Greater Glasgow and Clyde NHS Board

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Mr Andrew Howlett
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Scottish Parliament
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Our Ref: RC/LL033

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Dear Mr Howlett

Petition PE1517 On Polypropylene Mesh Medical Devices

Thank you for your letter of 5th June 2014 and for the opportunity to comment on the specifics of the petition.

As the Committee will be aware, the CMO issued guidance to professionals in Scotland on this subject in July 2013, building on the advice from the RCOG and MHRA and international organisations have also produced similar statements.

The Scottish Government working group looking at mesh related issues is scheduled to issue further guidance in the near future, and in the meantime NHS Greater Glasgow & Clyde (NHSGGC) will abide by the recommendations issued by the CMO in 2013.

We would make the following observations in relation to the petition.

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

   Very few transvaginal mesh procedures for prolapse are being undertaken. In NHSGGC, services have been streamlined so that only selected appropriately trained surgeons perform these procedures. All patients are counselled and receive written information. No vaginal meshes have been used for prolapse in recent months. Our main concern with the petition is that it also seeks to stop ALL tapes and meshes for other indications, for example Sacrocolpopexy. These remain recommended by NICE and evidence supporting their use is well established.

   It should be noted that the alternatives to TVM may also be associated with complications. As noted above, all women seen in NHSGGC receive information leaflets and non-mesh alternatives (such as colposuspension/slings) are discussed with them. These alternatives are available to them if that is what they choose.

   It is the view of NHSGGC that TVM procedures should continue to be offered after a fully informed consent process by appropriately trained and experienced surgeons.

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***

It is for the Scottish Government to decide on the merit of a public enquiry taking account of the expected benefits and outputs against costs. Whatever that decision, NHSGGC will be happy to contribute to any public enquiry initiated.

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

   NHSGGC would support mandatory reporting in principle. In NHSGGC there are already arrangements in place to ensure that reporting takes place; however we would note that reporting is resource intensive and compliance can only be achieved by factoring in resource for clinicians. There needs to be a proportionate approach to the issue of reporting, ensuring that clinical time is not significantly diverted from time spent with patients.

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

   NHSGGC would support the setting up of a register, but would note the significant resource implications in setting up and maintaining such a register. Again we believe the approach to this should be proportionate and not divert significantly from clinical resource; it is likely therefore that additional resource would be required. We believe that such a register would be best co-ordinated at Scottish Government level.

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

   NHSGGC would support the standardisation of procedural information for consent purposes.

   We believe that a consent leaflet covering the use of vaginal tapes is anticipated from the Scottish Government in the near future, and leaflet covering the use of meshes in the treatment of prolapse will follow. We will use as advised by Scottish Government, and in the meantime will continue to use our own/RCOG documents for all continence and prolapse procedures.

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

   We would support any approach to the MHRA on this matter. The MHRA will take an evidence based approach to determining any reclassification of TVM devices.

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

Robert Calderwood
Chief Executive
NHS Greater Glasgow and Clyde