PE1517/J

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Mr Andrew Howlett
Assistant Clerk
Public Petitions Committee
Scottish Parliament

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Your Ref
Our Ref AG/AT

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Dear Mr Howlett

Thank you for your recent correspondence with respect to Petition PE1517 on polypropylene mesh medical devices. I am pleased to respond on behalf of NHS Ayrshire and Arran.

The Urogynaecology team in NHS Ayrshire & Arran are very sympathetic to the significant problems that these women have faced and continue to face. The team are also dedicated to dealing with these problems effectively in order to improve the quality of life of these women.

We wholly acknowledge the effect that the complications of any type of surgery, in particular pelvic floor surgery can have on a woman's health. However, it is important to acknowledge that complications are not necessarily a result of direct insertion of the mesh. Whilst we acknowledge that mesh surgery has complications which may be solely attributed to the use of mesh it is important to note that significant complications are also well documented for other alternative non-mesh procedures.

With respect to the specific actions called for in the Petition, please see below:

1. Suspend the use of polypropylene trans-vaginal mesh (TVM) procedures

We believe it is important to distinguish between surgery for stress urinary incontinence with mid-urethral polypropylene mesh tapes and surgery with polypropylene mesh for prolapse repair. We believe that both should be dealt with entirely separately.

With respect to polypropylene tapes for continence surgery we would highlight the following points.

- We believe that the large majority of women who have a mid-urethral tape for incontinence have a significant improvement or cure of their problem which has the hugely positive impact on their quality of life. Thus to suspend such surgery will deny many women access to an effective treatment recommended by NICE.
- NHS Ayrshire and Arran has contributed to national studies with respect to continence surgery and is also currently undertaking a large retrospective study of patients who have undergone mid-urethral tape surgery.
- Serious complications have been well documented in both the MHRA York review and Cochrane reviews and are generally below 1%.
- As highlighted in the latest NICE Guidance, alternative procedures for urinary incontinence are associated with either a significantly higher failure rate (peri-urethral bulking agents) thus leaving many women requiring further surgery, or a longer hospital stay, longer recovery time and a different and significant complication profile (Burch colposuspension and autologous fascial sling).

With respect to the use of mesh for prolapse surgery, we would agree that there is a lack of long term data with respect to outcome. Current data suggests that up to 1 in 20 women require further surgery for mesh removal. Although, in many situations, this is generally a minor procedure, we acknowledge that some women did require repeated excision procedures and even complete mesh removal in a smaller number of women.

NHS Ayrshire and Arran has participated in the large randomised trial (PROSPECT) and recruited women to have surgery for prolapse with or without mesh. The results of this trial should report later this year and will help inform with respect to outcomes and complications.

It is the view of NHS Ayrshire & Arran that Transvaginal Mesh procedures should continue to be offered after a fully informed consent process by appropriately trained and experienced surgeons, for urinary stress incontinence

2. Initiate a public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that form across the world

The Urogynaecology Team in NHS Ayrshire and Arran would support such an initiative and is already undertaking a large retrospective study of patients who have undergone mesh surgery for urinary incontinence and pelvic organ prolapse.

3. Introduce mandatory reporting of all adverse incidents by health professionals

We agree entirely with the proposal that reporting complications to the MHRA should be mandatory. To date, clinicians in NHS Ayrshire and Arran have reported 13 trans-vaginal mesh-related incidents to IRIC/MHRA.

4. Set up a Scottish Transvaginal Mesh Implant register with view to linking this up to national and international registers

We agree that all clinicians should regularly audit the results of all surgical procedures (particularly if medical devices are used) for both urinary incontinence and prolapse,

preferably using a national registry such as that provided by BSUG or BAUS. Discussion of audit results should be considered during annual appraisal.

5. Introduce fully informed consent with uniformity throughout Scotland's Health Boards

The issue of adequate pre-operative counselling with respect to outcomes, complications and alternative surgical and non-surgical alternatives is clearly a dominant issue. The investigation and management of all patients with urinary incontinence should follow National Institute for health and Care excellence (NICE) guidance. We agree that the consent process should be standardised to comply with up to date evidence and risks at a UK level.

Our subspecialist urogynaecologist in NHS Ayrshire & Arran is a member of the short life working group (SLWG) convened by the Deputy Chief Medical officer at the request of the Health Minister and Scottish Government. This group has strived to produce a standardised patient information leaflet for synthetic mid-urethral tapes (using polypropylene mesh) for the treatment of stress urinary incontinence and is also working on a similar standardised information leaflet for women having prolapse surgery. We would welcome their introduction into clinical practice.

6. Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide

We understand the reasons behind the recent FDA proposal to reclassify trans-vaginal mesh for prolapse to 'high-risk device' status; however, we believe the situation with mid-urethral polypropylene tapes could be different. Asking the MHRA to reclassify all TVM devices to a heightened alert status is best considered after the findings of the Scottish independent inquiry are available.

Further to your letter, we have now received the Chief Medical Officer's letter of 20th June 2014, confirming the Cabinet Secretary's announcement that an Independent Review will be set up, with an expected reporting timescale of early 2015. The letter requests that Boards consider suspending the use of synthetic mesh products in surgery for pelvic organ prolapse and stress urinary incontinence until the review is concluded and has reported. I can advise that it is our intention to urgently convene a group of clinical experts to consider the CMO's request and how we should proceed.

I trust that these comments are helpful to the Committee.

Yours sincerely

Dr Alison Graham
Medical Director