



PUBLIC PETITION NO.

PE01517

Name of petitioner

Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign

Petition title

Polypropylene Mesh Medical Devices

Petition summary

Calling on the Scottish Parliament to urge the Scottish Government to:

1. Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;
2. Initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world;
3. Introduce mandatory reporting of all adverse incidents by health professionals;
4. Set up a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers;
5. Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards; and
6. Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.

Action taken to resolve issues of concern before submitting the petition

1. Meeting with Scottish Health Secretary Alex Neil to raise concerns over the safety of polypropylene Transvaginal Mesh implants.
2. Victims have taken part in a working group alongside health officials to draw up improved consent forms to include all possible adverse effects and information about alternative procedures.
3. Victims have engaged in a nationwide awareness campaign and established Scottish Mesh Survivors to educate and provide support, engaging in dialogue with medical experts across the world.

Petition background information

The wholesale use of polypropylene mesh medical implants to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) has been described as one of the biggest medical disasters of all time, with ongoing litigation in countries such as the US, Canada, Australia, New Zealand, Israel and the UK. Australian media report that mesh litigation could become the biggest class action in Australian legal history. In just two

US courts there are 59,561 legal cases pending, including over 21,695 against Ethicon, a subsidiary of Johnson and Johnson – with thousands more throughout the US. In a number of US cases manufacturers have been ordered to pay millions of dollars in compensation.

With surgeons able to perform as many as six mesh operations compared to one using natural tissue, mesh has become the “gold standard” for treating stress urinary incontinence in NHS hospitals. However, while the majority of operations appear successful, the life-changing complications when mesh procedures go wrong can be devastating, leaving many women facing a life on, or fighting for, disability benefits and facing multiple operations.

Globally, tens of thousands of victims have suffered life-changing side effects, with many ending up in wheelchairs, enduring multiple organ trauma and extensive nerve damage. Mesh implants are meant to be permanent. They are designed to encourage tissue growth through and around the mesh structure. Surgeons warn attempts at removal can cause further nerve damage and liken it to “removing chewing gum from hair”. Yet many Scottish patients were unaware the mesh implants they were treated with are permanent. Many Scots victims have already been subjected to a dozen or more operations as surgeons battle to remove it from inside their bodies.

One of the main reasons our petition is asking for the immediate suspension of mesh procedures, to treat pelvic organ prolapse and stress urinary incontinence, is the wildly differing ‘official’ figures charting how many patients have actually had the procedure and how many have had to undergo corrective surgeries.

Figures relating to TVM implants obtained from NHS Information and Statistics Division (ISD) reveal that 2915 women have received mesh implants since 2007 while other data from the same ISD source shows inconsistency.

However, figures from individual health boards, obtained through Freedom of Information requests, show three times as many women - over 10,700 - have had Transvaginal Mesh devices implanted. With no time limit on mesh going wrong, many women describe implants as a “ticking time bomb” inside them.

Official figures for those suffering adverse effects or serious complications are also full of discrepancies. Initially the Cabinet Secretary Alex Neil reported that six ‘adverse incidents’ had been reported but Parliamentary Answer (S4W-18274) detailed that 101 women had devices partially or fully removed.

However, information from individual health boards, obtained through FOI, shows that 328 women have had mesh removed. Because of the impending implications and the unacceptable discrepancies between ‘official’ figures, we are calling for the Scottish Government to suspend these procedures until such times as independent and comprehensive research and/or a public inquiry is undertaken and completed to give the true scale of the problem.

Alex Neil has publicly stated that the current consent system “is not working” and that he wishes patients to be given all available information some time before they undertake any mesh procedure and that they should be offered alternatives. Until accurate data is available and there is uniformity throughout Scotland’s Health Boards we cannot achieve informed consent. Until we are able to provide patients with accurate data, we ask that mesh procedures are suspended.

One of the key factors in achieving accurate data is to ensure every doctor is compelled to report adverse incidents. At present, it is not mandatory for doctors to report such matters. Because of this, official figures state just six adverse incidents have been reported from Scotland. This glaring failure has allowed mesh manufacturers to continue to insist their products are safe, despite the hundreds or thousands of women suffering adverse incidents and complications worldwide. Anything less than mandatory reporting represents a failure by doctors in their duty of care.

It is documented that as long as accurate coding is used in theatre then the data would provide an accurate reflection of procedures undertaken but the use of operation codes are not specific enough to identify a particular mesh device or indeed specific organs in

some operating procedures.

To monitor the safety of implants, along with mandatory reporting, we urge the Scottish Government to establish a register of devices detailing the patient, manufacturer, batch and serial numbers and when and where it was made and used. Currently, and unlike cars or electrical devices, there is no Scottish Register for TVM devices to follow up patient progress or recall devices if potential problems arise.

Unique web address

<http://www.scottish.parliament.uk/GettingInvolved/Petitions/scottishmeshsurvivors>

Related information for petition

Do you wish your petition to be hosted on the Parliament's website to collect signatures online?

YES

How many signatures have you collected so far?

0

Closing date for collecting signatures online

30 / 04 / 2014

Comments to stimulate online discussion

Suspension of mesh procedures must be immediate, until such times as we really understand the risks from this procedure. We also believe that compelling doctors to report adverse incidents related to mesh implants must be introduced. Transvaginal Mesh devices are having a devastating impact on tens of thousands of women across the world and hundreds in Scotland. We believe that fully informed consent must be provided as well as stringent monitoring, assessment and registration of this procedure. We believe the Scottish Government should register all medical devices, this would not stifle innovation, it would help with patient safety. Please sign our petition to support a suspension of polypropylene Transvaginal Mesh devices.