Fife NHS Board

Hayfield House
Hayfield Road
Kirkcaldy
Fife KY2 5AH
Telephone: 01592 643355
Fax: 01592 648142
www.show.scot.nhs.uk

PE1517/K

Mr Andrew Howlett
Assistant Clerk to the Public Petitions Committee
T3.40
Scottish Parliament
EDINBURGH
EH99 1SP

Date	8 July 2014
Your Ref	
Our Ref	JW/HK/VM/letters/0708howlett
Enquiries to	Valerie Muir
Extension	28080
Direct Line	01592 648080
Fax No	
Email	valerie.muir@nhs.net

Dear Mr Howlett

PETITION PE1517 ON POLYPROPYLENE MESH MEDICAL DEVICES

Thank you for your letter dated 5 June 2014, regarding the above.

NHS Fife would comment as follows:

No. 3: The Petition calls for the introduction of mandatory reporting of all adverse incidents by health professionals. We do feel there needs to be more clarity regarding this, specifically in relation to what is deemed an adverse incident, who would be deemed to be a health professional and where these incidents should be reported to. NHS Fife already has a system in place for the reporting of incidents on DATIXWEB (NHS Fife's Risk Management Databse).

The Medical and Healthcare Products Regulatory Authority (MHRA) have issued advice on what sort of problems related to mesh should be reported. Adverse events related to these devices that MHRA expect clinicians to report to them include the following:

Pre-procedural:

- mesh appears unsuitable to implant e.g. rough or sharp edges; too hard or brittle; not to specification
- packaging compromised affecting sterility.

Procedural related:

- tape/mesh tears or disintegrates when implanting or fixing mesh in place
- bladder perforation.

Post operatively:

- patient has an unexpected severe adverse/allergic tissue reaction to the mesh
- bladder perforation.

Longer-term patient follow-up:

- evidence of mesh shrinkage, disintegration, hardening, brittleness
- recurrence of prolapse
- bladder perforation
- vaginal perforation
- recurrence of stress or urge incontinence
- mesh erosion/extrusion through tissues - especially where further surgery is needed for partial or total mesh removal
- dyspareunia
- persistent pelvic/groin pain.

These should all be recorded in the surgeon's audit information. Within NHS Fife we have not been able to use the British Society Urogynae Surgical Database due to Caldicott concerns. However, it is available through the N3 Server (BT-run connection that all Boards have running between them). The advantage of this site is that it allows individual's data to be compared to peers. The use of the database is a requirement for accreditation of a urogynae unit (currently for commissioning care in English units).

We have agreed that MHRA should be notified, but would be keen to clarify any requirement to also record this within our DATIX system. We are keen to avoid duplication, for instance we have regarded some of the longer term problems such as urgency as not necessarily related to a tape or where there is a recognised complication such as urinary retention.

No. 4: From the discussions at the evidence session it appeared that in several cases no records were available which detailed the mesh used and this has obviously been a major problem for the patients involved. In all reported cases involving NHS Fife, we have been asked by the patients legal representatives to provide details of the batch numbers of the devices used. This can be a labour intensive and time consuming task as each patient's health records require to be retrieved, checked and relevant information extracted. We would therefore be keen to explore the use of device registers.

Historically it has been necessary to retrieve health records for every query. Unfortunately, there have been circumstances where this has not proved possible as in accordance with Board policy, health records have been destroyed, e.g. where the

surgical procedure was undertaken in 2002. This is very time consuming both in retrieving and also reviewing health records as there was no agreement as to where the information should be recorded in records. Currently the device labels recording LOT/Batch number are adhered to the theatre care plan filed in a patient's records. In addition the information is also recorded in the theatre tray diary.

These diaries are retained for a minimum of 6 years. A request for such information was received from a patient who had the insertion of tape carried out in 2005 where the theatre diary has been destroyed. We are considering whether we should retain these diaries for longer than the required 6 years.

We are now using the agreed consent booklet produced through the short life working group for vaginal mesh use: http://www.scotland.gov.uk/Resource/0045/00453999.pdf.

I hope these comments are helpful.

Yours sincerely

John Wilson
Chief Executive