Consultation Response: Mesh Complications Management Training Pathway

A joint consultation response from Patient Safety Learning and Sling the Mesh (10 February 2022)

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Executive Summary

This is a joint submission to the Mesh Complications Management Training Pathway consultation by Patient Safety Learning and Sling the Mesh.

- Patient Safety Learning is a charity and independent voice for transformational change in how health and social care organisations think and act in regard to patient safety. Our vision is to help create a world where patients are free from avoidable harm.
- Sling the Mesh is the largest campaigning group providing peer support, information and a tenacious drive for the provision of services and redress for those that are mesh injured.

Our consultation response is divided into the following sections:

General Comments
In this section we set out our comments on five issues that relate more broadly to the Mesh Complications Management Training Pathway:

1. Patient engagement – outlining concerns about the length of time allowed for this consultation and the need for further engagement with mesh inured patients and mesh patient support groups.
2. Patient experiences – highlighting issues fed back by members of Sling the Mesh that it is important that this consultation considers.
3. Patient reported outcomes – drawing attention to the absence of references to logging patient outcome measures in the consultation and the need for these to assess the effectiveness mesh removal surgery and identify any emerging common patient safety concerns.
4. Rectopexy mesh – highlighting feedback from members of Sling the Mesh on specific issues relating to rectopexy mesh that it is important that this consultation considers.
5. IMMDS Review – outlining recommendations from the Independent Medicines and Medical Devices Safety (IMMDS) Review which we think the Pathway should specifically address.

Comments on the Purpose Statement
In this section we make specific comments on the Purpose Statement part of this consultation. One specific area of focus is in reference to Specialist Mesh Centres, ensuring that these have the necessary competencies required and that concerns raised by patients about these services are acted on.

Comments on the Mesh Complications Management Training Pathway
In this section we highlight specific points on the detail of the pathway itself, including the following concerns:

1. The Pathway uses language such as ‘the entirety of the mesh’ or ‘complete’ when in the case of some procedures which only involve a partial mesh removal, which could be misleading and confusing. We think this needs to be changed so that such terms are only used for surgical procedures where the mesh device is removed in its entirety.
2. Two procedures, ‘Total mesh excision – Anterior Compartment’ and ‘Total mesh excision – Posterior Compartment’ are listed as an ‘Optional’ requirement. We believe this is unhelpful as in practice the UK does not currently have any surgeons who are able to perform these types of total removals of vaginal prolapse mesh, meaning they are not an available option for patients.

General comments

Patient engagement

We were disappointed with the approach taken to engage mesh injured patients in this consultation process. Although the consultation itself was formally launched on the 12 January 2022 according to RCOG's website, many mesh injured patients were not aware of this until it was publicised on Twitter on the 27 January 2022, only a week before the response deadline. While we welcome the subsequent decision to extend the deadline to 11 February 2022, in practice this still provided a very limited window for patients to feedback their views on a complex consultation document. We believe this consultation process has been too short and efforts should have been made to reach out to mesh patient support groups at the start of this process.

This consultation has involved engagement with a Women's Voices Focus Group, composed of six women who had all used urogynaecological services and with two waiting for mesh removal surgery, to help inform the development of the Pathway. We appreciate being provided sight of the outcomes of this work as part of the consultation and believe that it provides valuable insights in terms of the attitudes and behaviours that patients expect of clinicians working in mesh removal services. We would suggest that these are submitted to Mesh Centres and commissioners for their consideration and action.

There is much debate in the patient community about the best way to engage with patients on patient safety matters and the opportunity to collaborate with well-informed representative groups of patients, taking a co-production approach. We think it this case there has been a missed opportunity to engage more widely on this issue, in particularly with patient groups.

Patient engagement is key to improving patient safety, and even more so in cases such as surgical mesh where there has been a significant loss of trust for many patients in healthcare professionals. We believe it is vital that RCOG, further to its focus group approach, engages directly with patient groups on these issues to hear their concerns and experiences and to genuinely co-produce guidance in this area, such as this Pathway. While members of Sling the Mesh are sending submissions directly as part of this process, we believe there has been a lost opportunity to coordinate feedback of this type through direct engagement with patient groups.

These groups with large membership bases are often extremely well placed to provide insights, evidence, and expertise on specific areas of care. If effectively engaged with, they can provide a vast repository of patient experience to draw on in improving patient safety and services. This has been recognised by the Chair of the IMMDS Review Baroness Julia Cumberlege, who at the start of the Review's final report noted about such groups that:

> *"Their knowledge of these medical interventions and the effect they have had on those they represent is extraordinarily comprehensive. The support they provide to those who have suffered is quite remarkable, all the more so given that many of the groups are led by people who have themselves suffered harm."*

Patient experiences

We would like to highlight the following patient experiences issues fed back by members of Sling the Mesh that we believe it is important that this consultation considers:

- Women are still reporting being told by healthcare professionals that mesh is not the problem.

- In some cases, women have been coerced out of a mesh removal procedure and advised that it will not help them and will leave them worse off.
- There are being reports of extremely poor aftercare following procedures, with little or no follow up.
- Women due for a second mesh removal have been advised that this will no longer happen following a Multi-Disciplinary Team (MDT) meeting (without the patient being present), instead offered pain medication. In some cases, patients have reported being told this just days before the planned surgery and having signed consent forms for the initial surgery on the explicit understanding that a second surgery would also take place. In the case of the latter, they understandably feel misled by the process and are questioning whether this undermines the legality of the initial consent process.

Patient reported outcomes

The consultation documents do not refer to logging patient outcomes, with specifically no reference to surgeons using a database or unified Patient Reported Outcome Measures (PROMS) for this purpose.

The IMMDS Review makes specific reference to this, highlighting that there was no specific PROM for mesh complications, despite the need for one being raised in November 2018 at a meeting of the Health Quality Improvement Partnership. The Review recommends specifically that:

> *"Patient-reported measures such as PROMs and PREMS should become common currency in the assessment of the benefits and risks of current and new interventions."*

If we are to gather outcomes of mesh removal procedures that are meaningful, then an essential set towards this is mesh removal centres employing unified measures to allow for monitoring and comparison. It is important that mesh centres are proficient at using databases to capture evidence that can be used to compare all the centres, this will create training requirements which we believe should also be included in this document. We also believe that it is also important that surgeons are directly involved in this process, receiving feedback on their performance and being equipped to listen and learn from this insight

Rectopexy mesh

The removal of rectopexy mesh requires skilled colorectal and urogynaecology teams working in unison. Members of Sling the Mesh who have received rectopexy mesh have emphasised the importance of having both these teams involved in aftercare and have also asked that the following points be noted as part of this consultation:

- A key consideration in the removal of rectopexy mesh is how this relates to the need for a stoma. Patients need to be given appropriate pre-op and post-op information and support in this regard.
- Rectopexy patients sharing their experience after removal surgery often have a number of ongoing issues, many of which result in the need for additional surgery. It is imperative therefore, as talked about in more detail in the previous section, that patient outcomes are recorded after surgery. This can help to better inform patients about the impact of surgery and chances for improvement afterwards.
- Rectopexy and sacrocolpopexy patients often have many mesh fixation devices. There are risks that these could be left behind following removal surgery, and therefore it is important that surgeons are developing the skills needed to ensure all

these are also removed to avoid patients having to have further surgery to remove remnants of mesh and surgical tacks.
- To support the above, intraoperative imagery can help to locate mesh fixations at the beginning, during and at the perceived end of surgery. This technique is already used in orthopaedic surgery for placement of fixations and implants and to ensure their successful removal.
- From patient experiences received by Sling the Mesh, rectopexy patients may often find a lot of issues with nerve damage due to where the mesh is placed in the sacrum area and adhesions forming. It is therefore important that neurologists are also part of the MDT involved in rectopexy mesh removal.
- Due to the significance of this surgery there needs to be psychological assessment and support for patients; it's a long journey and patients have told us that the support is still not there.

The IMMDS Review

It is welcome that RCOG acknowledges the importance of recommendations of the IMMDS Review in this consultation. We believe that it would be valuable to specifically identify the elements of the Pathway proposals that relate to the below recommendations in the review, and what further work is planned in this regard:

- Recommendation 5.56 - Professional bodies should lead on ensuring surgeons only operate within their capabilities. They must provide guidance for their members and ensure that surgeons are appropriately trained, and this should be assured through the appraisal process.
- Recommendation 5.58 - A culture must exist where all MDT members feel able to speak up and that their input will be listened to. Trusts must work to create a culture that facilitates effective MDTs.
- Recommendation 5.60 - Clinicians must ensure patients have sufficient understanding of their treatment including the benefits, the potential risks it presents, and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.
- Recommendation 5.68 - Clinicians need to establish and agree terminology and definitions related to both mesh insertions and removals.
- Recommendation 5.124 - Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators.

Comments on the Purpose Statement

Scope

The initial paragraph of this document sets out the purposes of the Training Pathway, noting what conditions this applies to (a wide range of mesh implant complications originally inserted for urinary incontinence, pelvic organ prolapse and rectal prolapse) and what it does not include (management of patients with complications of mesh inserted for other reasons including abdominal wall hernia or for complications following non-mesh surgery for UI, POP or rectal prolapse).

We believe that the rationale for including certain procedures but excluding others needs to clearer. In the case of excluded procedures, there needs to be an indication of when further work in this area might be undertaken and by whom.

Specialist Mesh Centres

We are very concerned that the training requirements that are needed for mesh centres do not form part of the commissioning specification. Without this, we believe that there is a risk that service provision may be variable and that, without appropriate oversight, women may be at risk of inadequate services provision and an increase in avoidable harm. We would be grateful to understand what role the RCOG is having in promoting the need for a common service specification for these specialist centres

We would also note the following issues in relation to mesh centres that we believe it is important that this consultation considers:

- For a mesh centre to be accredited or credentialled it must demonstrate the surgical competency to perform total/complete/entire removal of the mesh device. In our view this competency should be mandatory.
- We believe it needs to be made clear that there is currently no mesh centre in the UK that can perform a full removal of vaginal prolapse mesh of the vaginal portion and obturator section.
- There remains significant concerns among patients that some mesh removal centres are run by surgeons who have previously implanted mesh and told the women involved that mesh is not an issue. In some cases, women are having to return to the surgeon who initially implanted their mesh, which can be extremely traumatising.
- Evidence from patient experiences gathered by Sling the Mesh states that many women are finding they are having to jump through hoops of psychiatric and pain management before getting an opportunity to discuss mesh removal with a consultant.
- Sling the Mesh have had reports that the mesh centre in Bristol is currently only accepting women from South West England.

Service and patients' needs

We welcome the document's acknowledgement of the need for patients to have confidence in the training and standard of care offered by specialists in the UK dealing with mesh complications and the use of a credentialling processes as part of this.

Absence of a current approved training package/significant risks to patients

We support the proposal for a single cross speciality training package to equip gynaecologists, urologists, and general surgeons with the skills to manage this specialised area of practice as set out in this part of the document.

Complexity and expertise in clinical care

The document states that:

> *"Within the curriculum, there is particular emphasis on teamworking and collaboration with other professionals. Due to the complexity of complications arising following mesh insertion, it is not feasible or desirable for an individual surgeon to manage all complications and collaboration with other professionals is an essential aspect of the proposed credential."*

We acknowledge that this Purpose Statement recognises the importance of MDT working and culture, the importance of which is also identified in the IMMDS Review. We would be grateful to know what collaboration there is with other professional bodies to ensure that the curriculum and training pathway being developed for this wider MDT. We are concerned that training one professional group in isolation of other members of the MDT will not lead to the knowledge, skills and new ways of working that is needed for patient safety

Scope of practice

We support the proposed approach to the mesh management credential curriculum set out in the Purpose Statement.

Speciality Specific: Mesh Complication Management credential

The table states that:

> *"CiP1: The doctor has the knowledge, skills and attitudes required for clinical assessment of patients presenting with suspected mesh-implant complications".*

We would like to see the details of the knowledge, skills and attitudes being developed and the criteria to be used in performance appraisal. These details would be valuable in providing patients with the confidence of the standards that they should expect from their surgeon and MDT. This would enable patients to engage directly with the MDT and to raise concerns if the service is not being provided as planned.

The curriculum supports flexibility and transferability of learning

We support these aims detailed in this section relating to the curriculum and will be looking to see evidence of them being implemented consistently at all specialist mesh centres

Outline of the proposed training pathway

We are very concerned at the timescale and the consequence that women will be having surgery during this time with surgeons/MDTs that have not undertaken the training. Will there be a register of which surgeons are undertaking the training and when? This would help women with their decision making and giving informed consent for this complex surgery.

Comments on the Mesh Complications Management Training Pathway

Capabilities in practice

CiP 1

Key skills include:

> *"… uses standardised assessment tools when assessing patients."*

We would value seeing these standardised tools. Have they developed with experts in information communication with patients and with patient groups?

CiP 4

Key skills include:

> *"Counsels patients wishing surgical management of mesh complications."*

We support these and would value seeing these decision-making tools and leaflets. Have they developed with experts in information communication with patients and with patient groups?

Key skills also are listed to include:

> *"Actively participates in clinical audit and national registries."*

We think this also needs to include reference to reporting patient safety incidents either within the NHS Trust or to regulatory bodies such as the MHRA and reporting back to patients if something has gone wrong and legal requirements of Duty of Candour.

Procedures

We think it would be helpful to expand the rationale as to why some of the knowledge and skills requirements are mandatory or optional.

Procedures: Trans-Vaginal Prolapses

Listed on page 14 the below four procedures which are marked as 'Mandatory' for Urogynaecology:

1. Anterior Compartment Partial Vagina Mesh Excision
2. Posterior Compartment Partial Vagina Mesh Excision
3. Anterior Compartment Complete Vaginal Excision
4. Posterior Compartment Complete Vaginal Excision

We are deeply concerned at these proposals making it mandatory to perform a partial removal of vaginal prolapse mesh, taking out the vaginal section only and leaving in the arms embedded deep in the pelvis. Sling the Mesh have members who have undergone this procedure in the UK and have been left with significant disability and pain as a result of a partial removals of this type. We would be particularly concerned that the guidance as written may result in this becoming the default treatment option for women with vaginal prolapse mesh.

We also believe that the language employed regarding Anterior Compartment Complete Vaginal Excision and Posterior Compartment Complete Vaginal Excision is potentially misleading for patients. In the case of both these procedures the Pathway talks about excising 'the entirety of the mesh', which could be easily misunderstood by patients as a full mesh removal, when in practice that is not what the procedure entails.

Furthermore, in relation to subsequent issues in cases where women may experience pain or disability following these procedures, it would be misleading if formal documentation on their medical records referred to mesh removal in 'entirety' when in practice these procedures do not mean the removal of all the implanted mesh.

To ensure clarity for patients and surgeons, we would advise that the term 'total' or 'complete' should be reserved to describe only the surgical procedures where the mesh device is removed in its entirety. Any other type of removal surgery should include the word 'partial'.

Listed at the bottom of page 15 the below two procedures are marked as 'Optional' for Colorectal, Urogynaecology and Urology:

1. Total mesh excision – Anterior Compartment
2. Total mesh excision – Posterior Compartment

This is referencing the full removal of vaginal prolapse mesh, removing the implant in its totality, including the arms that are deeply embedded in the tissue of the pelvis. We believe that this currently being listed as a 'Optional' requirement in the Pathway, as opposed to mandatory requirements in relation to partial removals of mesh, is misleading. This is because in practice the UK does not currently have any surgeons who are able to perform

this type of total removals of vaginal prolapse mesh, and as such presents this as an option for patients despite this surgery not being available in practice.

Procedures: Continence Mesh

Listed on page 12 of the Pathway, as with the previous point in regards to vaginal prolapse mesh, we again note concerns about thhe langauge used in this section for certain procedures.

In the case of Complete Vaginal Excision, this is describe as removing ‘the entirety of the mesh that is in contact with the vagina’. We believe this could cause confusion for patients as to how much of the mesh has been removed and not make clear that mesh remains folloiwing a procedure. To re-emphasise the point made in the previous section, we would advise that the term ‘total’ or ‘complete’ should be reserved to describe only the surgical procedures where the mesh device is removed in its entirety.