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Llywodraeth Cymru
Welsh Government

To: Medical Directors
Via email

1st August 2018

Dear colleagues

High vigilance arrangements required for the use of synthetic vaginal mesh and tape

In early July I wrote to you outlining the recommendations of the task and finish group set up by the Cabinet Secretary for Health and Social Services to review the use of synthetic mesh in the management of prolapse and stress urinary incontinence (SUI). I subsequently wrote to you on 10 July drawing your attention to the " pause" recommended by Baroness Cumberlege in the use of vaginally inserted mesh to treat stress urinary incontinence, until six conditions identified by her could be adequately met. Following Baroness Cumberlege's announcement, NHS England established a Clinical Advisory Group to propose guidance for the safe management of those undergoing mesh procedures due to clinical need. The Welsh Government had an observer on this group.

New guidance prepared by the Clinical Advisory Group was issued in England on 20 July 2018 to NHS (England). I am now writing to you to confirm that the same guidance will be adopted in Wales with immediate effect. A copy of the Clinical Advisory Group's advice is attached.

The recommended governance and assurance process in Wales builds on the 2014 NHS Wales Patient Safety Notice PSN002/18 July 2014 : 'The Surgical Management of Urinary Incontinence and Pelvic Organ Prolapse'. This required management to follow NICE guidance (CG171, IPG 267and IPG 283) , to ensure good quality consent processes, clinical competence, and audit and adverse event reporting.

The advice also aligns with the report of the Welsh task and finish group which emphasised the key patient safety principles of using non-surgical approaches as a first step, avoiding potentially risky procedures, careful multi disciplinary team assessments, fully informed consent, registration of all operative procedures, and the audit and monitoring of complications and outcomes.

The new guidance , requires Medical Directors to be assured about the clinical competence, process and outcomes for any surgeons undertaking this work, for whom they are Medical Directors or Responsible Officers. Assurance to undertake this work will require an initial 'critical interview' with each surgeon, in parallel with their appraisal, and a review of the clinical pathway, including patient selection, consent, operative logs, operative registers, participation in audit and clinical outcome reviews.

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The guidance requires participation in multi disciplinary teams with at least 2 consultant surgeons appropriate to the condition, and each surgeon's participation in these, and the trail of clinical decision making, will have to be evidenced.

It is envisaged that these 'critical interviews' will need to be repeated at least every 6 months, and more often if there are concerns. This high vigilance process is necessary at present until some key questions are clarified about potential patient harm following such procedures.

You may be aware that there are two main professional surgical organisations in this area, BAUS and BSUG (see below). There are also specialist groups for continence nurses, physiotherapists, pelvic pain specialists and service user groups, focused at The Pelvic Floor Society (TPFS) http://thepelvicfloorsociety.co.uk/pages.php?t=Patient-Information&s=Patient-Information&id=92

Data collection, audit and benchmarking

The British Association of Urological Surgeons (BAUS) Data and Audit project publishes a range or data and audit sets and combined site outcome indicators https://www.baus.org.uk/professionals/baus_business/data_audit.aspx
An audit done in March 2018 on 3 years of data (2015-2017) is available on the BAUS website. This includes data from surgeons at Cardiff and Wrexham. Cumulative analysis of 2015, 2016 & 2017 Stress Urinary Incontinence (SUI) data
The British Society of Urogynaecology (BSUG) has accreditation standards for units, https://bsug.org.uk/pages/information/accreditation-of-units/102 for which the assessment document can be downloaded **here** and the re-accreditation pro-forma can be downloaded **here.**

Dealing with complications and adverse incidents

Serious incident or no surprise reporting should follow current WG guidance in the event of any harm, significant near miss or organisational failure.

Patients and service users should be given information about using Putting Things Right and the option of yellow card reporting in the event of any complications or problems at any point of the patient pathway.

Medical Directors will need to be assured that logbook and register data are being linked to outcomes and any relevant adverse incident reports for these procedures.
Scoping work is currently underway by the Department of Health on establishing a registry for mesh implants and setting up a national database. There is no date as yet as to when these will be introduced.

Next steps

The Women's Health Implementation Group established by the Cabinet Secretary for Health and Social Services to take forward the recommendations of Welsh review into the use of synthetic mesh and tape meets for the first time on 16 August. They will take the high vigilance requirements into account in planning implementation of the wider recommendations.

I should be grateful if you would ensure that this letter is distributed to appropriate clinicians and other relevant individuals within your health board area.

Please confirm that you have put the necessary arrangements and governance in place to confirm compliance with these high vigilance requirements **by Friday 31 August 2018.**

Yours sincerely

DR FRANK ATHERTON