Citizen Participation and Public Petitions Committee Wednesday 22 January 2025 1st Meeting, 2025 (Session 6)

PE1865: Suspend all surgical mesh and fixation devices

Introduction

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

• guidelines for the surgical use of mesh are established

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

- The Committee last considered this petition at its meeting on 20 March 2024. At that meeting, the Committee agreed to write to the Cabinet Secretary for NHS Recovery, Health and Social Care and to the Scottish Parliament Corporate Body.
- 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 written submissions from the Scottish Parliament Corporate Body, and the Minister for Public Health and Women's Health, which are set out in **Annexe C.**
- 4. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.
- 5. <u>Further background information about this petition can be found in the SPICe briefing</u> for this petition.
- 6. The Scottish Government gave its initial position on this petition on 2 July 2021.
- 7. Every petition collects signatures while it remains under consideration. At the time of writing, 13 signatures have been received on this petition.
- 8. The Committee led a debate on this petition on 17 January 2023.

Action

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

Clerks to the Committee January 2025

Annexe A: Summary of petition

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 20 March 2024

The Deputy Convener: Welcome back, everyone. Our next continued petition, 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.

We last considered the petition at our meeting on 14 June 2023, when we agreed to write to the Minister for Public Health and Women's Health and the British Hernia Society. As with previous considerations of the petition, we are joined by Katy Clark MSP. In addition, Clare Adamson MSP joins us remotely.

We have received a submission from Katy Clark with further details of the freedom of information responses on the number of patients readmitted following complications with surgical mesh that were referred to during our previous consideration.

The response from the Minister for Public Health and Women's Health tells us that there is subspecialist coverage in complex hernia repair, including non-mesh repair, operating in NHS Lothian, NHS Fife and NHS Grampian, with a further subspecialist based at the NHS Golden Jubilee national hospital.

The minister also provided an update on the development and implementation of the scan for safety programme, and indicated that further options for improved data collection, such as a registry of hernia repair procedures, are also being looked at by Government officials and their national health service colleagues. Reference was also made to OK to Ask, which is a public awareness campaign that aims to support patients and healthcare professionals having positive conversations about care and treatment.

We have a response from the British Hernia Society stating that it cannot support the suspension of all surgical mesh and fixation devices, as that would run counter to the best scientific evidence guidelines that have been published by the European Hernia Society. The British Hernia Society recognises the need to improve patient outcomes and offers information on the work that is being done to develop the hernia registry, which it hopes to roll out nationally this year.

We have also received submissions from the petitioners, which respond to the British Hernia Society's submission and highlight that the improved patient pathways that the minister referred to has not led to improvements in the everyday experience of mesh patients so far. They are also concerned that little progress is being made to bridge the skills gap between natural tissue repair and mesh repair, and have highlighted a number of surgeons around the world who are developing their own non-mesh hernia repair techniques.

One of the petitioners, Roseanna Clarkin, has also shared her experience of mesh-related complications and the barriers faced when requesting non-mesh repair.

Members will also be aware that, since our previous consideration of the petition, Parliament has passed the Patient Safety Commissioner for Scotland Bill. That legislation will enable the establishment of a commissioner to advocate for systemic improvements in the safety of healthcare and to promote the importance of the views of patients and other members of the public in relation to the safety of health care.

I ask Katy Clark to put her submissions to the committee.

Katy Clark (West Scotland) (Lab): Thank you very much. I am very grateful to the committee.

I appear on behalf of both petitioners. Roseanna Clarkin, whom you have already spoken about, convener, continues to suffer from mesh-related complications and is attempting to obtain support through NHS and Social Security Scotland. There are a number of issues in relation to that. She hopes that the mesh will eventually be removed, although there are some complications with that.

I also appear on behalf of Lauren McDougall, whose mother unfortunately died shortly after a hernia mesh procedure. The petitioners work with a number of campaigners who have been negatively impacted specifically by the use of mesh in hernia processes. They believe that a number of outstanding issues remain and that mesh is still used in hernia procedures in many situations where alternatives could be used.

I will focus on the second part of the petition, which relates to guidelines for the surgical use of mesh. It would be helpful if we could get more evidence of current practice, and I would ask the committee to consider whether it would be willing to look at examples of individuals who are currently receiving mesh in situations where they believe that alternatives should have been considered and would be more appropriate, with a view to looking at the type of guidelines that perhaps could be created in Scotland.

The Deputy Convener: Thank you. I call Clare Adamson.

Clare Adamson (Motherwell and Wishaw) (SNP): Thank you. I trust that you can hear me, convener.

The Deputy Convener: Yes.

Clare Adamson: I am very pleased that the committee has given me this opportunity to speak to the petition on behalf of my constituent, Ms Janet Weatheritt. Ms Weatheritt is one of many women whose lives and livelihoods have been harmed by complications following mesh implants. She had two vaginal mesh devices fitted in 2012 and 2013, and has had to endure chronic pain and has been prescribed multiple medications since that time. Her story speaks to the heart of the injustice that those who have suffered from mesh complications face.

Ms Weatheritt travelled to the USA in August last year. She had a referral for surgery for mesh removal with Dr Veronikis. The removal procedure was successful; however, Ms Weatheritt has suffered post-removal complications. She was advised at the time of the removal that she required medical repairs. She has reported that

Doctor Veronikis lamented that he could perform the repairs "there and then", but the contract with the NHS allowed only for mesh removal and any post-surgery repairs would have to be done back in the United Kingdom.

Ms Weatheritt was then advised through the national services division that the agreed position was that any post-removal reconstructive surgery would be undertaken in Scotland by local services. Questions remain over whether her aftercare can be done locally within NHS Lanarkshire or whether it will require a further referral. Indeed, Ms Weatheritt's NHS Lanarkshire consultant has already raised issues to do with post-surgery care with the national transvaginal mesh accountable officers' group.

Ms Weatheritt's case is emotive. She has faced intense uncertainty, unbearable pain, delay and disappointment. Although she is relieved that the mesh has been removed, she is still in need of medical help.

I would ask the committee to ensure that it prioritises a clear clinical pathway for mesh use and removal that sets out accurate expectations for those who require surgery or post-surgery care of repairs following removal from a funded provider outwith NHS Scotland.

Ms Weatheritt is keen that those considering travelling for surgery are aware of her experience so that they can make a fully informed decision about whether to go ahead with mesh removal outwith Scotland. She also hopes that her experience informs the committee as it deliberates on the petition.

I have taken up Ms Weatheritt's concerns with NHS Lanarkshire and the minister. However, women—anyone—affected by mesh deserve our continued support and care not just in relation to what has happened the past; that needs to be provided for their present and future, to ensure that they have the best possible outcomes and quality of life.

I thank the committee for the opportunity to speak to the petition this morning.

The Deputy Convener: I thank Katy Clark MSP and Clare Adamson MSP for their statements. Members, do you have any comments or suggestions for action?

Maurice Golden: Thank you, convener. I think that we should write to the Cabinet Secretary for NHS Recovery, Health and Social Care to set out the evidence that the committee has gathered to date, including what we have heard from Katy Clark and Clare Adamson today. We should also recommend that he meet the petitioners to discuss continuing concerns about patient pathways for those harmed by mesh implants, as well as highlight concerns about the work that is being undertaken to bridge the skills gap between natural tissue repair and mesh repair in Scotland.

I also think that we could write to the Scottish Parliament Corporate Body to seek details of the process and timeline for recruiting the patient safety commissioner for Scotland.

The Deputy Convener: Do members of the committee agree to take that action?

Members indicated agreement.

The Deputy Convener: I thank Clare Adamson and Katy Clark for their attendance.

Annexe C: Written submissions

Scottish Parliamentary Corporate Body (SPCB) written submission, 12 April 2024

PE1865/SSSS: Suspend all surgical mesh and fixation devices

Thank you for your letter of 25 March 2024 asking the Scottish Parliamentary Corporate Body for information about the appointment of the new Patient Safety Commissioner for Scotland.

The Presiding Officer has established a cross-party selection panel under Standing Orders to undertake the recruitment of the Patient Safety Commissioner for Scotland.

Prior to the post being advertised and to include those with a lived experience of patient safety issues in the recruitment process, the selection panel met with members of the Scottish Government's Advisory Group who had assisted with the drafting of the Patient Safety Commissioner for Scotland Bill, to seek their feedback on the job role and the skills and experience the Commissioner should have. This was a very productive and helpful meeting.

The post was advertised on Wednesday 20 March 2024 and the closing date for applications was Monday 8 April 2024.

The cross-party selection panel will meet on Wednesday 17 April 2024 to short list the candidates to be invited to interview. Interviews are scheduled for Monday 29 April 2024.

Following pre-appointment checks, a Motion will be lodged seeking the Parliament's agreement to nominate the successful candidate to His Majesty for appointment as the inaugural Patient Safety Commissioner for Scotland.

When the Commissioner takes up office will depend, if they are currently in employment, on any notice period they have to give to their employer.

I hope the above is helpful to the Committee.

Minister for Public Health and Women's Health written submission, 22 April 2024

PE1865/TTTT: Suspend all surgical mesh and fixation devices

Thank you for your letter of 25 March concerning the above named petition. I am responding as Minister for Public Health and Women's Health as mesh falls under my portfolio responsibilities.

I note the further evidence outlined in <u>the Committee's Official Report dated 20</u> March 2024.

Patient pathway following mesh removal with an independent provider

Firstly, I would like to address concerns raised about the patient pathway for women who have undergone mesh removal surgery with an independent provider in Bristol or the US.

Regardless of where mesh removal surgery takes place, whether it is undertaken by the specialist service in Glasgow or by one of the two independent providers, it is expected that aftercare is provided by the patient's local Health Board, <u>as set out on page 8 of NHS National Services Scotland's patient leaflet</u>, which is provided to all patients considering surgery with an independent provider. The independent provider is expected to share the patient's consultation report, operative report and pathology report with their Health Board in Scotland. The intention of this process is to ensure that patients can, where possible, receive treatment as close to home as possible.

The contracts with the independent providers are for mesh removal surgery. It is however recognised that, following such surgery, some patients will require subsequent revision/reconstructive procedures. This is considered in each case after a period of time to allow for tissue healing and recovery of function. This care will be undertaken within the NHS and, in most cases, this will be in Scotland. This approach means that patients that choose to have mesh removal surgery with one of the independent providers or with the NHS centre in Glasgow (or in England) are in the same position in relation to subsequent procedures. If for any reason a patient's local Health Board is unable to provide care, processes are in place to access treatment elsewhere within the NHS.

Any patient who has concerns after returning from the independent provider should not hesitate to seek assistance from their General Practitioner or local clinical team, who will be able to provide advice and ongoing care as required.

Guidelines for the surgical use of mesh

In the Official Report, Katy Clark MSP queried current practice and guidelines surrounding the continued use of surgical use of mesh in Scotland.

The halt on the use of transvaginal mesh for treating Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP), implemented in September 2018, remains in place. The use of mesh in gynaecology in other sites, for instance abdominally inserted gynaecological mesh, is subject to high vigilance protocols, which includes assurance of competence and documentation of the decision-making process. Some of the procedures for which mesh continues to be used are complex and long established, and there are few, if any, viable alternatives.

The high vigilance protocol was issued to Health Boards at the same time as the halt was announced, and was reiterated in a letter from the Chief Medical Officer in October 2023. Accountable Officers are in place in each Health Board to oversee adherence to the high vigilance protocol. Furthermore, proposed treatment must adhere to the principles outlined in Realistic Medicine, particularly patient centred care and shared decision making. A patient should decide upon their treatment with their clinician, following meaningful discussion and sharing of all necessary information, including benefits, risks and alternative treatments.

In respect of the ongoing use of mesh in hernia repair, the Committee is aware of the two reports commissioned by the Scottish Government to investigate the use of mesh in hernia repair. The first concentrated on inquinal hernia repair and second examined hernia repair more generally. Both reports were carried out by Scottish Health Technologies Group (SHTG). The reports support the continued use of surgical mesh in hernia repair whilst recommending that consideration should be given to patient preferences and access to alternative hernia treatment options like non-mesh repair should be made available where possible and where clinically appropriate. The British Hernia Society provides guidance on a range of treatments, which can be accessed here. Secondly, the General Medical Council provides guidance on informed consent, which can be accessed here.

The Scottish Government expects all NHS Boards and their clinicians to adhere to GMC guidelines and to have clinical governance in place to ensure this is the case. We are also clear that all discussions on treatment options between a patient and their clinician must be documented. With respect to mesh, including hernia mesh, this was made clear in the Chief Medical Officer's letter to Medical Directors of February 2018 and October 2023.

Surgeons' skills (natural tissue repair)

I note Ms Clarkin's concerns about the skills of surgeons to perform natural tissue repair, and I would like to reassure the Committee that a significant number of hernias are repaired without mesh in Scotland. With specific regards to natural tissue inguinal hernia repair, officials are working with a collaborative of Scottish surgeons with specific interests in hernia surgery, and individuals have been identified in Scotland who have the skills to take this forward. However, this type of surgery is for a defined population consistent with physical characteristics as were identified by the Shouldice report and previously discussed with the Committee. This means that there will be recognition of the need to ensure that anyone presenting for surgical hernia repair is in an appropriate physical condition for their procedure.

Meeting request

Mr Terry O'Kelly, Senior Medical Advisor, and I met with Katy Clark MSP and three of her constituents, including Ms Clarkin and Ms McDougall, on 15 November 2023 and heard a detailed report of their experiences and their concerns, including patient pathways following mesh removal surgery and guidelines for clinicians who use surgical mesh. As an action from this meeting Scottish Government officials are in the process of arranging for Ms Clarkin and Ms McDougall to meet with SHTG to discuss the SHTG reports into hernia repair in more detail, ensuring key representatives from SG and SHTG are available to attend.

As such I believe that another discussion on these topics may not be productive at this time. However, please be assured that the Petitioners' views and concerns have been carefully noted and are being given careful consideration.

Yours sincerely,

Jenni Minto MSP