Citizen Participation and Public Petitions Committee

10th Meeting, 2023 (Session 6), Wednesday 14 June 2023

PE1865: Suspend all surgical mesh and fixation devices

Lodged on 17 May 2021

Petitioner Roseanna Clarkin and Lauren McDougall

Petition summary Calling on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while—

- a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and
- guidelines for the surgical use of mesh are established.

Webpage https://petitions.parliament.scot/petitions/PE1865

Introduction

1. The Committee last considered this petition at its meeting on 28 September 2022. At that meeting, the Committee agreed to write to the Scottish Government, and to seek a parliamentary debate on the issues raised in the petition.

2. The petition summary is included in **Annexe A** and the Official Report of the Committee's last consideration of this petition is at **Annexe B**.

3. The Committee has received new responses from the then Minister for Public Health, Women's Health and Sport, and the Petitioner, which are set out in **Annexe C**.

4. A Committee-led debate on the petition took place on 17 January 2023. The Official Report of the debate is available here.

5. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.

6. Further background information about this petition can be found in the SPICe briefing for this petition.

7. The Scottish Government's initial position on this petition can be found on the petition's webpage.

8. Every petition collects signatures while it remains under consideration. At the time of writing, 2 signatures have been received on this petition.

Action

The Committee is invited to consider what action it wishes to take.

Clerk to the Committee

Annexe A

PE1865: Suspend all surgical mesh and fixation devices

Petitioner

Roseanna Clarkin and Lauren McDougall

Date lodged

17 May 2021

Petition summary

Calling on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while—

- a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and
- guidelines for the surgical use of mesh are established.

Previous action

I have been in contact with my MSP, and Scottish Government officials who advised that the concerns of hernia and other mesh survivors would be heard along with those of TVT and pelvic mesh survivors. They never were. I also met with the Cabinet Secretary for Health and Sport.

Background information

Information on polypropylene and polyester mesh and stitches clearly states the potential complications of their use and titanium protacks carry a cancer warning. We understand mesh must be used in life or death situations, but we want to ensure that—

- mesh is only used when essential;
- patients have alternatives to mesh; and
- mesh is only used with the fully informed consent of the patient.

We want the use of mesh devices and stitches to be suspended while a review of all surgical procedures which implant any form of polyester, polypropylene or titanium products – for example hernia mesh, rectomesh, mesh used in hysterectomies – is carried out and guidelines for the use of surgical mesh are established. We are also calling for suspension of the use of titanium protacks that are used with hernia mesh, as these carry a cancer warning.

While we recognise and support women with TVT or pelvic mesh implants, the mesh that we are talking about is not the same. It is put into the body differently and used for different purposes.

Annexe B

Extract from Official Report of last consideration of PE1865 on 28 September 2022

The Convener: PE1865, which was lodged by Roseanna Clarkin and Lauren McDougall, calls on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while a review of all surgical procedures that use polyester, polypropylene or titanium is carried out and guidelines for the surgical use of mesh are established.

I am delighted that we have Katy Clark with us. Welcome, Katy. I will invite you to contribute in a moment.

We last considered the petition on 8 June, when we heard evidence from Maree Todd, Minister for Public Health, Women's Health and Sport; the chief medical officer, Professor Sir Gregor Smith; and the senior medical adviser, Terry O'Kelly.

Following that meeting, we received two new responses from the petitioners, who both remain unconvinced that the Scottish Government has listened to the concerns raised through the petition. We have also received a submission from James Young, who shares a powerful account of the impact that a mesh implant had on his quality of life.

In a moment, we will discuss in the round the evidence that we have received, in addition to the evidence that we heard from Shouldice hospital in Canada. Before we do so, I invite Katy Clark to speak to us in relation the petition.

Katy Clark (West Scotland) (Lab): Thank you, convener. I am grateful for this opportunity. As you know, I have not been to the committee before. I am here to represent the lead petitioner, who is a constituent and is unable to be here due to medical conditions associated with the mesh procedure, which, I have to say, was undertaken on her without her knowledge or consent. I think that it is fair to say, from my meetings with her, that she is someone who is very well informed, had very detailed discussions with her medical practitioners before her procedure and was given information about what would be used that was very different from what happened in reality.

It is fair to say that the people who are involved in the campaign have life-changing conditions that are completely associated with the mesh procedure that they underwent. Indeed, there have also been deaths that it is believed were associated with the procedure. What they are asking for is that mesh is used only when it is essential—there are alternatives to mesh—and that it should be used only with the fully informed consent of the patient.

I know that the committee is very aware of the previous debates about transvaginal mesh and other procedures. The mesh used in relation to things such as hernia operations is, I understand, different and used for different purposes, but many of the issues are similar. It has to be said that the campaigners still believe that they are not being listened to, that their concerns are not being taken into account and that practice has not changed in relation to these matters in Scotland.

I am grateful for your consideration of what the campaigners are saying.

The Convener: Thank you. Colleagues, there is an opportunity for us to consider this. I note that our colleague Daniel Johnson will have a members' business debate on transvaginal mesh tomorrow in the chamber. However, that does not touch directly on the issues arising from the broader extension of mesh, which has been the focus of the petition and our inquiry.

We raised with the minister, in passing, suggestions that there was a campaign to have the ban on transvaginal mesh lifted. However, if I recall correctly, we got assurances from the minister that there were no immediate plans to do anything in relation to that.

However, in relation to the issue in this petition, we have heard a mixed bag of evidence, together with the Shouldice hospital evidence, which suggested that there were alternatives that might yet be useful, albeit that the individuals concerned would require quite rigorous discipline before they would be physically capable of withstanding the rigours of the technique. There was some concern from the Scottish Government that there might be something of a cherry-picked waiting list of people who would only get treatment under certain circumstances, although I was not sure whether there was not a way to get around any of that.

What thoughts do colleagues have?

Carol Mochan: I have read the evidence in detail because I have also been approached by constituents about the issue. For me, the key was the fact that the petitioners have said that mesh should be used only where it is essential. We should drill further into that. People should be properly informed and consent to these procedures, because we know from previous work on the use of transvaginal mesh just how life changing these things can be. Therefore, it is an important issue, and I would like to see the petition go further so that we have clarity on the issue.

The Convener: Before I bring in David Torrance, I will say that, obviously, we can make further inquiries, but one suggestion is that we try to take the issue to the chamber for a debate in order to inform colleagues more broadly about the wider issues arising from this particular aspect of the use of mesh. We might want to consider that, but is there anything that we might want to do ahead of that?

David Torrance: I was going to suggest that we take the issue to the chamber for a debate, but there is also a whole list of things that we could ask the Government for

information on. I will not read them out because the list is so long, but can the clerks write to the Government to ask it for that additional information?

The Convener: There are two or three areas in particular that we could look at. One that we could explore in a debate is the fact that it has now been repeatedly stated that responsibility for medical devices rests with the Medicines and Healthcare products Regulatory Agency and that there is a general view across all parties in Parliament that it has fallen short in its responsibility. All parties have offered support to the Government, not just in complaining about that but, potentially, in seeking to do something more directly about it, and that has not happened. That is one strand.

There is information relating to the Shouldice hospital that shows alternative ways forward. One of the themes from the petitioners is that their experiences were not taken seriously. It was a bit like the whole transvaginal mesh situation all over again, because they were treated as though they were imagining their pain and as though other people knew what was best for them. They felt that they had not received the same informed advice as others had. The minister suggested to us that a lot of work was being done in relation to the wider criteria and guidelines, so there is scope for a debate in the chamber. Are we content to do that?

Members *indicated agreement*.

Annexe C

Minister for Public Health, Women's Health and Sport submission of 28 October 2022

PE1865/KKKK: Suspend all surgical mesh and fixation devices

Thank you for your letter dated 30 September and I write here to address the points you raise. Before doing so, however, let me say that I did take careful note of the report of the committee's meeting on 28 September. I noted in particular important points made and concerns raised in relation to informed consent, and in that connection, reports of instances where clinicians were said to have not communicated in the empathetic way that I think all would reasonably expect. These issues, which are of course partly cultural ones, have and continue to be a focus for the Government and for the NHS in Scotland.

I take these concerns very seriously and as you are aware, both informed consent and effective communication are key features in Realistic Medicine, which the Scottish Government champions. The Chief Medical Officer has written to Health Board Medical Directors on this and it will be drawn to their attention again. Also, as I reported to the Committee in June, work is ongoing to empower patients to better engage in meaningful discussions with clinicians and the promotion of "BRAN" (benefits, risks, alternatives and the option of doing nothing) as a simple aide-memoire is an example.

What scope there is for Scotland to independently test devices, in addition to the work done by MHRA

As you know, the regulation of medical devices is reserved to the UK Government. The MHRA is currently reforming medical device regulation in the UK and recently ran a UK-wide consultation on proposed changes.

The MHRA proposals intend to increase the classification of surgical mesh implants from a Class IIb device to a Class III device (generally regarded as high risk devices). Devices are classified according to

guidance set out by the MHRA and the certification process is different for each class of device. This change will involve a greater level of scrutiny on surgical mesh in both pre- and post-market assessment and surveillance and require manufacturers to regularly provide clinical evidence of their safety as part of the recertification process required for high risk devices.

The UK Government has now published the response to the public consultation: Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

All medical products that are procured by NHS Scotland must meet the requirements of the UK medical devices regulations and be appropriately CE marked. This is the minimum requirement for all medical devices.

With regard to implants, due to their certification level, there are specific compliance requirements on evidence and control as well as post-market surveillance. This aspect is audited by the independent approval organisation that will award the CE marking certificate. More information is available online at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#overview

What discussions the Scottish Government has had, or plan to have, with Shouldice Hospital, or similar European centres, to explore opportunities for sharing expertise in natural tissue repair, and what the outcomes of those discussions have been

The Scottish Government commissioned two reviews by the Scottish Health Technologies Group (SHTG) into the use of mesh in hernia repair. The subsequent reports were shared with your Committee and the findings were discussed during the evidence sessions I attended. Based on comparative outcome data derived from peer-reviewed and published studies, including those involving non-mesh surgery, SHTG concluded that "…evidence supports the continued availability of surgical mesh as an option for elective repair of primary ventral hernias, incisional hernias and primary inguinal hernias in adults in Scotland". This notwithstanding, SHTG also concluded that "Patient preference may be for a non-mesh (suture) hernia repair and access to alternative

hernia management options should be available to accommodate this". In this context, the report from Shouldice Hospital is helpful and the Scottish Government has drawn it to the attention of SHTG, relevant Royal Colleges, Specialist Associations and the Scottish Association of Medical Directors (SAMD).

Furthermore, and to encourage provision of patient choice where this is clinically appropriate, the Scottish Government has asked SAMD to report on the availability of non-mesh surgery in individual Health Board areas and to highlight any skills or training gaps. The outcome of this exercise is awaited and further discussion will take place. The Scottish Government is mindful however that this is a clinical issue and appropriate boundaries need to be observed.

What progress has been made on establishing the medical information system to help track the outcomes of mesh and non-mesh hernia repair and identify opportunities for improvement;

With regard to the UK Medical Devices Information System (MDIS), the four UK nations are working collaboratively to develop a model that will improve knowledge of outcomes for medical devices. NHS England is leading the development of technical options, and these discussions continue.

Further to this, the Scottish Government is taking forward improvements in the recording of procedures and implanted devices. This is with a view to improving traceability, allowing rapid and efficient recall of devices in the event of an issue with a particular procedure or device, and also to improving our knowledge of clinical outcomes.

Four Health Boards will shortly begin a pilot of a UK-wide Pelvic Floor Registry, which will allow the recording of all treatments for pelvic organ prolapse and stress urinary incontinence, as well as mesh removal procedures. Furthermore, an NHS Scotland Scan for Safety Programme is being developed: all medical devices are in scope, but with a primary focus, until 2025, on high risk implantable devices used in acute healthcare settings. This will include mesh, joint replacements and cardiac devices.

The British Hernia Society has also been working on a hernia specific registry and are engaging with NHS Digital on the overlaps between this and the MDIS.

What further consideration has been given to extending the scope of the existing Complex Mesh Surgical Service or establishing a specialised unit or centre of expertise for hernia repair

The National Complex Pelvic Mesh Service in NHS Greater Glasgow and Clyde has been established specifically to provide expertise in the management of complications associated with the use of mesh in female urogenital surgery and in particular following transvaginal mesh insertion. A multi-disciplinary team (MDT) of clinicians has been brought together with this focus and it is for that reason that they do not accept referrals for abdominal and groin hernia mesh problems.

With regard to establishing a similar national centre for hernia mesh complications and removal, at present the Scottish Government does not believe this is required although it will be important to learn and share relevant experience from the centre in Glasgow. Within each Health Board there is expertise in hernia repair with more specialist interest and skills being developed by some surgeons. The Scottish Government has encouraged the establishment of Health Board clinical groups and networks so that complex cases can be discussed and expertise and experience shared across Scotland. Involvement of clinicians with non-surgical skills can be recruited as required. This has already been discussed with SAMD and further conversations will follow.

Whether the Scottish Government plans to commission an independent review of all mesh devices.

There are no plans to undertake an independent review of all surgical mesh. The Scottish Government has brought forward a substantial programme of work on this issue, including reports from the Health and Social Care Alliance and SHTG, and we expect the Transvaginal Mesh Case Record Review to conclude later this year. In addition to this, the Scottish Government accepted all the recommendations made by Baroness Cumberlege in her Independent Medicines and Medical Devices Review (IMMDS), where these were within Scottish powers, and

committed to working with the UK on the matters which are reserved. It is unclear what an additional review would add to this but I hope our commitment to improving services for all harmed by mesh is clear.

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 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.

[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/

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.