Citizen Participation and Public Petitions Committee Wednesday 19 February 2025 3rd 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

- 1. <u>At its meeting on 22 January 2025, the Committee agreed to defer</u> <u>consideration of this petition to a future meeting</u>.
- 2. <u>The Committee previously considered this petition at its meeting on 20 March</u> <u>2024.</u> 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.
- 3. 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**.
- 4. The Committee has received new written submissions from the Scottish Parliament Corporate Body, the Minister for Public Health and Women's Health, and the Petitioners, which are set out in **Annexe C.**
- 5. <u>Written submissions received prior to the Committee's last consideration can be</u> found on the petition's webpage.
- 6. <u>Further background information about this petition can be found in the SPICe</u> <u>briefing</u> for this petition.
- 7. The Scottish Government gave its initial position on this petition on 2 July 2021.
- 8. Every petition collects signatures while it remains under consideration. At the time of writing, 13 signatures have been received on this petition.
- 9. <u>The Committee led a debate on this petition on 17 January 2023</u>.

Action

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

Clerks to the Committee February 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 Reports

Extract from Official Report of consideration of PE1865 on 22 January 2025

The Convener: Our second item is consideration of continued petitions. The first of those, 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.

Katy Clark had hoped to be here to speak to the petition but is unable to join us, and I understand that one of the petitioners has been ill and, therefore, was not able to make a submission that they would have liked us to consider as part of our consideration of the petition this morning. In the light of that, I suggest that we defer consideration of the petition until our next meeting, in order that the petitioner be given the opportunity to make their additional submission. Do colleagues agree?

Members indicated agreement.

Extract from Official Report of 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 meshrelated 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> <u>March 2024</u>.

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 inguinal 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

Petitioner written submission, 22 January 2025

PE1865/UUUU: Suspend all surgical mesh and fixation devices

We would like to submit the following article published in the Journal of Abdominal Wall Surgery about hernia surgery in adolescents titled:

• No reason to use mesh in groin hernia repairs in adolescents

While we understand that there are complexities and differences regarding surgical options for adults, adolescents and children, we would also like to highlight that no hernia surgery is the same for any person at any age. We would like to draw the Committee's attention to the following quote from the article, in particular the final sentence (italics added for emphasis):

"When repairing groin hernias in adolescents, surgeons must decide between mesh or non-mesh repair. In case of non-mesh repair, the risk of recurrence must be acceptable, and in case of mesh repair mesh-related complications must be acceptable. It seems counterintuitive to place a synthetic foreign body like a mesh, static in size, in the groin of adolescents who still have growth potential. *Also, the prospect of living many years with a foreign body in the groin naturally raises concerns*, and therefore, ideally, using mesh in this age group should perhaps be avoided."

While the context of growth potential may not be relevant for adults, we want to strongly advocate that all hernia surgery must be considered in this view. Each patient's medical history, risk factors and personal circumstances should be considered individually to enable genuine choice and informed consent. If the risk of living many years with a foreign body is considered enough to warrant a suggestion that mesh should be avoided in young people, why is this also not the case for an adult who will also live for many years with the same foreign body implanted in them?

We ask the Scottish Government and the NHS to consider this principle as a foundation and framework to allow for investment in both surgical expertise and research within hernia surgery, as well as other surgeries using mesh implants.

Hernia repair should be approached the same way for an adolescent as for an adult. Questions should be asked to ensure the best possible long-term outcomes for each patient, and this should be the basis for choosing the most appropriate surgical interventions. This includes considering factors such as: could this patient change something in their life to ensure that a natural repair is a sustainable option? Would this lead to a healthier life and improved outcomes? Patients must be made aware of their options, and of the risks of both natural tissue repair and mesh repair. Do patients understand the risk of lifelong disability from mesh complications? Do they understand the possibility of intractable pain, migration and shrinkage associated with mesh, or are these outcomes presented as low risk? Our community members tell us they were not adequately informed before their surgery, and this is unacceptable.

We believe hernia surgery should be considered a principled surgery, meaning a hernia surgeon should be trained specifically in Shouldice and natural tissue repair, as well as mesh techniques. As it stands, we do not have the appropriate expertise within Scotland to make this possible. Hernia surgery, with the known risks of recurrence and complications, should be treated as an area of specialism rather than a small part of a general surgeon's practice. We know that hernia surgery is not as routine as it has been considered in the past, particularly in light of mesh complications and recurrences; specialised expertise is a must.

Although the true rates of mesh complications remain unclear, the harm from mesh is now known globally, with patients from across the world speaking out about their experiences. These voices will continue to grow and will get stronger as patients come together through online support groups. With every newly published news article, more and more people join our group to share their stories. Patients are also aware that other jurisdictions are taking stronger action against the use of mesh, and wonder why this is not being taken as seriously in Scotland.

We need to create guidance and training for every stage of hernia care, including both pre-op, and post-op. This includes guidance for general practitioners to help them spot and record mesh complications in their patients. We have heard countless stories of patients whose doctors are unaware that mesh could be causing their health problems.

We continue to implore the Scottish Government and the NHS to work with agencies, such as the Shouldice Hospital and beyond, to enhance the skills and expertise of surgeons in Scotland. The people of Scotland deserve the same degree of choice as those living elsewhere, and at present that is not feasible.

Petitioner written submission, 10 February 2025

PE1865/VVVV: Suspend all surgical mesh and fixation devices

When we began this petition, we launched a parallel campaign and support group under the name Scottish Global Mesh Alliance. We would like to update the Citizen Participation and Public Petitions Committee on a recent name change to Sling The Mesh Scotland, to align with the rest of the UK. This enables us to work more closely with groups in the other UK nations and support one another in furthering the work to minimise harm from all uses of surgical mesh. This name change applies to our campaigning work, and our online support community, but does not impact our petition to the Scottish Government or our aims.

We are still calling for dedicated patient pathways for those who are injured by mesh surgeries. We continue to hear from new members in our group whose doctors are not informed about possible mesh complications, and who are left with nowhere to go for help. There are very few surgeons in Scotland who are appropriately experienced to do removals and/or natural repairs, and these surgeons are not known to patients until they seek out support from our group. Essential medical care should not be left to chance or word of mouth from other patients. There must be a clear pathway to named surgeons with appropriate expertise and we remain committed to working with the Scottish Government and NHS to achieve this. Our

previous submission dated 22 January 2025 covers the issue of training and surgical expertise in Scotland, and should be read in parallel with this submission.

We continue to advocate for an independent review into the use of mesh with a view to understanding the true rate of complications. This aim remains a top priority for us, particularly in light of our meeting with the Scottish Health Technologies Group (SHTG) and Terry O'Kelly on the 24th of October 2024. During the course of that meeting, the representatives from SHTG agreed with our assertion that the datasets used were incomplete and outdated. One key example is the lack of any follow-up beyond 12 months, despite the knowledge that mesh complications do not always appear immediately after surgery. We also raised issues with the robustness of the data, as not all mesh complications are being recorded; particularly when both patients and their doctors are unaware the symptoms experienced could be related to the use of mesh implants and devices. As a result, we raised our significant concerns that not all of the recommendations in the report may be in-keeping with the true reality of the situation. In addition, many of the recommendations have not been implemented in practice and Terry O'Kelly and the representatives from SHTG offered a follow-up meeting with us to discuss the implementation of the recommendations around patient choice and informed consent, as these should be prioritised as a matter of urgency. We hope to arrange this within the next couple of months.

Despite the concerns over the data used in the SHTG report, the Scottish Government appear to be unwilling to commission any further reviews, which we believe could uncover the scale of mesh harm in Scotland. This report was an academic desk-based exercise using narrow and incomplete datasets. This is something the Scottish Government should be concerned with putting right. We are not blaming the SHTG who carried out the review as they were working within parameters set by the Government, however we feel patients like ourselves should have been involved in working with the Government to ensure the right research questions were being asked. We do not have faith in this report or its conclusions that mesh is still the safest option for most patients. As the Scottish Government appear happy to leave that report as it is, we are not and continue to call for an independent review. No one, whether that is patients, surgeons, policy-makers, or politicians will truly know the impact of mesh and mesh harm until an independent review is undertaken.

Also, within the SHTG report it stated that patients should have options including natural tissue repair. Yet this appears not to have been filtered down to the NHS. Our work with patients across Scotland makes it clear that surgeons are still not offering choice or natural repairs, which makes informed consent from patients impossible. We also do not have adequate surgical expertise in Scotland to offer this choice, which again prevents patients from true informed consent. This underlies our ask for patient pathways and for investment in appropriate surgical skill and expertise by those qualified to do removals and natural repair. In order to achieve this, we need a centre of excellence with skilled surgeons who can offer a range of options, including natural tissue repair and mesh removals.

Thank you for your time.