Petitioner submission of 23 May 2023

PE1865/LLLL: Suspend all surgical mesh and fixation devices

Having watched back the petition meeting 28th of September and the debate in Parliament on 17th January, we want to thank the Committee for keeping the petition going and for getting it debated in the Chamber. We have a few points to address regarding both meetings.

There needs to be viable and safe alternatives to mesh. In a previous Committee meeting in June 2022, Maree Todd MSP and Terry O'Kelly agreed that the skills gap between mesh and natural tissue repair needs to be bridged. Has there been any progress on this? This is a matter of urgency for us, and for the hundreds of people we've engaged with throughout this petition. Patients in Scotland deserve the right to have choice and to make informed decisions about their healthcare. In the same meeting the Chief Medical Officer stated that we must have "shared decision-making" between patients and medical professionals. Medical professionals must be able to confidently answer patient questions including: What are the risks? What are the alternatives? What if I do nothing? This doesn't seem to be reflected in current practice in the NHS in Scotland. Through our campaign group we have heard from patients who have very recently had mesh inserted with no discussion about the risks, nor were they offered any alternative treatment. We have heard from people who are now suffering complications as a result of recent mesh repairs, and who are having their significant complications ignored by implanting surgeon.

Shouldice Hospital have specified strict guidelines regarding patient eligibility for successful Shouldice repair; there are other techniques available. We also want to raise the point that when surgeons remove mesh from a patient experiencing complications, they close those patients back up with natural repair – patients should have this option in the first instance. We appear to have made no progress in Scotland regarding offering patients alternative treatment. Patients - men, women and children - are continuing to be harmed by mesh, with no alternative being offered and with no awareness of the potential risks.

Throughout the discussion of this petition the question around what we do if we stop using mesh has been asked repeatedly. The simple answer is what did we do before mesh? Surgeons used patients' own tissue, and this remains an option which patients should be informed of. We appreciate there is no appetite to ban mesh, and we are not asking for this, what we are asking is to stop using it as the sole option and to establish clear guidelines for use. Guidance needs to include:

- when mesh should be used;
- how mesh should be used;
- how much should be used; and
- who should use it.

This is vital to establish, only then will this ensure patient safety along with informed consent.

We also have no clear patient pathways. GPs do not know how to help patients or where to refer patients experiencing complications. The number of surgeons who can remove mesh is severely limited; we simply do not have the skills or expertise required in Scotland. Patients are currently relying on each other to find information, via online support groups, which is unacceptable. There needs to be clear guidance shared with all GP practices and health boards.

The Convener also mentioned the MHRA, who are meant to ensure safety of all patients with devices being used in the UK. MHRA have failed us. They are meant to be an independent body for patient safety, but the majority of their income (approx. 80%) comes from the pharmaceutical industry so how can they ever be independent? We in Scotland, especially our government, have a duty of care to each patient. We need to ensure these devices are fit for purpose and are not being pushed for financial gain; people's lives should not be risked for profit. We are aware of studies being carried out by researchers at the University of Sheffield on the safety of medical devices[1].

Former Health Secretary, Jeane Freeman, indicated she would like to see a separate medical regulator; however we have seen her colleagues hide behind the fact MHRA say mesh is safe with very little evidence. We want the safety of patients put first, and for alternative treatments to

[1] Medical device safety: effective testing is key: https://www.pslhub.org/learn/improving-patient-safety/equipment-and-facilities/medical-devices-new/medical-device-safety-effective-testing-is-key-r9423/

be offered so that patients can make their own informed risk assessments.

In watching the debate, we observed confusion from members who have not been involved in the petition committee meetings, and who do not appear to understand the complexity of the issues involved. They thought we said mesh causes cancer when we said Titanium ProTacks carry a cancer warning, as advised by Canada, this is an important distinction. They think we want to leave patients with no alternative, but that has never been the aim of our petition. We have stated repeatedly that our aims are to better understand the scale of the problem through a transparent and independent review, and to have patients be equipped with the information they need to make informed decisions including being offered alternatives to mesh. There are surgeons here doing the procedure without mesh, this is not an unrealistic aim. Data from Public Health Scotland states that between 2016 - 2020 62% of patients have been treated with mesh, meaning 38% were treated without mesh. These figures alone prove there are alternatives to mesh, yet we know many patients are not being offered alternatives. Only through an independent review will we all, surgeons, patients, ministers, policy-makers, be fully informed.

The data shows an average of 32 mesh removal surgeries completed each year. From our patient advocacy work, we know that numbers are low in part due to the lack of patient pathways and guidance to GP surgeries. Until we have clear patient pathways, we have no way of accurately recording how many patients need mesh removal, while patients are being left to struggle with life-changing complications.

The SHTG has published 2 reports, which we do not have faith in; in our view this was a whitewash. The recommendations state that non-mesh repair should be offered first; alternatives to mesh and patient choice were highlighted and yet this is still not being filtered down to primary care providers. The report does not take account of the true scale of the issue, and this makes the report useless in any real-world application. We again call for an independent review, which takes account of the lived experience of patients – many of whom do not know their symptoms are mesh-related until they meet someone else in similar circumstances.

We understand Katy Clark MSP has lodged an amendment to the Patient Safety Commissioner for Scotland Bill, which calls for an investigation into the use of surgical mesh.

We are 2 years into our campaign with this, we recognise that this is still early days; it took the transvaginal campaign nearly 10 years to get support that they so rightly deserved. However, we do not want to look back in a decade in regret at all the people who continued to be harmed whilst not being offered alternatives or being supported to make informed decisions. It is of the utmost importance that this is dealt with this sooner rather than later, through an independent review and the implementation of patient pathways.

We again thank the Committee and other MSPs supporting us.