

PE1517/JJ

Petitioners' submission of 8 May 2017

On behalf of Scottish Mesh Survivors we would like to thank the Petitions Committee for giving us the opportunity to provide this statement in relation to the recently published Final Report on the Scottish Government Mesh Review (SGMR). Following the resignation of the ex-Chair Dr Lesley Wilkie in November 2016 and the appointment of Dr Tracey Gilles, a serving medical director, this became a government review rather than an independent inquiry. The review has simply lost its independence. The Current Final Report is clearly a whitewash and the recommendations expose women to unnecessary harm.

We are very proud and appreciative of the cross party support we have achieved. It gave us hope and belief when almost one hundred MSPs signed our 'Pledge Poster' at Holyrood in March this year, in support that the review would remain independent and would not be a government whitewash. The eyes of the world were watching, as Scotland led the way.

Despite our best efforts to ensure that the Final Report would be open and honest and publish information good or bad, as long as it was in the best interests of women suffering from Pelvic Organ Prolapse (POP) or Stress Urinary Incontinence (SUI) - we failed. The Final Report was hastily published just before the Easter recess.

After three years of extremely hard, often challenging work as patient representatives in this review, it was with heavy heart we decided to resign. The review had not only lost its independence, it lost transparency, integrity and its process and purpose. Patients were not at the heart of the review, we were marginalised and our requests were ignored. We were not invited to any meetings for 10 months. We repeatedly requested minutes from meetings that had taken place – none were shared.

Unfulfilled Remit/Pledge and Ignored Requests:

1. The patient-friendly shared-decision tables and a whole chapter deleted:

Despite repeated verbal and written requests to the Scottish Government Officials (SGO) in the group, that all four tables be included in the final report (exactly as the first table was included in the Interim Report) - we were ignored. As a result, we were unable to discuss and compare the benefits and risks of non-mesh and mesh procedures. One clinical expert (Dr Agur) believes the evidence in these tables is that non-mesh procedures are safer than mesh ones but we did not have the chance to discuss this view with him or with the rest of the group. Dr Agur's resignation and the manner in which these tables have now been presented raises serious concerns.

We resigned from the review group because we were ignored, marginalised and the stress was having a negative effect on our health. We didn't realise that Dr Agur had resigned before us, as no one told us. We'd like to thank him publicly for being honest with us. As group members we didn't always agree with each other, but he listened to us and was never dismissive of our views. He is an honest man with integrity.

Eventually, and after concerns were raised about the omission of these tables, the SGOs have decided to publish the tables - scattered and fragmented. Table 2 is in an Appendix at the end of the main body of the report but Tables 1, 3 and 4 are outside the report and published online - hidden out of sight and among meeting minutes and agendas.

Our questions:

1.1 Why are all the patient-friendly shared-decision tables not together in one place inside the report? Why are they scattered and fragmented with Table 2 in an appendix while Tables 1, 3 and 4 are hidden away among the meetings minutes and agendas?

1.2 Why did the SGOs ignore our repeated requests since November 2016 to see these tables when they existed since May 2016?

Our Request:

All four patient-friendly shared-decision tables must be put back together and the deleted Chapter restored and discussed.

2. Top research evidence on mesh adverse events totally ignored:

Our repeated requests that the best study of the mesh adverse events (Blavais et al 2015) published in the top medical journal Nature be included in the report were ignored. The study shows that 1 in 7 women had serious adverse incidents of mesh.

Our questions:

2.1 How did SGOs not include this study in the report when it is the most important study describing the mesh adverse events?

2.2 Is that because it showed a high rate of mesh adverse events?

2.3 Is there evidence that this study was on the agenda for discussion in any review meeting?

Our Request:

The review must discuss this study and the report must mention it.

3. Publishing a biased and misleading Chapter:

The current Chapter 6 directs the reader to the conclusion that mesh procedures are better than non-mesh ones. 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.

Conversely, it names the specific disadvantages of the standard non-mesh continence procedure (colposuspension) but does not mention any of its advantages. This chapter encourages surgeons to direct patients towards having mesh surgery which contradicts Conclusion 1 of shared-decision making.

While Chapter 6 of the Independent Interim Report describes one procedure in ten pages, the current chapter 6 of the final report describes over seven procedures in less than four pages! It sends the wrong message to surgeons that the transobturator

procedure is OK and ignores the risk of pain. It also suggests the transobturator mesh tape can be removed, which clearly contradicts what all clinicians agreed on in our updated and approved Patient Information Leaflet.

Our questions:

3.1 Who wrote this chapter and was it approved by all members?

3.2 Why did it not mention the most common adverse event of mesh surgery (erosion)?

3.3 Why did it not mention the most serious adverse event of mesh surgery (chronic pain and inability to have sex)?

3.4 Why did it not mention the advantages of non-mesh surgery when it did mention the advantages of mesh surgery?

Our Request:

The report must remove the biased chapter and replace it with the well-balanced original one with its four detailed and patient-friendly tables.

4. Reporting of mesh adverse events made mandatory in the 11th hour:

Our repeated requests for **mandatory** reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) were ignored. Despite our repeated requests and despite the recommendation from prominent members of the review group, the three drafts of the final report circulated to the review group in January and February did not recommend mandatory reporting. Following our resignation and our meeting with the Cabinet Secretary for Health, Wellbeing and Sport Shona Robison, Chief Medical Officer Catherine Calderwood and others on 16 March 2017, the recommendation to make reporting mandatory was inserted by SGOs. This took place only 11 days before publication of the report and is clear indication that it is the government that is calling the shots, not the group members. **This provides further evidence that independence had been lost.**

Our questions:

4.1 Why did SGOs ignore all our requests (and those from prominent group members) to make reporting of adverse events **mandatory**?

4.2 Were there any members of the Review Group opposed to mandatory reporting?

4.3 For what reason did SGOs suddenly change their position and agree to mandatory reporting 11 days before publication of the report?

5. Failure to recommend mandatory recording of mesh procedures on a national registry:

Our repeated requests for **mandatory** recording of mesh procedures and follow-up data to a national database were ignored. Despite our repeated requests and despite the recommendation from the two representatives of the clinical societies, the final report failed to recommend mandatory reporting.

Our questions:

5.1 How will SG be able to obtain accurate information on the adverse event rate if the surgeon's recording of mesh procedures (and their follow up) on national databases is not made **mandatory**, especially if national coding is incorrect?

5.2 How will SG improve the percentage of surgeons (currently 27% as reported by the two representatives of the clinical societies) who use the current database if recording remains voluntary?

Our Request:

Recording of mesh procedures and follow-up data to a national database must be made mandatory if we are to obtain accurate figures in the future about the mesh adverse event rates.

6. Failure to include 2017 figures from MHRA on the reported mesh adverse events:

Our request that the report must include updated figures of adverse incidents reported to MHRA from Scotland – was simply ignored.

Our questions:

6.1 How did SGOs not include the 2017 MHRA figures on the reported mesh adverse events?

6.2 What is the current total number of mesh adverse events reported to the MHRA?

6.3 Did SGOs ask the MHRA for the updated figures? When did that happen?

Our Request:

The report must mention the updated 2017 figures from the MHRA.

7. Failure to include the 2016 FDA safety alert: Urogynecologic Surgical Mesh implants:

Our repeated requests that the report must include US Food and Drug Administration (FDA) safety alert: Urogynecologic Surgical Mesh implants - Notification for Potential Counterfeit Raw Material, were ignored.

Our questions:

7.1 How did SGOs not include the 2016 FDA alert while the matter of counterfeit material is being investigated?

Our Request:

The report must mention the 2016 FDA alert to warn women and clinicians of additional potential risks.

8. Failure to include the EU Reclassification of mesh to the highest risk category:

We wrote to four SGOs group members and the Cabinet Secretary herself on 27 February 2017 informing them of this important EU announcement when it was made. This was ignored.

Our questions:

8.1 How did SGOs not include the 2017 EU reclassification of mesh to the highest category?

8.2 Why does the SG report (page 12) still say mesh is a medium risk device?

Our Request:

The report must mention the approved EU proposal that mesh is now reclassified as highest risk medical device.

9. Failure to include the legal action of US Attorney Generals (AGs):

Our repeated requests to include, in the legal chapter, the recent legal action from the AGs of California, Washington and Kentucky have been ignored. The AGs have initiated legal action against the main mesh manufacturer for failure to warn women of known mesh risks.

Our questions:

9.1 How did SGOs not include the 2016 AGs legal action against the main mesh manufacturer?

9.2 How can the Final Report mention litigation by US patients and ignore the stronger litigation initiated by three US states?

Our Request:

The legal chapter of the report must include the 2016 AGs legal action against the main mesh manufacturer. It is more important than the already mentioned legal action from individual mesh-injured American women.

10. Failure to remove our input after our resignation:

Despite repeated clear communication, verbally and in writing to the Cabinet Secretary and the Chair of SGMR, that **ALL** Scottish Mesh Survivors (SMS) input be removed from patient Chapter 3 of the report, 11 days before the report published, this was ignored. We made it very clear that this report was **NOT** in our name. At our meeting with the Cabinet Secretary, CMO, Neil Findlay MSP and Jackson Carlaw MSP, the Cabinet Secretary acknowledged and noted our request to remove **ALL** our input – 11 days before the report was published. The Chair of the Review wrote to us six days after the meeting, asking us to confirm what aspects of our contribution we wished to be removed.

We responded as follows:

Please remove **ALL** our input including:

- (a) Our input to Chapter 3, **including** that from the interim report and anything else planned for publication in Appendices or websites. This can be done in a similar manner to the way Chapter 6 of the interim report was deleted after it was already published.
- (b) SMS Minority Opinion and anything else planned for publication in Appendices or websites.
- (c) Our October 2016 survey of women who had a complete removal of TVT mesh tapes and anything else planned for publication in Appendices or websites.

We have a legal and moral responsibility so please remove our names from this report. We didn't contribute to this report, we don't want an acknowledgement and we don't want associated with it.

THIS REPORT IS NOT IN OUR NAME.

Our questions:

We still don't understand how the final report published our data against our expressed will.

10.1 Did the Cabinet Secretary Shona Robison ask the Chair Dr Gillies to delete our input in the chapter?

10.2 Did the Chair not comprehend the message communicated by the Cabinet Secretary?

10.3 How could the Chair ask us again when we had already resigned from the review and we had made it clear to the Cabinet Secretary that we wanted all our input removed?

Our Request:

All our input in this whitewash report must be removed. We have a moral and legal responsibility towards the mesh-injured women we represent. We will say it again; **“This report is not in our name”**.

In addition to all the above failures, the final report has failed to firm up the conclusions of the Interim Report

1- The disappearing concerns about the most common mesh procedure done in Scotland:

The Interim Report had serious safety concerns about the Transobturator mesh procedure and restricted its use. This is the mesh procedure most commonly used in Scotland. Instead of firming up these concerns in the Final Report and stating that the risks outweigh the benefits, the SG report has recommended an alternative mesh procedure and stopped short of advising against the risky Transobturator procedure. This will put women at unnecessary risk and re-open the door for a procedure that none of the clinical experts in the group perform. All clinicians in the review group voluntarily stopped this procedure before the mesh suspension because of the risks.

More details in the Appendix 2.

- Why did the final report remove the concerns expressed in the Interim Report with regards the transobturator procedure?
- If the procedure is entirely avoidable, its risks outweigh the benefits and its adverse events are irreversible, why didn't the Government explicitly recommend against its use?
- Why is the Interim Report concerned about this but the Final Report has removed these concerns and preferred to recommend the other procedure instead?
- Is there any new evidence we are unaware of that suggests re-opening the door for this transobturator procedure?

2- Reopening the door for surgeons Pelvic Organ Prolapse (POP) Mesh:

Despite the long awaited PROSPECT study results and Scottish and International evidence agreeing of the huge and unnecessary risks of prolapse mesh, the SGMR suggests to

surgeons they may consider this procedure in certain situations by adding the word 'routinely'.

- Why does the SGMR consider it acceptable to re-open the door to the most risky prolapse procedure by adding 'routinely' when all Scottish surgeons have already stopped doing it?
- Is there any evidence we are not aware of that suggests re-opening the door for this procedure, despite all surgeons in Scotland having closed the door for POP mesh?

3- Omitting the limitation of the ISD Study:

The ISD data Chapter 4 has serious limitations such as: data is collected using patients that required a bed, did not include out-patients or GP visits. Patients enduring multiple mesh removals were only counted as one removal, which is so wrong. It fails to report the severity of the complications, the pain or impact on daily quality of living. Some patients are in wheelchairs or using walking aids. A mesh tape can be shown to be effective even when a patient is left in chronic pain. Some mesh injuries don't come to light until 10-15 years later. It may take years for polypropylene mesh to shrink, harden or fragment through the body.

We fear Dr Wood has used words that are her own assumptions, rather like assurance from surgeons describing mesh like 'the best thing since sliced bread'.

Statement conclusion:

The four resignations within only four months of the publication of the report is an indication of a whitewash. The independent ex-chair, the lead expert clinician and the two patients supposed to be at the heart of this review have all resigned. Former Cabinet Secretary for Health and Wellbeing Alex Neil commented "without the confidence and trust of patients it is not worth the paper it is written on."

What is most important to us is that no other women will endure what we are going through because of the mesh procedures we had. The way forward is to refrain from lifting the mesh suspension until a judiciary or similar stand-alone independent body examines **ALL** the evidence in a transparent public manner. Until such a review is complete, suspension should mean a blanket suspension, including trials, and any mesh procedures by MDT must be verified by another clinical source out-with the MDT concerned. In the meantime the government can continue establishing all the safeguards of Conclusions 1 to 6 and ensure they are in place, being monitored and audited sufficiently. Do not apply Conclusions 7 and 8 and ask surgeons to restart harming women before ensuring that all safeguards in Conclusions 1 to 6 are well-implemented in all Scottish hospitals.

MHRA have confirmed that: ***"While they (Scottish Government) can't ban the device being sold or supplied, they can decide not to use devices if they wish. That is a decision for them to consider."***

We look forward to and appreciate the offer to discuss these matters further and in depth at a subsequent meeting.

Thank you for your time and allowing the submission of this statement.

Elaine Holmes and Olive McIlroy
Scottish Mesh Survivors Group

Notes on the suspension that was ignored by two main Scottish Health Boards:

Alex Neil said: “When a Health Minister requests Health Boards to consider a request, he would take a dim view of any non-compliance.” His requested mesh suspension was defied by certain health boards. Two of them, NHS Greater Glasgow & Clyde and NHS Lothian, where the most experienced clinicians dealing with mesh complications are based, continued to perform hundreds of mesh procedures... before they knew the outcome of the review investigation.

- How can two clinical expert SGMR group members who made their minds up about mesh and continued doing these procedures despite the suspension, give unbiased views to the Scottish Government on the safety of mesh?
- How many women were exposed to unnecessary harm?
- How many women were offered non-mesh alternative choices?
- How many women were fully informed of ALL known risks risks?

This is a betrayal of all Scottish Mesh Survivors and others who contributed to this report.

Appendix 2: How the wording changed from Interim Report to final report with regards to the transobturator procedure.

The most serious change between the Interim report and the final report reads: where concern was expressed in the interim then that concern completely disappeared in the final report.

The text changed from **Conclusion 7 on page 74 of Interim report** “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.”

That text changed in the final report to: **Conclusion 7 on page 93** “When surgery involving polypropylene or other synthetic mesh tape is contemplated, a retropubic approach is recommended.

Transobturator concerns brushed well and truly under the carpet. **Transobturator is the procedure most commonly used in Scotland prior to the suspension and the procedures associated with the highest number of litigation.**

No evidence to justify the removal of concern for transobturator that was in the interim report and removed from the content of the final report. This is serious.

In the Final Review report on Transvaginal Mesh Implants there is a sentence on page 94 “**We can now see a way by which transvaginal mesh implant surgery can be supported on a case by case basis.**”

Even this has changed since the Interim report which said on page 76 “**We can now see a way by which surgery can again take place.**”

This pretty much sums up the process right from the beginning, instead of looking at what had gone wrong, they were looking for ways to get mesh procedures routinely back into operating theatres as quickly as possible.