risks". They stated:

” "However, we do not accept that any polypropylene mesh is safe. Mesh devices are no better than traditional surgery and they have more risks of long-term complications. There are better treatment options available that do not have mesh complications."

73. The minority report welcomed the interim report's confirmation, in stark contrast to MHRA's position, that the risks of mesh procedures outweigh the benefits. The petitioners highlighted the criticism of MHRA and suggested that it was not fulfilling its regulatory duties effectively. They stressed their belief that "Scotland needs to establish its own medical watchdog".

74. The minority report identified other points which, while not part of the remit of the Independent Review, they said still needed to be considered by the Scottish Government, including:

- every woman with a mesh implant should be contacted, warned of potential complications, and where to go for help
- long-term toxicology evidence to establish beyond any doubt whether mesh is safe and fit for purpose
- the variation in approach to the use of mesh across Scotland's health boards

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<sup>xxxviii</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 20.

<sup>xxxix</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 22.

- the relationships between manufacturers, clinicians and the regulatory body need to be much more transparent.

75. The Scottish Mesh Survivors also addressed the issue of coding, which meant there was no unique device identifier to record, monitor and evaluate data:

”Manufacturers of all implants must be required to ensure their products are capable of being identified and traced from moment of manufacture to placement with a patient and beyond. This data must be auditable and available for public scrutiny.”

## Scottish Government position on interim report recommendations

76. The Cabinet Secretary for Health, Wellbeing and Sport, Shona Robison, gave evidence to the Committee following the publication of the interim report, alongside Chief Medical Officer, Catherine Calderwood.

77. The Cabinet Secretary confirmed that the Scottish Government accepted all of the recommendations in the interim report, and outlined how they would be acted upon, through existing or new groups, projects or workstreams:

”We accept all the recommendations. However, we understand that some of them may take a bit longer than others to implement.”<sup>xi</sup>

78. The Committee was keen to understand why, after the previous Cabinet Secretary had requested the suspension of all use of mesh with the exception of as part of clinical trials, some health boards had appeared to completely disregard that request.

79. The Cabinet Secretary suggested that the reason for the continued use of mesh in some health boards was due to some women still wanting to go ahead with the procedure having been given "full information" about the procedure and potential complications. She stated that "the number of such procedures has dropped dramatically, with very few having been carried out since the suspension".

80. The Chief Medical Officer provided more information:

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<sup>xi</sup> Public Petitions Committee (Session 4), *Official Report*, 6 October 2015, col 34.

” “When the previous CMO wrote to health boards asking them to consider suspending the use of mesh, there were women on the waiting list who were expecting a procedure. I undertook to speak individually to the clinicians, who called in the women from the waiting list to have a conversation with them about the suspension. By that time, we had produced a comprehensive consent form with a lot more detail on it for use in all health boards. The women who subsequently went ahead to have their procedures were fully apprised of the risks. They were made aware of the suspension and the complications that some of the women behind me in the public gallery had brought to light. Therefore, they went into the procedures with a lot more information; they also understood that questions were going to be looked at in the independent review that had been commissioned.”<sup>xli</sup>

81. The Committee was advised by the CMO that somewhere in the region of 76 mesh procedures had been carried out for stress urinary incontinence, and potentially fewer than ten for pelvic organ prolapse.

82. The Committee sought a clearer explanation for the Scottish Government's understanding of why mesh procedures had been carried out when it had been widely understood that a suspension meant precisely that. It reflected concerns that people, especially affected women, had been misled. The Cabinet Secretary stated:

” “First, we need to remind ourselves that the MHRA has not banned the procedure. It is the regulatory authority that would ban a procedure in the light of evidence that it should not be used.”<sup>xlii</sup>

83. She added:

” “I was not involved in the detail of this at the time, but if we look back at what was said, there was always the chance and the choice for a woman to go ahead with the procedure in the full light of all the information.”<sup>xliii</sup>

84. Given the evidence that the Committee had seen and heard, and that the MHRA appeared to be almost alone in its view that the benefits outweighed risks the Committee sought the Cabinet Secretary's view on how she expected the regulatory body to respond to the interim report. In response, she said:

” “I understand some of the issues that are being raised about the attention that the MHRA is able to give to individual products. Given the extent of the concern around the issue, we would expect the MHRA to give particular attention to it.”<sup>xliv</sup>

85. The Committee turned to the apparent prejudice that had existed among manufacturers, clinicians and the regulatory body, that women simply had not been believed when they first raised concerns about the safety of mesh. The Committee queried whether any action would have been taken if the petitioners had not brought the issue into the open. The Cabinet Secretary agreed:

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<sup>xli</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 27.

<sup>xlii</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 28.

<sup>xliii</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 28.

<sup>xliv</sup> Public Petitions Committee (Session 4), [Official Report](#), 6 October 2015, col 30.

” "I can only say what I have said regarding my view, which is that women should not have had to campaign in that way to have their voices heard. Government, along with anybody else out there, needs to be better able to pick up on issues at an earlier stage when concerns are raised. This campaign has shone a spotlight on the need to ensure that, when concerns are raised, there are ways for us to pick up on and respond to them."<sup>xiv</sup>

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<sup>xiv</sup> Public Petitions Committee (Session 4), *Official Report*, 6 October 2015, col 37.

## Clinical studies completed after publication of the interim report

86. The [SCENIHR final opinion](#) was published on 3 December 2015. Its recommendations included—
- Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects to consider when choosing appropriate therapy
  - the implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery
  - for all procedures, the amount of mesh should be limited where possible
  - a certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.
87. The final report from the [PROSPECT study](#) was published in the Lancet in December 2016. It identified through the course of the study that approximately twelve percent of women who had undergone some form of mesh procedure experienced complications. It concluded that follow-up was vital to identify any potential longer term benefits or potential serious adverse events. It noted that—
- ” “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.”

# Publication of the final report

## Recommendations of the final report

88. The Independent Review's [final report](#) was published on 27 March 2017. It set out eight recommendations regarding the use of mesh. These are set out in the annex (TBC) alongside the conclusions and recommendations set out in the interim report.
89. The Committee highlights two phrases from within the conclusions of the final report, which it considers captures the concerns that it has heard from the petitioners, in that they had to fight in the face of a 'protectionist' mindset to have their voices heard.
90. Conclusion 6 of the interim report said:
- ” The Independent Review expressed serious concern that some women who had adverse events found they were not believed...”
91. In the final report, that changed to:
- ” The IR expressed serious concern that some women who had adverse events felt they were not believed...”
92. The Committee considers that the change from "found" to "felt" demonstrates that, even at this point in the process, there remains an attitude from within the medical establishment that infers that these many women who have had the courage to describe the debilitating impacts that mesh has had on their lives are just imagining it.
93. Conclusion 8 states that, in relation to pelvic organ prolapse, "transvaginal mesh procedures must not be offered routinely".
94. The Committee considers that the use of the word "routinely" offers surgeons an option to continue using mesh in some circumstances. The Committee is concerned that, despite evidence from the Cabinet Secretary and Chief Medical Officer on improvements made to ensure that women are fully informed of the risks associated with mesh procedure, and the fact that there are non-mesh alternatives, the use of the word "routinely" takes surgeons away from the "precautionary principle".
95. The Committee remains concerned that, despite the publicity that has surrounded this entire issue, there is still a mindset within the medical profession that focuses on potential benefits rather than the risks.

## Resignations from the independent review

96. In November 2016, Lesley Wilkie resigned as chair of the Independent Review. She was replaced by Tracey Gillies, medical director at NHS Forth Valley and subsequent to being appointed as chair of the independent review, medical director at NHS Lothian.



97. Shortly before the publication of the Independent Review's final report, three other members of the review resigned. The petitioners resigned from the Independent Review amid reports of a 'diluted' report and concerns about a 'whitewash'. They were followed shortly thereafter by one of the expert clinicians on the Review, Dr Wael Agur.
98. The Committee heard that there were significant concerns about the content of the final report. The petitioners expressed their dismay at what appeared to be an entirely different approach to reflecting the seriousness of the issues being considered.
99. The Committee invited the petitioners to give evidence following the evidence from Dr Gillies, the Cabinet Secretary and the Chief Medical Officer. The Committee also agreed that it would be helpful to receive evidence from Dr Wael Agur, the medical expert who had resigned from the Independent Review.
100. In his written submission of [15 September 2017](#), Dr Agur requested that the final report should be subject to a public consultation process. He considered that—
- the report could further reduce harm to women considering surgery for pelvic organ prolapse and/or stress urinary incontinence
  - for pelvic organ prolapse, the report allowed the highest risk mesh procedures despite lack of proven benefit over standard non-mesh alternatives
  - for stress urinary incontinence, the report did not adequately warn surgeons and patients of the risks associated with transobturator mesh tape
  - there was no reliable evidence on the safety and efficacy of mesh products/devices
  - there was a lack of balance within chapter 6 of the report
  - the report ignored the current best available evidence on mesh-related adverse events, and did not recommend mandatory [underlined] reporting of all mesh procedures which he argued would lead to a "certain failure to obtain accurate figures on mesh-related adverse events in the future".
101. In their submission the petitioners concentrated on five key concerns that they considered had not been satisfactorily addressed during the 18 May meeting—
- miscommunication leading to the inclusion of their input within the final report, when they had requested for all of their input to be removed
  - the report down-played the significance of the EU reclassification of all surgical meshes to class III, the highest risk category
  - clarification on deregistration of mesh products by Australia's Therapeutic Goods Agency, the equivalent to the MHRA
  - concerns about continued use of mesh for stress urinary incontinence, which they consider to be partly as a result of the CMO's "wrong and misleading" statement in December 2016, and because the MHRA has stated that "the benefits outweigh the risks"

- outdated patient information leaflets.

## Evidence from the Chair of the review and the Scottish Government

102. In evidence to the Committee on 18 May 2017, Dr Gillies acknowledged that members of the review had "many experiences and strongly held views and, in such circumstances, it proved to be difficult to reach agreement and, in particular, consensus around the interpretation of the evidence".

103. Dr Gillies set out some of the challenges that she had faced when taking over as chair of the review, likening it to "mission impossible". For example, she indicated that she had not spoken to the previous chair and that, if she had been the chair from the start of the process she might not have chosen to approach it in the same way. She explained:

” ” "My role as the group's chair is to draw the views together in what has been set up as a multi-author review rather than to pass judgment on the technical views that are contained in the report."<sup>xlvi</sup>

104. The Committee raised concerns with the Cabinet Secretary that there appeared to have been no form of handover between the former and incumbent chairs of the review. The Cabinet Secretary replied:

” ” "On whether there should have been a handover, the new chair would have made a judgment on whether it was necessary to make contact with the previous chair. For continuity, there might have been some advantage in doing so."<sup>xlvi</sup>

105. The Cabinet Secretary informed the Committee that she had commissioned Professor Alison Britton to conduct a review of the independent review. This is discussed towards the end of the report, but in making her announcement to the Committee, the Cabinet Secretary said:

” ” "Professor Britton, who works at Glasgow Caledonian University, is a specialist in public healthcare, clinical negligence, mental health law and professional ethics. She will produce a report on how the independent review process was undertaken and, importantly, what lessons can be learned for the future."<sup>xlvi</sup>

106. Despite the clear concerns that had been expressed following the publication of the final report, and resignations of three members of the review, Dr Gillies said:

” ” "...the view of the remaining review group members was that it actually strengthened the findings of the interim report."<sup>xlvi</sup>

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<sup>xlvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 12.

<sup>xlvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 29.

<sup>xlvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 24.

<sup>xlvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 2.

107. In relation to the surgical treatment of stress urinary incontinence, the final report recommends that “women must be offered all appropriate treatments (mesh and non-mesh) as well as the information to make informed choices”. It recommends a retropubic approach when surgery involves polypropylene or other synthetic mesh tape. (Conclusion 7). For the surgical treatment of pelvic organ prolapse, the report recommends “[T]ransvaginal mesh procedures must not be offered routinely”. (Conclusion 8)
108. During the Ministerial Statement on 30 March 2017, the Cabinet Secretary stated that “[T]hose recommendations are clear, unambiguous and incredibly important”. However, with regard to conclusion 8, the petitioners queried the use of “routinely”, asking if it is acceptable to “re-open the door to the most risky prolapse procedure ... when all Scottish surgeons have already stopped doing it”.
109. Due to the widely publicised resignations from the group and reports in the media of a “whitewash” concerns about the content of the final report was covered extensively, both in advance of and subsequent to the publication of the final report, including at Topical Questions on 7 March 2017, and during the Ministerial Statement on 30 March.
110. On 30 March, in response to a question from Alison Harris about the removal of an entire chapter and the way in which information was presented, the Cabinet Secretary sought to assure the Parliament that all information and evidence presented to the independent review was available:
- ” “The chair has assured me that all the evidence that was received is either in the final report or on the website”.<sup>i</sup>
111. In response to similar concerns that the final report did not recommend the reclassification of mesh to the highest-possible risk category, the Cabinet Secretary added:
- ” “The MHRA is the body that would reclassify mesh, and we would of course await any reclassification from the MHRA. It is the responsibility of the MHRA, not the Scottish Government, to determine the classification of mesh. Our responsibility is to give clear guidance to clinicians on the circumstances in which they should or should not undertake the procedure. That is what the independent review was set up to do, and it has made its recommendations. I understand that many women wanted the review to ban mesh. I think and hope that I have explained that that was not within the gift of either the independent review or the Scottish Government. Only the MHRA could do that, and it has not done so.”<sup>ii</sup>
112. In a written submission to the Committee on 8 May 2017 the petitioners highlighted particular concerns of the content of the final report, on a number of issues, discussed further in this report.
113. The petitioners set out their concerns about the lack of publication of all tables that were expected to be considered to enable the group to fully consider and discuss the benefits and risks of non-mesh and mesh procedures. They suggested that

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<sup>i</sup> Meeting of the Scottish Parliament, [Official Report](#), 30 March 2017, col 64.

<sup>ii</sup> Meeting of the Scottish Parliament, [Official Report](#), 30 March 2017, col 64-65.

there was evidence within the tables to show that non-mesh procedures are safer than mesh ones.

114. They stated that, although a decision was taken to publish the tables, only one – table 6.1 – was contained within the body of the report, with the others being “outside the report and published online – hidden out of sight and among meeting minutes and agendas”.
115. The Committee explored this further in evidence with the chair of the independent review, and also with the Cabinet Secretary and Chief Medical Officer. The Committee was told that it was not the case that the tables were not available but that it was simply a matter of how the tables had been presented in the publication process.
116. In her evidence to the Committee, Dr Gillies explained that the tables were presented differently from the interim report because “there was a lack of consensus around the content of those tables, which were no longer agreed by the clinician members of the group”. She considered:
- ” ” “For a report to be sufficiently credible to influence clinical practice, it needs to be transparent for clinicians and the broader clinical group need to be able to read through it and see all the different outcomes that might be considered.”<sup>lii</sup>

## Process for agreeing and publishing the final report

### Chapter 6

117. The petitioners considered that chapter 6 of the final report was “biased and misleading”, in that it “directs the reader to the conclusion that mesh procedures are better than non-mesh ones”. They expanded on this point:
- ” ” “It does so by describing all advantages of mesh procedures but not mentioning the important mesh-related adverse events, including the most common one of mesh erosion/exposure or the most serious one of chronic pain.”<sup>liii</sup>
118. They compared and contrasted chapter 6 of the final report to that within the interim report, noting how the interim report described one procedure in great detail (over 10 pages) while the final report described “over seven procedures in less than four pages”. They said:
- ” ” “This chapter encourages surgeons to direct patients towards having mesh surgery which contradicts Conclusion 1 of shared-decision making.”<sup>liiv</sup>
119. The petitioners could not understand why the chapter failed to mention the most common or most serious adverse events of mesh surgery, and failed to mention the advantages of non-mesh surgery.

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<sup>lii</sup> Public Petitions Committee (Session 5), *Official Report*, 18 May 2017, col 10.

<sup>liii</sup> Public Petition PE1517. Petitioners' submission of 8 May 2017.

<sup>liiv</sup> Public Petition PE1517. Petitioners' submission of 8 May 2017.

120. The Committee also discussed concerns around the removal of the original chapter 6 from the interim report, and how the information, including tables, was presented in the final report. There was some concern that, despite assurances from the Cabinet Secretary and the chair of the review that all the information was still accessible, it was not easily and readily accessible and not set out in its entirety. Instead, the information presented in the interim report chapter 6, was fragmented and only accessible online. The Cabinet Secretary acknowledged concerns about how the information was presented, but said:

” “All the information is there in some form, but it is in a different form from how it was presented in the interim report. The chair has explained the rationale behind that. I understand the complexity of the issue. The report is not particularly easy to read, which is why there is a commitment to producing a version of it that will be easier to understand. That is the right thing to do, and Professor Britton will look at how complex information - some of it very clinically complex - is translated into a public-facing report.”<sup>iv</sup>

## Mandatory reporting of mesh adverse events

121. The petitioners stated that they repeatedly asked that reporting of mesh adverse events to MHRA should be mandatory, and that these requests were ignored until they had resigned from the review group and subsequently met with the Cabinet Secretary.

122. In evidence to the Committee, Dr Gillies stated—

” “At the meeting [of the independent review] on 6 March, we had a discussion around the use of the word “mandatory”, and the group thought that it could be difficult to implement mandatory reporting. However, at the time, it seemed that, if there was a strongly held view about mandatory reporting of adverse events, it would be appropriate to include the word “mandatory” in the final report. I checked that with the group and it was agreed.”<sup>vi</sup>

123. While they welcomed the belated recommendation to make the reporting of mesh adverse events mandatory, the petitioners consider that this demonstrated a “clear indication that the government is calling the shots, not the group members”, and that the review was not fully independent.

124. The petitioners also stated that they repeatedly requested to make it mandatory for all mesh procedures and follow-up data to be recorded on a national database. They expressed their disappointment that these requests, which were supported by other representatives on the review, were ignored, and asked how accurate information on adverse events can be obtained if the recording of procedures is not made mandatory.

125. The Committee questioned the chair of the independent review, the Cabinet Secretary and the Chief Medical Officer, to understand what benefits or knowledge were expected to be gained from mandatory reporting of adverse events, if there

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<sup>iv</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 34-35.

<sup>vi</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 11.

was no mandatory requirement to record mesh procedures. The Committee queried how accurate any figures on adverse events would be. The Chief Medical Officer acknowledged this point and advised the Committee that she had spoken with all medical directors who had received her correspondence relating to mandatory reporting. She stated that:

”They have since been asked to confirm with me their arrangements for starting to audit all the procedures on a recognised database so that a surgeon will not be able to do the procedures unless they are recording their outcomes, including complications, on a recognised database.”<sup>lvii</sup>

## Inclusion of petitioners' contributions in the final report

126. The petitioners expressed their frustration that, “[D]espite repeated communication” their input to patient chapter 3 was not removed. They explain that this was clearly communicated at a meeting with the Cabinet Secretary and Chief Medical Officer, and also in writing to the Chair of the review.

127. The Committee sought clarity around the chronology of the petitioners requesting that their input to chapter 3 of the final report be removed. In evidence to the Committee the chair of the review confirmed that the Cabinet Secretary had advised her that the patient representatives had requested their information to be removed from the report. However, the chair suggested that the inclusion of the petitioners’ input was a decision taken by remaining members of the group—

”In discussion with the review group, there was a very strong feeling among its remaining members that, after individuals have resigned, they should not be able to influence the content of the report as agreed by the review group as it stood at the end of the process.”<sup>lviii</sup>

128. The suggestion by the chair, therefore, was that as the request for the removal of some content within the final report came after the content of the report had been agreed by the remaining members of the review and that the view of the remaining members was that content should be retained, irrespective of any formal requests from patient representatives or via the Cabinet Secretary. She stated—

”It is right to listen to requests, but that does not mean that I would necessarily accede to those requests.”<sup>lix</sup>

129. Dr Gillies set this position in the context of the number of individuals involved in drafting the final report:

”Part of the difficulty of producing a report that is written by many different people and in which we are trying to build consensus is that, if people choose to leave the process because they are not happy with the conclusions, it is not possible to disaggregate the contributions that they have made in the development of the report.”<sup>lix</sup>

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<sup>lvii</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 35.

<sup>lviii</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 6.

<sup>lix</sup> Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 7.

130. During evidence, the chair of the review was asked to explain why no reference was made to a most recent study produced in the Nature journal, which showed that one in seven women experiences a serious mesh adverse event. Dr Gillies said—

” “The safety reviews that were included were published by agencies that are charged with device safety, and Cochrane reviews were the systematic review method that was used to assess effectiveness. The Nature review does not follow the guidelines for a Cochrane systematic review report, so it was not considered.”<sup>lxi</sup>

## Classification of mesh devices

131. On 18 May 2017, the Committee sought further clarification from the Cabinet Secretary and the Chief Medical Officer with regard to the issue of the reclassification of mesh to the highest-level risk, and that there was only passing mention of this in the final report. The Committee asked whether, in light of the EU reclassification of all mesh, the Cabinet Secretary considered it would not be safer to simply advise to not conduct any mesh procedure at all. The Chief Medical Officer responded in the context of the updated guidance and informed consent process to be adopted:

” “Some women will have no treatment at all, and that will be their decision or a shared decision between them and their clinician. However, we want the other women to have all the options laid out with all the complications and risks and the things that these women were not fully aware of because, at the time, they did not have what we now see as fully informed consent.”<sup>lxii</sup>

132. Concerns about the use of counterfeit material was raised briefly with the Chair of the Independent Review at the 18 May meeting, in the context of the FDA's warning on counterfeit mesh and the EU's risk classification. Dr Gillies responded by noting that the MHRA - not the FDA - is the regulatory body for devices in the United Kingdom.

## Expert clinician evidence - Dr Wael Agur

133. Dr Wael Agur stated to the Committee that he had, prior to the issues and concerns about the use of mesh coming to light, performed mesh procedures but had ceased as soon as the issues had come to light. He also expressed concerns about how and what evidence was taken account of within the independent review.

134. Dr Agur explained that he resigned four weeks prior to publication of the final report and expressed a level of disappointment with the content of the final report:

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lx Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 9.

lxi Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 12.

lxii Public Petitions Committee (Session 5), [Official Report](#), 18 May 2017, col 34.

” "I believe that the Government's final report could have done more to reduce harm without losing value, to highlight the details of mesh-related risks while maintaining a patient-centred approach and to promote shared decision making between patients and their clinicians while striking a good balance with the trade-offs to be considered. More needs to be done to bring the report up to the standards and principles outlined in the chief medical officer's framework document "Realistic Medicine".<sup>ixiii</sup>

135. Dr Agur asked that, as a straightforward matter of transparency, the Scottish Government should open the final report up to full public consultation. He noted that the EU had adopted that approach and that it "is a well-recognised procedure" undertaken by NICE before the publication of clinical guidelines. He added:

” "I believe that alongside the announced review of the process by Professor Britton, an accompanying review of the outcome or the content - by which I mean the report itself - would restore full credibility and public confidence to the mesh report and, more important, reduce harm to women considering surgery for incontinence and prolapse."<sup>ixiv</sup>

136. Dr Agur was asked to summarise the key differences between the interim and final reports, and what the implications of those differences were. He identified differences in chapter 6 and the conclusions.

137. He explained in detail the methodology applied by the Independent Review in compiling and presenting information in chapter 6 of the interim report. He had previously set out a clear position on this in his written submission.

138. He highlighted how the independent review analysed and weighted evidence from international studies on the topic, the trade-offs between the pros and cons of undergoing a mesh procedure, and how best to present the information so that it could be easily understood by the lay-person. He referred to the conclusion presented in the interim report and how it was received:

” "The Scottish independent review group was the first authority in the world to formally express concerns about a procedure that many clinicians and surgeons and other authorities around the world considered to be a gold standard."<sup>ixv</sup>

139. Dr Agur considered that approach to be a "huge success" by expressing concerns about a procedure which was previously considered the gold standard but noted that that concern was not expressed in the conclusions of the final report. He considered that the recommendation in the final report sent an "ambiguous message".

140. Dr Agur gave his account to the Committee of why he considered the conclusion had removed any reference to concerns about the procedure:

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<sup>ixiii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 2.

<sup>ixiv</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 2.

<sup>ixv</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 4.



” "I believe that the concerns were removed with the significant changes that were made to the format and content of chapter 6 between the publication of the interim report and the publication of the final report. All the methodology that we followed prior to the publication of the interim report was completely changed with the deletion of the previous chapter 6 in January. That has now been replaced by a chapter of only four pages that sets out the current opinion of the majority of clinicians and contains no references. Unfortunately, that chapter now very cleverly expresses all the advantages of the mesh procedures for incontinence without mentioning the most common adverse event, which is mesh erosion, or the most debilitating adverse event, which is chronic pain."<sup>ixvi</sup>

141. The Committee also heard from Dr Agur that the advantages of mesh procedures that were highlighted were the quicker recovery time, noting that in terms of efficacy of the mesh procedure in contrast to non-mesh procedure there was no difference. So patients appeared to be essentially told that they would be in and out of hospital quicker if they chose the mesh procedure. Dr Agur also estimated that the use of mesh saved the NHS approximately £100 per procedure.

142. The Committee sought Dr Agur's view on whether the independent review had had the opportunity to sufficiently consider all available evidence, noting that the Nature study was circulated twice to the review group, but never put on the group's agenda for discussion. He explained that Cochrane review criteria involved looking at short-term randomised controlled trials. He said:

” "The best designed study is to look retrospectively at analysis of large databases. The Nature study that you referred to looked into more than 300 studies that describe mesh-related adverse events and is currently the best evidence summary of mesh-related adverse events."<sup>ixvii</sup>

143. The Committee also sought Dr Agur's understanding of why some of the tables were removed from the final report:

” "The reason that was given at the time was that the figures were not accurate, but we ensured that the figures were accurate. The reason that was given later was that all the evidence should be in chapter 5, not chapter 6, but my view was that we needed to maintain consistency. If we publish something in the interim report and it has worked well and patients have signed up to it, there is no need to change the format."<sup>ixviii</sup>

## Petitioners' evidence

144. In their evidence on 28 September 2017, the petitioners reiterated concerns about the report being a whitewash and that they had been marginalised within the latter stages of the independent review process, and how "vital evidence was ignored, deleted, or hidden".

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<sup>ixvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 5.  
<sup>ixvii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 7.  
<sup>ixviii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 10.

145. Elaine Holmes stated that when Dr Wilkie was replaced as the chair of the review by Dr Gillies "the review group lost its focus and transparency".
146. Among other concerns expressed by the petitioners were that their views were not removed from the final report, despite formally requesting for them to be removed, their voices were "drowned out and stifled by the pro-mesh lobby", patient information leaflets not being updated and concerns about the regulators:
- ” "We can see that medical watchdogs across the world have been useless, toothless and far too close to the manufacturers who make billions from the medicines and medical devices that they are supposed to police."<sup>lxix</sup>
147. In their [written submission of 13 September 2017](#), the petitioners also outlined figures of surgical procedures involving mesh which had been undertaken since the moratorium was announced in June 2014. They did not consider that these procedures were as a result of shared decision making by surgeons and patients:
- ” "Despite Alex Neil calling for a mesh suspension in June 2014, more than 400 women have received mesh implants since that time, and less than 100 women have received non-mesh alternatives. We believe the high number of mesh procedures is as a result of directive counselling and NOT shared decision making."
148. The Committee explored the petitioners' position with regard to being marginalised, and information being limited. The petitioners indicated that within the independent review group, they had to fight against the views of the clinicians and other medical professionals to get their views heard. Olive McIlroy said:
- ” "If you read the minutes, you will find that the group was "not unanimous" in some decisions or discussions. The phrase "not unanimous" usually meant that Elaine and I objected. We had to fight at every meeting. We had to fight even to get the words "safety" and "mesh" put in. We had to fight to get the word "mesh" put in front of the word "tapes", because they kept saying that tapes were not mesh."<sup>lxx</sup>
149. The petitioners also indicated that they were not invited to attend some meetings and that they did not have sight of minutes of any sub-group meetings:
- ” "Even if there were sub-group meetings that perhaps were not pertinent to us, there were never any minutes published or updates on what had happened. We were involved in a sub-group years ago, and afterwards the minutes were published and shared with the wider patient group. We had no updates for 10 months."<sup>lxxi</sup>
150. The Committee identified these issues as matters that could perhaps be addressed in the review of the review by Professor Britton.
151. The petitioners described in oral and written evidence how the updated patient information leaflets, developed to encourage informed consent, were not available

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lxix Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 25.

lxx Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 28.

lxxi Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 29.

in Scotland and that the "information leaflet published on the Scottish Government website is outdated and the explanation of risks is inadequate". In their written submission of 13 September 2017, they stated:

” "A Patient Information Leaflet (PIL) developed by the Scottish Government Expert Group: 'Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women' was adopted by and published in the rest of the UK in May 2017 but not in Scotland – (with the exception of our Scottish Mesh Survivors website)."

152. The petitioners were asked whether their experience in dealing with the MHRA had improved through the course of the review. Elaine Holmes said:

” "I found the MHRA totally frustrating, as well as being a waste of space. I do not know what purpose it serves apart from saying that the benefits outweigh the risks. When regulators around the world have issued safety alerts and advice, the MHRA just continues to say that the benefits outweigh the risks."<sup>lxxii</sup>

153. Olive McIlroy added:

” "I do not know how it can talk about that benefit to risk ratio when it has already acknowledged the severity of the adverse incidents that go unreported. It does not have the information to make that analysis and that statement."<sup>lxxiii</sup>

154. When asked for their views on whether the MHRA was part of the "pro-mesh lobby" within the independent review, the petitioners noted the outcomes when they suggested surgeons who might participate in the review to provide a balance:

” "The MHRA found a problem with every surgeon whom we suggested - it could not contact them or they did not respond to emails."<sup>lxxiv</sup>

155. The petitioners were asked for their views on what changed between publication of the interim report and the final report. They acknowledged that, within the interim report, even though they produced their own minority report, there was a willingness to reach a consensus among the group. They indicated that they felt the review was "heading in the right direction".

156. They reflected the evidence presented previously, that the expectation was that the findings of ongoing studies would provide further evidence for the review to consider in advance of publishing its final report:

” "If anything, the studies that we were waiting for should have strengthened the conclusions and the recommendations in the final report. When we saw the draft final report, we could not believe what we were reading. It told of the benefits of mesh but not the risks, and it mentioned the risks of the non-mesh alternative but not the benefits. It was directing patients towards mesh."<sup>lxxv</sup>

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<sup>lxxii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 30.

<sup>lxxiii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 30-31.

<sup>lxxiv</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 31.

<sup>lxxv</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 32.

157. The petitioners compared the content of the final report to the interim report - "It was like day and night; the approach had been totally changed" - adding that the concern about transobturator mesh tape identified in the interim report had been "totally brushed under the carpet in the final report".
158. The Committee heard and read from the petitioners that they had queried why new evidence from the SCENIHR and PROSPECT studies, as well as the studies in the Nature journal, were overlooked in the content of the final report. They suggested that they were first told that there was "no new evidence", and that when they asked why the tables were being removed, they were advised by a Scottish Government official that that was how it was being done. Elaine Holmes said:
- ” It seems that the group almost had the report ready to go, and I think it was hoping that we would just quietly put our names to it.”<sup>lxxvi</sup>
159. In their written submission of 13 September 2017 the petitioners set out a timeline of requests they made to the Cabinet Secretary for Health and Sport, requesting that all of their input be removed from the final report. In evidence to the Committee the petitioners said that they "felt quite assured that Dr Gillies would listen to the Cabinet Secretary about our concerns". It was the petitioners' opinion that, in these circumstances, the final report was void. Elaine Holmes said:
- ” We do not agree with a large part of the content. That is why we went to the Cabinet Secretary for help, but she did not listen. Eleven days later, she published the report. We asked her to wait and at least to investigate our concerns. What harm would it have done to suspend publication for a month or two to investigate the concerns that we and Dr Agur had and to speak to the previous chair, who had resigned for personal reasons or whatever reasons? I feel that it was rushed, and we would like to know why it was rushed. What was the hurry?”<sup>lxxvii</sup>
160. The Committee sought to establish from the petitioners what had materially changed from publication of the interim report to the publication of the final report, in terms of communication and transparency. Elaine Holmes and Olive McIlroy referred to the fact that they did not receive any communication or updates for up to ten months (during which period Dr Wilkie resigned and Dr Gillies was appointed) but felt that "after we lost the independent chair of the review group, things started to go haywire". Olive McIlroy added:
- ” The only thing that I would say is that, when it started, the review represented patients with a good outcome and patients, like us, with a not-so-good outcome, and the approach should have been the same for clinicians.”<sup>lxxviii</sup>
161. The petitioners were asked whether they had been invited to contribute to the review being conducted by Professor Alison Britton, and whether there were aspects of the review process which they felt could be considered as part of Professor Britton's review. They indicated that, at that time, they had not been invited to provide their input but that they expected there to be time for them to do

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<sup>lxxvi</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 33.

<sup>lxxvii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 39.

<sup>lxxviii</sup> Public Petitions Committee (Session 5), [Official Report](#), 28 September 2017, col 35.

so. However, Olive Mcllroy expressed concerns about the impact and more generally her lack of confidence in anything arising from Professor Britton's review:

” "The review of the review is a waste of money and time. Maybe the health minister should have considered contacting every patient in Scotland who has had one of the mesh procedures to find out what their health status is and going from there, rather than having a review of a review, which will have no effect on the outcome of the final report."<sup>lxxix</sup>

162. Further to the announcement of Professor Britton's review, during the Committee's debate on this petition on 5 December 2017, the Cabinet Secretary confirmed that she had appointed Professor Laura McKee, emeritus professor of management and health services research at the University of Aberdeen to chair the oversight group, established to take forward development work on areas identified within the final report. Noting that the first full meeting of the group was scheduled for January 2018, the Cabinet Secretary said:

” "The oversight group will regularly review data relating to mesh procedures and will scrutinise adverse event reporting. What is particularly significant is that it will continuously review new studies and new evidence, and will carefully consider how that new evidence can be incorporated into pathways of care. The group will also help to ensure that patient information is relevant and up to date."<sup>lxxx</sup>

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<sup>lxxix</sup> Public Petitions Committee (Session 5), *Official Report*, 28 September 2017, col 36.  
<sup>lxxx</sup> Meeting of the Scottish Parliament, *Official Report*, 5 December 2017, col 34-35.

## Professor Britton's review

163. The remit of the review announced by the Cabinet Secretary, to be led by Professor Alison Britton, was to:
- ” "Consider the evidence on how to improve the investigative review process. Specific reference will be made to the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report of March 20171. This will inform recommendations for process of establishing, managing and supporting Independent Inquiries and Reviews in Scotland."
164. Its purpose was to consider and compare processes adopted in other similar reviews in health, and will also make recommendations for conducting such reviews in the future.
165. The Committee asked what effect Professor Britton's review would have on the implementation of recommendations and conclusions within the independent review's final report. The Committee asked whether it was possible that, subject to Professor Britton's findings, the independent review would be revisited. The Cabinet Secretary replied that the independent review had been an extremely complex process and that she had asked Professor Britton "to focus on whether there are things that could have been done better and to make recommendations on how to proceed in the future so that, if possible, we avoid difficulties that the independent review of mesh implants has faced".
166. In response to the Committee's comments about the level of trust or confidence that people could have in Professor Britton's review, given the events that had led to the review of the review being announced and concerns about the true independence of the independent review, the Cabinet Secretary stated that Professor Britton would have the opportunity to speak to all of the individuals, clinicians, experts, patients, involved in the independent review group.
167. The Committee understands that Professor Britton will report her findings later this year.

## Conclusions and recommendations

168. The petition has brought some very serious issues to the attention of the Parliament. The Committee is grateful to the petitioners, Elaine Holmes and Olive McIlroy, for bringing forward this petition and commends their courage and commitment in doing so. In reaching our conclusions and recommendations, the Committee has considered not only whether the actions called for in the petition have been taken but also whether the processes that have been followed and the decisions made have been satisfactory. While the Committee recognises that the recommendations set out in the final report of the Independent Review do address the actions called for in the petition, we have serious concerns about the credibility of the final report as a basis for informing both clinicians and patients to make fully informed decisions.
169. The Committee understands that the governance of healthcare in Scotland means that a request to suspend a particular treatment may not necessarily result in all such treatments being stopped. However, the Committee considers that the Scottish Government could have communicated more strongly that this request be put into effect by all Health Boards. The Committee also considers that patients should have been made aware of the non-binding nature of the request. It is clear to the Committee that the intention of the former Cabinet Secretary was that the use of mesh should have ceased at the point that the 'moratorium' was announced. In that regard, the Committee is disappointed that all Health Boards did not follow the Scottish Government's request for a moratorium.
170. The Committee remains extremely concerned about the changes that occurred between the publication of the interim report and the publication of the final report. The evidence provided to the Committee has at no point provided a clear rationale for the changes in content and layout. The final report may address the issues asked for in the petition, but it is clear from the evidence the Committee has received that they do not do so to an acceptable extent. Given this, the Committee is concerned at the potential for the conclusions and recommendations within the final report being used to justify the lifting of bans on mesh in other jurisdictions.
171. The Committee notes that the Cabinet Secretary has indicated that she does not intend to revisit the final report of the mesh review and that the 'review of the review' being undertaken by Professor Alison Britton will focus on process only. If the findings of Professor Britton's review cast any doubt that issues such as decision-making processes, disclosure of potential conflicts of interest and communication of information to all review members were not adequate, the content of the final report must be reconsidered, including the way in which information was presented.
172. The Committee has also been concerned, on occasion, about a perceived lack of urgency on the part of the Scottish Government about making sure patients are being provided with appropriate information in all contexts, including placing greater emphasis on steps it is taking to ensure up to date information is available to patients whether online or in places such as GP surgeries.
173. The Committee has sought assurances from the Cabinet Secretary and the Chief Medical Officer about the measures that need to be put in place in order for the

recommendations of the final report to be implemented, and these assurances have been provided. This includes the establishment of Healthcare Improvement Scotland's transvaginal mesh oversight group, which has been given responsibility for monitoring the use of mesh implants in Scotland until a managed clinical network can be established. The remit of the multidisciplinary group includes to review data on the use of transvaginal mesh implants in NHSScotland, scrutinise reporting of adverse events by NHS boards, ensure that all patient information is up to date, and to consider how any significant new evidence can be incorporated into agreed care pathways. It was indicated that the group would meet quarterly in 2018 and six monthly in 2019. The Committee is therefore concerned to see that, at the time of writing this report, there appears to have been only one meeting of the group, in January 2018. The Committee is also concerned about whether patients and carers are adequately represented in the membership of the oversight group.

174. The Committee's preference is for the use of mesh devices to treat SUI and POP to cease in Scotland. We do, however, recognise that this is not something that is within the Committee's gift to deliver. The Committee emphasises that any information made available regarding mesh procedures must highlight that there are non-mesh alternatives which have a number of benefits to the patient but do not have the same potential long-term debilitating, sometimes devastating, effects.
175. The Committee recognises that there are grave concerns on the use of mesh, including counterfeit mesh, emerging internationally. The Committee notes that Alex Neil MSP suggested that, due to the international nature of the concerns around the use of mesh devices, there may be merit in an international summit or meeting being held in Scotland.
176. The Committee accepts that licensing and regulation of medicines and medical devices is a reserved matter. The Committee notes the concerns that have been raised during consideration of the petition about the effectiveness of the MHRA as the regulatory body. That aside, the Committee observes that the question of whether a treatment should be used, for a number of criteria, is something that can be considered in a devolved context, especially on the grounds of patient safety.
177. The Committee has heard too often, in respect of this and other petitions, about the difficulties that patients face in being believed when they tell clinicians what they are experiencing. In particular, on this petition, the Committee emphasises its alarm at the apparent disregard of patients' evidence of the devastating and debilitating impact that mesh has had on their lives. The Committee recommends that the Scottish Government undertakes an exercise to understand why this is such a common concern and what steps can be taken to ensure that patient voices are listened to and heard.
178. It is essential that independent reviews have the confidence and trust of the Parliament and, most importantly, the public. The Committee shares the concerns expressed by other members and mesh survivors, about the transparency and true independence of the mesh review. The Committee has been struck by the determination of the petitioners throughout the consideration of the petition. We consider the fact that the petitioners felt compelled to resign from a review into an issue that they cared so deeply about raises serious questions. These questions have not been satisfactorily addressed by the Scottish Government and NHSScotland.



179. Given the significance of the issue, the Committee requests that the Scottish Government provides the Parliament with a full update at the earliest opportunity on progress toward implementing the recommendations of the final report, and an opportunity for a debate once Professor Britton's report is published. The Committee also calls on the Office of the Chief Medical Officer to ensure that all advice issued to health boards regarding the use of mesh and data about the use of mesh are made available to the public.

180. The Committee considers that the Scottish Government should have sought confirmation from health boards that the suspension was being implemented as intended. The Committee recommends that the Scottish Government reviews the processes by which it makes recommendations to health boards on the use of medicines and medical devices, about which significant concerns have been raised, to ensure that accurate information is available to policy-makers and patients.

181. Should Professor Britton's review of the Independent Review highlight significant flaws in the processes of that review, the Committee's view is that the final report of the Independent Review must be regarded as lacking credibility to the extent that it requires to be revisited and calls on the Scottish Government to make a commitment to do so.

182. The Committee also draws the Scottish Government's attention to the suggestion from Alex Neil MSP regarding an international meeting and recommends that the Scottish Government considers hosting such a meeting.

183. The Committee accepts that licensing and regulation of medicines and medical devices is a reserved matter, regulated by the Medicines and Healthcare products Regulatory Agency. Notwithstanding the Committee's concerns about the MHRA's approach to the issues raised in the petition, the Committee recommends that the Scottish Government takes all steps available to ensure that no mesh procedures are carried out in Scotland until such time as the Committee, the Parliament and the public can have confidence in the findings of the Independent Review.

# Annexe A - Extracts from Minutes and links to oral evidence

## **11th Meeting, 2014 (Session 4), Tuesday 3 June 2014**

**2. Consideration of new petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices and took evidence from Elaine Holmes, Olive McIlroy, and Marion Scott, Sunday Mail. The Committee agreed to write to the Scottish Government, the Medicines Healthcare Products Regulatory Agency, NHS National Services Scotland, the European Commission, the Royal College of Surgeons of Edinburgh, the British Medical Association Scotland and NHS boards. The Committee also agreed to invite the Cabinet Secretary for Health and Wellbeing to give evidence at a future meeting.

[Official Report of the meeting](#)

[Meeting papers](#)

## **12th Meeting, 2014 (Session 4) Tuesday 17 June 2014**

**1. Consideration of a current petition:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices and took evidence from Alex Neil, Cabinet Secretary for Health and Wellbeing, and Dr Frances Elliot, Deputy Chief Medical Officer, Scottish Government. The Committee agreed to invite Adam Slater, Mazie Slater Katz & Freeman, LLC, to give evidence via video link at a future meeting. The Committee also agreed to explore the possibility of meeting the European Commissioner for Health and Consumer Policy at a future date.

[Official Report of the meeting](#)

[Meeting papers](#)

## **16th Meeting, 2014 (Session 4) Tuesday 11 November 2014**

**2. Consideration of current petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices. The Committee agreed to write to the Scottish Government and the Department of Health.

[Official Report of the meeting](#)

[Meeting papers](#)

## **2nd Meeting, 2015 (Session 4) Tuesday 27 January 2015**

**3. Consideration of current petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices. The Committee agreed to reschedule the evidence session with Adam Slater. The Committee also agreed to invite the Cabinet Secretary for Health, Wellbeing and Sport, the Medicines and Healthcare Products

Regulatory Agency, the Chair of the Independent Review of Transvaginal Mesh Implants and the European Commission to give evidence at a future meeting.

[Official Report of the meeting](#)

[Meeting papers](#)

**5th Meeting, 2015 (Session 4) Tuesday 24 February 2015**

1. **Consideration of a current petition:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices and took evidence from Dr Neil McGuire, Consultant in Intensive Care and Anaesthesia, Clinical Director Devices, and Sally Mounter, Senior Medical Device Specialist, Biosciences and Implants Devices Division, Medicines and Healthcare Products Regulatory Agency; and then, via videoconference, from Adam M Slater, Mazie Slater Katz & Freeman, LLC. The Committee agreed to write to the Scottish Government to seek its assurance that the evidence of the Medicines and Healthcare Products Regulatory Agency and Mr Slater would be taken account of by the Independent Review of Transvaginal Mesh Implants. The Committee also agreed that the evidence sessions with the Cabinet Secretary for Health, Wellbeing and Sport, the Chair of the Independent Review and the European Commission would take place after publication of the Independent Review's Findings.

[Official Report of the meeting](#)

[Meeting papers](#)

**10th Meeting, 2015 (Session 4) Tuesday 12 May 2015**

3. **Consideration of continued petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices. The Committee agreed to write to the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, the Royal College of Obstetricians and Gynaecologists and the British Society of Urogynaecology.

[Official Report of the meeting](#)

[Meeting papers](#)

**16th Meeting, 2015 (Session 4) Tuesday 6 October 2015**

2. **Consideration of a continued petition:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices and took evidence from Dr Lesley Wilkie, Chair, Independent Review of Transvaginal Mesh Implants, Dr Rachael Wood, Consultant in Public Health Medicine, NHS Information Services Division and Dr Phil Mackie, Lead Consultant in Public Health, Scottish Public Health Network; and then from Shona Robison, Cabinet Secretary for Health, Wellbeing and Sport, and Catherine Calderwood, Chief Medical Officer, Scottish Government.

The Committee agreed to consider the evidence heard at a future meeting.

[Official Report of the meeting](#)

[Meeting papers](#)

**2nd Meeting, 2016 (Session 4) Tuesday 26 January 2016**

**2. Consideration of continued petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices. The Committee agreed to write to the Scottish Government.

[Official Report of the meeting](#)

[Meeting papers](#)

**6th Meeting, 2016 (Session 4) Tuesday 8 March 2016**

**1. Consideration of continued petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices. The Committee agreed to include the petition in its legacy paper for consideration by the Session 5 Public Petitions Committee. In doing so, the Committee agreed to write to the UK Government.

[Official Report of the meeting](#)

[Meeting papers](#)

**4th Meeting, 2016 (Session 5) Thursday 29 September 2016**

**1. Consideration of continued petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy, on behalf of Scottish Mesh Survivors – Hear Our Voice campaign, on polypropylene mesh medical devices. The Committee agreed to defer further consideration of the petition until the final report of the Independent Review is published and to seek an update from the Scottish Government on the work of the expert group.

[Official Report of the meeting](#)

[Meeting papers](#)

**10th Meeting, 2017 (Session 5) Thursday 18 May 2017**

**1. Consideration of a continued petition:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign on polypropylene mesh medical devices and took evidence from Tracey Gillies, Chair, Independent Review of Transvaginal Mesh Implants; Shona Robison, Cabinet Secretary for Health and Sport and Catherine Calderwood, Chief Medical Officer. The Committee agreed to invite the petitioners to provide oral evidence at a future meeting, to invite members of the Independent Review to make submissions to the Committee, to seek time for a debate on the petition and to seek clarification about powers in relation to the regulation of medical devices.

[Official Report of the meeting](#)

[Meeting papers](#)

**17th Meeting, 2017 (Session 5) Thursday 28 September 2017**

**1. Consideration of a continued petition:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign on polypropylene mesh medical devices and took evidence from— Dr Wael Agur, Consultant Gynaecologist and Obstetrician; Elaine Holmes; Olive McIlroy. The Committee agreed to consider a note by the Clerk at a future meeting. The Committee also agreed to write to the Cabinet Secretary for Health and Sport in relation to the availability of patient information.

[Official Report of the meeting](#)

[Meeting papers](#)

**19th Meeting, 2017 (Session 5) Thursday 26 October 2017**

**2. Consideration of continued petitions:** The Committee considered PE1517 by Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign on Polypropylene Mesh Medical Devices. The Committee agreed to consider a draft report in private at a future meeting.

[Official Report of the meeting](#)

[Meeting papers](#)

**10th Meeting, 2018 (Session 5) Thursday 7 June 2018**

**3. Consideration of a continued petition (in private):** The Committee considered a draft report on petition PE1517 by Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" on Polypropylene Mesh Medical Devices. The Committee agreed to continue consideration of the draft report in private at future meetings.

[Official Report of the meeting](#)

[Meeting papers](#)

# Annexe B - Written evidence submitted to the Committee

Below is a list of all [written evidence](#) submitted to the Committee in relation to this petition:

- PE1517/A: Professor Tom Joyce Email of 23 March 2014
- PE1517/B: Dr Michael Margolis Letter to the Cabinet Secretary for Health and Wellbeing of 8 September 2013
- PE1517/C: NHS Dumfries and Galloway Letter of 10 June 2014
- PE1517/D: NHS Grampian Letter of 16 June 2014
- PE1517/E: Adam M Slater Letter of 13 June 2014
- PE1517/F: NHS Shetland Email of 14 June 2014
- PE1517/G: NHS Greater Glasgow and Clyde Letter of 1 July 2014
- PE1517/H: NHS Lothian Letter of 21 June 2014
- PE1517/I: NHS Western Isles Letter of 2 July 2014
- PE1517/J: NHS Ayrshire and Arran Letter of 1 July 2014
- PE1517/K: NHS Fife Letter of 8 July 2014
- PE1517/L: NHS Forth Valley Letter of 3 July 2014
- PE1517/M: Petitioner Letter of 12 August 2014 (revised 3 November 2014)
- PE1517/N: NHS Borders Letter of 14 August 2014
- PE1517/O: NHS Lanarkshire Letter of 14 August 2014
- PE1517/P: NHS Orkney Letter of 14 August 2014
- PE1517/Q: Medicines Healthcare Products Regulatory Agency Email of 14 August 2014
- PE1517/R: NHS Tayside Email of 22 August 2014
- PE1517/S: British Medical Association Scotland Letter of 28 August 2014
- PE1517/T: European Commission Letter of 1 September 2014
- PE1517/U: NHS National Services Scotland Letter of 3 October 2014
- PE1517/V: NHS Highland Letter of 16 October 2014
- PE1517/W: Royal College of Surgeons Edinburgh Letter of 4 November 2014

- PE1517/X: Department of Health Letter of 12 December 2014
- PE1517/Y: Scottish Government Letter of 16 December 2014
- PE1517/Z: Scottish Government Letter of 5 February 2015
- PE1517/AA: Chartered Society of Physiotherapy Scotland Letter of 2 March 2015
- PE1517/BB: Scottish Government Letter of 5 May 2015
- PE1517/CC: Petitioner Letter of 7 October 2015
- PE1517/DD: Scottish Government Letter of 9 December 2015
- PE1517/EE: Scottish Government Letter of 11 February 2016
- PE1517/FF: Department of Health Letter of 12 April 2016
- PE1517/GG: Scottish Government Letter of 1 July 2016
- PE1517/HH: Medicines and Healthcare Products Regulatory Agency Email of 9 September 2016
- PE1517/II: Scottish Government Letter of 27 October 2016
- PE1517/JJ: Petitioners' submission of 8 May 2017
- PE1517/KK: Dr Peter Gordon submission of 17 May 2017
- PE1517/LL: Cabinet Secretary for Health and Sport submission of 17 May 2017
- PE1517/MM: Cabinet Secretary for Health and Sport submission of 31 May 2017
- PE1517/NN: Cabinet Secretary for Health and Sport submission of 26 June 2017
- PE1517/OO: Marilyn Weir submission of 24 August 2017
- PE1517/PP: Charlotte Korte submission of 16 June
- PE1517/QQ: Yvonne Tobyn submission of 3 July 2017
- PE1517/RR: Kath Sansom submission of 24 July 2017
- PE1517/SS: Susan Doyle submission of 9 August 2017
- PE1517/TT: Maureen McLaughlan submission of 28 August 2017
- PE1517/UU: Norma Roberts submission of 29 August 2017
- PE1517/VV: Lorna Farrell submission of 31 August 2017
- PE1517/WW: Isobel McLafferty submission of 31 August 2017
- PE1517/XX: Jackie Harvey submission of 31 August 2017
- PE1517/YY: Marion Garland submission of 31 August 2017

- PE1517/ZZ: Gillian Watt submission of 1 September 2017
- PE1517/AAA: Ann Van Looy submission of 1 September 2017
- PE1517/BBB: Marian Kenny submission of 2 September 2017
- PE1517/CCC: Ingrid Hardacre submission of 3 September 2017
- PE1517/DDD: Annemarie Conley submission of 10 September 2017
- PE1517/EEE: Carolyn Chisholm (Australian Pelvic Mesh Support Group) submission of 11 September
- PE1517/FFF: Jemima Williams submission of 11 September 2017
- PE1517/GGG: Claire Daisley submission of 1 September 2017
- PE1517/HHH: Karen Neil submission of 15 September 2017
- PE1517/III: Petitioner submission of 13 September 2017
- PE1517/JJJ: Dr Wael Agur submission of 15 September 2017
- PE1517/KKK: Fiona Paterson submission of 20 September 2017
- PE1517/LLL: Damian Murtagh submission of 26 September 2017
- PE1517/MMM: Bea Burrows submission of 24 September 2017
- PE1517/NNN: Melanie Hill submission of 26 September 2017
- PE1517/OOO: Joy Clarkson submission of 27 September 2017
- PE1517/PPP: Julie Barr submission of 21 September 2017
- PE1517/QQQ: Debbie McGeachy submission of 26 September 2017
- PE1517/RRR: Joanne Lloyd submission of 21 September 2017
- PE1517/SSS: Janis Nicolson submission of 26 September 2017
- PE1517/TTT: Sheila Cassidy submission of 21 September 2017
- PE1517/UUU: Marion McMillian submission of 14 September 2017
- PE1517/VVV: Alison Bradshaw submission of 21 September 2017
- PE1517/WWW: Linda McLaughlin submission of 21 September 2017
- PE1517/XXX: Jacqueline Day submission of 23 September 2017
- PE1517/YYY: Susan McLarnon submission of 26 September 2017
- PE1517/ZZZ: Angela Spaniak submission of 26 September 2017
- PE1517/AAAA: Sharon Davies submission of 26 September 2017



- PE1517/BBBB: Gill Hayward submission of 26 September 2017
- PE1517/CCCC: Kylie Stott submission of 27 September 2017
- PE1517/DDDD: Justine Watson submission of 27 September 2017
- PE1517/EEEE: Christine Whitewood submission of 27 September 2017
- PE1517/FFFF: Sharon J Mercado submission of 22 September 2017
- PE1517/GGGG: Cabinet Secretary for Health and Sport submission of 24 October 2017

# Annexe C - Conclusions and recommendations of the Independent Review's interim report

## Conclusion 1

Robust clinical governance must surround treatment, the decision to use mesh and the surgical approach used. To support decision making, management of the individual patient should take place in the context of multi-disciplinary team assessment, audit and review. The use of a comprehensive information system will underpin this. **The Expert Group should address this with NHS planners, including an assessment of any administrative support required for the clinical teams.**

## Conclusion 2

Evidence of involvement in multi-disciplinary team working, engagement in audit activity and recording and reporting of adverse events should be an important part of consultant appraisal and thus statutory revalidation of medical staff. **The Expert Group should work with Medical Directors as Responsible Officers to include this in the conduct and supervision of appraisal. In addition the Scottish Government should consider the alternative methods for the capture of adverse events set out in chapter 8 to determine further the most effective way to ensure complete notification.**

## Conclusion 3

Informed consent is a fundamental principle underlying all healthcare. There has been extensive work done by the Expert Group which preceded the establishment of the Independent Review, with leadership by both patients and clinicians. This has resulted in an SUI information leaflet and consent form. **Following on from this the Independent Review concludes that additional work is required to ensure that this work is extended to include POP procedures and that the SUI leaflet is reviewed in the light of this work and other recent developments. This should be addressed by the Expert Group as a matter of urgency. Other points highlighted by the Independent Review include the provision of adequate time for discussion and reflection. Patients should be provided with information enabling them to report adverse events if these occur.**

## Conclusion 4

The Independent Review does not consider that current research studies on safety and effectiveness will provide evidence on long term impact of mesh surgery. The lack of extended long term follow up and related outcome data, including information on quality of life and activities of daily living, should be addressed. **The Independent Review recommends the Expert Group highlights this knowledge gap to funders of health research and the research community. Opportunities for routine audit should be explored by the Expert Group in conjunction with NHS Scotland.**

## Conclusion 5

Good information, as stated before, is essential to good patient care. The experience of the Independent Review has been that there are many gaps although there is information both in a professionally led database (the BSUG database) and routine NHS information (SMR01 and SMR00). **It is recommended that the Expert Group works with ISD, BSUG and others to ensure that an information system is developed which is universal, robust, clinically sound and focused on fostering good patient outcomes. Work already underway on consistent coding by ISD will be vital to this endeavour.**

### Conclusion 6

The Independent Review expressed serious concern that some women who had adverse events found they were not believed, adding to their distress and increasing the time before any remedial intervention could take place. Improving awareness of clinical teams of the possible symptoms of mesh complications together with good communication skills, (including good listening and empathy) is an essential part of good clinical care. **The Independent Review concluded that the Expert Group should review the training and information available to clinical teams and find ways of incorporating patient views in multi-disciplinary working. It should also continue oversight of the mesh Helpline.**

### Conclusion 7

A review of the different sources of evidence available to and considered by the Independent Review (patient experience, clinical expert opinion, research evidence and epidemiological evidence from routine information) has led us to express concern in this Interim Report at the use of the transobturator rather than the retropubic approach for routine surgery for stress urinary incontinence using mesh. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views. **We await the final publication of key research reports but wish to register these concerns and to recommend that the Expert Group in the following months before the publication of the final report explore further appropriate pathways to ensure the techniques chosen take the differential patient and clinical experience, as well as research evidence into account.**

### Conclusion 8

Similar concern is expressed, both for effectiveness and adverse events, at the use of transvaginal mesh in surgery for pelvic organ prolapse. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views. **We await the final publication of key research reports but wish to register these concerns and to recommend that the Expert Group in the following months before the publication of the final report explore further appropriate pathways to ensure the techniques chosen take the differential patient and clinical experience, as well as research evidence into account.**

# Annexe D - Conclusions and recommendations of the Independent Review's final report

## Conclusion 1

Fundamental to the treatment of patients with SUI and POP is patient-centred care which should include patient choice and shared decision making supported by robust clinical governance. To support shared decision making, management of patients must take place in the context of a multidisciplinary team (MDT), supported by a quality assurance framework. In addition, the Scottish Government should consider the alternative methods for the capture of adverse events set out in chapter 8 to determine the most effective way to ensure complete notification.

## Conclusion 2

Evidence of involvement in MDT working; engagement in all relevant local and national audit activity; and the mandatory recording and reporting of adverse events, in line with GMC guidance, should be necessary parts of consultant appraisal and thus statutory revalidation of clinical staff. The Expert Group should work with Medical Directors and Responsible Officers to ensure this is included in the appraisal of all relevant staff.

## Conclusion 3

Informed consent is a fundamental principle underlying all healthcare interventions. Extensive work was carried out by the Expert Group prior to the establishment of the IR, with leadership by both patients and clinicians. This has resulted in an information leaflet on Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women and consent form. Following on from this, the IR concludes that additional work is required to ensure that this work is extended to include all appropriate SUI and POP procedures and that the existing SUI leaflet is reviewed in the light of this work and other recent developments. This should be addressed by the Expert Group as a matter of urgency. Other points highlighted by the IR include the provision of adequate time for discussion and reflection. Patients should be provided with the information they need in order to make informed choices. Patients also require appropriate information, which must include device identification, to allow them to report adverse events if these occur.

## Conclusion 4

The IR does not consider that current research studies on safety and effectiveness provide sufficient evidence on long-term impact of mesh surgery. The lack of long-term follow up and related outcome data, including information on quality of life and activities of daily living, should be addressed. The IR recommends the Expert Group highlights this knowledge gap to the research community and those that fund health research. Opportunities for routine audit should be explored by the Expert Group in conjunction with NHSScotland.

## Conclusion 5

Good information is essential to good patient care. The experience of the IR has been that, although data on the provision of SUI and POP surgery is held both in professionally-led databases and routine NHS activity data, the information derived from such sources could be improved. It is recommended that the Expert Group works with key stakeholders to address information gaps and ensure that available information is used as effectively as possible to support safe and effective care. The IR notes that, as an important first step towards this, ISD has already secured the creation of new data codes that will allow more precise recording of mesh surgery and any subsequent mesh removal/revision within routine NHS activity data records.

### **Conclusion 6**

The IR expressed serious concern that some women who had adverse events felt they were not believed, adding to their distress and increasing the time before any remedial intervention could take place. Improving awareness amongst clinical teams of the possible symptoms of mesh complications together with good communication skills, (including good listening and empathy) is an essential part of good clinical care. The IR concluded that the Expert Group should review the training and information available to clinical teams in primary and secondary care and find ways of incorporating patient views in MDT working. The importance of developing pathways for the treatment of complications is emphasised, ensuring involvement of clinicians with the appropriate skills to take forward the personalised and holistic care necessary in these situations.

### **Conclusion 7**

In the case of surgical treatment for SUI, a review of the different sources of evidence has led us to recommend that women must be offered all appropriate treatments (mesh and non-mesh) as well as the information to make informed choices. Management of patients must follow agreed care pathways and the importance of multidisciplinary assessment is emphasised. When surgery involving polypropylene or other synthetic mesh tape is contemplated, a retropubic approach is recommended. The Expert Group must develop appropriate pathways, including one for management of those suffering complications. Work with Medical Directors and Planners will be required to ensure their smooth implementation.

### **Conclusion 8**

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. The Expert Group must develop appropriate pathways to meet clinical needs and also for the management of those suffering complications. Work with Medical Directors and Planners will be required to ensure their smooth implementation.

