PE1517/KKKK
Petitioner submission of 23 February 2020

The Independent Medicines and Medical Devices Safety Review (IMMDSR) will be published at 11.30am on Tuesday 24th March 2020 and will be available to be down loaded from the Review's website from that time. There will also be a press conference.

Our last submission to the Petition's Committee was 10th October 2019. We requested that the Committee invites Dr Agur to give further evidence and participate in any questions committee members may have. We would also like to request that the Committee invites Dr Dionysios Veronikis, Mesh Removal Surgeon in Missouri, to give evidence and participate in any questions on his correspondence with Scottish Government officials. We strongly believe it would be beneficial for MSPs in the Committee to hear new evidence and to continue to support our safety campaign.

Possibly consideration of this petition in April or May 2020, given the publication date of the (IMMDSR) report and any other outstanding evidence?

The Public Petitions Committee is the only group that actually listens to the mesh injured women and their families and does its best to help us – thank you.

Petitioner: Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign and a selection of mesh injured individuals, met with the First Minister Nicola Sturgeon, Cabinet Secretary for Health and Sport Jeane Freeman along with Chief Medical Officer Catherine Calderwood in Glasgow on 25th November 2019. There was an additional meeting in Edinburgh on the 26th of November 2019. During the Glasgow meeting we left documents with the First Minister. The First Minister commented she would give careful consideration to everything. These same documents were emailed to the First Minister on 22 November 2019. The Petition Committee members may find their content useful

- Mesh Service Evaluation – Co-designed by Patients and Clinicians (PE1715/HHHH)
- SBAR Document – Submitted to Accountable Officers Group in June 2019 (PE1715/HHHH)
- Commitments we ask of the First Minister
- Mesh Removal Surgery – Patient Decision Aid. (Annexe) This was drafted by Dr Agur and the Scottish Mesh Survivors. A copy was provided to the First Minister, ahead of her meeting with mesh-affected women, to be considered by the planned Specialist Service for further development and practical use to enhance counselling. Women need to know their options and the risks and benefits of each one of them.

Annexe

Patient

Label

What Matters to You in Choosing Treatment for Vaginal Mesh Complications?

Patient-Decision Aid

PLEASE COMPLETE AND HANDBACK THIS FORM TO A MEMBER OF STAFF OR PUT IN THE POST

Contents: Page:

A) Who is this form for?

We are working to improve Person-Centred Care for women considering treatment for complication(s) arising from vaginal mesh devices. It is important that the type of treatment chosen is personalised. As well as being safe and effective, treatment will focus on your individual needs and preferences as much as possible.

We know that by finding out a bit more about you, we can improve shared-decision making and subsequently the overall outcome of treatment. One of the ways to make this better is for the doctor/surgeon to find out what is important to you. During decision-making, it is important to establish with your doctor/surgeon *'what matters to you'*.

What happens after I complete this form?

Please hand back to your surgeon for further discussion. The Specialised Multidisciplinary Team will discuss your condition and your choice during a dedicated meeting. Your surgeon will inform you of the outcome of team discussions, especially if there are further recommendations to consider.

Can I change the shared information once completed?

Yes, we recognise that *what matters to you* may change during the decision-making process. For example, you may have concerns about recovery from a particular operation, but as you find out more about it, this may no longer be important. You can change what you provide at any time as it's your shared information.

B) My values and expectations- What matters to me?

- Please let us know what is important to you from the list of values below.
- A member of staff can help you complete it, if you wish.
- Some things that matter to you may be physical, psychological/emotional or social.
- There are no "right or wrong" answers as it is about you.

Please add a value from 0 to 10 (0 low priority, 10 high priority) next to each of the following items:

What matters to you examples	**Importance out of 10**	**Top 3 (Please tick)**
• Cure from chronic pain	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Just using less pain killers	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Improvement of sexual function	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Complete removal of the mesh device	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid repeat surgery for mesh complications in the future	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid repeat surgery for recurrent incontinence and/or prolapse in the future	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid organ damage during surgery (e.g. bladder, bowels and nerves)	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Undergoing Day Surgery / Shorter hospital stay	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Quick recovery and quick return to normal activities	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid major abdominal surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid general anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoid local anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Other (please specify _____	**0** 1 2 3 4 5 6 7 8 9 **10**	

C) Care Pathway

Broad Management Pathway for Women with mesh complications

- Women with **symptomatic and bothersome** mesh complications requesting treatment

Non-Surgical Treatment

- **Watchful Waiting**
- **Pelvic Floor Physiotherapy:**
  Some women react to chronic pain by involuntary overuse of the pelvic muscle, leading to what is known as muscle 'knots. An appropriately trained therapist can help release these knots, which could improve your pelvic pain.
- **Review in Pain Clinic**
  Pain-killers / tablets and other intervention.
- **Mindful Meditation:**
- **Vaginal Estrogen Preparations:**
  Some women with small (<3mm) painless vaginal mesh exposure may be offered this option instead of or prior to surgery.
- **A combination** of the above treatment options may work for you to avoid surgery.

Preparation for Surgery

- Surgery should be considered if the above treatments options have not improved your symptoms and your quality of life is reduced.
- Referral to a recognised Regional / National **Mesh Removal Centre** is required in the vast majority of women presenting with mesh complications. An exception would be women with small (<3mm) painless vaginal mesh exposure who may be cured by 'trimming' of the exposed part in their local hospital.
- Individual patient condition must be discussed at the specialised mesh complications multidisciplinary team (**MDT**)
- **Pelvic Floor Imaging**, e.g. Translabial Ultrasound and Magnetic Resonance Scans, is optional and may be useful to your surgeon(s) in planning and in conducting the removal surgery. The decision to undergo the scan is shared between yourself and the MDT. Further imaging (scans) may be required to rule out other causes of chronic pelvic pain.
- About half of women will experience **recurrence of incontinence / prolapse** following mesh removal surgery. Your surgeon will discuss whether a procedure using your own tissues is best performed at the time of removal surgery or at a later date if required.

Surgical Treatment

- In general, the **surgical techniques**, particularly in total removal of the mesh device, is developing. It is important to carefully discuss with your surgeon(s) how best to proceed.
- A vaginal cut is required to remove the middle part of the device. Separate groin cuts on both sides are required to remove the rest of a transobturator device. Similarly, an abdominal cut (bikini-line or keyhole) is required to remove the rest of the retropubic device.
- In general, transobturator mesh devices are more difficult to remove completely, compared to the retropubic devices. Few surgeons are skilled in completely removing a transobturator mesh device with little damage to surrounding muscles and nerves. A prior partial removal will further increase the technical difficulties.
- **Reconstruction** of the urethra (tube that takes the urine from the bladder to the outside) is usually required, particularly if the urethral was damaged during surgery.
- Total removal of **abdominal mesh** devices (following mesh sacropexy procedures) requires more extensive abdominal surgery.
- **Intraoperative risks** include bladder, urethral or bowel damage, depending on the location of the mesh device.
- **Photographs** of the removed mesh device (explant) will be taken and you will be given a copy if you wish.

Following Surgery

- The removed mesh device (explant) will be sent for **histopathology** laboratory for examination. If you wish, please ask your surgeon for special preservation for legal purposes.
- **Postoperative complications** include fistula formation, need for further repair surgery, long-term self-catheterisation and persistence of symptoms.
- Your surgeon will arrange a **follow up** appointment to check how you are getting on, explain the results of the histopathology and discuss further management. Further pelvic floor imaging e.g. Translabial ultrasound or MRI may be required to identify any mesh remnants.
- **Pelvic Floor Rehabilitation**: An appointment will be made for you with a specialised pelvic floor physiotherapist to assist with restoring function of the pelvic muscles to enhance your recovery and maintain good outcome of surgery.
- Further appointment in **Pain Clinic** may be required to address any residual pain.
- In general, a half of women who undergo such surgery report short term cure or improvement of all or some of their symptoms. The other half experience no change or sometimes worsening of their symptoms. You will be followed up regularly by your surgeon as per regional / local protocol

D) My Decision to undergo Surgery

Table comparing the main advantages and disadvantages of the two surgical procedures for treatment of mesh complications in women

Options	Main Advantages	Main Disadvantages	What if it does not work?
No Surgery See previous page for details	• Avoid surgical risks • Avoid recurrence of incontinence and/or prolapse (if the device was successful in treating the condition)	• Current symptoms will persist • The mesh device remains inside the body	• You may consider surgery at any stage in the future
Partial Removal Surgery Your surgeons will remove the part of the device believed to be responsible for your symptoms	• Less surgical risks of organ damage and nerve injury • Avoid extensive total removal surgery • Quicker recovery	• A large part of mesh device remains inside the body • The foreign body reaction will continue • Removal of the middle part of a transobturator mesh device reduces the chances of a successful total removal surgery, if required in the future • Risk of recurrence of incontinence and/or prolapse. Repeat surgery may be required.	• Further partial removal surgery is not advisable • Total removal surgery would be required and may be more difficult as the device lost its continuity • You may go back to non-surgical treatment
Total Removal Surgery Your surgeons will remove the entire mesh device to cure/improve your symptoms	• The mesh device is completely removed • The foreign body reaction will stop • Believed to offer the best chance for cure / improvement of symptoms of mesh complications	• Higher surgical risks of organ damage and nerve injury • Extensive surgery that requires higher technical skills • Longer recovery • Risk of recurrence of incontinence and/or prolapse. Repeat surgery may be required.	• You may go back to non-surgical treatment

E) My Choice (PLEASE COMPLETE THIS TABLE)

Options	I will choose this option because…	I will NOT choose this option because…
No Surgery		
Partial Removal Surgery		
Total Removal Surgery		

Patient's signature: ……Patient Name: ……: Date:……

Please write any further comments here:

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Options	Outcome of MDT Discussion Date:	Outcome of further patient consultation if necessary Date:
Continue non-surgical treatment		
Partial Removal Surgery		
Total Removal Surgery		

Clinician's signature: ……Clinician's Name: ……..……: Date:……