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AC/DM

PE1517/C

10th June 2014

Andrew Howlett
Assistant Clerk
Public Petitions Committee
The Scottish Parliament
EDINBURGH
EH99 1SP

Dear Mr Howlett

SCOTTISH PARLIAMENTARY PUBLIC PETITION PE1517 ON POLYPROPYLENE MESH MEDICAL DEVICES

Thank you for your invitation to comment on the specific points regarding this public petition. I am responding as Medical Director in NHS Dumfries & Galloway, having discussed the public petition with Consultant and Associate Specialist staff in our Gynaecology Department. Our views are as follows :

1. Suspend use of polypropylene transvaginal mesh (TVM) procedures?
Following the concerns that have been raised nationally and internationally we have taken a local decision to suspend the use of meshes and this has been in place since last year. It is obvious from national and international studies that the rate of longer-term severe complications is relatively high and we feel that the benefit / risk ratio that is now apparent does not support the use of meshes. What is not clear from this petition is whether “polypropylene transvaginal mesh (TVM) procedures” includes the use of tension-free vaginal tapes (TVT) which we are still using for stress urinary incontinence. The tape used in TVT is made from polypropylene mesh. It would be appropriate to review the rate of longer term complications from TVT procedures and consider whether their use should be suspended. Our local practice is that this is still available as an option for the management of stress urinary incontinence.
2. The public would expect that full assessment of new implantable devices and materials is carried out before any new procedure or technique is used, and while there is a balance to be struck between delaying the introduction of

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beneficial new procedures and safety, recent events (including for example all metal hip prostheses) suggests that the piloting review and licensing of new procedures or techniques requires improvement. We would support independent research to identify the benefit / risk issues in the use of transvaginal meshes. If there is to be a public enquiry it would be appropriate to have a public enquiry into the introduction of new procedures and materials to capture the broader issues here.

3. We would support the mandatory reporting of all adverse incidents by health professionals and indeed we have processes in place to ensure that this happens. However we believe the wording of this question is misleading and should read "mandatory reporting of all outcomes". An adverse incident is commonly recognised as applying to an incident where healthcare delivery has been below the standard expected. In these cases the surgery may well have been performed competently but of much greater significance is reporting of adverse outcomes.
4. The set-up of a Scottish transvaginal mesh register will require considerable resources to develop and maintain but we would support this approach. In setting up a register considerable thought will require to be given to the issue of obtaining reliable patient feedback from all patients who have undergone this procedure.
5. While we have ceased providing TVM we would completely support and indeed require high quality written information to provide to patients before consent is sought for this procedure in the future.
6. We agree that communication with the MHRA regarding the reclassification of TVM devices is appropriate.

I hope that these comments are helpful in the assessment of the public petition.

Yours sincerely

DR ANGUS CAMERON

Medical Director