Briefing for the Citizen Participation and Public Petitions Committee

Petition Number: PE1865

Main Petitioner: Roseanna Clarkin and Lauren McDougall

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.

Introduction

This petition briefing has been updated in December 2022 to take account of the evidence gathered and heard since its introduction.

Petition timeline

- 17 May 2021: Petition published.
- 2 July 2021: Written submission from Cabinet Secretary for Health and Social Care.
- 13 July 2021: SPICe briefing published.
- 6 October 2021: Oral evidence from Minister for Public Health, Women's Health and Sport and her officials.
- 9 December 2021: Scottish Health Technologies Group publishes its recommendation on "Elective surgery using mesh to repair primary or incisional hernias in adults".
- 9 December 2021: Written submission from Minister for Public Health, Women's Health and Sport.

- 7 March 2022: Written submission from Minister for Public Health, Women's Health and Sport.
- 12 May 2022: Oral evidence from Dr Fernando Spencer Netto, Shouldice Hospital
- 8 June 2022: The Committee heard from the Minister for Public Health, Women's Health and Sport, and the Chief Medical Officer.

A SPICe blog was published 'Surgical Mesh Complications on 30 June 2022.

Background

The petitioners wish to see a suspension of the use of all surgical mesh and fixation devices while a full review of all surgical procedures using this method is carried out. Their petition has so far raised 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 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 be 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.

On the continued use of mesh for hernia repair, at the meeting on 8 June 2022, when the Minister for Public Health, Women's Health and Sport appeared before the Committee, she said:

> "the Scottish Health Technologies Group has looked into the use of mesh in hernia repair and published two reports on the subject, one of which was published shortly after my previous committee appearance. Those reports, which are based on current published evidence, support the continued use of mesh in a variety of abdominal wall and groin herniae. That is, of course, subject to all the tenets of realistic medicine: ensuring shared decision making and informed consent with knowledge of the benefits, risks, alternative measures and the possibility of doing nothing."

What is a hernia, how is it treated and what are the potential complications

Hernias are protrusions of tissue - eg the bowel, or organs – eg the stomach, through a weakness in surrounding tissue or muscle. Most occur in the abdominal area, and are classified depending on where they occur. Complications from hernia left untreated include obstruction of the bowel or strangulation of the bowel. They cause discomfort, pain and can hinder normal activity. Surgery is not always necessary, and hernias don't always get worse – people can opt to live with them.

Surgery can either be 'open' or 'keyhole', which is less invasive but more complex. The National Institute for Health and Care Excellence (NICE) published guidance on keyhole or laparoscopic surgery in 2004, which was reviewed in 2016. Guidance is reviewed if new evidence emerges that might affect the recommendations.

Post-operative complications, such as chronic pain, numbness and recurrence of the hernia are recognised and acknowledged. The NICE guidance discusses this, but in the context of comparing open surgery and keyhole surgery. From a systematic review of the literature, covering 37 randomised controlled trials (total 5560 participants) 10% or less experienced persistent pain from either procedure and 23% or less experienced persistent numbness.

Other studies reported other, more immediate post-operative adverse events (complications such as haematoma (blood pooling due to blood vessel damage), seroma (build-up of clear fluid/plasma), wound-related infection, mesh infection, vascular (blood vessel) or visceral (internal abdominal) injuries and port-site hernia following laparascopic surgery).

The NICE guideline recommends future research into chronic pain and numbness, as well as setting up a registry to monitor adverse events and recurrence rates. It also sets out criteria for audit of laparoscopic inguinal surgery repair. Details of a study carried in 2019 out with men who had mesh hernia repair in Scotland is detailed below.

A major study is underway currently to look at different aspects of inguinal (groin) hernia surgery.

A National Audit of Small Bowel Obstruction (NASBO), was carried out in 2017, which included consideration of the treatment of hernia as well as other causes of small bowel obstruction.

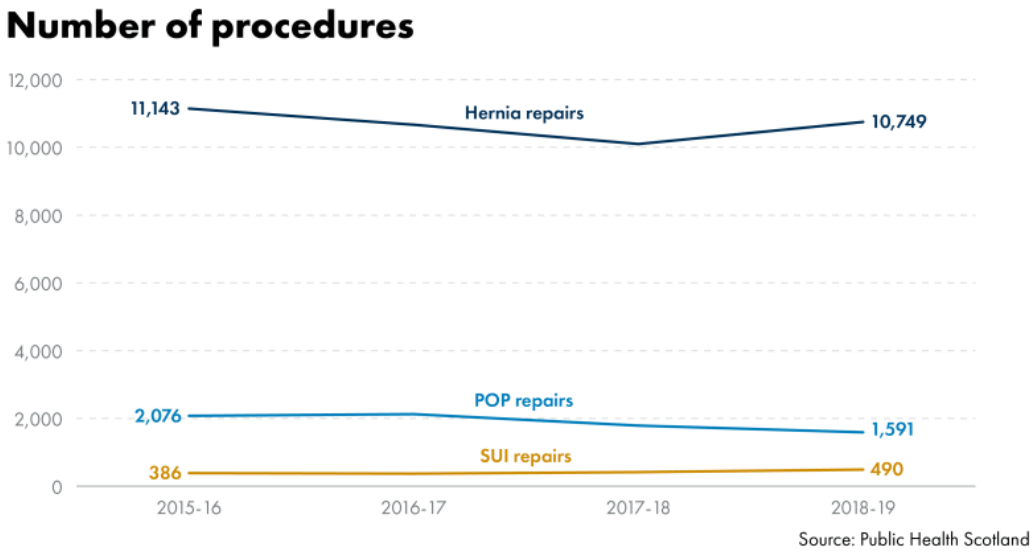
Comparing the procedures using mesh in Scotland

Between 2015-16 and 2019-20 hernia repairs accounted for around 1% of all procedures in NHS hospitals in Scotland (approximately 10,500 per year on average). Mesh was used in 62% of these hernia repairs (approximately 6,500 per year on average).

There were 161 procedures to remove mesh from a previous hernia repair (32 per year on average). This represents 0.5% of the mesh repairs performed in this period. Data were not available on the reasons for mesh removal.

(Data: Public Health Scotland and Scottish Health Technologies Group).

Between 2015-16 and 2018-19 in Scotland, around five times as many hernia repair procedures were performed as SUI and POP repair procedures combined (see below).



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.

Shouldice natural tissue repair and the Shouldice Hospital

The evidence session on 12 May 2022, with Dr Fernando Spencer Netto of the Shouldice Hospital in Canada, focused on the work of the specialist hospital in their use of a technique for hernia repair developed by Dr Edward Earle Shouldice in 1945.

The written submission from Shouldice Hernia Hospital and its website demonstrate how unique a hospital it is:

- It is the only licensed hospital in the world dedicated to repairing hernias.
- The only procedures it performs are **abdominal wall hernia repairs**. These hernias are groin hernias (inguinal and femoral) and ventral hernias (incisional, epigastric and umbilical)
- Each surgeon performs 600 – 700 hernia surgeries per year: "more than a typical General Surgeon would do in a lifetime."
- It states that it holds the "largest single, updated database of hernia patients in the world", which allows it to calculate lifetime recurrence rates among its patients.

High quality independent studies have found that Shouldice repair is the best natural tissue inguinal hernia repair technique, as it has the lowest rates of recurrence. In 1996, a systematic review of nine RCTs concluded that "the Shouldice method is the best current conventional technique for inguinal hernia repair" (Simons et al. 1996, *British Journal of Surgery*). In 2012, a Cochrane systematic review "Shouldice technique versus other open techniques for inguinal hernia repair" (16 RCT studies, representing 2566 hernia repairs) came to the same conclusion:

> "Shouldice herniorrhaphy [surgical repair of a hernia] is the best non-mesh technique in terms of recurrence, though it is more time consuming and needs a slightly longer post-operative hospital stay."

There are concerns that the Shouldice technique is 'technically difficult', and that becoming proficient is a lengthy process. The Hernia Institute of Florida writes that "few surgeons do the Shouldice operation today

because of the difficulty in mastering the technique, and the introduction of tension-free mesh repairs."

In the meeting on 8 June 2022, when the Minister for Public Health, Women's Health and Sport appeared before the Committee for a second time, the Shouldice technique and hospital was discussed, as well as the evidence presented by Dr Netto on 12 May 2022. The Minister agreed that the results at the hospital were impressive but pointed out that there was a degree of selection of patients that were suitable for surgery and that weight control pre-surgery was critical: "It is therefore not a population that would be reflective of the general population who seek surgery in Scotland... as I understand it, if we were to compare the population who use the unit in Canada with that seeking hernia repair in Scotland, there might be significant differences, for example in terms of obesity or ambulation." Terry O'Kelly said at that meeting:

> "The results and outcomes at Shouldice are very impressive. However, it has said that the relative contraindications and risks with regard to successful surgery are smoking; obesity; diabetes and other pre-existing conditions; the quality of the underlying structures; and the size of the defect. We do not have a great deal of control over some of the aspects that Mr Torrance mentioned in his question, but the build-up to surgery—or prehabilitation, which I think he might be alluding to—could have a significant role in getting patients fitter for surgery by getting them to stop smoking, increase their exercise levels if they can, lose weight, reduce alcohol consumption and so on."

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.

In July 2022 NICE published a 'Medtech innovation briefing' - Cyanoacrylate glue for hernia mesh fixation. It is a synthetic glue. The summary states:

- The **innovative aspects** are that using glue limits trauma to surrounding tissues. Innovative applicators have also been developed for precise, accurate placement of the adhesive.

- The intended **place in therapy** would be as an alternative to mechanical mesh fixation methods such as sutures and tacks in people having surgical hernia repair.

- The **main points from the evidence** summarised in this briefing are from 3 systematic reviews and 2 randomised controlled trials, including

a total of 1,374 people who were randomised to cyanoacrylate glue groups. These studies show that cyanoacrylate glue is as effective as alternative methods of mesh fixation, such as mechanical methods or fibrin glue. The evidence does not show any advantage of cyanoacrylate glue for the incidence of postoperative chronic pain.

However it highlights the lack of consensus among clinicians on standard mesh fixation methods.

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 and 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 ended 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..."

In evidence on 8 June the Minister said that it was not always easy to trace exactly what products had been used in all procedures and which were causing harm. Regulation of medical devices is reserved to the UK Parliament and that there had been issues with data collection on the devices used in order that proper audit could be carried out relating to exactly what mesh was used in any procedure, and which might be causing complications.(OR col. 6)

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 Health Technologies Group (SHTG) were then also commissioned by the Scottish Government to assess the safety of surgical mesh in groin and abdominal hernia repairs in all (ie also women) adults (published 2021). The SHTG concluded that the available evidence supports the continued use of surgical mesh in hernia repair. Detailed advice was issued by Healthcare Improvement Scotland and the Scottish Health Technologies Group in December 2021

The Scottish Government have procured a specialist mesh removal service for SUI and POP procedures for those seeking treatment outwith the NHS in Scotland. However, in June 2022 the Minister acknowledged that some issues for women seeking treatment in the US were still ongoing. There is also a specialist national NHS TVM mesh removal service based in NHS Greater Glasgow and Clyde. Women will be referred to this service in the first instance. Legislation has also been passed 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.

On 8 June, the Minister recounted actions taken:

- December 2021 – Chief medical Officer wrote to health boards to highlight the SHTG report,

- Letter asked boards to consider the availability of non-mesh surgery,

- To consider how to address any skills gaps

- To promote the development of broader clinical networks for complex cases

Progress on all of these was to be discussed at a meeting of the Scottish Association of Medical Directors in August 2022. These

The Minister did not believe that a complete suspension of the use of mesh for hernia repair was indicated, as it could leave some people with limited or no treatment options.

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.

The Citizens Participation and Petitions Committee continues to investigate the issues raised by this petition. A Chamber debate is planned for early in 2023.

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.

A similar petition to this was opened on the UK Parliament website. In England and Wales, petitions require signatures to proceed. The petition was closed after the standard 6 months, having received 541 signatures.

There is an All-Party Parliamentary Group on Surgical Mesh.

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