NHS Borders
Chair & Chief Executive's Office

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NHS Borders
Headquarters
Borders General Hospital
Melrose
Roxburghshire TD6 9BD

Tel : 01896 826000
www.nhsborders.org.uk

Mr Howlett

Date 14 August 2014
Your Ref
Our Ref /IB

Enquiries to Iris Bishop, Board Secretary
Extension 5525
Direct Line 01896 825525
Email iris.bishop@borders.scot.nhs.uk

Dear Mr Howlett,

Thank you for the opportunity to provide a response to the Scottish Parliament Public Petition PE1517 on Polypropylene Mesh Medical Devices on behalf of NHS Lothian.

1. Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;

NHS Borders has only ever undertaken only 9 TVM procedures for prolapse, and none since 2011. There are no plans to re-start this procedure.

We do, however, undertake TVTO procedures for stress urinary incontinence. Since 2007 we have carried out 768 of these procedures: 33 (4%) have required mesh trimming at some point afterwards but none have needed to be removed and success rates have been excellent.

We continue to support the use of the TVTO procedure in the management of stress urinary incontinence. We would like to highlight that, contrary to the proposal by the petitioners, there is a fundamental difference between the TVTO procedures for stress urinary incontinence and the transvaginal mesh (TVM) procedures for the management of prolapse. Although they are both made of the same synthetic material, they differ significantly regarding the amount of mesh material used, the technique of insertion and the evidence for safety and effectiveness.

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

We would support independent research into 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 around surgical implants in general.

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

We would support the mandatory reporting of all adverse outcomes by health professionals.

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

Assuming that Caldecott permission is granted to use patient identifiable data in the BSUG database then a separate register would not be required.

5. Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards; and

Would completely support fully informed consent for all procedures.

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

We agree that communication with the MHRA regarding the reclassification of TVM devices is appropriate.

We would like to emphasize that we aim to base our recommendations and advice to patients on the best available evidence from medical literature, high quality medical research focused on patient-reported outcomes and clinical expertise. Whilst we sincerely sympathize with the suffering of the petitioners, we do not support their proposed ban on TVTO procedures; while we never claim any procedure to be completely safe and effective, the success rates are very high and the complications rates low.

We hope this is helpful to the Scottish Parliament Public Petitions Committee in making recommendations for future practice.

Yours sincerely

Calum Campbell
Chief Executive