Citizen Participation and Public Petitions Committee

7th Meeting, 2021 (Session 6), 17 November 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 continued petition that was last considered by the Committee at its meeting on 6 October 2021. At that meeting the Committee took evidence from Maree Todd, Minister for Public Health, Women's Health and Sport; David Bishop, Mesh Team Leader and Terry O'Kelly, Senior Medical Advisor, Scottish Government.

2. The Committee agreed to consider the evidence it heard at a future meeting.

3. The evidence session highlighted a number of key themes which included:

    - The work of the Scottish Health Technologies Group on mesh;
    - The importance of informed consent for patients undergoing mesh treatments; and

- Future data collection.

4. The Petitioner has also provided a further submission in response to the evidence session.

Review of Mesh use

5. The Minister recognised the efforts of the petitioners in bringing forward their petition. She also acknowledged their concerns regarding complications arising from the use of mesh in sites elsewhere in the body (i.e. not trans-vaginally).

6. The Minister explained that the Scottish Government requested that the Scottish Health Technologies Group review available evidence on the use of mesh in inguinal hernia repair.

7. In its report published in January 2020, the Group concluded that, compared with non-mesh procedures, using mesh for such procedures resulted in lower rates of recurrence, fewer serious adverse events and similar or lower risks of chronic pain.

8. The Minister explained that there were other complex gynaecological procedures for which the use of mesh has not been halted. In those circumstances, a high vigilance protocol is in place across the whole of NHS Scotland.

9. At the request of the Scottish Government, the Scottish Health Technologies Group has also undertaken a review of the use of mesh for abdominal wall and other abdominal hernias. The publication of this report is due imminently.

10. Mr O'Kelly confirmed that the evidence suggests the use of mesh has benefits, but that there are also risks. He stated that the introduction of mesh for hernia repair was transformational and made hernia repair much less haphazard, improving outcomes for patients, particularly in respect of avoiding reoccurrence.

Informed Consent

11. Another area highlighted in the evidence session was the importance of informed consent being obtained from a patient before a procedure took place. Mr O'Kelly acknowledged that there was a power imbalance in medicine that can often make it difficult for patients to ask questions of their surgeon. He suggested that hierarchies needed to be flattened and attitudes adjusted in order to ensure patients were able to able to have such discussions.

12. Mr O'Kelly explained that there should always be two people involved in the decision-making process: the patient and the surgeon. He explained that the

culture in clinical spaces must ensure that meaningful, equal discussions are allowed to take place in order for informed consent to be obtained.

Data Collection

13. Mr O'Kelly acknowledged that the issues with trans-vaginal mesh had highlighted the need to ensure appropriate data collection for all mesh implants.

14. The unique device identification project is an on-going piece of work that will allow for the recording of information regarding each device that is implanted to be recorded using a barcode will allow surgical and device performance to be monitored over time. The information captured can include:

    - who the patient was;
    - who the surgeon was;
    - where and when the operation took place and
    - the name of the product.

15. Mr O'Kelly advised that between 5,000 – 6,000 mesh operations take place with approximately 20 – 30 removal operations occurring every year. Information for other complications such as chronic pain and bleeding are not recorded. He explained that the question with mesh complications is whether the complication has been caused by the mesh itself or whether the mesh is caught up in some other condition that is causing the complication.

16. With regards to mesh removal, Mr O'Kelly advised that removal is dependent on when the mesh was put in and how soon after surgery complications arise. If the mesh has been in for a while, there will be associated connective tissue fibrosis and the impact of removal will be determined by what other structures are adjacent to it. In the first instance, any complications arising from mesh surgery should be reported to the patient's GP who should then refer to clinical colleagues thereafter.

Lessons learned

17. The Minister stated it would be challenging to undertake an exercise to gauge patient experiences of mesh surgery more widely, given the sheer number of operations that have taken place.

18. She advised that the continued use of mesh in other sites for gynaecological procedures not subject to the halt (for trans-vaginal mesh) are subject to the high-vigilance protocol, which has a number of procedures in place which will ensure patients experiencing complications know how to escalate any issues.

19. The Committee asked how the quality of products being used for such these procedures could best be assessed.

20. The Minister stated that it is the Medicines and Healthcare Products Regulatory Agency that grants licences for those products on a United Kingdom-wide basis. As a result of issues raised regarding the quality of trans-vaginal mesh products being used, a review of procedures for granting licences for mesh products was undertaken and this is ongoing. The Minister advised the Agency is also taking forward new medical device regulations as a result of Brexit, but that work is also ongoing.

21. The Committee also enquired about the practice of using natural tissue repair rather than mesh. Mr O'Kelly advised that the Shouldice hospital in Canada carries out non-mesh tissue repair for inguinal hernia and this is a treatment which may be offered if patients did not want mesh to be used.

22. Mr O'Kelly advised, however, that the Shouldice method of repair is not something that every surgeon undertaking hernia repair in Scotland would be familiar with. The technique will also not be applicable to non-inguinal hernias; it might also not be appropriate for patients with larger defects, or for very degenerative tissues. Mr O'Kelly advised that it is certainly a technique that could be investigated further and that this may raise the requirement to do a skills assessment to address any skills gap identified in Scotland.

23. The Committee observed that the onus seemed to be on the patient to demand an alternative to mesh repair, noting that, again this raised power imbalance issues, including where people felt they lacked knowledge or might need to be quite robust in their challenges.

24. The Minister explained that every patient and clinician should sit down together, understand the condition that the patient presents with and talk over the options. Patients should be able to ask questions. She highlighted the acronym BRAN which sets out the key elements a medical practitioner should be explaining to a patient before undertaking a particular course of treatment - the benefits, the risks, the alternatives and the effect of doing nothing.

Petitioner Submission

25. In her response, the petitioner questions the data presented by the Scottish Government regarding how many operations occur each year and the reported rate of complications. The petitioner states that Jackie Baillie MSP requested this information previously, only to be told that the Scottish Government did not hold such data.

26. The petitioner praises the work of the Shouldice Hospital using natural tissue repair. The petitioner states that only 1% of patients using the Shouldice repair technique suffer recurrence and importantly, face fewer severe long term chronic pain and complications.

27. The petitioner asks the committee to write to the surgeons at the Shouldice Hospital to request their views on the actions called for in this petition.

Action

28. 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/UUU: Anne Monie submission of 10 November 2021
- PE1865/VVV: Petitioner submission of 12 November 2021