

From the Chief Medical Officer
Dr Michael McBride

HSS(MD)12/2018



FOR ACTION

Chief Executive, Public Health Agency
Chief Executive, HSB
Chief Executive, HSC Trusts (*for onward distribution to relevant staff*)
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (*for onward distribution to practice staff*)

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Your Ref:
Our Ref: HSS(MD)12/2018
Date: 11 July 2018

Dear colleague

VAGINAL MESH

URGENT – IMMEDIATE ACTION REQUIRED

ALL CASES SHOULD BE POSTPONED IF IT IS CLINICALLY APPROPRIATE AND SAFE TO DO SO

I am writing to you to instigate a pause in the use by the HSC of surgical mesh/tape to treat stress urinary incontinence (SUI) and for urogynaecological prolapse where the mesh is inserted through the vaginal wall.

This decision follows the announcement in England, which resulted from a recommendation BY Baroness Cumberlege, Chair of the Independent Medicines and Medical Devices Safety Review. Analysis of routinely available data locally shows similar rates of insertion and removal of devices as apply in The NHS in England. There is no concurrent change in the evidence base.

Background

Surgery for stress urinary incontinence with mesh/tape has provided successful relief of symptoms in many cases – however, some patients have experienced severe and debilitating complications following mesh/tape surgery.

Approximately 300 tape procedures for SUI were performed in HSC hospitals in Northern Ireland in 2016/17. This represents a 51% reduction in comparison with 2008/9.

The pause will remain in place until the following conditions are met:

- (a) surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly;
- (b) surgeons report every procedure to a national database;
- (c) a register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery;
- (d) reporting of complications via MHRA is linked to the register;
- (e) identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh;
- (f) NICE guidelines on the use of mesh for SUI are published.

Work is ongoing on each of these elements with an anticipated completion date of March 2019.

Implementation

For the majority of patients, a delay until all of the elements ((a) to (f)) above will be the preferred position. Items (a), (b) and (e) are the subject of the Northern Ireland Vaginal Mesh Review led by the PHA.

It is clear that for some patients, mesh procedures may be the only viable treatment option for a debilitating condition. However, this treatment should only be used for a group of carefully selected patients who understand the risks. For such patients, in line with existing NICE guidance, requirements include:

- (a) a strict adherence to Interventional Procedure Guidance (IPGs) published by NICE for these procedures [reproduced as an annex for ease of reference];
- (b) an MDT assurance at trust level to support the necessity of the procedure without undue delay;
- (c) fully supported patient choice and sign off in advance of the procedure;
- (d) evidence of the competence of the surgeon.

It is recognised that non-tape surgical procedures for SUI (e.g. culposuspension) are more technically complex, may have a higher rate of complication than tape procedures and many surgeons will not have the training and skills to perform these procedures. However, there are a small number of suitably skilled surgeons locally.

A Clinical Advisory Group has been established under the chairmanship of Professor Keith Willett, National Director for Acute Care at NHS England. Membership of the Group includes clinical expertise from The British Society of

Urogynaecologists (BSUG) and the British Association of Urological Surgeons (BAUS). The Department is liaising with the Group and further communication will follow in the coming days as work progresses.

Pending further advice, all patients requiring management of SUI should be managed as above and should be postponed if it is clinically appropriate and safe to do so. This excludes women where clinicians judge that there is clinical urgency to carry out the procedure, and no suitable alternative exists. Surgery should proceed if a delay would risk harm to the patient and must be based on a multidisciplinary team decision and informed consent.

Trusts will need to provide support to patients affected by this high vigilance pause, including:

- (a) those already on the waiting list for vaginal mesh surgery;
- (b) those for whom there is no alternative treatment;
- (c) those who are appropriate for an alternative procedure (eg culposuspension).
For this group, secondary referral might be required;
- (d) those who have previously had treatment that involved vaginal mesh, who become concerned and seek medical advice. For this latter group <http://www.hscboard.hscni.net/our-work/commissioning/mesh-frequently-asked-questions/> refers.

I welcome your assistance in taking this forward.

Yours sincerely



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Chief Medical Officer

This letter is available on the Department of Health website at
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>

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