From:

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To: NHS medical directors

Dear Colleague

VAGINAL TAPES AND MESHES

This letter is to draw your attention to

i the publication of a report from the Health Economics Consortium of York University on the rates of common adverse events associated with vaginal tapes (for treatment of stress urinary incontinence, SUI) and meshes (for pelvic organ prolapse, POP)

ii the action agreed by the Department of Health, the NHS Commissioning Board, the MHRA and the relevant professional associations to reduce the rates of these adverse events;

and to ask you in the meantime to ensure familiarity with existing NICE and professional guidance on the safe and appropriate use of these devices.

NICE guidance

2. NICE's guidance on the use of vaginal tapes for stress urinary incontinence is set out in clinical guideline CG40. The guidance can be summarised as saying that these procedures can be recommended provided that

- conservative management has already been tried and is no longer effective
- surgeons have had specialist training and carry out a sufficient case load to maintain their skills
- surgery takes place under the oversight of a nominated clinical lead
- all surgeons should maintain audit data and contribute to national outcomes registries such as those maintained by the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS).

3. Guidance on the use of vaginal meshes for pelvic organ prolapse is set out in a series of interventional procedure guidance notes (IP 267, 280-284). NICE considers that, on the available evidence, surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional repair without mesh; however, the available evidence is limited in particular on longer term effectiveness and safety. NICE therefore recommends special clinical governance arrangements for most variants of these procedures.

The York University report

4. In the light of reported adverse events and concerns expressed by patient groups about vaginal tape and mesh procedures, the MHRA commissioned a report from the Health Economics Consortium of York University, reviewing the published literature on the most frequently reported adverse events. A summary table of the key findings is attached and the full report will be available on the MHRA website at either of the links in paragraph 6 below. In brief,

- adverse event rates associated with the various surgical techniques using vaginal tapes for SUIs are generally in the range 1-3% (9% for deterioration in sexual function for one technique);
- adverse event rates for surgical techniques using vaginal meshes for POP are in the range 2-6% for most outcomes, but 14-15% for deterioration in sexual function.

5. Interpretation of these findings is not straightforward; many patients were already experiencing symptoms such as sexual problems before surgery, and rates of adverse events for surgery not using implants are believed to be as high as or higher than those using implants. A current trial, the PROSPECT trial due to report in 2014, will give us evidence on the relative safety of prolapse repairs using native tissue repair and mesh implants.

Proposed action plan

6. In response to earlier concerns, the MHRA, working with the two professional associations – the British Society for Urological Gynaecology (BSUG) and the British Association for Urological Surgery (BAUS), has developed a range of materials for clinicians and patients, including patient information leaflets and a set of questions which patients should ask their surgeons when considering possible surgery. These will be available from tomorrow on the MHRA website at the following addresses:

Stress urinary incontinence:
http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice–M–T/Syntheticvaginaltapesforstressincontinence/index.htm

Pelvic organ prolapse:
http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice–M–T/Vaginalmeshforpelvicorganprolapse/index.htm

It would be helpful if these materials could be adapted locally as necessary for women who do not have English as their first language or who might have other difficulties in accessing them.

7. Building on this earlier work, DH, the NHS Commissioning Board, MHRA, and the professional associations have reviewed the findings of the York review, and have agreed the following action plan:

- To develop proposals for a single registry of vaginal tapes and meshes, building on the existing registries maintained by the professional associations;
- To develop and issue professional guidance for vaginal meshes, complementing existing NICE guidance, on aspects such as selection of patients, choice of device, and processes for informed patient consent;
- To develop and issue guidance to commissioners to encourage them to commission services from providers which maintain high standards of training and clinical audit;
- To develop and issue professional guidance on those centres competent to carry out surgery for women with recurrent problems from incontinence or prolapse, or women needing further surgery as a result of complications of tape or mesh surgery.

In addition, the review of cosmetic surgery which ministers announced in January 2012 is considering the possibility of developing outcomes registries for all high-impact medical devices.

Summary

8. We would welcome your support in making surgery using vaginal tapes and meshes as safe and effective as possible, and in reassuring patients that – appropriately used – they remain useful additions to the treatment options available for these distressing conditions. Any comments on this letter should be sent in the first instance to Charles Dobson (NHS Medical Directorate, Quarry House, Quarry Hill, Leeds LS2 7UE; charles.dobson@dh.gsi.gov.uk).

Yours sincerely

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Summary table of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse

	Postoperative pain/discomfort after 6 months	**Erosion**	**Deterioration in sexual function six months after operation**	**Need for reoperation on sling/tape/mesh**	**Organ perforation (POP only)**
Incontinence surgery					
TVT / SPARC	0.0% (0.0% - 1.5%) Included studies = 3	1.1% (0.0% - 5.8% Included studies = 24	9.3% (3.8% - 13.5%) Included studies = 3	0.9% (0.5% - 6.0%) Included studies = 6	N/A
TOT	0.9% (0.6% - 5.1%) Included studies = 4	2.4% (0.0% - 5.6%) Included studies = 25	2.5% (1.9% - 3.2%) Included studies = 2	0.0% (-) Included studies = 1	N/A
Single incision system	1.1% (0.0% - 1.9%) Included studies = 3	0.0% (-) Included studies = 1	No studies	No studies	N/A
		0.0% (-) Included studies = 1	No studies	No studies	N/A
Prolapse surgery: anterior/ posterior					
Synthetic non-absorbable	5.5% (-) Included studies =1	6.5% (0.9%-19.6%) Included studies = 13	15.3% (12.8%-17.7%) Included studies = 2	4.8% (0.9%-10.9%) Included studies = 9	2.1% (0.9%-2.8%) Included studies = 4
Biological absorbable	2.7% (0.8%-7.5%) Included studies = 3	1.2% (0.0%-21.4%) Included studies = 7	No studies	3.2% (1.0%-5.4%) Included studies = 2	0.0% (-) Included studies = 1
Prolapse surgery: Uterine / vault					
Synthetic non-absorbable	2.0% (1.2%-2.3%) Included studies = 3	5.5% (0.0%-25.6%) Included studies = 31	14.5% (-) Included studies = 1	4.0% (0.8%-7.1%) Included studies =12	1.8% (0.4% - 7.9%) Included studies = 16
Biological absorbable	No studies	No studies		No studies	No studies