



PE1517/O

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Public Petitions Committee
The Scottish Parliament
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Date 14th August 2014
Our Ref JB/PM

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Dear Committee Members

RESPONSE: PETITION PE 1517 ON POLYPROPYLENE MESH MEDICAL DEVICES

I refer to your emailed correspondence dated 5 June 2014. I am attaching an assessment undertaken in relation to this issue which will be formally considered and ratified through our normal governance structure.

I would highlight that NHS Lanarkshire has had no related adverse events and our gynaecologists are not supportive of the petition.

Yours sincerely

DR JANE BURNS
Divisional Medical Director (Acute)



SBAR Synthetic Transvaginal Implants	
Situation	<p>The Scottish Government issued a request to all Health Boards via the acting chief medical officer in June 2014 to consider suspending the use of synthetic mesh products in surgery for pelvic organ prolapsed and stress urinary incontinence pending findings of a review set up by the European Commission Scientific Committee on Emerging and Newly Identified Health Risks anticipated to report in January 2015.</p> <p>Additionally Boards have been asked to review their adverse incident procedures in relation to these implants.</p>
Background	<p>Synthetic meshes and tapes have been used for several years for the management of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). They were developed as an alternative to traditional surgeries which reported high failure and recurrence rates. Concerns relating to mesh or tape erosion, long term post operative pain and sexual dysfunction have been recently highlighted in the media and been a precipitant for the review highlighted above. Additionally an increasing number of class actions have been raised against Health Boards including Lanarkshire.</p> <p>Lanarkshire has thus reviewed local procedures and processes for the management of POP and SUI including governance processes in this regard.</p>

<p style="text-align: center; color: red; font-weight: bold;">Assessment</p>	<p><i>Current status in relation to operative procedures:</i> There are currently 4 Urogynaecologists in Lanarkshire undertaking mesh and tape procedures for management of POP and SUI. The urogynaecologists withdrew the use of synthetic polypropylene mesh for POP in April 2013 and since then have been using a Biodegradable graft “Surgisis” which is subject to prospective audit (attached ppt). The recommendation for suspension relates solely to synthetic and not biological grafts. Until the recent Scottish government correspondence Lanarkshire urogynaecologists had continued to use synthetic polypropylene mid-urethral slings (SMUS) commonly referred to as tapes for the management of SUI due to the wealth of medical evidence and NICE guidance supporting their efficacy and low complication rate (1-4.). This service has currently been suspended. Lanarkshire have R+D approval for the prospective multi-centre study of single incision mini sling “SIMS Study” , and have published interim findings in this regard (5,) and will continue to offer women recruitment to this study for management of SUI. The Cabinet Secretary has endorsed the use of synthetic mesh for women being entered into clinical trials. Women who decline entry and wish to opt for traditional surgery will be referred to the Tertiary Urogynaecology Centre in Glasgow for ongoing care. All women having surgery are given patient information leaflets and consent is fully documented within the case record. Current Audit and <i>Governance:</i> Lanarkshire have been productive in both retrospective and prospective audit in relation to urogynaecology procedures.</p>
<p style="text-align: center; color: red; font-weight: bold;">Assessment</p>	<p>The datix system is used to report adverse incidents following surgery but it is recognised that this has not been robust in the past . A gynaecology risk management group has been established and a trigger list for reporting has been launched and is now incorporated into the electronic datix reporting system . Administrative support has also been provided recently which will aid with the production of monthly reports. Lanarkshire Urogynaecologists support the Scottish Pelvic Floor Network statement that all complications following mesh/tape procedures are reported to MHRA and audit their outcomes using a national database such as one provided by British Society of Urogynaecologists (BSUG) (6). Both statements are also supported by Royal College of Obstetricians and Gynaecologists, British Society of Urogynaecology, European Urogynaecological Association and International Urogynaecological Association.</p>

Recommendation

- 1.Lanarkshire continue to use Surgisis for the management of POP.
- 2.Women requiring surgery for the management of SUI are given the option of recruitment into ongoing SIMS clinical trial or referral to Tertiary Services for traditional surgery no longer available in Lanarkshire.
3. Lanarkshire develop a standardised process for documentation of informed consent in relation to surgery for POP and SUI and provision of patient information leaflets.
- 4.Lanarkshire report all adverse incidents relating to the use of mesh via the datix system and to the MHRA.
- 5.Lanarkshire urogynaecologists propose that funding is secured for operators to have access rights for reporting to the BSUG database (~£110 per individual/year).
6. Annual reports in relation to operative activity and audit outcome data in this field are produced.

References

1. Summary of the Safety /Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse. **Medicines and Healthcare Products Regulatory Agency (MHRA)**. *York Health Economics Consortium*. November 2012.
<http://mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf>
2. Cochrane database of Systematic reviews 2009, Issue 4. Art. No: CD006375:10.1002/14651858.CD00637.PUB2
3. Updated Systematic review and Met-analysis of the Comparative data on Colposuspension, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. *Eur Urol*. 2010;58:218-238
4. <http://www.nice.org.uk/CG40>
5. Prospective multi-centre study of adjustable single-incision mini-sling(Ajust) in the management of stress urinary incontinence in women: 1 year follow-up study. Abdel-Fattah et al. *BJUI*.2011; **109**:880-886
6. <http://www.bsug.net>

SBAR prepared by D McLellan
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Lanarkshire Health Board, 4th July 2014