PE1517/CC

Petitioner Letter of 7 October 2015

Dear Committee Members

The attached document contains the views of the Scottish Mesh Survivors Group on the Interim Report. We understand that these views will be taken into account when the final report is published.

Elaine Holmes and Olive McIlroy
Scottish Mesh Survivors Group

Scottish Mesh Survivors would like to thank Dr Lesley Wilkie and members of the Independent Review Group for their time, effort and input. We would like to thank the group for highlighting the reasons why the suspension of mesh procedures, requested on 17th June 2014, must remain in place.

The Interim Report has expressed serious concern about prolapse mesh and obturator approach mesh tapes. The retropubic approach has been recommended as the default mesh tape procedure as it carries the least mesh risks. 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.

The severe nature of the injuries suffered by many women affected demands that until our petition points and each and every one of the Review Group's recommendations in the interim and final reports are all agreed, actioned and able to be monitored, NOTHING has changed and the suspension must remain in place. These points and recommendations include:

- A mesh registry must be fully functional and used by all surgeons, with mandatory reporting of all adverse incidents. Currently the BSUG database can only be accessed by members and only 20-30% of their members use it. It cannot be accessed by other surgeons who use transvaginal mesh or GPs who are usually the first point of contact for patients or specialist physiotherapists who can often identify painful mesh erosions. It is not mandatory to report adverse incidents.
  We need the introduction of a precautionary principle. If a mesh implant device appears to be 'safe' on paper but performing poorly within a registry then that procedure is automatically stopped until an investigation is complete.
- Patient information, consent and pathways have not been updated, completed and published.
- Transvaginal mesh must be reclassified to the highest risk category, particularly for procedures where the Review has expressed serious concerns.

  MHRA has described favourable benefits vs risks ratio for all devices. The Interim Report highlights serious concerns for most devices and suggests that the risks outweigh the benefits. This confirms what we have said all along and as evidence gathers, we believe the risks will continue to outweigh the

benefits for all mesh devices and this will be proven, especially in the long-term.

MHRA has been roundly criticised by mesh victims and has presided over the PIP breast implant scandal, the hip and heart implant scandals, which have all left victims with life changing and threatening injury. We strongly believe that Scotland needs to establish its own medical watchdog.

The FDA in the US recently proposed to reclassify prolapse mesh to the highest risk category. They also proposed that manufacturers will be required to conduct reliable research on humans before bringing a device to market. The UK classifies permanent mesh implants which can rarely, if ever, be removed completely and not without significant risk as medium to high risk.

Scottish Mesh Survivors do NOT agree that any mesh procedure can be reinstated, and definitely not before all the aforementioned safeguards are actioned and functioning. This is essential to ensure the safety of Scottish women, especially when many Scottish Health Boards did not follow the government suspension last year.

In addition, we would like to make the following important points, which were not in the remit of the Review Panel but need to be considered by the Scottish Government and/or the Expert Group:

- We strongly believe that every woman with a mesh implant should be contacted, informed of symptoms and signs of mesh complications, and advised where to go for help.
- We still do not know why complications develop. Is it an allergic reaction? Will those who have had a seemingly good outcome suffer the same further down the line? We are still awaiting the MHRA toxicology report and as some victims have experienced adverse reactions after 12 years, we need long-term toxicology evidence to know if polypropylene mesh is safe and fit for purpose. Medical legal evidence, clinicians, toxicologists and lawyers need to draft guidelines as to how to preserve mesh removed from the body. There can be no assumption that any amount of petroleum based plastic mesh inside the human body is safe.

- We believe mesh must not be implanted in anyone considering future pregnancies. We do not know the long-term effects of polypropylene mesh on a woman's sex organs and it should never be used.
- We are concerned about the variation in Scotland's Health Boards in using mesh devices. The only way to reduce the division is to maintain the suspension.
- The professional organisations need to ensure that the relationship between clinicians and mesh manufacturers are more transparent, in line with the 'Sunshine Rule', in England this year.
- Pelvic floor education is very important. Pelvic Floor Muscle Training (PFMT) added to the curriculum for all secondary school female pupils could help prevent future generations suffering from prolapsed organs and stress urinary incontinence. It is known that if PFMT is done properly and the exercises maintained it can make a huge difference.
- Women must know that there is a mesh helpline. Awareness can be raised by introduction of a mobile phone App, DVD, posters in hospital waiting areas and GP practices etc.
- This is an Interim Report and we still do not have the full information.

It is worthwhile reading the comments made by former Health Secretary Alex Neil in retrospect. His reasons for calling for a mesh suspension have been justified. He put Scotland in the lead, ahead of the rest of the world when he announced the suspension in the Scottish Parliament, and at this time it is crucial that we revisit what he said and why.

He stated: "I came to the conclusion that we must suspend these procedures until we know why so many are going wrong.

"And we must find out why doctors were not reporting these complications."

"Women are suffering significant, life-changing complications."

"Patient safety is my No1 priority and the benchmark must be: Are we doing all we can to ensure the safety of these women?"

“Quite frankly, we had got to the stage where we had to suspend right across Scotland.”

“Some of our medical directors had already come to that conclusion and had been doing so.”

Until all the recommendations of the Review Group are all agreed and in full operation, NOTHING has changed since Alex Neil made that statement.

He said: “I’m proud Scotland has taken this stance and I believe we are leading the way on what is a significant global problem.

“After speaking to the medical watchdogs, my own health officials and the extremely courageous women who have been through so much, I decided I did not wish to take the risk that one more woman could be injured.

“I was advised by the Medicines and Healthcare products Regulatory Agency that the majority of the women’s operations were successful. Official figures suggest a low rate of problems.

“But after meeting those women and listening to their stories, I made up my mind what I needed to do.”

The initial findings of the Independent Review Group support Mr Neil’s concerns. And despite hundreds of women suffering life-changing injuries, doctors are STILL not compelled to report adverse incidents. There is STILL a lack of long-term data to show just how dangerous, or safe, mesh implants are.

Alex Neil pledged: "In the future, no other patient will leave hospital without all the details of any implant or device."

In line with the pledge made by Alex Neil, every woman treated with a mesh implant should be contacted, given details of which implant was used and any relevant product identification numbers.

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.

There is no unique device identifier (UDI) in place to record, monitor and evaluate data.

In light of the £1.5BILLION of settlements currently being paid in the US alone, and with many judgements over ‘defective’ implants the Independent Review should properly acknowledge the impact not only on injured women, but the NHS in terms of further treatment and legal costs. There are currently 368 lawsuits in Scotland and potentially many more in the future as mesh complications manifest, and this may prove very costly to our NHS.

Until each and every one of those critical points are overcome the Scottish Government has by its very act of suspension, acknowledged the clear and present danger of mesh procedures.

The Scottish Government has a duty to ensure that until not one more patient is put at risk of life changing injury, the mesh suspension must remain.

Scottish Mesh Survivors will accept nothing less.