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Dear Colleague

TRANS-VAGINAL MESHES

Following a meeting of the Vaginal Meshes Working Group Chaired by the Deputy Chief Medical Officer, Frances Elliot, where the women described concerns over the management of a number of patients with vaginal meshes for pelvic organ prolapse (POP) and tapes for stress incontinence (SUI), I would like to take this opportunity to give an update on meshes.

Annex A outlines some common frequently asked questions which are also available on the NHS Inform website
http://www.nhsinform.co.uk/behind-the-headlines/special-reports/2013/04/transvaginal-tape-and-mesh-treatments

Vaginal tapes and meshes are classified as medical devices and are governed via the EU medical device regulations. Women with symptoms of POP or SUI may have a reduced quality of life and can request and be offered a surgical solution. In the great majority of cases the operations that use tapes for SUI and meshes for POP repair are safe and effective but as with all surgery, there is an element of risk. A minority of women do experience side effects from the surgery, and in some cases, require additional surgery, which maybe extensive.

It is essential that women with these conditions have the opportunity to make informed decisions about their care and treatment, in partnership with their surgeon, supported by evidence based information they can study in their own time, tailored to their needs and that all other treatment options are carefully considered first.

Any side effects or adverse events should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA), in common with any problem with a medical device

and can be initiated by healthcare professionals and/or patients, through the online reporting system via this link:

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm

The MHRA is part of the Meshes Task Force set with the UK, Denmark, Sweden and The Netherlands, including expert input from European surgical associations, to explore the issues and uncertainties related to these devices and a mandate of work is being scoped to put to the European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). We will be kept informed of this work and will take account of its findings.

I would like to thank you for your continued support for the women affected by this issue.

Yours sincerely

Harry Burns

HARRY BURNS

Annex A

Frequently asked questions on vaginal meshes

Transvaginal Tapes and Meshes

There has been publicity about the use of transvaginal tapes and meshes which are used for the treatment of pelvic organ prolapse or stress incontinence.

If you are concerned about the use of tapes or meshes, you should consult with your surgeon or GP.

Further information is available from the Medicines and Healthcare products Regulatory Authority (MHRA) website:

Vaginal mesh for pelvic organ prolapse:
http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Vaginalmeshforpelvicorganprolapse/

Vaginal mesh for stress incontinence:
http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice–M–T/Syntheticvaginaltapesforstressincontinence/index.htm

A. The technology

Q1 Why do women have these implants?

The relevant implants we are referring to here are

- vaginal tapes, used to treat stress urinary incontinence (SUI); and
- vaginal mesh, used to treat pelvic organ prolapse (POP).

These can be very distressing conditions. SUI in particular is very common with 30% of women over the age of 30 reporting troublesome SUI. Severe urinary incontinence reported in one in 5 women over the age of 85.

Q2 Why were these implants introduced?

Previous traditional surgery for these conditions (SUI and vaginal prolapse) uses sutures and a patient's existing tissue to support the urethra and the prolapsed organs respectively. Such surgery has been associated with complications such as recurrence of the condition, short term and longer term pelvic pain, and difficulties with sexual intercourse. Synthetic (non-absorbable) tapes and meshes were introduced in to surgery as supporting materials in the surgical treatment of SUI and POP to address the high risk of recurrence and decrease the significant rates of adverse effects.

Q3 How many women have these devices?

We do not have exact figures but are reviewing the available data. About 1,500 tapes for Stress Urinary Incontinence and around 350 vaginal mesh for POP are implanted annually.

Q4 What are these devices made of?

They are made from a porous non-absorbable synthetic material called Polypropylene.

Q5 What is the difference between vaginal mesh for pelvic organ prolapse and vaginal tapes used to treat stress urinary incontinence (leakage of urine when you exercise, sneeze or strain)?

The tapes used for SUI consist of a 1cm wide strip of polypropylene non absorbable mesh which is placed under the mid-urethra. There are a number of different techniques used for inserting the tapes.

The mesh used to support vaginal prolapse is again made of polypropylene *mesh but is larger (approximately* 8x6cm). There are again a number of different techniques for placement of the POP mesh.

Q6 Is special training needed to insert vaginal tapes and meshes/what special arrangements are needed?

Yes, both insertion of tapes for SUI and meshes for prolapse require additional surgical training. It is important for surgeons and gynaecologists who wish to offer this treatment to carry out a sufficient annual caseload to maintain their skills, and to audit their outcomes against those achieved by their peers. In addition, NICE have advised that a number of the variant techniques for pelvic prolapse surgery should be carried out under special clinical governance arrangements.

Q7 How was stress urinary incontinence (leakage of urine when you exercise, sneeze or strain) treated before tapes were available?

There are a number of treatment options available for SUI. These include changes to diet to reduce weight and physiotherapy to strengthen the pelvic floor muscles. Surgical treatment is recommended only if conservative (non-surgical) management is ineffective*. Number of surgical procedure were performed for this condition. Since the introduction of mid urethral tapes other surgical procedures are less commonly performed.*

Q7a How was pelvic organ prolapse treated before mesh was available?

Traditional surgery for vaginal prolapse has used a patient's existing tissue to reinforce the prolapsed organs, however this has historically been associated with complications such as prolapse recurrence, short term and longer term pelvic pain and difficulties with sexual intercourse.

Q8 Do we have figures on the side-effects and success rates of these previous treatments?

The literature demonstrates that the mid-urethral tapes produce a similar success rates to other procedures (such as colposuspension and fascial sling) but the tapes are associated with a shorter post-operative recovery and a lower incidence of the development of vaginal prolapse in the years after surgery. The proportion of women suffering significant post-operative pain appears to be similar for tapes and other procedures.

Q8a Do we have figures on the side-effects and success rates of these previous treatments?

Before the advent of vaginal mesh, surgery for pelvic organ prolapse was associated with a failure rate of 40-50% and a reoperation rate of 30% within 10 years.. A large multi-centre trial, funded by the Department of Health, is now underway (the "PROSPECT" trial). This will give us better information on the relative rates of adverse events associated with traditional surgery and surgery using mesh.

B. Safety and efficacy

Q9 Are these devices effective?

Tapes for SUI: yes, there is good evidence, including a randomised controlled trial, that procedures using vaginal tapes for SUI are effective when conservative management has failed.

Meshes for pelvic organ prolapse: ***Yes*** on the basis of the available evidence, NICE has recommended a number of variants of this procedure provided appropriate clinical governance procedures are in place. We will have better information when the PROSPECT trial [see Q8a] has reported.

Q10 Are these devices safe?

No surgical procedure can be entirely free of risk. Women should be fully informed about the potential risks and benefits before being asked to give their consent to surgery.

Tapes for SUI: Some women have experienced problems after vaginal tape surgery for stress urinary incontinence, but the proportions are relatively low (about 1-3% for most variants of the procedure). In general, therefore, procedures involving vaginal tapes for treating SUI can be recommended for women where conservative management is ineffective.

Pelvic organ prolapse: A proportion of women who have had vaginal mesh surgery to treat pelvic organ prolapse have suffered problems afterwards and in some cases several years after surgery. This sometimes necessitates removal of the mesh which may be difficult as often the mesh can become incorporated in the body tissues. This requires very specialist surgery. The general view of clinicians is that, given careful selection of the patients likely to benefit from surgery, the use of meshes for pelvic organ prolapse can still be recommended. It should be remembered that the surgical treatments used before meshes became available were also associated with significant rates of adverse event. We will have better information once the PROSPECT trial [see Q8a] has reported.

Q11 What does the York report say?

In the light of concerns expressed by patient groups, the MHRA commissioned an independent review of the published literature from York University Health Economics Consortium. The findings of this report were published in November 2012 and can be found here
http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice–M–T/Vaginalmeshforpelvicorganprolapse/Summariesofthesafetyadverseeffectsofvaginaltapesslingsmeshesforstressurinaryincontinenceandprolapse/index.htm

They confirm that, for vaginal tapes for stress urinary incontinence, the rates of adverse events are low [and probably much lower than the complications reported from earlier surgical methods, although good quality historical evidence is sparse]. For vaginal meshes for prolapse surgery the rates of adverse events are rather higher and this is a factor which patients considering surgery will wish to take into account in discussion with their surgeons.

Q12 What are the most common and most serious side effects of vaginal tapes used for SUI or vaginal mesh used for pelvic organ prolapse?

The most common side effects listed in the York report are :

- pain/discomfort after the surgery (at 6 months)
- erosion of the tape or mesh
- deterioration in sexual function
- need for re-operation
- organ perforation (only with meshes for pelvic organ prolapse)

The York report indicates that sexual dysfunction has the highest incident rate of the reported side effects (2-9% for vaginal tapes and 14-15% for vaginal meshes). However, many patients suffer sexual problems before surgery. In one trial of vaginal tape for SUI, between one third and two thirds of women reported sexual problems before surgery, compared with between one in 10 and one in 4 after surgery.

Q12a Doesn't the mesh break up inside the body?

There has been very little evidence of this so far.

Q13 Are the side-effects/problems treatable? Will women get sexual function back if the tape/mesh is removed?

This will depend on the cause of the sexual dysfunction and cannot easily be predicted. In many cases, women were already experiencing sexual problems before the surgery.

Q14 Is the mesh or tape easy for surgeons to remove?
No. Removal should only be performed by surgeons with appropriate training and experience with an appropriate ongoing caseload.

Q15 Does this mean thousands of women have been given meshes/tapes unnecessarily?

No. In the majority of cases, these mesh and tape implants have improved the lives of many women, relieving them from the problems they were suffering from of pelvic organ prolapse and stress urinary incontinence following the failure of conservative (non-surgical) management.

Possible problems with the devices

Q16 Are the reports of adverse events linked to a single manufacture?

These reports have not been linked to a single manufacturer's brand or model. However, if we are able to set up an outcomes registry as proposed in our outline action plan, it will become easier to compare the outcomes of different techniques and products and this will help surgeons in future in making an informed choice of products.

Q17 Are the devices inherently unsafe? Should they be removed from the market?

As with all forms of surgery, a proportion of patients will suffer side effects as a result of treatment and patients need to discuss the potential risks, as well as the potential benefits, with their surgeon before deciding on surgery.

For vaginal tapes, the overwhelming view of clinicians is that the benefits outweigh the risks.

For the mesh used in prolapse surgery the risks and benefits may be more finely balanced, and there is a trial in progress [the PROSPECT trial – see Q8a] to examine exactly this issue. The general view of clinicians is that, given careful selection of patients likely to benefit from surgery, the benefits outweigh the risks.

In both Europe and in the US, regulators consider that there is no evidence of inherent problems with the devices themselves that would necessitate removal from the market.

Q18 The York report shows that women have sexual problems after using tapes/meshes, surely this is enough evidence to remove these devices from the market?

The available evidence suggests that the use of vaginal tapes and meshes in appropriate cases can actually improve sexual function.

Q19 Surely there must be evidence from other countries about the performance of these devices?

No. Other European countries have reported very few adverse incidents for these devices, however they are following the UK lead in considering the concerns raised.

Q20 Why has the FDA taken action on tapes and meshes, in contrast to the position in the EU?

The FDA have publicly stated that problems associated with mesh for POP are “not rare” – this is consistent with the information we have in the UK, and with the York report which was published in November 2012. The FDA have not taken any other action other than to request further information from manufacturers of their clinical evidence of safety and post market surveillance follow up activities.

Possible problems with surgeons/the NHS

Q21 Are adverse reactions the fault of the surgeon?

There is some degree of risk inherent in any form of surgery, however careful the surgeon. Some of this risk will relate to potential failure in the device used. However, surgeons who do not maintain an adequate caseload or who do not follow existing best practice in selecting patients are likely to have higher rates of adverse events. That is why it is vital for all surgeons to maintain records of their outcomes and to enter their data into the registries maintained by the professional associations, so that they can audit their outcomes against those of their peers.

Q22 Are surgeons not being trained properly?

Surgeons with a subspecialty interest in incontinence and prolapse surgery receive appropriate training in these techniques. The introduction of any new technique demands

appropriate mentoring and surgeons are aware of the need to follow relevant guidance and include their patients in the national audits. As yet this is not mandatory but the introduction of medical revalidation is likely to enhance the need for compliance with national audits to demonstrate good outcomes. Hospitals are responsible for supporting clinicians in the necessary training, and ensuring through their clinical governance arrangements that staff are properly trained and have maintained their skills across their whole area of clinical practice.

Q23 Are the manufacturers responsible for training surgeons to use their meshes and tapes?

It is not mandatory for manufacturers to train surgeons to use their products, however under the Medical Device Regulations, manufacturers are required to provide appropriate instructions for use for their devices taking account the intended user, which therefore may involve the need for direct training. Manufacturers usually offer training but have no power to prevent an untrained surgeon from using their device and have no monitoring of whether the training was adequate.

Q24 Are women receiving bad advice from the NHS?

It is essential that women should have the opportunity to make informed decisions about their care and treatment, in partnership with their urologist or gynaecologist, supported by evidence-based written information tailored to the needs of the patient. The professional associations [BSUG and BAUS], working together with the MHRA, have developed a range of patient information for this purpose.

Q25 Are these operations to insert mesh and tape seen as low cost for the NHS and that's why women are being badly advised?

No – tapes and meshes are an additional cost although the shorter recovery seen in most cases makes economic sense for the NHS and the patient.

C <u>Action to improve the safety of surgery using vaginal tapes and meshes</u>

Q26 What actions have been taken so far?

MHRA launched an investigation early in 2011 to better understand the use of tapes used for SUI and the complications associated with their use. MHRA subsequently held 2 workshops with key clinical representatives, NICE and representatives of leading manufacturers of these devices, covering:

- Product development
- Introducing a new device into clinical practice
- Device implantation in a safe environment
- Reporting of patient outcomes and adverse events
- Responsibilities of involved parties (clinicians, regulators, manufacturers)

Based on the workshops, MHRA has made a number of recommendations to the parties involved in the manufacture, regulation and surgical provision of these implants (see the MHRA website for more detail)

In addition, the MHRA

- Has developed patient information on its website, in close association with the professional associations, which set out clearly the potential benefits and risks of

surgery with vaginal tapes and meshes. This includes a series of questions that patients can ask their surgeon before deciding on surgery

- Is working closely with the European Commission over its proposals for strengthening the directives governing all medical devices

Q27 What further action has been taken?

The following actions are being developed by professional bodies and organisations:

- Developing proposals for a single registry of vaginal implants, building on the existing registries maintained by the professional associations;
- Developing professional guidance for vaginal meshes, complementing existing NICE guidance on vaginal tapes, on aspects such as selection of patients, choice of device, and processes for informed patient consent;
- Issuing guidance to commissioners to encourage them to commission services from providers which maintain high standards of training and clinical audit;
- Developing professional guidance on 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.

In addition, the review of cosmetic surgery led by Sir Bruce Keogh has made recommendations to develop outcomes registries for cosmetic interventions and support the development of unique device identifiers for all medical devices.

D. Advice to women considering surgery

Q28 What is your advice to women with SUI or pelvic organ prolapse who are considering surgery with vaginal tapes/meshes?

Women with POP/SUI should carefully consider and explore all the available options open to them. They should discuss other, non-surgical, treatments before considering implants; and should know what questions to ask when speaking to their doctor or surgeon. Patients can find a list of questions to ask, developed in consultation with the clinical experts, on the MHRA website.

Q29 What are the alternative options for women?

SUI: a number of conservative treatments are available (weight loss by diet, physiotherapy to strengthen pelvic floor muscles).Surgery for SUI can also be performed without use of a tape. Such surgical procedures (colposuspension or fascial sling) may be equally effective as a tape procedure but may have other possible risks. For example colposuspension has a longer recovery after surgery and a 15% risk of chronic groin pain and a 1 in 4 risk of development of prolapse.

POP: Surgery for POP can be carried out without mesh (ie using the woman's own tissue) but may have a higher risk of recurrence..

E. Advice to women who already have implants

Q30 What advice do you give women who have tapes/meshes?

For the majority of women, tapes and meshes appear to result in a successful treatment of the SUI and prolapses respectively. However, if a woman has adverse symptoms or problems that she thinks might be due to her surgery, it is important that she should talk to

her GP for onward referral to an appropriate specialist who has experience with tape or mesh complications. Information is available on the MHRA website or form the relevant professional bodies [BAUS and BUSG].

Q31 What should women do who are experiencing problems?

Women experiencing problems should go back to their implanting surgeon or see their GP for onward referral to an appropriate clinician. They should also report their problems to the MHRA, with as much detail as possible about the device involved.

The patient should be referred to a centre that specialises in operating on complex cases.

F. Regulation of medical devices – general issues

Q32 How are devices like these regulated? What degree of scrutiny is there before/after they come to market?

The Regulations implement the EC Medical Devices Directives into UK law. They place obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any EC member state. A number of scientific organisations accredited by the EC – "Notified bodies" – are responsible for assessing the evidence presented by manufacturers against the requirements for the particular type of device. National regulators (such as the MHRA in the UK) are responsible for collating and investigating reports of adverse events arising out the use of these products, alerting the relevant Notified Body to any points of concern, and taking further action as needed to protect patients.

Q33 Why don't these products have the same level of scrutiny as medicines?

Devices are regulated in a different way to medicines, because of the very different characteristics of the two sectors. Typically, medical devices tend to evolve over time, with continuous incremental improvements in the light of experience of use. An excessively rigid form of regulation would inhibit innovation and would not serve the interests of patients. Further information is available on the MHRA website.

Q34 How could the regulation of medical devices be improved?

The EU is bringing forward proposals for strengthening the current medical devices directives, and the UK has been contributing to this process. In England, the review of cosmetic surgery led by Sir Bruce Keogh is considering the potential role of registries for the most significant medical devices. These registries would collect information on patient outcomes and would enable very quick identification of patients with particular kinds of device and the Scottish government will consider the report once published.

Q35 Is this another PIP scandal?

No. In the case of PIP breast implants, the manufacturer deliberately substituted a sub-standard silicone gel in contravention of the requirements of the EU license. No regulatory system can be entirely proof against this kind of deliberate and systematic fraud. Nevertheless, a number of lessons have been learnt from the PIP story which may be relevant to the regulation of other medical devices.

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