Citizen Participation and Public Petitions Committee

3rd Meeting, 2021 (Session 6), 8 September 2021

PE1865: Suspend all surgical mesh and fixation devices

Note by the Clerk

Petitioner	Roseanna Clarkin, Lauren McDougall and Graham Robertson
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	petitions.parliament.scot/petitions/PE1865

Introduction

1. This is a new petition that has been under consideration since 17 May 2021.

2. A SPICe briefing has been prepared to inform the Committee's consideration of the petition and can be found at **Annexe A.**

3. While not a formal requirement, petitioners have the option to collect signatures and comments on their petition. On this occasion, the petitioner elected not collect this information.

4. The Committee seeks views from the Scottish Government on all new petitions before they are formally considered. A response has been received from the Scottish Government and is included at **Annexe B** of this paper.

5. Four submissions have been provided by the petitioners. These are included at **Annexe C**. More than sixty written submissions have also been received in support of the petition. Links to these submissions are included at **Annexe D**.

Scottish Government submission

6. In his written submission, the Cabinet Secretary for Health and Social Care states that the Scottish Government takes all issues relation to the use of mesh very seriously.

7. The Cabinet Secretary highlights that, in February 2018, the then Chief Medical Officer wrote to all Health Board Medical Directors about the use of mesh in sites other than the vagina.

8. This guidance highlighted the importance of—

    - Sharing information with patients to ensure that they can consider all possible treatment options, surgical and non-surgical, and that any consent to the use of mesh is fully informed.

    - Carefully listening to patients who report complications or side-effects following mesh surgery, taking those concerns seriously and acting upon them appropriately.

    - Managing patients with mesh related complications by following the agreed pathways. This should involve a multidisciplinary team of clinicians with appropriate skills and experience.

9. The Cabinet Secretary notes that in September 2018, the use of transvaginal mesh for the treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse was halted.

10. The Cabinet Secretary further notes that, at that time, a high vigilance scrutiny protocol was introduced for some other procedures including abdominally-inserted mesh for pelvic organ prolapse (e.g. sacrocolpopexy, hysteropexy, rectopexy), which are highlighted in the petition. He states that these measures are still in place across NHS Scotland.

11. In his submission, the Cabinet Secretary agrees that it is essential that patients fully understand their treatment options, including the risks, in order to be able to give fully informed consent. He explains that fully informed consent is a key principle of Realistic Medicine as well as the recently updated General Medical Council guidance on consent.

12. The petition calls for a review of all surgical procedures which use polyester, polypropylene or titanium.

13. In response, the Cabinet Secretary states that the Scottish Government has commissioned research in to the use of mesh in a commonly performed hernia repair (primary inguinal).

14. The resulting report concluded that, compared to non-mesh procedures, using mesh resulted in lower rates of recurrence, fewer serious adverse events and similar or lower risk of chronic pain. As such, the advice for NHS Scotland was that surgical mesh should be used for elective repair of inguinal hernia in adult males, following a process of shared decision making and informed consent.

15. The submission explains that, in the light of this, the Scottish Government does not consider that there is evidence at present that might justify a 'pause' in the use of relevant devices.

16. The Cabinet Secretary states that the Scottish Government has commissioned further research, to examine hernia repair in men and women, and to analyse the outcome of mesh surgery in different hernia types as well as tacking devices.

17. The report is due to be published in late summer and will be drawn to the attention of NHS Medical Directors as well as professional bodies.

18. The Cabinet Secretary states that the Scottish Government will encourage Health Boards to consider development of local clinical groups and broader clinical networks for the management of complex cases.

19. The Scottish Government will also consider the development of skills in non-mesh procedures where these are required.

20. With regard to outcome data, the Cabinet Secretary explains that NHS Scotland is working with NHS Digital on a UK-wide initiative to develop a Pelvic Floor Database and Registry with NHS England. This registry will monitor and improve both quality of care and patient safety in respect to gynaecological procedures.

21. Information on other implants should be captured by the Scottish Government's Unique Device Identifier Programme, and then added to electronic patient records.

22. The Cabinet Secretary explains that it is envisaged that analysis of outcomes will be possible through links with routinely collected data. This work will also facilitate accurate recording and reporting of adverse events and to enable patients to be traced in the event of a product recall or a safety concern.

Petitioners' submissions

23. In her response to the Cabinet Secretary, PE1865/JJJ, the petitioner states that she was offered mesh at a gynaecology clinic, when the suspension was in place. Furthermore, she states that she was not offered an alternative treatment.

24. While the Cabinet Secretary wholeheartedly agrees that fully informed consent is critical, in her own case, the petitioner did not consent to the use of mesh in her operation, yet it was still used.

25. The petitioner notes that the other submissions received in support of the petition, show that these are common issues, for both male and female patients.

26. With respect to TVT/pelvic mesh, the petitioner states that —

> "the Scottish Government is saying the right things, but our evidence shows that it isn't filtering down to patient care."

27. The petitioner believes that the care pathway for gynaecology mesh patients to have their mesh removed is flawed, however, she notes that for people with hernia, bowel or other types mesh, there is currently no care pathway to have their mesh removed.

28. The petitioner raises concerns that there is a lack of robust data being recorded in relation to the—

- number of mesh operations carried out each year;
- complication rates;
- number of revision surgeries; and
- devices that are implanted, should there be a recall.

29. Although exact figures are not available, the petitioner believes there are over 10,000 hernia mesh operations each year, and that one person in ten will suffer severe chronic pain.

30. Highlighting the work of a specialist hernia centre, the petitioner notes that its surgeons clearly record and store their data. Those surgeons have concluded that natural tissue repair is safer as—

- Less than 1% of patients experience minimal chronic pain;
- 3% experience herniation recurrence, and
- The procedure doesn't cause a foreign body reaction.

31. In the submission, the petitioner challenges whether patients in Scotland have meaningful alternatives to mesh given that, at present, there is no training being delivered for natural tissue repair in Scotland.

32. In submission PE1865/RRR, the petitioner highlights that, following post-market surveillance of transvaginal mesh devices, intended to treat pelvic organ prolapse (POP), the U.S. Food and Drug Administration recently updated information regarding its regulatory oversight of urogynecologic surgical mesh products.

33. The update states that "the FDA continues to believe that these devices do not have a favorable [sic] benefit-risk profile".

34. The petitioner argues that this provides a pathway to prove that hernia mesh and other mesh devices are causing the same issues and calls on the Scottish Government to suspend use of mesh until more testing is done, and more guidelines can be established.

Other submissions

35. The Committee has received more than sixty submissions from people, including the petitioners, detailing their experience of living with a mesh implant, or supporting a loved one.

36. Although each submission shares a very personal experience, there are similarities in the issues raised, including—

- A lack of information and discussion about possible complications from the use of mesh;
- Surgeons discussing mesh treatment options, without using the term 'mesh';
- Patients' pain and distress being dismissed by medical professionals;
- A reluctance by medical professionals to believe that mesh could be the cause of any pain or reduction in mobility; and
- The considerable impact that these complications on their personal wellbeing; their relationships with partners, family and friends, and on their careers.

Action

37. The Committee is invited to consider what action it wishes to take on this petition.

Clerk to the Committee

PE1865: SUSPEND ALL SURGICAL MESH AND FIXATION DEVICES

Petitioner

Roseanna Clarkin, Lauren McDougall and Graham Robertson

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 A

Briefing for the Citizen Participation and Public Petitions Committee

Petition Number: PE1865

Main Petitioner: Roseanna Clarkin, Lauren McDougall and Graham Robertson

Subject: suspension of use of certain types of surgical mesh and fixation medical devices

Calling on the Scottish Parliament to urge the Scottish Government 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.

Background

The petitioners wish to raise awareness of complications that have arisen from the use of synthetic mesh in surgical repairs. The petitioners make it clear that this petition is not about transvaginal tape (TVT) or pelvic mesh implants, but about mesh and other devices and fixings used in surgery elsewhere in the body, particularly in hernia repair.

Transvaginal tape (TVT) 'mesh', is used for stress urinary incontinence (SUI) and pelvic organ prolapse and (POP). These two conditions, and their treatment with mesh, have been the subject of much controversy, debate and a wide review internationally, as well as the production of new clinical guidelines over recent years.

Routine use of mesh for treatment of SUI and POP ceased in Scotland in 2014. This suspension was tightened in 2018 until a restricted use protocol was established. See also PE 1517.

The petitioners are highlighting that similar problems with these other synthetic meshes, such as infection, pain and adhesion can occur with mesh after it is used for hernia and other repairs, and are calling for a suspension of its use. They want this suspension so that a review can done on existing guidelines and evidence. They also wish to see the introduction of bespoke services for removal if complications occur, and argue that specialist training of surgeons is required. Removing TVT is not the same as removing mesh from the digestive tract for example. The petitioners want the same attention that has been given to treatment by mesh for SUI and POP given to the use of mesh in other parts of the body.

The petitioners are also calling for similar caution to be applied to other devices, such as titanium staples that are used in securing mesh, because of a reported cancer risk.

Repairs where mesh and mesh stitches might be used

A common use for surgical mesh is for hernia repair. There are several types of hernia, that occur in the abdominal area, but the most common is an inguinal (groin) hernia. Such hernias most commonly affect men, when part of the bowel or fatty tissue pokes through the muscle wall into the groin area causing painful swelling. Treatment is by open or laparascopic (key hole) surgery. NHS Inform say that the operation is routine and can be carried out as day-surgery. Mesh is used to strengthen the muscle wall. In keyhole surgery, there are two methods used:

- Transabdominal preperitoneal (TAPP) – instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum). A flap of the peritoneum is peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.
- Totally extraperitoneal (TEP) – this is the newest keyhole technique. It involves repairing the hernia without entering the peritoneal cavity.

NHS Inform goes on to describe the pros and cons of all three methods, including open surgery, which remains the most common.

Clinical Guidelines for hernia repair

The mesh in use for hernia and other abdominal repair has been in use since the 1970s. It was later approved for use in pelvic repair surgery. The National Institute for Health and Care Excellence (NICE) published guidance for a certain type of hernia repair that dates from 2004, and was reviewed in 2016 with no changes deemed necessary. However, more recent guidance for the treatment of a different type of hernia with mesh was published in 2019, and recommends caution and fully informed consent and the involvement of clinical governance leads.

Other guidelines:

Society of American Gastrointestinal and Endoscopic Surgeons guidelines (2016)

Scottish Needs Assessment Programme, Hernia Repair 1996

How are medical devices and materials regulated?

Regulation of medicines and medical devices is reserved to the UK Parliament. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for issuing licences to manufacturers and wholesalers to enable licensed products to be used in the UK. This SPICe briefing provides more information. Once licensed, health boards and clinicians are able to order and use the products and devices.

In 2017, NHS England set up a Mesh Working Group to address concerns. However, the focus was only on evidence related to vaginal mesh implants for Pelvic Organ Prolapse (POP) and Stress urinary incontinence (SUI).

In June 2021, NHS National Services Scotland published Guidance on the Management of medical Devices and Equipment in Scotland's Health and Social Care Services. This brings together MHRA guidance (as the competent authority) with Scotland specific guidance so that there is alignment between UK and Scottish public bodies and government, partly as a consequence of the UK leaving the European Union.

How are adverse events reported?

Adverse events are occasions when a procedure or treatment has cause harm to individuals or groups of people. NHS Healthcare Improvement Scotland has led work in learning from adverse events over recent years, and in reviewing how such events are managed. The report of the transvaginal mesh short-life working group recommended to:

- Mandate the use of a national database to record the details of the mesh removal surgery, report adverse events to MHRA and audit the outcome in patients' own terms of success and failures

The Guidance published in June 2021 explains the processes for reporting adverse events in NHS Scotland, updating guidance with changes to duty of candour and adverse event reporting procedures in Scotland.

The SPICe briefing that accompanied PE 1517 also describes the processes for reporting adverse incidents by clinicians and manufacturers. Adverse events must be reported by manufacturers, and CEL 43 (2009) sets out reporting and monitoring arrangements for health professionals in Scotland. Individuals can also report issues through the MHRA 'yellow card' reporting scheme.

When a product is suspected or known to be faulty, the MHRA works with the manufacturer and wholesaler to agree the most appropriate action to take. In serious circumstance, the product has to be recalled and taken out of the supply chain. The MHRA oversees:

- Field Safety Notices (FSNs) - sent out by medical device manufacturers or their representatives outlining actions they are taking in relation to a product.
- Medical Device Alerts (MDAs) - issued by the MHRA to communicate safety information to device users in health and social care.

The MHRA also operates the Yellow Card Scheme which monitors the safety of medicines and devices in the UK. Reports can be made by healthcare professionals and patients about safety concerns on products via the Yellow Card Scheme.

Issues raised about mesh for hernia treatment and repair

This article, published by the Royal College of Surgeons discusses the materials used and types of mesh used for hernia repair. This more recent US website describes in some detail the use of hernia mesh and some of the types of mesh used. It also discusses complications. It also highlights lawsuits filed in the US against a number of manufacturers. It should be noted that brands licensed in the US will not necessarily be licensed for use in the UK. However, hernia mesh claims have been made in the UK with a number of solicitors advertising their services for such claims.

In 2018, the BBC conducted an investigation into hernia mesh use in England, highlighting the complication rate. Hernia affects about 10% of the population according to the report.

Commenting on the Victoria Derbyshire programme's claim that hernia
mesh complications 'affect more than 100,000' people, the Royal College of Surgeons issued a statement seeking to contextualise the BBC report and end by supporting the introduction of a UK mesh implant registry to monitor the safety and effectiveness of mesh implants and to allow early intervention when problems are identified.

The British Hernia Society issued a mesh safety leaflet for patients in 2018.
This states that:

> **"Surgical mesh, regulations and safety**
> The use of mesh to repair the majority of hernias has been the preferred method in the UK and worldwide for over 25 years. There is a large volume of data on the outcome of various hernia operations and different meshes. Indeed when surgeons themselves have hernias they opt for mesh repairs. Meshes used in surgery are tightly regulated…
>
> **Is a repair with mesh a 'gold standard?'**
> Many patients who develop a hernia, have a 'tissue weakness' which doesn't hold stitches well. This explains why repairs with stitches have a higher failure rate than those with additional mesh. For the vast majority of patients,

> mesh poses little if any additional risk, and coupled with a lower recurrence rate, has resulted in the use of mesh becoming the gold standard in hernia repairs."

How many people in Scotland have experienced post-operative complications?

According to an answer given on 16 July 2020 by the then Cabinet Secretary for Health and Sport, Jeane Freeman:

> "routine health data records hernia operations, bladder operations, etc., using prosthetic implants, not those specifically using mesh implants. … NHS Information Services Division (ISD) confirmed that reported complications or problems following surgery cannot accurately be established..."

Mesh fixation devices (eg titanium ProTacks™)

Sometimes repairs will involve the use of metal staples. Titanium has not been regarded as a serious allergen, although clinical experience shows that it can induce allergic reactions. The petitioners say that cancer risks have been reported in connection with titanium. Titanium is a metal that has been used extensively in medicine, along with many other metals. The US Food and Drug Administration published a wide-ranging review Biological Responses to metal Implants in September 2019. Page 52 of this report reviews research and evidence on carcinogenic effects of metals, but makes no mention of titanium. However, the review says that 'the clinical response to metal implants is complicated and no simple explanation for the wide variety of reported adverse responses is available'.

This academic article compares different fixation methods used in hernia repair, including titanium ProTacks™, and tested for adhesion and mechanical strength. They are fitted with a fixation device in 'key-hole' surgery. The titanium staples are designed to stay in the body permanently as part of the repair. This research article says that they have been associated with the formation of

‘dense adhesions’ erosion and cause of the formation of so-called ‘tack hernias’. The most clinically important aspect though, it says, is acute and chronic post-operative pain.

Scottish Government Action

In answer to a Parliamentary question about research into hernia mesh, put by Neil Findlay MSP in February 2020, the then Cabinet Secretary for Health and Sport, Jeane Freeman responded:

> “In 2019, the Scottish Government asked the Scottish Health Technologies Group (SHTG) to undertake an assessment of the evidence on the use of surgical mesh for elective repair of primary inguinal hernia in male patients, comparing such repairs with those carried out without surgical mesh (for example, suture repair). In particular, the SHTG was asked to consider safety and patient aspects relating to mesh repair of inguinal hernias.
>
> The SHTG published its report last week, and it can be viewed here . Health Boards are expected to give consideration to the SHTG's findings.
>
> Officials will now consult the Chief Scientist's Office on whether any further research into hernia repair is required and, separately, will approach Healthcare Improvement Scotland to ask that it considers whether a guideline on clinical care, including using recently published international studies, would be helpful for NHS Scotland.”

The SHTG reported the following in its report:

- Around 5000 inguinal hernia repairs are carried out each year using mesh.
- Use of mesh meant that men were less likely to have their hernia return (compared to having surgical stitches).
- Use of mesh meant that the men were less likely to suffer urinary retention, injury to nerves, blood vessels or internal organs.
- They were more likely to develop a build up of fluid or swelling soon after surgery.

- Between 2013 and 2018 there were 70 operations in Scotland to remove surgical mesh after hernia repair. (This represents 0.3% of the 25,188 patients where mesh was used).
- There was no difference (or slightly lower risk) of developing chronic pain whether stitches or mesh was used.
- Detailed discussion with patients should precede surgery regarding risks of surgery and of not repairing the hernia.
- Systems should be in place to routinely collect data from all hernia repairs to inform practice and to generate data on new types of mesh.

The Scottish Government are in the process of procuring a specialist mesh removal service for SUI and POP procedures for those seeking treatment outwith the NHS in Scotland. They are also proposing legislation to reimburse women who have paid for private treatment to remove transvaginal mesh.

The petitioners in the case of this petition believe that any specialist mesh removal service should also offer specialist expertise for the removal of other mesh devices and fixings, not only for TVT and POP devices.

Scottish Parliament Action

Numerous parliamentary questions have been asked about hernia mesh over recent years. These have covered topics such as efficacy, complications, restriction of use, adverse events and the number of people affected by complications.

UK Parliament Action

Research briefing on surgical mesh implants, including hernia mesh. Section 8 of the briefing provides statistics for England on hernia procedures involving mesh, as well as statistics on removal operations of both prosthetic mesh and mesh or stitches made from natural materials. More recent data for NHS England procedures has been published (via FOI request for waiting times for femoral hernia surgery).

A debate was held on surgical mesh in April 2018, one on medical devices in February 2019, and one specifically on hernia mesh in men on 5 September 2019.

Key Organisations and relevant links

British Hernia Society – According to a brief patient information leaflet on their website, the Society, created by a group of surgeons with an interest hernia surgery in 2003, seeks to reassure patients on the use of mesh.

British Journal of Surgery Vol 106 Issue 7 June 2009 In support of mesh for hernia repair
https://onlinelibrary.wiley.com/doi/full/10.1002/bjs.11240

Cochrane review Comparing surgical groin hernia repair performed with or without mesh September 2018
https://www.cochrane.org/CD011517/COLOCA_comparing-surgicalgroin-hernia-repair-performed-or-without-mesh

Past Present and Future of Surgical Meshes: A Review, Baylon et al, 2017.

Anne Jepson
Senior Researcher, Health and Social Care
18/06/2021

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Annexe B

Cabinet Secretary for Health and Social Care submission of 1 July 2021
PE1865/BB

I refer to the above petition, currently under consideration by the Public Petitions Committee. The Scottish Government takes all issues relating to the use of mesh very seriously. As a consequence and mindful of public concerns, the then Chief Medical Officer wrote to all Health Board Medical Directors in February 2018 about the use of mesh in sites other than the vagina. I think the key points of guidance offered then to Health Boards do align closely with the current concerns raised by the petitioners:

- Sharing information with patients and allowing them to consider the options available for treatment are fundamental. This must include consideration of non-surgical management and interventions that do not involve the use of mesh. Colleagues should be reminded of this as well as the importance of ensuring that patients understand and consent to the use of mesh as part of any procedure.

- Patients who report complications or side-effects following mesh surgery must be carefully listened to. Their concerns should, at all times, be taken seriously and acted upon appropriately.

- The management of patients with mesh related complications must follow agreed pathways which should involve a multidisciplinary team of clinicians with appropriate skills and experience.

I have included the full text of the CMO letter, an as annex, for your information.

With regard to the use of mesh in gynaecology, this was addressed in the Chief Medical Officer's letter of September 2018. The use of transvaginal mesh for the treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse was halted, and a high vigilance scrutiny protocol was introduced for some other procedures including those raised by the petitioners. These measures are still in place across NHS Scotland. You can view the letter online here [https://www.sehd.scot.nhs.uk/cmo/CMO(2018)12.pdf].

Consent

The petitioners assert that mesh should only to be used with the fully informed consent of the patient. I wholeheartedly agree with this. It is essential that patients understand the nature of their surgery and give their permission for the use of implanted materials such as mesh. They must have knowledge of the risks involved and these risks must be balanced against the potential benefits. Meaningful discussion arising from the consideration of risks and benefits is crucial in shared decision making. This is a key principle of Realistic Medicine [https://www.realisticmedicine.scot/] as well as the recently updated General Medical Council guidance on consent, in which Scottish Government officials were closely involved. This guidance is available here [https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent].

Further, Scottish Government officials have also been in liaison with the British Hernia Society [https://www.britishherniasociety.org/] and EIDO healthcare (who produce patient information to support shared decision-making), to encourage the development of improved information resources and consistent practices.

Evidence and further research

With reference to the petitioners call for a review of relevant surgical procedures and connected matters, the Scottish Government has commissioned research in to the use of mesh in a commonly performed hernia repair. This resulted in the publication of the Scottish Health Technologies Group (SHTG) report on the use of mesh in primary inguinal hernia repair in adult males, published in early 2020. This is available online here [http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/topics_assessed/shtg_01-20.aspx]. The report concluded that, compared to non-mesh procedures, using mesh resulted in lower rates of recurrence, fewer serious adverse events and similar or lower risk of chronic pain. The advice for NHS Scotland was therefore that surgical mesh should be used for elective repair of inguinal hernia in adult males, following a process of shared decision making and informed consent. In the light of this, the Scottish Government does not consider that there is evidence at present that might justify a ‘pause’ in the use of relevant devices.

The Scottish Government has now asked SHTG to examine hernia repair in men and women, and to analyse the outcome of mesh surgery in different hernia types as well as tacking devices. Patient engagement is included and the responses gathered will be considered alongside analysis of the published evidence in developing recommendations.

The report is due for publication in late summer, and this will be accompanied by a clinical consensus statement as well as a plain language summary. On

receipt, the Scottish Government will write again to Medical Directors and relevant professional bodies to draw the report to their attention and also to note public interest in this matter. The Scottish Government will encourage Health Boards to consider development of local clinical groups and broader clinical networks for the management of complex cases. Consideration will also be given to the development of skills in non-mesh procedures where these are required. I would be very happy to keep the Committee and/or petitioners updated as this progresses.

Outcome Data

NHS England / NHS Digital are developing a Pelvic Floor Database and Registry to monitor and improve both quality of care and patient safety. The intended focus is gynaecological procedures and NHS Scotland is currently working with NHS Digital on this UK-wide initiative.

Although it is not anticipated that hernia mesh will be included here, it is planned that through the Scottish Government's Unique Device Identifier Programme, information on use of all implants will be captured and entered into electronic patient records, and it is envisaged that analysis of outcomes will be possible through links with routinely collected data. This work will also facilitate accurate recording and reporting of adverse events and to enable patients to be traced in the event of a product recall or a safety concern.

The issues raised by the petitioners are important and I hope this letter explains how they are being addressed by the Scottish Government. I trust this response with commentary on ongoing activity is helpful but I will be happy to provide any further information, if necessary.

HUMZA YOUSAF

Annex – Chief Medical Officer's letter

Chief Medical Officer Directorate
Chief Medical Officer and Deputy Chief Medical Officer

Medical Directors
Primary Care Leads
NHS Scotland Health Boards

19 February 2018

Dear colleague

I am writing to you to make you aware of ongoing issues associated with the use of mesh implants. These have attracted media coverage, they have been raised in Parliament and they have also been the subject of enquiries from MPs, MSPs and the general public.

Although most attention has focused on vaginal mesh, concern has also been raised about the use of mesh at other sites and in particular in repair of abdominal wall herniae. In recent months, use of mesh for the latter has been the subject of a number of letters received by Ministers from Parliamentarians and patients. These have highlighted consistent themes, some of which are generic. I believe they are important and I feel I should draw them to your attention.

Consent

Patients have the right to make choices about their own lives and doctors have both an ethical and legal responsibility to involve their patients as much as possible in making decisions about their own health and care. Furthermore, sharing information with patients and allowing them to consider the options available for treatment are fundamental. This must include consideration of non- surgical management and interventions that do not involve use of mesh. Colleagues should be reminded of this as well as the importance of ensuring that patients understand and consent to the use of mesh as part of any procedure. This must be recorded in the patient record.

Adverse events

It is important to stress that patients who report complications or side-effects following mesh surgery must be carefully listened to. Their concerns should,

at all times, be taken seriously and acted on appropriately. An e-learning aid created by NHS England (and modified for use here in Scotland) will shortly be circulated to Primary Care Leads. It is intended that this will be disseminated widely to relevant clinicians in Primary Care and is designed to assist recognition of complications in those with vaginal mesh implants.

The management of patients with mesh-related complications must follow agreed pathways which should involve a multi-disciplinary team of clinicians with appropriate skills and experience. In a situation where a patient requests a second opinion, clinicians should take care to ensure that they provide necessary support, advice and assistance. It will be helpful to consider the progress you have made with clinical pathways at board, regional and national level. I will ask Ian Wallace to include this on the agenda for a forthcoming SAMD meeting, ideally to coincide with discussion about the work of the Oversight Group with the Chair and colleagues from HIS also present.

Adverse event reporting

Adverse event reporting and analysis for clinical care in general remain a key aspect of the Patient Safety Programme and local learning methodologies. Reporting adverse events is therefore mandatory, in line with The General Medical Council's *Good Medical Practice* [http://www.gmc-uk.org/guidance/good_medical_practice/systems_protect.asp] which states that, to help keep patients safe, clinicians must:

> "report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk."

Further, in paragraph 47 of the Prescribing guidance, the GMC states that the MHRA must be informed. This can be achieved either directly by the Yellow Card scheme (MHRA) or reporting to Health Facilities Scotland's Incident Reporting and Investigating Centre (IRIC: IRIC website [http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/how-to-report-an-adverse-incident/]).

Conflicts of interest

The suggestion that clinical practice might be influenced by financial or other gain is not new however, it has recently been the subject of concerns aired in the Scottish Parliament and we should all be aware of the possibility of increased scrutiny that could follow. I think colleagues need to be made aware how their activities might be misconstrued and they should be encouraged to declare interests where appropriate. Declarations should be held by Health Boards and made available for public examination.

I would be grateful if you would ensure that this letter is distributed to appropriate clinicians and other relevant individuals within your Health Board area.

Yours faithfully

Catherine Calderwood
Chief Medical Officer

Annexe C

Petitioner submission of 28 July 2021 PE1865/III

I am the lead campaigner and petitioner for all mesh and fixations. I have suffered for 5 years. I supported the previous petition Hear Our Voice. I was made promises from the government that were never fulfilled.

In 2015 after a hernia repair I woke up in severe pain. The pain never left. I never healed. I was fighting to see the surgeon as knew something wasn't right. It was 18 months before I was finally seen. To be dismissed told no issue with the surgery. I saw a second surgeon who agreed mesh needed to be removed. Finally, I knew it wasn't in my head. But I didn't realise the fight I'd have in my hands. The third surgeon I've seen for removal made me aware of the protacks. They shouldn't be in the human body and carry a cancer warning. So he wants them removed also. I never knew I had these until that appointment. These protacks have caused me a lot of issues. As has the mesh. Combined they have left me without a life I once knew.

5 years I have suffered from severe mesh complications. Also complications of the titanium protacks I have holding my mesh in place. For 5 years I have been dismissed and not believed. In 2018 I was told this was all in my head by a GP. I planned on taking my life as I couldn't do it anymore. Until I saw a media show with people suffering the same as me. Then I was aware that it was in fact mesh that was used in my surgery.

My mobility is poor. When I can do things with ease I know I will pay for it for days later. I feel no GP fully understands me. I feel like a burden to my family. I am only 37 and feel like I'm not living but I'm dying. The life I once had is only a dream. I've lost my job, my interests and me. Most of all I've lost me. I don't like the new me cause it's not who I am. But how do you cope and try and be who you once were? When you have a pain so deep that nothing touches it unless you medicate yourself until your non-existent. What way is that to live? I try to put a brave face on for my family but I can't hide my pain. What life is it for my family? To see me debilitated by a medical device that was meant to heal me? I just want to be me again. The me I was 5 years ago. The newly married woman with a career in accountancy. The world at her feet. Nothing stopping her. The truth is I will never be her

again. Nothing can fix me. Even mesh/protack removal can't ever fully fix me to the me I was before. But the chance to have some of that back is all I can hope for. It’s all I have left to hold onto.

This petition and changing the future of these devices is all I have left to fight for. It's all that keeps me going. I have been severely damaged and affected by this operation. It will never leave me as long as I live. It's ingrained in me. All I ask is for the government to work with us and make the changes. Not just say they will but actually do it. I ask they also hear our voices and unite us. Help us before you have a country of people like myself. This is happening world-wide and all eyes are on Scotland. I have faith and hope. It's all I have left. I ask please don't take that away from me. From us all.

Petitioner submission of 29 July 2021
PE1865/JJJ

The Cabinet Secretary's response has left me somewhat upset and angry. It proves exactly why this petition is needed.

In it, he focuses on TVT and pelvic mesh but this petition is about all types of mesh. This is why all other mesh patients feel they are being fobbed off by our own government.

Although the Scottish Government wrote to all Health Boards in 2018 regarding sharing information with patients and giving them treatment options, this is not being fulfilled. I was offered TVT mesh in 2018 at the gynaecology clinic, when the suspension was in place. I was offered no other treatment. I have also been battling since 2015 to get fair treatment following a hernia mesh implant. I have had to fight so hard for better care for myself. I am getting it now, but no one should have to fight for good treatment. Still, we hear daily of women and men only being offered mesh, as the 'gold standard' treatment. I'm sure if you read the submissions of this petition you will see what the reality of this 'gold standard' can be.

Patients have been reporting side effects and complications. We have been ignored and gaslit every step of the way. We have reported to the yellow card scheme, which clearly isn't fit for purpose. We have reported to GMC and hospitals, and still with receive no support.
In general, neither surgeons nor the medical profession seem to take this seriously. Even our own government doesn't seem to understand the extent of the problem. Who will stand up for us?

There is no clear pathway for people with hernia, bowel or any other meshes in place. Although the gynaecology mesh patients now have a pathway, most have to see the same surgeons who maimed and gaslit them. Surgeons who are now using them to practice removing the mesh they put in.

Despite supporting and working alongside the campaign for TVT/pelvic mesh, and attending every meeting with these women, the government has ignored the needs of all those with non-gynaecological mesh.

On TVT/pelvic mesh, I agree that the Scottish Government is saying the

right things, but our evidence shows that it isn't filtering down to patient care.

Fully informed consent is critical, yet I wasn't given this and – read the submissions – it's still not happening in many other cases.

We have examples of patients who have—

- not been given all the information about potential complications,
- not been told that mesh may potentially be used, and
- mesh implanted against their explicit wishes.

That is not fully informed consent.

The Cabinet Secretary mentions the British Hernia Society (BHS). I am a patient representative for BHS. I should point out that the organisation—

- can't collect data from NHS patients;
- is pro-mesh, preferring mesh to natural tissue repair; and
- their database will in no way help patients being injured.

At present, there is no training being given for natural tissue repair in Scotland. Only mesh implant. How can patients' have a meaningful treatment choice if there is only one option that is being offered?

In a reply to my MSP, you confirmed that you don't—

- know the exact figures of hernia or bowel mesh operations over a 10- year period; or
- have a clear indication of complication rates or revision surgeries.

This data needs to be collected by the NHS, as a matter of urgency. We need a database that logs all mesh surgeries and monitors if a mesh has been recalled so that patients can be informed. My mesh was recalled as it is defective, however, I only found out through being in support groups, not from the surgical team that implanted it. It needs to be monitored more closely. My vacuum has more data kept on it than the NHS has on the device inside me. How is that right?

I was involved in the Scottish Health Technologies Group (SHTG) report. I don't think that the report was promoted enough, which impacted on the number of people who shared their experiences. That said, even if they had hundreds of responses, would the report have

been allowed to say the use of mesh should be restricted to life or death circumstances? I don't think so.

I am stunned by the suggestion that there isn't enough evidence mesh is flawed. Read the submissions to this petition, look at the legal cases in the USA.

Also, the MHRA is not willing to say that they are happy with the testing on certain mesh devices and deem them safe. Does the Scottish Government have information that the MHRA doesn’t have? Why is it content for untested mesh devices to be implanted in patients?

Surgeons at the Shouldice Hospital, a specialist hernia hospital, clearly record and store their data. They have concluded that natural tissue repair is safer. Less than 1% of patients experience minimal chronic pain; 3% of herniation recurrence and, it doesn't cause a foreign body reaction. These numbers speak for themselves.

Although exact figures aren’t available, there are over 10,000 hernia mesh operations in Scotland per year. 1 in 10 will suffer severe chronic pain. Other issues include foreign body reaction and mobility issues to name a few.

Petitioner submission of 4 August 2021

PE1865/NNN – Suspend all surgical mesh and fixation devices

The destructive impact of mesh has touched so many parts of my life for such a long time, despite not having any of it in my own body. I was 11 when my mum first had a small incisional hernia repaired using a mesh "patch" and over the following decade she had several recurrences, as well as new hernias, all repaired using surgical mesh. With each surgery my mum become more unwell, with symptoms beginning shortly after emerging from the anaesthesia. She suffered immediately from tugging and ripping around the mesh implant sites, and later began experiencing extreme nausea and vomiting, severe bowel problems, repeated infections, and chronic inflammation. I watched as my vivacious, carefree and vibrant mum became seriously unwell and a shadow of her former self. Soon I was spending a lot of my time in hospitals; I became a carer for my mum while I was still a child and had to become her advocate when she became too ill and worn down to fight for herself. This was something I found incredibly difficult because my early childhood was filled with my mum's activism and her desire to make the world a better place for everyone, and suddenly she was so unwell and exhausted by her illness that she could barely speak up for herself.

Over the next 2 decades I experienced first-hand the denial by medical personnel that any of my mum's symptoms could be attributed to mesh, in fact one surgeon wrote in my mum's notes that she 'and her family need to give up their obsession with mesh'. We endured years of gaslighting, suspicion and accusations of 'drug-seeking behaviour' when in reality all we wanted was for my mum to have a shot at normal life again; she was younger than I am now when she first had mesh implanted and had over a 1/3 of her life dominated by pain and sickness. She lost her job as an adult educator due to how unwell she became, which broke her – it was never just a job it was her calling and passion. She was diagnosed with PTSD as a result of the medical trauma she endured and became suicidal at the realisation that the surgeons did not believe her that mesh was causing such widespread and devastating

symptoms. It was not until my mum discovered the first mesh petition in 2014, and realised this was the same material, that she finally felt she was not alone.

Unfortunately, little was known at the time of that first petition about the impact of polypropylene mesh implants used elsewhere in the body, and when we raised our concerns with my mum's surgeons we were dismissed and told that it was not the same thing and the issues caused by TVT/O mesh was due to the surgical techniques and the location within the body. However, we both realised that these other women were telling stories which were identical to my mum's own experiences; the pain, the ripping, the inflammation and infections, the subsequent diagnoses of fibromyalgia and auto-immune diseases – this all echoed my mum's own experience. Even when my mum had mesh protruding through the skin on her abdomen, doctors simply cut off the plastic above the skin and told her it could not be the cause of her ill health because mesh is inert. I spent so much time fighting for my mum, begging doctors to listen and yet it was all for nothing.

In 2017 my mum was diagnosed with cancer. The systemic impact of mesh on her body, including the well-documented inflammatory and immune responses, meant that my mum was advised she was not strong enough to endure chemotherapy or surgery. My mum died just 11 months after her diagnosis, at the age of 55. My mum who devoted her life to challenging injustice and fighting for equality, my role-model and inspiration in everything I do, has been gone for 3 years now and the pain of knowing how needless it was, that she may still be here if she hadn't been worn down so physically by the impact of mesh, is something that will haunt me for the rest of my life. Mesh caused my mum to lose everything, her relationships, her job, her joy and her life.

Mesh robbed me of my mum too soon, and I implore you to consider the submitted evidence with compassion and heart; put yourselves in the shoes of those whose lives have been ruined by the impact of mesh and commit to a suspension followed by a full, transparent and robust investigation of these implants to ensure no one else has to suffer so needlessly.

Petitioner submission of 2 September 2021
PE1865/RRR: Suspend all surgical mesh and fixation devices

The US Food and Drug Administration (FDA) has been conducting post-market surveillance of transvaginal mesh devices intended to treat pelvic organ prolapse (POP).

It recently it announced that the results of this surveillance show that patients who received mesh repair had increased risk of mesh exposure and tissue erosion compared to patients whose prolapse was repaired with native tissue.

As a result, the FDA updated its webpage which details its regulatory oversight of urogynecologic surgical mesh products to state that “the FDA continues to believe that these devices do not have a favorable [sic] benefit-risk profile”.

It has taken the FDA a long time to admit this. Something we have all fought long and hard for.

I believe that it's now time for the Scottish government listen and change things for the better for all affected. These devices are still being offered now on the NHS, even though there is a ban. This also provides us with a pathway to prove that hernia mesh and other mesh devices are causing the same issues.

Therefore, a suspension until more guidelines and testing is done would be the best option save more people being damaged.

Annexe D

The following submissions are circulated in connection with consideration of the petition at this meeting —

- PE1865/A: Ray Taylor submission of 13 June 2021
- PE1865/B: James Snell submission of 17 June 2021
- PE1865/C: Iana Buckley submission of 17 June 2021
- PE1865/D: Elizabeth Cunningham submission of 17 June 2021
- PE1865/E: Norma Roberts submission of 19 June 2021
- PE1865/F: Kathleen Wilson submission of 19 June 2021
- PE1865/G: Cathleen Macleod submission of 19 June 2021
- PE1865/H: Shadia Hernandez submission of 19 June 2021
- PE1865/I: Anonymous submission of 25 June 2021
- PE1865/J: Anonymous submission of 25 June 2021
- PE1865/K: Anonymous submission of 25 June 2021
- PE1865/L: Michelle Cree submission of 25 June 2021
- PE1865/M: Isobel Mclafferty submission of 25 June 2021
- PE1865/N: Anonymous submission of 25 June 2021
- PE1865/O: Agnes Thomson submission of 25 June 2021
- PE1865/P Anonymous submission of 25 June 2021
- PE1865/Q: Fiona Robinson submission of 25 June 2021
- PE1865/R: Fiona Stephenson submission of 25 June 2021
- PE1865/S: Maureen Kane submission of 26 June 2021
- PE1865/T: Lesley Hughes submission of 27 June 2021
- PE1865/U: Graham Bute submission of 29 June 2021
- PE1865/V: Amy Hughes submission of 29 June 2021
- PE1865/W: Margaret Thomson submission of 29 June 2021
- PE1865/X: Patricia Conlon submission of 29 June 2021
- PE1865/Y: Anonymous submission of 30 June 2021
- PE1865/Z: Nicole MacNiven submission of 2 July 2021
- PE1865/AA: Marie Steele submission of 2 July 2021
- PE1865/BB: Cabinet Secretary for Health and Social Care submission of 2 July 2021
- PE1865/CC: Anne Monie submission of 2 July 2021
- PE1865/DD: Grace Kilna submission of 7 July 2021
- PE1865/EE: Marie Dolan submission of 7 July 2021
- PE1865/FF: Dawn Kennedy submission of 7 July 2021
- PE1865/GG: Julie Barr submission of 7 July 2021
- PE1865/HH: Cindy Gray submission of 7 July 2021
- PE1865/II: Anonymous submission of 7 July 2021
- PE1865/KK: Adele Newton submission of 7 July 2021
- PE1865/LL: Cathie Maison submission of 7 July 2021
- PE1865/MM: Debbie Millar submission of 7 July 2021
- PE1865/NN: John Mcfadden submission of 7 July 2021
- PE1865/OO: Anonymous submission of 19 July 2021
- PE1865/PP: June Mackay submission of 19 July 2021
- PE1865/QQ: Carole Coutts submission of 19 July 2021

- **PE1865/RR: Yvonne Cameron submission of 19 July 2021**
- **PE1865/SS: Brendan Clarkin submission of 23 July 2021**
- **PE1865/TT: Jacqueline Boyle submission of 26 July 2021**
- **PE1865/UU: Jennifer Radema submission of 26 July 202**1
- **PE1865/VV: Jacqui Shaw submission of 26 July 2021**
- **PE1865/WW: Jennifer Snowden submission of 26 July 2021**
- **PE1865/XX: Anonymous submission of 26 July 2021**
- **PE1865/YY: Jacqueline Mitchell submission of 26 July 2021**
- **PE1865/ZZ: Marian Kenny submission of 26 July 2021**
- **PE1865/AAA: June Connolly submission of 26 July 2021**
- **PE1865/BBB: David Hardy submission of 26 July 2021**
- **PE1865/CCC: Jacqueline Thomson submission of 26 July 2021**
- **PE1865/DDD: Anonymous submission of 26 July 2021**
- **PE1865/EEE: Anonymous submission of 26 July 2021**
- **PE1865/FFF: Antonia McCulloch submission of 26 July 2021**
- **PE1865/GGG: Melvin Clarke submission of 27 July 2021**
- **PE1865/HHH: Jean Sutherland submission of 28 July 2021**
- **PE1865/III: Petitioner submission of 28 July 2021**
- **PE1865/JJJ: Petitioner submission of 29 July 2021**
- **PE1865/KKK: Gillian Watt submission of 29 July 2021**
- **PE1865/LLL: David Ellis submission of 29 July 2021**
- **PE1865/MMM: David Ellis submission of 29 July 2021**
- **PE1865/NNN: Petitioner submission of 4 August 2021**
- **PE1865/OOO: Elaine Anderson submission of 9 August 2021**
- **PE1865/PPP: Marion Garland submission of 23 August 2021**
- **PE1865/QQQ: Martin O'Neill submission of 1 September 2021**
- **PE1865/RRR: Petitioner submission of 2 September 2021**

All written submissions received on the petition can be viewed on the petition webpage.