PE1517/JJJ
Dr Wael Agur submission of 15 September 2017

Thank you for the invitation to appear before the Committee to provide oral evidence at its meeting on Thursday 28th September. I have provided appendices to support this submission.

In this submission, I request that the Government's Mesh Report to be a subject of a public consultation process. This process has been employed prior to the publication of the European Mesh Report and is an essential part of the normal procedures leading to the publication of clinical guidelines north and south of the border. This request for a public consultation process is based on the following points, and I have provided appendices to :

1) The Report can further reduce harm to women considering surgery for pelvic organ prolapse.

a) The Report allowed the highest risk mesh **procedures** despite lack of proven benefit over standard non-mesh alternatives. ***Appendix 2 - page 14.***

The Report added the word 'routinely' to Conclusion 8 and encouraged individual surgeons to select patients for mesh surgery for prolapse. This is currently in contrast with all available evidence. Authors of the Scottish-led PROSPECT trial (the largest trial of prolapse worldwide) described mesh-related risks to be 'unnecessary' as no benefit was seen. This is regardless of whether the procedure is primary or secondary. Emerging evidence from a European trial on only repeat surgery showed no benefit (short or long term) either. The Scottish 20-year look-back study confirms the risks are unnecessary. A Cochrane review of relevant randomised studies criticised the MHRA for stating 'benefit outweigh the risks' and proposed that prolapse mesh is not offered to patients unless approved by an Ethics Committee i.e. within research context. Legal evidence confirmed that using a prolapse mesh device is associated with the highest risk of litigation among all pelvic mesh devices. Surgeons in Scotland had already followed government suspension in June 2014 and voluntarily stopped using transvaginal mesh in prolapse surgery.

b) The currently available mesh **products/devices** used in these procedures have no reliable evidence on safety and efficacy.

The mesh devices used in the above trial are no longer available in Scotland as the manufacturer voluntarily withdrew them from the market, relabelled them 'for abdominal use only' or closed the business altogether. Therefore, the prolapse mesh devices that remain in Scotland's market, and are allowed to be used according to Conclusion 8, are relatively newer and had not been evaluated in clinical trials.

Therefore, I do believe the word 'routinely' must be removed from Conclusion 8 until long-term trials prove benefit - and prove that such benefit outweighs the serious risks.

2) The Report can further reduce harm to women considering surgery for stress urinary incontinence.

a) The Report did not adequately warn surgeons and patients against the serious risks associated with the **transobturator mesh tape**. ***Appendix 2 - page 13.***

The concerns expressed in Recommendation 7 of the Interim Report (Oct 2015) regarding the mesh risks of the transobturator tape (the commonest continence procedure performed in Scotland before the suspension) were removed. Such removal of the already expressed concerns gives an ambiguous message to the reader. I believe this procedure is entirely avoidable and its risks outweigh the benefits. Moreover, its serious adverse events are

irreversible as the device cannot be safely removed in its entirety.

Therefore, I do believe the Final Report must firm up the concerns already expressed in the Interim Report and explicitly recommend against the use of the transobturator mesh tapes in Conclusion 7 - except after approval of a national clinical network, at least.

b) The eleventh hour addition of the phrase **'other synthetic'** to Conclusion 7 can put women to unnecessary harm by suggesting that clinicians can use materials other than Polypropylene in pelvic surgery. This is clearly has no evidence base. If we are to learn from the current mesh crisis, such 'other synthetic' materials must never be used outside research context. ***Appendix 3 - page 15.***

c) The **current Chapter Six** directs clinicians and women towards choosing mesh tape procedures over the less risky non-mesh alternatives. The Chapter highlights all possible benefits of mesh procedures but overlooks the most common adverse event (mesh erosion) and the most debilitating one (chronic pain). Conversely, it highlights the disadvantages of non-mesh surgery and overlooks their advantages. Therefore, and in contrast to Conclusion 1 that promotes balanced shared-decision making, this chapter leads the clinicians and patients to believe mesh surgery is better.

d) The Report demoted the current best evidence (in the **deleted Chapter Six**) to an appendix and to an online annex. The deleted Chapter Six represented a balanced comparison of risks associated with mesh and non-mesh procedures. It contains the patient-friendly shared-decision tables in consistency with the Interim Report of 2015. ***Appendix 4 - page 18.***

Therefore, I do believe the Final Report must reinstate the original deleted Chapter Six to restore balance and be transparent about the comparative safety of mesh and native tissue procedures.

e) The Report ignored the current **best evidence on mesh-related adverse events** that described the prevalence of a negative outcome to be as frequent as 15% (1 in 7).

f) The Report did not scrutinise the emerging evidence on **surgical removal of retropubic mesh tape**, the mesh devices it recommends to be used as first line surgery. Such evidence suggested that, in the majority of cases, adverse events are not improved and can be worsened following surgical removal of the device.

3) The Report did not recommend **mandatory recording of all mesh procedures** on the currently available national registries, thus leading to a certain failure to obtain accurate figures on mesh-related adverse events in the future. ***Appendix 2 - page 11 (Conclusion 5).***

4) The Report did not identify the causes and **risk factors** that could lead to the development of mesh-related adverse events. Identifying these factors was an important part of the Review's original remit. Such factors are essential to describe individual patient's risks and to inform the patient consultation.

I believe the recently announced Review of the *process* of the Government Review by Professor Alison Britton is to be accompanied by a review of the *outcome*, the Report itself. This is best achieved by opening the Report to a public consultation at this stage. Such action will restore credibility and public confidence in the Report and, more importantly, reduce harm to women considering surgery for incontinence and prolapse.

List of appendices

Appendix 1 – Declaration of competing interests

This form was updated and submitted to Government officials on 29th November 2016.

In Jan 2014, I voluntarily published more details on the funds received from industry on this register: www.whopaysthisdoctor.org/doctor/33

I had previously given advice to lawyers acting on behalf of mesh manufacturers, lawyers acting on behalf of patients and lawyers acting on behalf of NHS Scotland. On July 24th and 25th 2017, I gave evidence in Court in Sydney, Australia after receiving instructions from lawyers acting on behalf of over 700 women in a product liability class action against a mesh manufacturer.

Declaration of Interests

NAME (block capitals) WAEL AGUR

1. Personal interests over the last 12 months

This involves payments[1] (or other support) from any one company to an individual member or their spouse/partner/cohabittee or close relative. The main examples are consultancies, fee-paid work, travel grants or company shares. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To
Astellas Pharmaceuticals (lapsed, personal non-specific)	Education Courses Sponsorship Consultancy Fees	2011	2015
Pfizer (lapsed personal non-specific)	Education Courses Sponsorship Speaker Honoraria	2007	2012
UCB Pharma (lapsed personal non-specific)	Speaker Honoraria	2007	2007
Ethicon Endoscopy (personal non-specific)	Education Courses Sponsorship Speaker Honoraria	2013	Now
Boston Scientific (lapsed personal specific)	Education Courses Sponsorship	2012	2012
Olympus (personal non-specific)	Education Courses Sponsorship	2014	Now
Bard (lapsed personal specific)	Education Courses Sponsorship Preceptor / Trainer Fees	2011	2012
Neomedic (lapsed personal specific)	Education Courses Sponsorship	2013	2013

SEP Pharma (personal non-specific)	Education Courses Sponsorship Preceptor / Trainer Fees – Training surgeons on non-mesh procedures (bulking agent)	2015	Now
NHS Ayrshire & Arran (personal non-specific)	Organisation of Surgical Workshop - Training surgeons on non-mesh continence procedures.	2015	2016
London Medical Education Academy (LMEDAC) (personal non-specific)	Organisation of Surgical Workshop - Training surgeons on non-mesh continence procedures	2016	Now
Central Legal Office, NHS Scotland (personal specific)	Provision of Medico-legal Advice on mesh litigation	2015	Now
Law Firms in Scotland, England, USA and Australia (personal specific)	Provision of medico-legal advice and/or expert opinion on mesh litigation	2016	Now
University of Aberdeen (non-personal specific)*	Ensuring accuracy and integrity of the SIMS pilot (short- and long-term) study*	2016*	Now*

*I do not believe this activity competes with the Government role, or vice versa. I am declaring it; however, as there has been a suggestion it could compete.

1 for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books etc.)

2. Non-Personal interests over the last 12 months

This implies support[2] from any one company for your unit or place of work. It may be financial or in kind e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To
Astellas Pharmaceuticals (Non-personal non-specific)	Financial support through a service development contract with Ayrshire O&G Dept. Funding training for nurses and other team members and purchase of equipment.	2010	Now
University of Aberdeen	Financial support through research payment as the Principal Investigator – SIMS pilot study	2010	2010
University of Aberdeen	Financial support through research payment as the Principal Investigator – PROSPECT studies	2010	2013
University of Aberdeen	Financial support through research payment as the Principal Investigator – VUE studies	2013	Now

2 for practical purposes, payments and/or support to a value in excess of £1000 annually should be declared. (Threshold of £1000 chosen to concord with Scottish Medicines Consortium guidance.)

Signature: Wael Agur Date: 29/11/2016

Aide-Memoire to Declaration of Interests at Meetings and Participation by Members

Working Group members are required to declare relevant interests and to state whether they are personal or non-personal interests and whether they are specific to the product under consideration or non-specific.

A member must declare a personal specific interest if he or she has at any time worked on the product under consideration and has personally received payment for that work, in any form, from any relevant body, including companies, charities etc. The member shall take no part in the proceedings if they relate to that product. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.

A member must declare a personal non-specific interest if he or she has a current personal interest in any relevant body concerned which does not relate specifically to the product under discussion. The member shall take no part in the proceedings as they relate to the product, except at the Chairman's discretion.

A member must declare a non-personal specific interest if he or she is aware that the department for which he or she works has at any time worked on the product but the member has not personally received payment in any form from the body for the work done. The member may take part in the proceedings unless he or she has personal knowledge of the product through his or her own work or through direct supervision of other people's work, in which case he or she should declare this and not take part in the proceedings.

A member must declare a non-personal, non-specific interest if he or she is aware that the department for which he or she works is currently receiving payment from any relevant body concerned which does not relate specifically to the product under discussion. The member may take part in the proceedings unless the Chairman rules otherwise.

Appendix 2 – My comments on the draft recommendations - circulated to the chair and group members on Feb 21st.

Chapter 9: Conclusions and Recommendations

No surgical intervention is without risk. This IR has shown that mesh procedures for both SUI and POP carry a risk of complications which, in some cases, are life changing and cannot be corrected. However, for the majority, such serious complications do not occur. The aim of our conclusions and recommendations is to minimise and manage that potential risk. Input from clinicians and provision of adequate information will allow patients to make informed choices regarding their treatment.

In the process of coming to its conclusions, the IR has considered evidence from a number of sources; this included patient stories, clinical expert opinion, published scientific evidence, legal reports and the rich epidemiological data provided by ISD. It also benefited from presentations from other bodies such as the Chief Scientist Office and IRIC. The following conclusions, and the recommendations contained within, are drawn from this evidence and discussion.

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. The Expert Group is considering the development of shared-decision tool/aid to support the counselling process and patient choice.

This recommendation is about moving away from directive counseling and into shared-decision making. The shared-decision tool/aid was drafted in Summer 2016 along the concepts of 'Request-for-Treatment' and 'Teach-Back' suggested by the chair of the Expert Group. The tool has already been reviewed and is under development. It is worthwhile to mention it here as a task for the Group to complete.

Conclusion 2

Evidence of involvement in MDT 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 effect mandatory reporting through the ~~include this in the conduct and supervision of~~ appraisal and revalidation processes.~~.~~ ~~In addition the Scottish Government should~~The Expert Group will review the outcome of the above process and may request to 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.

This recommendation is about reporting of adverse events to provide the '***numerator'*** figure essential for future calculation of the adverse event ***rate***.
Will this issue continue to sit with the Scottish Government itself after publication of the final report? How about with the Expert Group instead?

My understanding is all members of the Independent Review Group agree that adverse event reporting to IRIC/MHRA should be made mandatory, and most believe the appraisal/revalidation system is the best process to achieve this objective. If my understanding is correct, this recommendation needs to mention the word 'mandatory', regardless of the process chosen to implement.

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 a SUI information leaflet and consent form. Following on from this the IR concludes that additional work is required to ensure that this work is extended to include ~~POP procedures~~non-mesh 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 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.

POP mesh procedures have no proven benefit and will probably not be offered, at least in Scotland. Therefore, for a better use of the resources of the Scottish Expert Group, we would recommend to prioritise the development of information leaflets for colposuspension (the standard non-mesh SUI procedure), autologous fascial sling and bulking agent injections. These are now more important than POP mesh procedures, particularly as the number of surgeons keen to introduce/re-introduce these procedures into their practice appears to be on the increase.

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 extended 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 funding bodies and research ethics committees. Opportunities for routine audit should be explored by the Expert Group in conjunction with NHSScotland.

I think the Research Ethics Committees that are currently considering projects that involve the use of pelvic mesh would benefit from liaising with the Expert Group (which now accumulated a wealth of experience in the subject) prior to approval. I believe such liaison is important to safeguard the health of women who participate in future research projects that involve pelvic mesh.

Conclusion 5

Good information, as stated before, is essential to good patient care. The experience of the IR has been that there are many gaps although there is information both in ~~a~~ professionally ~~-~~led databases (the BSUG and BAUS databases) and routine NHS information (SMR01 and SMR00). It is recommended that the Expert Group works with ISD, BSUG, BAUS and others to ~~ensure~~ explore ~~that~~ the development of 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 is vital to this endeavour and the new codes will be available when OPCS4.8 is released. While these initiatives are underway, the Expert Group should work with Medical Directors as Responsible Officers to ensure mandatory use of the available registries from national societies (BSUG and BAUS) through the appraisal and revalidation processes. The Expert Group will review the outcome of the above process and may request to consider alternative methods to determine further the most effective way to ensure complete recording of the relevant surgical procedures.

This recommendation is about using a national registry for pelvic mesh procedures to provide the '***denominator'*** figure essential for future calculation of the adverse event ***rate***.

Developing a *universal information system* can take years and is partly dependent on organisations based outside Scotland. This task will not be the easiest for the Expert Group. In the meantime, there is a 'low-hanging fruit' to improve the use of registries by recommending it to be

mandatory, as MHRA reporting of adverse events.

My understanding is all members of the Independent Review Group agree that the use of a registry should be made mandatory, and most believe the appraisal/revalidation system is probably the best process to achieve this objective. If my understanding is correct, this recommendation needs to mention the word 'mandatory', regardless of the database chosen to use and regardless of the process chosen to implement.

Comment on both conclusion 2 and 5:

I believe the clinical community expects our two recommendations to make both MHRA reporting and the use of registry 'mandatory'. Important to remember it was mainly the lack of accurate figures on adverse event rates that had led politicians to suspend mesh procedures in the first place. If we do not recommend these two activities to be mandatory at this stage, the true adverse event rates will remain unknown in the future and politicians may have to re-commission this group in few years' time.

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 treatment of complications is emphasised, ensuring involvement of clinicians with the appropriate skills to take forward personalised and holistic care necessary in these situations.

Only one comment on this recommendation; to highlight to the Expert Group that one of the '*ways of incorporating patient views in MDT working'* is the shared-decision aid itself, mentioned in Conclusion One.
A 'pilot' started in Ayrshire in September 2016. MDT members read the patient's completed tool, in her own handwriting, describing her understanding, values and reasons of choice of surgery. Some interesting experiences to share at a later stage.

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, including colposuspension (the standard non-mesh procedure) and retropubic tape (the standard mesh procedure) ~~(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 mesh tape is contemplated, ~~the current evidence favours a~~we recommend the use of only the retropubic approach. Due to the associated risks, the transobturator tape procedure can be considered only with involvement of national MDT. The Expert Group must develop appropriate pathways, including one for management of those suffering mesh-related complications. Work with Medical Directors and Planners will be required to ensure the~~ir smooth~~ national implementation of the pathways.

Regarding colposuspension vs retropubic mesh tape procedures:

As it stands, this conclusion will suggest to (at least) some readers that the retropubic tape is the best surgery for all women with SUI. For balance, if the recommendation mentions the standard mesh procedure by name (retropubic tape), it would also need to mention the standard non-mesh procedure (colposuspension) by name.

The best '*information to make informed choices'* between the two standards are present in the shared-decision table in ***the original chapter six*** attached to the email (Lapitan 2016 Cochrane review). On reviewing this level 1 evidence, and other resources, I came to the conclusion that the benefit : risk ratio of the colposuspension procedure is more favourable than that of the mesh tape one.

No doubt other clinicians and patients will reach other conclusions, based on experiences, values and what matters to us. Therefore, I suggest the objective shared-decision tables of the original chapter six to be published in the Final Report, in consistency with the same format of the Interim Report. These will be useful for clinicians and patients who are considering the various 'trade-offs' of the decision-making process.

Regarding retropubic vs transobturator mesh tape procedures:

Using the word 'favours' will suggest to (at least) some readers that both mesh tape procedures are good - but one is 'favoured' because it is better than the other. I believe this is not realistic and could put patients to unnecessary risks.

The best '*information to make informed choices'* are present in the shared-decision table already published in the Interim Report (Ford 2015 Cochrane review) and part of ***the original chapter six*** attached to the email. On reviewing this level 1 evidence, and other resources, I came to the conclusion that the transobturator procedure is too risky to offer at all.

My understanding from discussions with clinician colleagues is that there is agreement to the following three statements regarding the transobturator procedure. These are the main three reasons all clinician members of the group had already stopped doing this procedure before the Government's suspension in June 2014:

1- Its risks outweigh its benefits (over the retropubic procedure).
2- It has no single absolute indication i.e. it is an entirely avoidable surgical procedure.
3- For the vast majority of women, the implanted mesh device cannot be safely removed in its entirety. Therefore, the adverse events, that had indicated surgical removal in the first place, would be irreversible and the woman's life is likely to change for good.

If my understanding is correct, this procedure should either not be offered at all or offered only following a discussion at a national (not local) MDT. I believe such advice will reduce harm without losing any substantial value.

If my understanding about the opinions of my colleagues is incorrect or only partially correct, we will discuss again at the next meeting.

The national MDT can simply be the email list of members of the Scottish clinical society, and Voula is the current chair.
A working example is BSUG which has done something similar at UK-level on several occasions in the last few years. A clinician member seeks advice on a national level by asking the secretary to email the membership with the clinical details of a difficult, rare or unusual case presentation. No unique identifiers are used and all responses are collated and emailed back to the membership, for learning purposes.

Lastly, I added 'mesh-related' to complications as the Expert Group is developing a pathway for management of only mesh complications, not all complications of pelvic floor surgery.

Conclusion 8
In the surgical treatment of POP current evidence does not indicate any additional benefit for the

use of transvaginal implants (polypropylene mesh or biological graft) over native tissue repair in primary or repeat surgery. Transvaginal mesh and graft procedures should therefore not be offered ~~routinely~~. The Expert Group must develop appropriate pathways, including one for management of those suffering mesh-related complications. Work with Medical Directors and Planners will be required to ensure their smooth implementation.

Using the word 'routinely' will suggest to (at least) some readers that POP mesh can be used in selected conditions. I believe this is not evidence-based, nor realistic, and could put patients to the 'unnecessary risks' described by the PROSPECT authors.

Maher 2016 Cochrane review suggests POP mesh to be used only within research context. On reviewing this level 1 evidence, PROSPECT and other resources, I came to the conclusion that transvaginal POP mesh procedures are too risky to offer at all until a) there is proven benefit and b) such benefit outweighs the risks. Therefore, at this juncture, deleting the word 'routinely' will reduce harm, without losing much (if any) substantial value.

If current evidence does not indicate benefit of POP mesh in either primary or secondary surgery, we need to mention both in the recommendation. If POP mesh does not offer benefit over native tissue surgery in the simple primary POP, I find it difficult to believe it could offer benefit in the complex recurrent POP.

Lastly, I added 'mesh-related' to complications as the Expert Group is developing a pathway for management of only mesh complications, not all complications of pelvic floor surgery.

Appendix 3 – Comparison of Conclusions 7 and 8 of the Interim and Final Reports

Procedure	Interim Report – October 2015	Final Report – March 2017	My suggestions – sent February 2017
Retropubic mesh tape (incontinence) **The 'Vertical Tape'** **Transobturator mesh tape (incontinence)** **The 'Horizontal Tape'**	**Conclusion 7** A review of the different sources of evidence … 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 ... We await the final publication of key research reports but wish to **register these concerns** and to recommend that the Expert Group...	**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… When surgery involving polypropylene **or other synthetic** mesh tape is contemplated**, a retropubic approach is recommended.** The Expert Group…	**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, **including colposuspension (the standard non-mesh procedure) and retropubic tape (the standard mesh procedure)** ~~**(mesh and non-mesh)**~~ as well as the information to make informed choices… When surgery involving polypropylene mesh tape is contemplated, **we recommend the use of only** the retropubic approach. **Due to the associated risks, the transobturator tape procedure can be considered only with involvement of national MDT.** The Expert Group…
Insertion of mesh patch during prolapse surgery **– the 'Prolapse Mesh'**	**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... We await the final publication of key research reports but wish to **register these concerns** and to recommend that the Expert Group...	**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…	**Conclusion 8** In the surgical treatment of POP current evidence does not indicate any additional benefit for the use of transvaginal implants (polypropylene mesh or biological graft) over native tissue repair **in primary or repeat surgery**. Transvaginal mesh **and graft** procedures should therefore not be offered ~~**routinely**~~. The Expert Group…

Appendix 4 – Notes on the deleted Chapter Six (The Narrative, Timeline and Page 1)

The Clinicians' Chapter Six of the Final Report was drafted in May 2016. Its aim was to accurately describe the benefits and risks of pelvic mesh procedures to aid the shared-decision process between patients and clinicians as to whether mesh is used during surgery. Building on the success of Chapter Six of the Interim Report (published Oct 2015) in accurately interpreting top-level research from the Cochrane Collaboration (Ford et al 2015), the same methods (described below) were employed in interpreting the recently-published Cochrane evidence (Lapitan et al 2016 and Maher et al 2016).

a) The Narrative:

1. **Summarising top-level evidence from Cochrane Reviews:**
    a. Listing all outcomes from the Reviews that would inform the shared-decision process between patients and clinicians
    b. Identifying the odds of good outcome, the odds of adverse events and the level of confidence in the results
    c. Identifying the surgical procedure favoured by the authors for each individual outcome

2. **Adding value of clinical experience:**
    a. Describing the size of difference in outcomes between surgical procedures (the effect size)
    b. Deciding whether a statistically significant result is clinically important
    c. Giving 'weight' to each outcome depending on clinical implications
    d. Reaching overall conclusions with regards to the benefits and risks of individual surgical procedures

3. **Presenting evidence transparently** in patient-friendly tables that would be useful during the shared-decision process with clinicians

4. **Seeking views from the larger group** for the Chapter's content

    On interpreting the evidence tables comparing safety of surgical procedures, I came to the following conclusions:

    - Non-mesh procedures are safer than mesh procedures for incontinence.
    - Transobturator mesh tape is too risky to be offered, except in very rare circumstances.
    - Prolapse mesh has no proven benefit and is too risky to be offered.

    As the chapter was deleted, its evidence did not inform the recommendations of the Final Report.

b) Timeline of Drafting and Deleting Chapter 6:

Date	Event	Notes
May 2016	1st Draft of the Chapter circulated	
	2nd Draft circulated	Clinicians suggestions incorporated
May	**1st Clinicians subgroup meeting**	Disagreement on the idea that non-mesh procedures have a better benefit/risk profile compared with mesh procedures
11 July	**2nd Clinicians subgroup meeting**	Suggestion that the figures in Table 1 are inaccurate. Author of the Cochrane Review was later contacted and confirmed figures are accurate.
	1st call to delete Table 1	Reason: Table 1 is not useful
31st Oct	**3rd Clinicians subgroup meeting**	The Chair resigns 2nd call to delete Table 1 1st call to delete the whole Chapter
	Suggestion not to make any recommendations based on Table 1	
10 Nov	Chapter reviewed by 2 clinicians 3rd call to delete Table 1	Chapter updated with new comments
22 Nov	4th call to delete Table 1	Reason: no need to summarise any studies as Chapter 5 already does so.
6 Jan 2017	**4th Clinicians subgroup meeting**	First meeting with the new Chair. Transparency rule was changed. 5th call to delete Table 1 or the whole Chapter
6th-10th Jan	Several email exchanges.	Majority now prefer deleting the Chapter.
10 Jan 08:54	Chair shuts down the discussion	Chair deletes the whole Chapter and asks a clinician member to draft a new one
10 Jan 18:49	First draft of the new chapter is circulated	New chapter is 4-page
13 Jan	**5th Clinicians subgroup meeting** (phone)	New 4-page chapter approved by majority
17 Jan	1st draft of Final Report circulated	Includes the new 4-page chapter
	2nd draft of Final Report circulated	
21 Feb	My comments circulated	Suggesting to reinstate the original chapter
	3rd draft of Final Report circulated	
28 Feb	I resigned from the group	

c) Page 1 of the original Chapter Six

Chapter 6: The use of vaginal implants (mesh and graft) for the surgical treatment of stress urinary Incontinence (SUI) and pelvic organ prolapse (POP) in women: Clinicians' view

What's new in this Chapter?

In addition to the evidence summary table on the choice between retropubic and transobturator mesh tapes (published in the Interim Report), this updated chapter now summarises the level I evidence on comparative safety and effectiveness from the Cochrane reviews published in 2016. The evidence relates to the choice between colposuspension and mesh tapes and the use of vaginal implants (polypropylene mesh and biological grafts) for women with pelvic organ prolapse.

Table (1): Comparison between **colposuspension and mesh tape procedures** for the treatment of stress urinary incontinence in women. ***NEW***

Table (2): Comparison between **retropubic and transobturator mesh tape procedures** for the treatment of stress urinary incontinence in women. Already published in Chapter 6 of the Interim Report

Table (3): Comparison between **native tissue and the transvaginal polypropylene mesh repair procedures** for the treatment of pelvic organ prolapse in women. ***NEW***

Table (4): Comparison between **native tissue and the transvaginal biological graft repair procedures** for the treatment of pelvic organ prolapse in women. ***NEW***

Table 2 was moved out of Chapter 6 to an appendix D at the end of the Final Report (page 103) without a title, narrative or conclusion.

Tables 1, 3 and 4 were taken out of the Final Report and published in an online annex, among meetings' agendas and minutes. The tables can be found in the ***second last document*** in the online list of the Review documents.

Appendix 5 – Resignation letter (with effect from 1st March 2017)

Wael Agur MB BCh MSc MD(res) MRCOG
Subspecialist and Lead Urogynaecologist | NHS Ayrshire & Arran
Honorary Senior Clinical Lecturer | University of Glasgow
University Hospital Crosshouse | Kilmarnock | KA2 0BE
13 March 2017

Dr Catherine Calderwood
Chief Medical Officer
The Scottish Government

Dear Dr Calderwood

Re: 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

I am writing to inform you of my resignation from the Review. I had already informed the chair of my decision on Tue 28th February.

I believe the current process is different from the one I had signed up for when appointed in 2014. At that time, independence and transparency were closely held which, I believe, made it easy for the team to reach consensus and to publish the Interim Report in 2015.

Clinicians have come a long way in resolving additional matters since May 2016 and we were close to reaching consensus in Jan 2017. Unfortunately, the deletion of the chapter we had been working on for several months has made consensus quite difficult to reach.

I did express my concerns on several occasions in writing, in meeting and during phone discussions. I did offer compromises but still failed to help the team reach consensus and to maintain consistency with the Interim Report. As a result, I believe the current recommendations of the report to be less safe than they were naturally going to be, had consensus been reached.

I am sure you will appreciate the significant commitment in time and effort of being a clinician member of this Group, in parallel to the day job and for almost three years. Since January this year, this role has become an uphill struggle for me and has affected personal and family's wellbeing.

As my only contribution to the current process was in the deleted chapter, I asked the chair not to include an acknowledgement in the final report. I remain proud of my contribution and of the teamwork in the run up to the publication of the Interim Report in 2015. It is, therefore, with regret that I write to resign today but hope you will appreciate my position and accept my resignation.

Kind regards

Wael Agur

cc Dr Tracey Gillies, Medical Director, NHS Lothian

Dr Terry O'Kelly, Senior Medical Officer, The Scottish Government

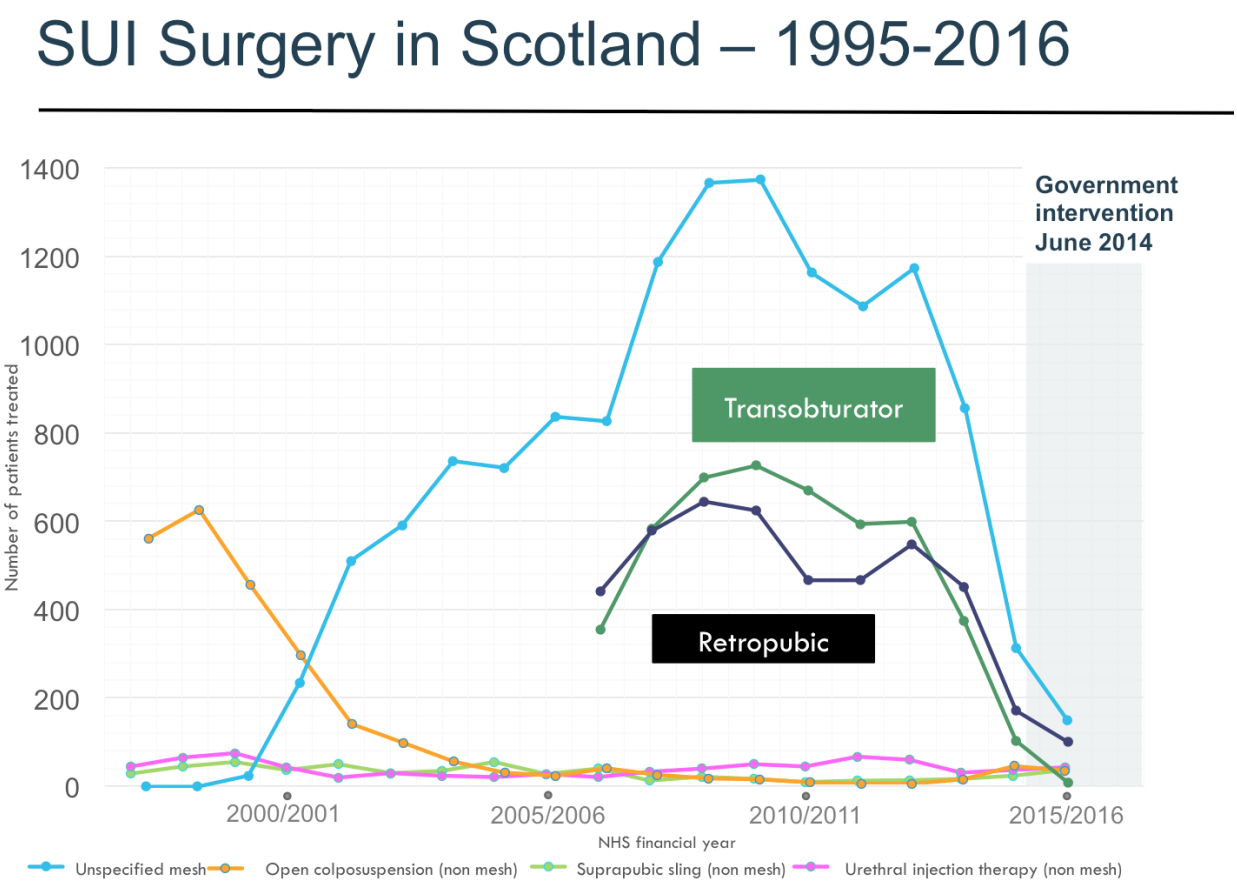
Dr Sara Davies, Public Health Consultant, The Scottish Government

Ms Shona Robison, Cabinet Secretary for Health, The Scottish Government

Appendix 6 – The 3 mesh procedures in question – Summary Factsheet

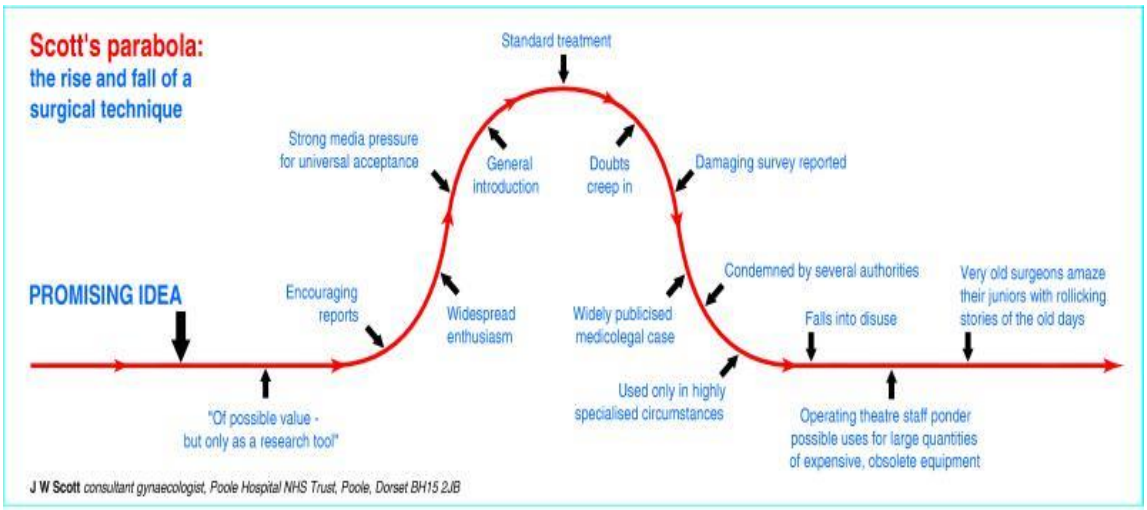
Procedure	Reason for introduction	Trends in Scotland	The Rate of mesh-related adverse events	Recent Research Evidence (discussed at group meetings)	Approach to the conclusion of the Final Review
Retropubic mesh tape (incontinence) **The 'Vertical Tape'**	To make continence surgery minimally invasive. To shorten patients' hospital stay and expedite return to normal daily activities.	Introduced around 1998 Peak at 2009/10 to become the second most commonly performed continence surgery Significant drop the year before SG suspension in June 2014	Lowest risks of all mesh procedures. The UK and Ireland TVT Trial Group reported the rate as: 2002 – <1% (<1 in 100) – rare 2004 – 1.7% (1 in 60) - uncommon 2008 – 3.5% (1 in 30) - common 2010 - at least 4.6% (1 in 20) - common	Cochrane Review (2016): Significantly higher short-term adverse event rates compared to standard non-mesh surgery. Evidence can be interpreted as showing the vertical tape is too risky to offer as first line surgical treatment.	No restrictions. Offer freely as first-line surgical treatment for all women, along with non-mesh options.
Transobturator mesh tape (incontinence) **The 'Horizontal Tape'**	To replace the Vertical Tape as it reduces the risk of bladder damage.	Introduced around 2003 Peak at 2009/10 to become the most commonly performed continence surgery Significant drop the year before SG suspension in June 2014	Six times more risk of chronic pain compared to the Vertical Tape due to: 1) Lateral penetration of thigh muscles 2) Lateral placement close to pelvic nerves	Following Cochrane Review (2015), the Interim Report expressed concerns about the Horizontal Tape.	No recommendations made. The concerns expressed in the Interim Report were deleted.
Mesh patch (prolapse) **The 'Prolapse Mesh'**	To reduce the risk of recurrence of prolapse (similar to abdominal hernias).	Introduced around 2005 Peak at 2009/10 Drop to zero in 2014/15. All surgeons followed the SG suspension in June 2014.	Highest risks of all mesh procedures due to: 1) Largest surface area of mesh material 2) Lateral penetration of thigh muscles (kits) 3) Lateral placement close to pelvic nerves (kits)	Cochrane Review (2016) criticised MHRA for stating 'benefit outweighs risk'. PROSPECT study (2016): no proven benefit - unnecessary risks Scottish 20-year look back (2016): no proven benefit - unnecessary risks	Allow its use in certain circumstances according to individual surgeons.

Appendix 7: The Rollercoaster Figure

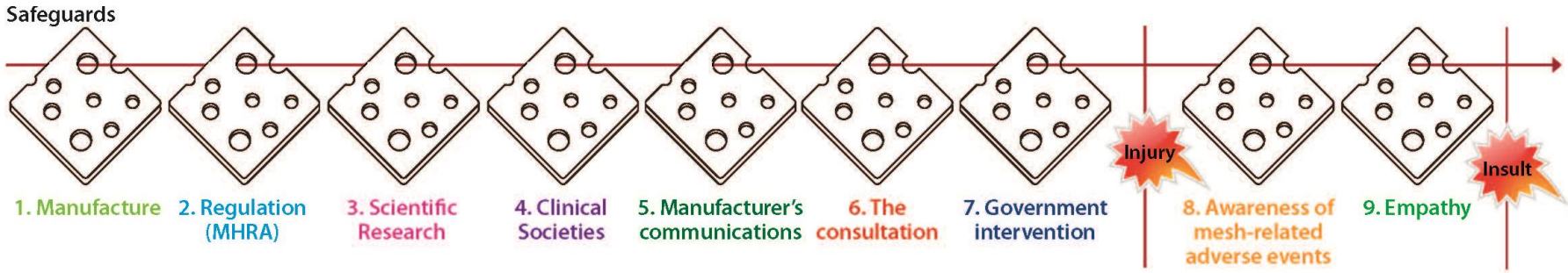


Some observations:

- The switch from colposuspension to mesh tape procedures took place around 2000.
- The steep rise in 2007/08 is mainly due to the transobturator procedure, to become the most commonly performed in Scotland for 5 consecutive years.
- The peak in 2009/10 is more than double compared to 2000.
- The fall happened ***before*** mesh suspension and was not accompanied by rise in non-mesh surgery.
- The shape is very similar to ***Scott's parabola – The rise and fall of surgical procedures, BMJ 2001;323:1477.***



Appendix 8 – The Swiss Cheese Model – How Safeguards work (and don't work)



Name of Safeguard	How it is supposed to work?	How it doesn't work	What could be done
1. Manufacture	By being inert.	Foreign body reaction, infection, trocar-related direct organ muscle and nerve damage.	Would other materials (synthetic or natural) be less harmful?
2. Regulation (MHRA)	Robust regulation to protect the public.	Devices are only Class II, reporting is not mandatory and the manufacturer investigates reported adverse events.	Reclassification to Class III, mandatory reporting, independent watchdog-led investigation in a public database.
3. Scientific Research	Robust clinical information to inform decisions.	Short term follow up. Manufacturer's bias (direct and indirect). Researchers confirmation bias.	Long-term follow up studies independent of manufacturers.
4. Clinical Societies	Forum to demonstrate best practice.	Manufacturers influence through sponsorship.	Create independent 'Evidence Subcommittee' and include patients.
5. Manufacturer's communications	Communication of latest reports on safety and efficacy.	Did the manufacturer fail to communicate reports of serious adverse events?	Watchdog would instruct the manufacturers to regularly communicate.
6. The consultation	Informed consent following shared-decision making.	Directive counselling - 'mesh is the best'.	Introduce a shared-decision tool.
7. Government intervention	Suspension of all procedures.	Some Health Boards continued.	
Injury (some women)			
8. Awareness of mesh-related adverse events	Clinicians must be aware, to recognise and to communicate a clear management plan when things go wrong.	Women were not believed. Clinicians cognitively couldn't make the link between the symptoms and mesh.	Improve awareness of mesh-related independent of the manufacturer's communications.
9. Empathy	Clinicians expected to show maximum empathy, especially if no cure and women are unable to move on.	'It's all in your head' conversation.	Awareness of the mesh-related adverse events will bring about the natural empathy in clinicians.
Insult (some women) **Letters from lawyers acting on behalf of over 400 Scottish women**			

MIS17-177-CC

Appendix 9: Surgeon or Device?

– Unpacking two main views on the subject

This table unpacks two common beliefs and highlights the complexities of the subject. It is by no means fully representative of all views and, in some situations; it is the 'surgical package' to refer to rather than the surgeon or device. There are probably crossovers between the two views.

	Surgeon, not device	***Device, not surgeon***
Origin of the problem	*It must be the surgeons as the problem is particularly bad in the West of Scotland.* *This is where a regional group of surgeons quickly adopted a wide variety of mesh procedures into their practice.*	*It must be the device as the problem is global.* *The mesh dose was simply higher in the West of Scotland, compared to other areas. If **all** mesh surgeons in Scotland are under litigation, it cannot be the surgeon's fault.* *They are the same experienced surgeons who perform non-mesh surgery as effectively. No Health Board is being sued for medical negligence following a non-mesh procedure.*
How did the problem happen?	There are many factors related to the practice of individual surgeons e.g. inappropriate patient selection, inadequate counselling, patchy training, incorrect surgical technique, low workload, inadequate experience, quick adoption of risky procedures, or various combinations of these factors.	There are many factors related to the device e.g. immediate damage by the introducers, delayed damage by the mesh material itself or because of the resulting scar tissue. The surgeons counselled the patients and performed the procedures according to the manufacturer's instructions. Surgeons did so with the best possible intentions, but not with the best possible information on risks at the time.
Do **benefits outweigh risks?**	*Yes, as the MHRA confirmed the **'benefits outweigh the risks'** of all these devices if used as intended. Their use in England continues with no problems.* Therefore, all mesh devices are safe if used in the appropriate patient by the appropriate surgeon, in an appropriate manner. This is particularly true for mesh tapes as they are the gold standard of continence surgery. Therefore, all devices and	No, the MHRA has got it wrong with a blank statement of 'benefits outweigh the risks' – at least with the prolapse mesh and the horizontal tape. Safety is defined in the MHRA document of October 2014 as 'freedom from unacceptable risk'. If chronic pain and loss of sexual function is unacceptable to women, mesh tapes cannot be safe for them. Therefore, the above two procedures must not be performed in Scotland, unless there is a national clinical

	procedures should somehow be allowed for use and the decision is for the individual surgeon and patient to make.	(MDT) consensus on case-by-case basis.
How to reduce harm?	Improve patient information and surgeon's training in patient selection, counselling, surgical techniques and awareness and reporting of mesh-related adverse events. The use of ***all*** these devices can then be safely resumed.	***Suspend*** *the procedures where the device is associated with the highest risk and no benefit e.g. prolapse mesh. No but's no if's.* ***Firmly restrict*** *the procedures where the device carries risks that outweigh the benefits for most women e.g. transobturator (horizontal) tape.* ***Cautiously consider*** *procedures where benefits appear to outweigh the risks for most women - but only as 'second line' after all non-mesh surgical alternatives are fully considered – e.g. retropubic (vertical) tape.* *Training alone would reduce the surgeon-related complications e.g. bladder injury but will not reduce the device-related ones e.g. chronic pain and loss of sexual function.*
Was the mesh suspension in Scotland justified?	*The suspension of mesh tapes in Scotland was an overkill.* *Much of the mesh problems were caused by prolapse mesh which is now less used anyway.* *The Health Minister suspended the procedure when pressurised by the campaigners.* Mesh suspension in Scotland is untenable position. It has made practice in Scotland an outlier. We need to gradually bring this practice back in line with England and the rest of the world.	*The suspension of procedures in Scotland was timely and well placed. It galvanised the debate and has put Scotland in the lead to resolve one of the* ***medical crises*** *of our time.*
Who failed to warn who?	*In many instances, the surgeon must have failed to warn the patient of the risks and possible consequences.*	*The manufacturers did not adequately warn surgeons (via instructions for use) or patients (via information leaflets) of the associated mesh risks, their magnitude and their possible consequences.*
Were women believed?	**The women *felt* they were not believed.** How can we be sure? Some women's symptoms appear to be for real but the whole situation is compounded by the fact that all	**The women were not believed.** Surgeons simply did not associate the current patients' symptoms to the mesh procedure they had in the past or to the presence of the mesh device itself. Surgeons did not know that the

	women are seeking financial compensation. Some women are psychologically vulnerable and could be exaggerating or catastrophising their symptoms. Surgeons probably believed the patients but were perhaps clouded with the subconscious denial that the procedure they performed can be associated with such significant consequences.	device can cause such devastation and they simply did not believe the patients. Many surgeons did not realise at all that the tape is a mesh *device* and the adverse events can be really serious. This is due to lack of awareness of the full range of mesh-related adverse events.
Impact on litigation against NHS Scotland	If the final report condemns mesh procedures, the position of NHS Scotland in court may become compromised and the position of claimants may be strengthened.	If the final report condemns mesh procedures, the position of NHS Scotland in court can not become compromised. Litigation is based on inadequate counselling (including consent) around the time of performing procedures, not around the time of publication of the final report.
Transobturator (Horizontal) Tape - TOT	Concerns about TOT expressed in Interim Report were *only* due to chronic pain. Concessions were given to the patient campaigners in 2015 unnecessarily. TOT benefits can still outweigh its risks, therefore, its use must not be restricted. TOT can be removed entirely if causing problems.	Chronic pain and nerve damage were only one of the reasons concerns were expressed about TOT in Interim Report. The other reasons included its 10 times likelihood to require repeat surgery for incontinence and low importance of its sole benefit of reducing bladder damage. TOT cannot be removed safely in its entirety.
Retropubic (Vertical) Tape	TVT is the (gold) standard continence surgery of the 21st century. TVT risks:benefits ratio is more favourable and more acceptable than that of the non-mesh procedure.	TVT is associated with lifetime risk of chronic pain that is becoming increasingly more common than previously thought. While complete removal can be done safely, emerging evidence suggests a long-term legacy. Non-mesh alternatives has acceptable risks, as those of caesarean section or hysterectomy procedure.
The non-mesh surgical alternatives (Colposuspension and autologous fascial sling)	These are archaic major abdominal procedures that are not suitable for the 21st century. Mesh tapes have already replaced these procedures and going back to these is a retrograde step in innovation. They may be indicated if mesh tapes fail. However, in view of the negative media around mesh and to be politically correct on	These two procedures are time-honoured i.e. they stood the test of time with respect to safety as well as success to treat incontinence. Significant progress was being made to make these procedures less invasive e.g. keyhole colposuspension and the short autologous sling technique. However, the introduction of mesh tapes has halted the natural

	patient choice, these procedures must be equally mentioned to all women.	progression of these excellent procedures.
Surgical competence in non-mesh alternative surgery	It's OK for surgeons to be competent in only one continence surgery, the mesh tapes, as long as they do it well and perform at least 20 procedures every year.	Surgeon who perform continence surgery must be well-trained and equally competent to perform both mesh and non-mesh surgery, to balance their confidence and attitude during patient counselling.
View on prolapse mesh	POP mesh is beneficial in some patients e.g. those with advanced uterine prolapse (procidentia) and recurrent prolapse. It is associated with high risks but it should not be suspended completely. Therefore the word 'routinely' needs to stay in Conclusion 8.	POP mesh is a failed surgical innovation. It is associated with the highest mesh risks and only manufacturer-sponsored studies sugested benefit. Large and low-bias studies confirmed no additional benefit over and above the standard non-mesh surgery in both primary and recurrent prolapse. POP mesh is contraindicated in procidentia.

General approach to conclusion of the Report	Conclusions must not be too prescriptive or restrictive to surgeons. The conclusions need to be set at a high-level without going into fine details of the difference in benefit:risk ratios of individual surgical procedures. In the end, the decision needs to be between the patient and the surgeon. Politicians, lawyers, campaigners and the media must not interfere with whatever happens inside the consultation rooms.	The conclusions must reduce harm to patients from mesh devices, even if perceived by surgeons to be too restrictive or too prescriptive. It is important that conclusions clearly address the benefit:risk ratio of each of the three procedures in comparison to each other and in comparison to the non-mesh alternative. As the true scale of the crisis unfolds, the lifetime long-term mesh-related risks is expected to outweigh the benefit of mesh procedures for the majority of women. During a medical crisis, much more is known centrally than that known by ordinary surgeons and patients inside consultation rooms. The recommendations needs to include an unambiguous description of benefits and risks and needs to be clearly communicated to surgeons and patients alike.
Specific approach to Conclusion 8 of the Final Report (use of mesh	Restrict the use of devices associated with the highest risk but still allow it to take place by adding the word ‘routinely’. Keep it vague enough and leave it to individual surgeons to decide what	Remove the word ‘routinely’ and confirm the current complete cessation of the use of these devices that is followed by all surgeons in Scotland. This advice may change if future evidence suggests a) some benefit and b) such benefit outweigh

in prolapse)	circumstances to use it in.	the highest mesh risks.
Specific approach to the Conclusion of the Final Report (use of mesh in incontinence)	Remove the concerns expressed about the transobturator devices in the Interim Report. There is no need for the relevant conclusion in the Final Report to mention the transobturator tape by name. Freely allow the use of the least risky devices (retropubic tapes, the standard mesh procedure) to be offered as first line procedures.	Firm up the concerns expressed in the Interim Report and clearly state in the Final Report that the risks of transobturator tapes (the most commonly used mesh device in Scotland prior to suspension) outweigh their benefits. Recommend that these devices could still be offered but only in exceptional circumstances and with the involvement of a regional / national network of clinicians. Restrict the use of the least risky devices (retropubic tapes) to be offered only as second line surgery. If non-mesh procedures (e.g. colposuspension or autologous sling) are not clinically suitable or were declined by patients, the retropubic mesh procedure can be offered.

Appendix 10 – Government suspensions and clinical restrictions of mesh procedures:

A) Government Suspensions

	Degree of Suspension	Description	Notes
1	Banning the medical device from the country	Device recall. No longer be available.	MHRA medical device alert (MDA). Manufacturer field safety notice (FSN). A power repatriated to Scotland?
2	Suspend the procurement of the device in NHS Scotland until better evidence efficacy is available.	The device is available but NHS Boards will not purchase it and/or surgeons must not use it.	Is suspension of procurement within Government control?
3	Consider suspension of procedures until Independent Review is completed	The device is available, the NHS can purchase but surgeons are asked not to use it.	The current suspension in place in Scotland since June 2014

B) Clinical Restrictions

	Degree of Restriction	Description	Recommended by
1	Use only in research context	The procedure is experimental and/or risks outweigh the benefit. It is offered only with approval of Research Ethics Committee.	Cochrane review for prolapse mesh. NICE 2017 Guideline for prolapse mesh (consultation document)
2	Use only in clearly-defined exceptional circumstances	Regional/national team decides upon these rare circumstances.	None.
3	Not done routinely	Rare circumstances decided upon by individual surgeon.	Conclusion 8 (POP mesh) – Final Report
4	Offer only as second-line if non-mesh options not suitable.	Mesh procedures are too risky to offer as first line to everyone. Therefore, offer only if non-mesh procedures carry higher risks or are declined.	None.
5	No restrictions. Offer as first-line to all.	The mesh procedure is as safe as the non-mesh option.	Conclusion 7 (SUI mesh) – Final Report

Patient Label

What Matters to You in Choosing Surgery for Stress Urinary Incontinence?

Shared-Decision Tool for Patients

PLEASE COMPLETE AND HANDBACK THIS FORM TO A MEMBER OF STAFF OR PUT IN THE POST

Contents:

A) Why complete this form?

Introduction

We are working to improve Person-Centred Care for women considering surgery for stress urinary incontinence. It is important that the type of surgery chosen is personalised. As well as being safe and effective, surgery will focus on your individual needs and preferences as much as possible.

We know that by finding out a bit more about you, we can improve shared-decision making and subsequently the overall outcome of surgery. One of the ways to make this better is for the doctor/surgeon to find out what is important to you. During decision-making, it is important to establish with your doctor/surgeon *'what matters to you'*.

If we know some things about you, it will allow us to get to know you as a person rather than just as a patient, as well as know what is important to you. Also having information about your routine activities allows us to adapt our care. Please complete page 3 and page 7 and hand back.

What happens after I complete this form?

Please hand back to a member of staff or put in the post to us.
Our team will discuss your condition and your choices during our dedicated meeting. Your clinician will inform you of the outcome of team discussions, especially if there are further recommendations to consider.

What if I do not want to give the information?

If you don't feel like sharing the information, please inform a member of staff so we don't bother you by asking. However if you change your mind, we will be happy to help you complete it.

Can I change the shared information once I have completed it?

Yes, we recognise that *what matters to you* may change during the decision-making process. For example, you may have concerns about recovery from a particular operation, but as you find out more about it, this may no longer be important. You can change what you provide at any time as it's your shared information.

Quotes from previous patients

> *"This is great, makes me feel that you want to take the time to know me."*
> *"The form was easy to use and made me think about what is really important to me."*

B) My values - What matters to me?

- Please let us know what is important to you from the list of values below.
- A member of staff can help you complete it, if you wish.
- Some things that matter to you may be physical, psychological/emotional or social.
- Or it could be something completely different. There are no "right or wrong" answers as it is about you.

Please add a value from 0 to 10 (0 low priority, 10 high priority) next to each of the following items:

What matters to you examples	**Importance out of 10**	**Top 3 (Please tick)**
• Cure from leakage	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Just using less pads	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid repeat surgery in the future	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Undergoing Day Surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Shorter hospital stay	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Quick recovery and quick return to normal activities	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid major abdominal surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid future surgery for prolapse	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Least pain after surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding mesh complications	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding self-catheterisation	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid general anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid local anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Other _____	**0** 1 2 3 4 5 6 7 8 9 **10**	

Examples that people have used before

Physical

- How I prefer to have surgery e.g. which anaesthetic / pain relief
- I find it difficult to be awake during surgery
- I am concerned about foreign materials left permanently inside my body.
- I do not want to stay overnight in hospital

Psychological/Emotional

- The information I need in a way that I understand
- I feel isolated in the room on my own and need staff to check in on me regularly.
- I am not good at tolerating pain at all and get distressed quite quickly. It is important for me to get pain relief on time.
- I live a long way from the hospital and am not able to return for repeat treatment. It is important for me to receive treatment that works in the long-term.

Social

- I would like my family (daughter) to be involved in the decision.
- My elderly husband will need to be in respite care while I am in hospital. It is important that I involve him in this decision too.

C) My non-surgical options

Reminder of the Management Pathway for Women with Stress Urinary Incontinence

- Women with **bothersome** leakage on coughing, sneezing or physical activities wishing treatment

↓

Lifestyle Advice

- Review of dietary and fluid intake
- Weight loss programme for women with increased weight
- Referral to continence nurse for bladder training, fluid management and further

↓

Pelvic Floor Muscle Training (PFMT)

- All women with SUI should be offered a PFMT programme by an appropriately trained specialist, usually a physiotherapist.
- PFMT can also be useful in women with mixed symptoms e.g. urgency.

↓

Medical Treatment

- Some women may consider a trial of Duloxetine therapy.
- Potential side effects and duration of treatment are to be considered.

↓

Vaginal Devices

- Some women may consider a continence pessary or device if suitable.

↓

YOU ARE HERE

Surgery for women with SUI*

- Surgery should only be considered if the above treatments options have not improved symptoms
- Patient refusal of any of the above treatment option should be documented

** Please ask your doctor for the specific leaflet of the treatment(s) you are considering.*

Referral to a different clinician (or a different hospital) may be required, depending on availability of surgical procedures

D) My surgical options

Table comparing the main advantages and disadvantages of the four surgical procedures for treatment of stress urinary incontinence in women

Procedure	Main Advantages	Main Disadvantages	What if it does not work?
Mesh Tape Surgery where a piece of plastic mesh tape is inserted to support the urethra (tube that carries urine from the bladder to outside the body).	• Day surgery • Quick recovery • The standard procedure since year 2000	• Mesh complications (can cause long-term pain and may require surgical removal) • Long-term risks remain unknown	• Repeat surgery carries increased risks and technical difficulties • Repeat surgery may be less successful
Colposuspension Surgery where the neck of the bladder is lifted upwards and stitched in place.	• Avoids mesh complications • The standard procedure prior to year 2000 • Can be done by keyhole surgery (some units)	• Major abdominal surgery • Risk of future pelvic organ prolapse (may require surgery)	
Natural Tissue Sling Surgery where a sling of your own tissues is inserted around the neck of the bladder to support it.	• Avoids mesh complications • Higher cure and improvement rate	• Major abdominal surgery • Higher risk of difficulty emptying the bladder (need for self-catheterisation)	
Urethral bulking agents Surgery where a substance is injected into the walls of the urethra to increase its size and allow it to remain closed with more force.	• Avoids mesh complications • Day surgery (usually local anaesthesia) • Least invasive as no skin cuts	• Short-term success compared to other surgical procedures • Repeated injections may be required – no reliable evidence on long-term success	• Repeat surgery is safest • No impact on success of future surgery

E) My Choice (PLEASE COMPLETE THIS TABLE)

Procedure	I will choose this option because…	I will NOT choose this option because…
Mesh Tape		
Colposuspension		
Natural Tissue Sling		
Urethral bulking agent injection		

Patient's signature: ……Patient Name: ……: Date:……

Please write any further comments here:

FOR OFFICE USE ONLY

Procedure	**Outcome of MDT Discussion** **Date:**	**Outcome of further patient consultation if necessary** **Date:**
Mesh Tape		
Colposuspension		
Natural Tissue Sling		
Urethral bulking agent injection		

Clinician's signature: ……Clinician's Name: ……: Date:……