# Citizen Participation and Public Petitions Committee

# 2nd Meeting, 2022 (Session 6), 2 February 2022

# PE1865: Suspend all surgical mesh and fixation devices

# Note by the Clerk

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| **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—<br>• a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and<br>• guidelines for the surgical use of mesh are established. |
| **Webpage** | https://petitions.parliament.scot/petitions/PE1865 |

# Introduction

1. This is a continued petition that was last considered by the Committee at its meeting on 17 November 2021.

2. At that meeting, the Committee agreed to write to the Minister for Public Health, Women's Health and Sport and Shouldice Hospital in Canada.

3. Responses have been received from the Minister for Public Health, Women's Health and Sport, Shouldice Hospital, Sling the Mesh campaign and the petitioners.

# Scottish Government submission

4. Following her evidence to Committee on 6 October, on the issue of hernia repair, the Minister explains that in 2019, the Scottish Government commissioned a review by the Scottish Health Technologies Group (SHTG) of the use of mesh in primary inguinal hernia repair in men. SHTG published their report in early 2020 and this concluded that, compared to non-mesh procedures, using mesh resulted in lower rates of recurrence, lower rates of serious adverse events and similar or lower risk of chronic pain. The advice for NHS Scotland was that surgical mesh should be used in elective repair of inguinal hernia in adult males.

5. After considering that report, the Scottish Government then asked SHTG to examine hernia repair more broadly, to include women, and to review the outcome of mesh versus non-mesh surgery in a variety of groin or abdominal wall hernias. SHTG have published their report and the key conclusion from the report is that current evidence does support the continued availability of surgical mesh for elective repair of primary ventral hernias, incisional hernias, and primary inguinal hernias in adults in Scotland. This notwithstanding, SHTG also recommends that consideration should be given to patient preference and that patients should have access to alternative hernia treatment options such as non-mesh (suture and natural tissue) repair. Once again, the importance of shared decision-making and informed consent has been emphasised.

6. The Chief Medical Officer (CMO) has written to Board Chief Executives and Medical Directors to draw their attention to the report's findings. The CMO has also asked Health Boards to consider the availability of non-mesh surgery within their Health Board, and how any skills gaps, where they exist, can be addressed. This will provide a clearer overview of provision of non-mesh surgery in Scotland, including the use of contemporary techniques, like Shouldice Natural Tissue repair. The CMO has also asked Health Boards to consider the development of local clinical groups and broader clinical networks for the management of complex cases.

7. The CMO will discuss this report at a forthcoming Scottish Association of Medical Directors (SAMD) meeting, and the Minister suggests that the Scottish Government will continue to work with Health Boards, Specialist Associations and relevant Royal Colleges on the issues raised.

**Informed Consent**

8. The submission acknowledges one of the key areas of concern raised by the petitioners is that around informed consent. The Minister indicates her agreement with the petitioners that with the exception of clinical emergencies, mesh should only be used with the fully informed consent of the patient. She confirms informed consent is a key principle of Realistic Medicine and was emphasised by the SHTG. Consequently, the CMO has asked Medical Directors to remind clinicians of their

obligations and has emphasised the importance of recording both the content and outcome of such discussions. The Scottish Government will also bring the SHTG report to the attention of NHS Scotland Realistic Medicine Clinical Leads.

9. The Minister highlights the Scottish Government funded public awareness campaign "It's Ok to Ask" to support patients and health and care professionals to have positive conversations about care and treatment and which include questions for patients to ask clinicians when discussing treatment. Furthermore, the Scottish Government has worked with the General Medical Council (GMC) on their updated guidance on decision-making and consent. The updated guidance focuses on person centred care and aligns with the Realistic Medicine agenda here in Scotland.

**Medicines and Healthcare Regulatory Agency (MHRA)**

10. With regard to issues raised with the quality of certain materials, the Minister states that the Scottish Government contacted the MHRA, in 2018, and in response the MHRA confirmed that it had not found any new evidence which would prompt regulatory action and, as such, and in its view, the products in question remained acceptably safe when used as intended. In addition, MHRA were contacted by the Scottish Government regarding the alleged use of counterfeit materials during the manufacture of mesh.

11. Again, MHRA confirmed that, it had contacted manufacturers, as well as the Dutch Healthcare Inspectorate and the US Food and Drugs Administration (FDA) and it found that there was no evidence to justify the claims. The MHRA also noted that the FDA, having itself investigated this issue, concluded that there were no safety or effectiveness concerns that warranted further action.

12. The submission highlights that the exit from the European Union has resulted in the introduction, in the UK Parliament, of a Medicines and Medical Devices Bill. The Bill gives UK Ministers power to make regulations about the way in which the MHRA will undertake its functions. The MHRA has thus commenced work to revise its corporate plan and ways of working and the Scottish Government will, of course, continue to work with and encourage the Agency during this period of development and reform.

# Shouldice Hospital submission

13. The Committee had written to Shouldice Hospital, Canada, as a leading expert in the practice of natural tissue hernia repair. Shouldice were also pioneers in the investigating the use of Surgical Mesh back in the 1980s. The hospital chose not to pursue its use unless it was absolutely necessary to do so. This currently equates to less than 2% of all cases.

14. The submission explains that Shouldice Hospital specialises exclusively on abdominal wall hernia repair and therefore its response should be interpreted

based on that surgical focus. This means that the responses given may not be relevant, or fair, to other surgical procedures where Surgical Mesh may have a different risk profile.

15. The submission explains that where the body's natural tissue is strong enough to support the surgical repair, natural tissue repair should always be used. This is in lieu of introducing a "foreign body" (Surgical Mesh) that may cause unwanted, and needless, post-operative complications. Specific to abdominal wall hernia repair, it is important to understand that this comprises "Groin" hernias (Inguinal and Femoral) and "Ventral" hernias (Incisional, Epigastric and Umbilical).

16. Shouldice believes that natural tissue repair should be the first choice for all primary Inguinal hernias, most recurrent Inguinal hernias, most Femoral hernias, most Epigastric and Umbilical hernias, and small Incisional hernias. Where the underlying patient tissue is poor or minimal, Surgical Mesh may be necessary in some Femoral and large Incisional hernia repairs. Even then it should be used as a last resort, not a default. At Shouldice Hospital all surgeons are trained to do a natural tissue repair as their first choice.

17. The submission explains that surgical mesh was introduced into hernia surgery in the 1980s to reduce the number of recurrent hernias and it became the default method of hernia surgery in Canada. Five decades later, the recurrence rate for inguinal hernia repair (over 85% of most hernia surgery) has not improved has resulted in a staggering increase in post-operative complications that were not generally seen prior to its introduction.

18. Looking specifically at hernia recurrence, the Shouldice submission explains that papers published on hernia recurrence rates may be unreliable given poor patient follow up and an unrealistic definition of "recurrence". Shouldice firmly believe a hernia repair should last a life-time. The submission raises the point that prior to the introduction of Surgical Mesh there was virtually no mention of post-operative pain in any medical literature. Now, chronic and debilitating pain, along with other severe complications, associated with mesh use such as mesh shrinkage, mesh migration, and related nerve entrapment are widespread.

19. In comparison, the submission explains that in terms of "side effects" a huge advantage of Tissue Repair, done right, is that there are none. This is essentially because you use the body's natural tissue as the basis for the hernia repair. This means the well-known "foreign body reaction" in response to the implanted Surgical Mesh is avoided.

20. In their experience, Shouldice explain that instances where natural tissue repair have been unsuccessful can be attributed to surgeon experience and competence. Shouldice states that for a Tissue Repair to be successful it requires a thoughtful and complete dissection of the groin area. Shouldice believes most general

surgeons have a poor understanding of the complexity of the human groin because typical surgical training does not focus on this area.

21. The submission explains that Shouldice does use Surgical Mesh when it is required due to the state of the underlying tissue being unable to support the hernia defect's repair. This equates to less than 1 % of all Groin repairs and up to 5% in large Femoral and Ventral hernias (less than 2% on average).

22. With regard to the duration of training for surgeons on the natural tissue technique, the submission explains that this depends on the experience of the Surgeon, and ranges from 3 months for an experienced Fellowship General Surgeon, to 6 to 9 months for an inexperienced General Surgeon. Shouldice believe it is simpler, and quicker, to train a General Surgeon to do a Mesh based hernia repair using the open technique but with the costs of complications and poorer surgical outcomes, it should not be the reason why surgical mesh is used as much as it is.

# Sling the Mesh Submission

23. The Sling the Mesh campaign has more than 9,300 members with experience of vaginal, abdominal, pelvic, rectal, hernia mesh and mesh following mastectomy. Results of a recent survey of members shows the impact that using mesh has had on members including:

- 1 in 4 have considered taking their life
- 6 in 10 suffer depression
- One third have been forced to give up work
- 1 in 5 reduce their hours in order to cope
- 1 in 4 who now need a stick to walk
- 1 in 14 who need a mobility scooter or wheelchair
- 6 in 10 suffer recurring urinary tract infections
- 1 in 14 are becoming antibiotic resistant

24. The submission explains that:

- Incontinence mesh was suspended in Scotland in 2014 and the rest of the UK in 2018;
- Vaginally inserted prolapse mesh was banned in the UK, America, Australia and New Zealand in 2019 but;
- the same prolapse mesh material, supporting the same organs, but inserted ABDOMINALLY, is still freely used across the UK.

25. Furthermore, the submission explains that Rectopexy (rectal) mesh is generally hernia mesh cut to size and one that Sling the Mesh consider to being used for something different to what it was originally intended for with devastating complications.

26. The submission explains that a high number of Sling the Mesh members suffer autoimmune conditions and allergies, caused by the polypropylene plastic mesh material. The submission states that there is no scientific evidence to support this

however that's only due to the fact that no large-scale studies have been undertaken.

# Petitioner submission

27. In her submission, Roseanna Clarkin states her agreement with the information provided in the Shouldice hospital submission. She asks the Committee to request Shouldice hospital for their expert opinion on the protacks that are used to hold mesh in place.

28. The petitioner also questions data collected by the Scottish Government as she feels hernia reoccurrence is only being considered but not the detrimental effect the use of mesh has on patients. As a result, the petitioner calls on the Scottish Government to 'sit down and speak with us' to hear the wider issues that the use of Mesh has caused and to help GP practices learn more about mesh and chronic pain.

29. In a subsequent submission, states that she believes there is evidence to suggest that a considerable sum of money has been spent recently extending contracts to procure hernia mesh and other fixation devices. The petitioner is 'disgusted' and feels that this money could have been spent on investigating and teaching natural tissue repair. The petitioner is upset this has happened while the Scottish Government is aware a petition is lodged in parliament against its use.

30. Lauren McDougall who is a co-petitioner has provided a submission which includes details of a mesh patient who had recently died with protruding mesh in his body. She also mentions her family member who died after doctors told her mesh had left her too weak to endure chemotherapy.

31. The petitioner also raises concerns regarding why contracts are still being issued by the Scottish Government for the use of mesh when clinicians are not accurately and systematically recording the effects of this material on patients. She calls for the use of mesh to be halted and a full review undertaken.

# Action

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

**Clerk to the Committee**

# Annexe

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

PE1865/WWW: Minister for Public Health, Women's Health and Sport submission of 9 December 2021

PE1865/XXX: Shouldice Hospital submission dated 10 January 2022

PE1865/YYY: Sling The Mesh submission of 26 January 2022

PE1865/ZZZ: Petitioner submission of 25 January 2022

PE1865/AAAA: Martin O'Neill submission of 26 January 2022

PE1865/BBBB: Petitioner submission of 27 January 2022

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