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BRIEFING PAPER

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Surgical mesh implants

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Summary

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue. Over recent years attention has increased on what are thought to be infrequent but sometimes serious complications that may be associated with the use of this mesh in uro-gynaecological procedures to treat pelvic organ prolapse and urinary incontinence.

These complications have included persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel.[1] In 2015, there was an acknowledgement by the NHS England working group that there was a lack of comprehensive data on complications, and work has been ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

There have been a number of reviews looking at the use of mesh, both Departments of Health in England and Scotland have undertaken work in this area, as have the MHRA and the European Commission. In August 2017, it was reported that the Welsh Government were setting up a working group to consider the recommendations on the use of mesh implants.

The NHS England oversight group published a final report of a review of the use of mesh implants in July 2017. This stated that the use of mesh to treat women with stress urinary incontinence and pelvic organ prolapse is a safe option, but there is a "need for better information for women experiencing SUI and POP, better data and a multi-disciplinary approach to caring for women." The report provided information on action in a number of areas:

- Providing information to patients on the procedures and potential complications;
- Updating clinical guidelines for surgeons and GPs;
- Ensuring that data on complications following procedures using mesh are collected and used to inform clinical practice; and
- The provision of a number of centres offering appropriate multidisciplinary services for women affected by mesh complications.

Individuals affected by mesh complications have expressed concerns about the safety of the mesh implants themselves, and disappointment that the recent review has not looked at this. It has been reported that a number of UK patients are pursuing legal action against the mesh implant manufacturers and the NHS. There has been legal action on this issue in other countries, where, in a number of cases, manufacturers have been ordered by courts to pay damages to those affected.

The most recent Government response on this issue, from the Under-Secretary of State for Health, Jackie Doyle-Price, has set out that there are ongoing discussions between Ministers, the NHS and the Medicines and Healthcare products Regulatory Agency on the support for patients, and continuing work to assess the risks of the mesh implants. However, the Minister also said that these procedures are effective for a number of women, a good review of the evidence was needed to make sure the procedures are used appropriately and that women are aware of the potential risks involved.[2]

1 NHS Choices, Treating a pelvic organ prolapse
2 HC Deb 10 October 2017 c148

1. The use of mesh implants

Mesh is a term used to describe a range of synthetic or biological implants that can be used to provide additional support when repairing weakened or damaged tissue. Concerns have been raised over procedures where mesh is used in surgery to treat pelvic organ prolapse and stress urinary incontinence.

1.1 Pelvic organ prolapse (POP)

Pelvic organ prolapse is where a pelvic organ (uterus, bowel, bladder) bulges into the vagina. It is caused by a weakening of the tissues that support the pelvic organs, and whilst there is unlikely to be a single cause the risk can be increased by a number of factors, including age, childbirth, menopause and being overweight.

In a lot of cases POP will not need to be treated as the symptoms will not impact significantly on daily life.

If POP is mild, lifestyle changes are recommended, such as exercises and weight loss. If symptoms require treatment, a vaginal pessary can be used to hold the prolapsed organ in place.

Surgery may be offered to some women. This usually involves giving support to the prolapsed organ, but these do not all involve the use of mesh.[3] Guidance now states that the use of mesh implants in primary procedures for POP is not supported by current evidence.[4]

1.2 Stress urinary incontinence

There are a number of types of urinary incontinence, these are set out on the NHS Choices website:

- **stress incontinence** – when urine leaks out at times when your bladder is under pressure; for example, when you cough or laugh
- **urge incontinence** – when urine leaks as you feel a sudden, intense urge to pass urine, or soon afterwards
- **overflow incontinence** (chronic urinary retention) – when you're unable to fully empty your bladder, which causes frequent leaking
- **total incontinence** – when your bladder can't store any urine at all, which causes you to pass urine constantly or have frequent leaking[5]

The treatment used for urinary incontinence will depend on the type, and the severity of symptoms. Bladder training, and lifestyle changes are often the initial treatment options. If these do not control the symptoms, medical or surgical treatments may be considered.

With stress urinary incontinence (SUI) in particular, surgery is usually recommended as the next treatment option. Surgical procedures which may be used in the treatment of SUI include:

- **Tape procedures** involve the use of plastic mesh tape to elevate the urethra. Holding it up in the correct position can reduce the leaking associated with SUI.

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3 RCOG, Pelvic Organ Prolapse, March 2013
4 NHS England, Mesh Oversight Group Report, July 2017
5 NHS Choices, Urinary Incontinence, October 2016

- **Colposuspension** involves the lifting of the neck of the bladder and stitching this in place. This can help stop leaking, and can be performed in an open operation or laparoscopically (keyhole).
- **Sling procedures** involve a sling being placed around the neck of the bladder to support it and prevent leaks. The sling can be made from an artificial material, tissue taken from the patient's body, or donated from another person.
- **Urethral bulking agent procedure** involves the injecting of an agent into the walls of the urethra. This increases the size of the walls and allows it to stay closed with less force.[6]

1.3 Clinical guidelines

The National Institute for Health and Care Excellence (NICE) has reviewed the clinical guidance on the use of mesh in procedures to manage POP and SUI recently in response to concerns related to complications associated with mesh implants for use in procedures to treat POP and SUI. The NHS England mesh working group provided the following information on this in the 2015 report:

> After careful consideration of various options, it was agreed that the most effective way to ensure surgeon practice is current and adheres to clinical guidelines is to use the medical appraisal process. If concerted effort is made in this area, this is the strongest lever we have in the system to effect improvement.
>
> The recommendations for the National Institute for Health and Clinical Excellence (NICE) to review its current clinical guidance and create new guidance were strongly supported by the group and have met with support from NICE. An updated and unified set of Clinical Guidelines for SUI and POP was seen as necessary for promoting best practice. This will be coupled with a number of measures designed to encourage greater adherence to NICE guidance.[7]

The NICE guidance, *Urinary incontinence in women and pelvic organ prolapse in women: management* is currently being updated and is due for publication in 2019.

1.4 Mesh implant complications

All medical procedures may carry risks and it is important that the patient and their doctor weight up the risks and benefits together before deciding on the best treatment option. The Royal College of Obstetricians and Gynaecologists (RCOG) advise women that:

> If you have been diagnosed with SUI or POP, you may be offered a number of different procedures to treat or manage your condition. If you are considering a procedure using mesh, you should have a detailed discussion with an expert healthcare professional about the benefits and risks of the surgery for you. If you decide to go ahead with a procedure using mesh, the operation should only be performed by a specialist with expertise in this technique.[8]

There are patients who have experienced serious complications following the use of mesh in surgical procedures for SUI and POP. These complications have included persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel.[9]

Recently produced patient leaflets on the use of mesh in surgical procedures provide more detailed information on the risks of the procedures:

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6 NHS Choices, Urinary incontinence - Surgery and procedures
7 NHS England, Mesh working group: Interim Report, December 2015
8 RCOG, Mesh (accessed 16 October 2017)
9 NHS Choices, Pelvic organ prolapse, February 2015

- RCOG, Patient leaflet: Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women, May 2017
- RCOG, Surgical procedures for treatment of pelvic organ prolapse in women, May 2017

As discussed further below, beyond complications with the specific procedures, patient and campaign groups have raised concerns about the safety of the mesh devices themselves, and there has been legal action taken against the manufacturers of these.

2. Statistics on mesh complications

The frequency of complications due to the use of mesh in uro-gynaecological procedures has been the subject of recent discussion. It was acknowledged by the NHS England working group in 2015 that there was a lack of comprehensive data on complications, and work has been ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Patient groups, campaigners and some academics have said that complications are more common than the official figures.[10]

2.1 How many women have had mesh implant procedures?

A comprehensive estimate of the number of women who have had mesh implants is not readily available. However, figures for the number of finished consultant episodes relating to the two most popular procedures for the treatment of stress urinary incontinence - introduction of tension-free vaginal tape and transobdurator tape - are routinely published as shown below.

Finished consultant episodes relating to introduction of vaginal tape (ICD 10 Codes M53.3 and M53.6), England

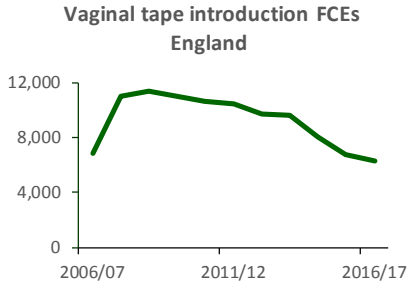
	Introduction of tension-free vaginal tape	Introduction of transobdurator tape	Total
2006/07	4,894	1,997	6,891
2007/08	7,015	3,971	10,986
2008/09	6,859	4,506	11,365
2009/10	6,682	4,275	10,957
2010/11	6,451	4,191	10,642
2011/12	6,580	3,872	10,452
2012/13	6,156	3,580	9,736
2013/14	6,149	3,494	9,643
2014/15	5,259	2,789	8,048
2015/16	4,520	2,274	6,794
2016/17	4,321	1,996	6,317
Total	64,886	36,945	101,831

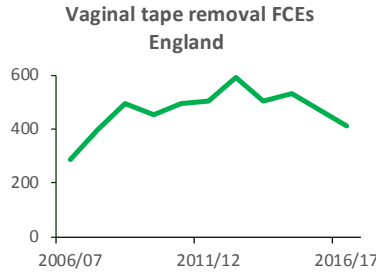
Source: NHS Hospital Episodes Statistics

Overall, a total of 101,831 procedure were carried out between 2006/07 and 2016/17. The number of procedures increased in 2007/08 and 2008/09, when 11,365 procedures were recorded. The figure then declined year on year to reach the lowest level over the past decade in 2016/17 (6,317 procedures). Please note that these figures relate to the number of procedures rather than unique numbers of women.

Over the same period a total of 5,143 procedures to remove such tapes were performed, as shown in the chart and table below. However, it is impossible to determine whether any of these procedures relate to the same women who had tape/mesh inserted.

[10] The Guardian, Senior doctors call for public inquiry into use of vaginal mesh surgery in UK, 18 July 2017





Finished consultant episodes relating to introduction of vaginal tape (ICD 10 Codes M53.5, M53.5 and M53.7), England

	Total removal of tension-free vaginal tape	Partial removal of tension-free vaginal tape	Removal of transobturator tape	Total
2006/07	87	147	53	287
2007/08	109	229	59	397
2008/09	137	283	76	496
2009/10	111	248	95	454
2010/11	128	290	77	495
2011/12	128	309	66	503
2012/13	142	349	100	591
2013/14	138	298	69	505
2014/15	148	302	83	533
2015/16	133	255	83	471
2016/17	120	219	72	411
Total	1,381	2,929	833	5,143

2.2 Adverse outcomes

There are some recent academic studies which have followed women who had surgical mesh procedures to determine the rate of adverse outcomes.

Keltie et al (2017 carried out a retrospective cohort study of first-time tension-free vaginal tape (TVT), trans-obturator tape (TOT) or suprapubic sling (SS) surgical mesh procedures between April 2007 and March 2015. A total of 92,246 first-time surgical mesh procedures were identified, including 68,002 unconfounded procedures. (Confounded procedure were those potentially confounded by concomitant procedures, and frequency, nature and timing of complications).

In the unconfounded cohort, peri-procedural and 30-day complication rates were 2.4% and 1.7% respectively. In addition, 5.9% of women were readmitted at least once within 5 years for further mesh intervention or symptoms of complications

Complication rates were higher in the potentially confounded cohort. Peri-procedural and 30-day complication rates were 5.2% and 3.0% respectively and 6.4% of women were readmitted at least once within 5 years for further mesh intervention or symptoms of complications.

Another recent research study by Morling et al 2017 suggests the efficacy of mesh may be procedure related. They followed a total of 13,333 women in Scotland who underwent a first, single incontinence procedure using mesh and 1,279 women who had a prolapse procedure involving mesh.

Morling et al's results supported the use of mesh procedures for incontinence, although further research on longer term outcomes would be beneficial. However, they argues that their results indicate that mesh procedures for anterior and posterior compartment prolapse cannot be recommended for primary prolapse repair.

3. The regulation of mesh implants

Summary

Mesh implants for use in surgical procedure are regulated as medical devices. This regulation is currently set out in three EU Directives that prescribe how devices should be tested before being marketed, sold and used across the EU.

These regulations are due to be updated by two EU Regulations that will come into force in 2020, and 2022. One Regulation will change the classification of mesh implants from a Class IIb device to a Class III device, reflecting concerns relating to these devices. This will mean that they will be subject to increased scrutiny during the pre-market approvals process.

Scrutiny of their safety and effectiveness of medical devices continues after their sale and use. Both clinicians and patients can report concerns about devices to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme.

A medical device is any instrument (other than a medicine) that is used to diagnose or manage a medical condition, including mesh implants. The definition covers a wide range of products including syringes, dressings, surgical tools, scanners and some medical apps.[11]

The regulatory procedures for medical devices is currently set out in the *Medical Devices Regulations 2002* (as amended) which implement the following three EU Directives:

- Medical Devices Directive (93/42/EEC);
- Active Implantable Medical Devices Directive (90/385/EEC); and
- In Vitro Diagnostic Medical Devices Directive (98/79/EC).

In April 2017, two new EU regulations were adopted by the European Parliament and the Council. [12] Regulation (EU) 2017/745 will regulate general medical devices and will come into force after a 3 year transition period, and Regulation (EU) 2017/746 will regulate In vitro diagnostic medical devices and will come into force after 5 years.

Medical devices that are certified under the 2002 regulations as conforming to the Directives are CE marked[13] and can be marketed and sold anywhere in the EU.

Classification

Devices are classified according to guidance set out by the European Commission and the certification process is different for each class of device. This classification system reflects the appropriate conformity assessment route to be taken to obtain a CE mark.

Under the new EU Medical Device Regulations (EU 2017/745), the classification of mesh implants intended for long term or permanent use will change from Class IIb device to a Class III device (generally regarded as high risk devices). This change reflected concerns

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11 More detail on the definition of medical devices is provided in MHRA, Guidance on legislation: Borderlines between medical devices and medicinal products, May 2016

12 European Commission, Revisions of Medical Device Directives [accessed 7 September 2017]

13 The CE marking is required for many products. It:

- shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements
- is an indicator of a product's compliance with EU legislation
- allows the free movement of products within the European market

relating to these devices and will mean a greater level of scrutiny on the devices in both pre- and post-market assessments.

A September 2017 European parliament Question response from the European Commission explains that the SCHENIR review finding contributed to the change in classification of mesh implants:

> The revised legislation on medical devices[(1)] published on 5 May 2017 establishes that surgical meshes are class III medical devices. In addition to this re-classification of surgical meshes to the highest risk group, the new legislation will ensure for this category of devices a stricter control via a new pre-market scrutiny mechanism, the reinforcement of the rules on clinical evidence and an improved transparency.
>
> In order to better understand the risks that may be linked to the use of surgical meshes, the Commission has given a mandate to its Scientific Committee on Emerging and Newly Identified Health Risks (SCHENIR) to assess the said risks. The final opinion[(2)] was adopted on 3 December 2015 and was aimed at informing both the Competent Authorities of the Member States responsible for controlling the devices put on the market and the health practitioners responsible for the clinical decisions.
>
> The conclusions of the opinion also contributed to the re-classification of surgical meshes decided through the new Regulation. […][14]

The Food and Drug Administration (FDA) in the United States changed the classification of mesh implants for use in POP procedures to class III devices in 2014 following reports of increased numbers of complications.[15] The FDA ordered mesh manufacturers to address safety concerns about these products, and submit appropriate premarket approval applications on all these products to show effectiveness and safety.[16]

3.1 Post market vigilance

The MHRA is responsible for monitoring medicines and devices after authorisation in the UK:

> Once a medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the competent authority, which is MHRA in the UK. See *guidance on reporting adverse incidents* for information on how to do this. This ensures the device is acceptably safe to use for as long as it is in use.
>
> See how to *report a non-compliant medical device* if you notice any issue with a medical device placed in the UK market.[17]

Yellow Card Scheme

The MHRA Yellow Card Scheme monitors the safety of medicines and devices in the UK. Reports can be made by healthcare professionals and patients about safety concerns about products.

The Royal College of Obstetricians and Gynaecologists sets out how complications about mesh implants can be reported to the Yellow Card Scheme:

> Complications

14 European Parliament, Question for written answer to the Commission: Surgical mesh erosion and risk classification, 8 September 2017
15 FDA, FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks, January 2016
16 Ibid.
17 MHRA, Guidance: Medical devices: how to comply with the legal requirements, 2013

All complications must be reported via the MHRA Yellow Card Scheme. More information about how to report mesh complications is available on the British Society of Urogynaecology (BSUG) website.

A number of units are able to see women who have significant mesh problems following surgery for SUI or POP where mesh was inserted. The clinical lead for each named unit has confirmed that they will:

- Comply with set criteria for discussing all women requiring surgery at a joint meeting to help determine best treatment options
- Submit data on all women undergoing surgery onto the national database and report them to MHRA

Information about these units is available from BSUG and the British Association of Urological Surgeons (BAUS).[18]

Concerns were raised during the NHS England review of mesh implants (see section 4) that there was a lack of awareness for both patients and healthcare professionals about using the Yellow Card Scheme.

[18] RCOG, Mesh

4. Review of mesh implant complications

Summary

In 2012, the Department of Health reported that whilst surgery for SUI and POP using mesh can effective for most women, a small percentage will suffer significant side effects. It said that the Department, NHS England, the MHRA and professional bodies were working together to ensure there was necessary clinical guidance, develop proposals for a national registry for implants and provide guidance for commissioners.

Since this time there has been a number of reviews of complications from vaginal mesh implant use. The most recent of these was a review coordinated by NHS England and launched in 2014. This group published its final report in July 2017. This said that whilst the use of mesh to treat women with stress urinary incontinence and pelvic organ prolapse is a safe option there was a need for better information for women experiencing SUI and POP, better data collection, a review of clinical guidance and a multi-disciplinary approach to caring for women with complications from mesh implants.

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) at the European Commission published an opinion on the safety of surgical meshes used in urogynecological surgery in December 2015. This made a number of recommendations to make the use of mesh safer in future. This included establishing European wide implant registries and clinical guidelines, undertaking studies on the long term safety and performance of mesh and setting up training programmes for surgeons.

There has also been review of these implants by the Department of Health in Scotland and the MHRA. In August 2017, it was reported that the Welsh Government were setting up a working group to consider the recommendations on the use of mesh implants. This group will report to the Health Secretary, Vaughne Gething.

Patient groups have expressed concerns about the findings of the recent reviews. There has been disappointment that the NHS England led review did not look at the safety of the mesh implants themselves and there have been calls for a public Inquiry.[19]

There has also been other international action in this area. The Australian Senate's Community Affairs References Committee is currently undertaking an Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters. This is due to report in November 2017. More information on the Inquiry is provided on the Inquiry webpage, and in a September 2017 Guardian article.

4.1 NHS England review (2014-17)

The Department of Health established a working group to look at the complications reported with vaginal mesh implants and the reporting of these.

NHS England has been facilitating this work, which also involves the MHRA, the Royal College of Obstetricians and Gynaecologists, the relevant professional societies (British Society of Urogynaecology and British Association of Urological Surgeons) and patient groups.

The Mesh working group published an interim report in December 2015. The report stated that current knowledge on mesh complications was insufficient. The working group stated that an interim report would allow the situation to be monitored and allow the analysis of further information on mesh complications.

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[19] BMJ, Patients harmed by mesh implants address emotional parliamentary meeting, 25 July 2017

Following the publication of the interim report, a Mesh oversight group was established to oversee implementation of the recommendations in the interim report and make further conclusions and recommendations.

More information on the findings of these reports is included below.

Working group interim report

The mesh working group published its interim report in December 2015. The report focused on three areas, clinical quality, data collection and information and informed consent.

Clinical quality

The group recommended that NICE should review existing and create new clinical guidance on the management of SUI and POP. It also agreed that awareness amongst GPs of mesh complications and how to address them should be improved.

Data collection

It was acknowledged by the group that there were issues surrounding the data collection and reporting of adverse events in relation to the use of mesh. In order to improve this, the report recommended:

- that hospital episode codes should be improved;
- patients should be made aware of the option of reporting to the MHRA; and
- that improving clinical leadership would promote awareness amongst clinicians of the importance of reporting of adverse events.

One of the issues that was raised during the considerations of the working group was the setting up of a register of vaginal mesh implant procedures. The working group concluded that there was a potential case for this and that a cost-benefit analysis of this measure should be carried out.[20]

Informed consent

The group highlighted the importance of informed consent in any surgical procedure. It worked with professional bodies and patient groups across the UK to produce patient leaflets on SUI and POP. The group recommended that these leaflets should be offered to all women considering procedure using mesh, and that they should be reviewed and updated as needed.

The working group also noted in its report that there were a number of studies in this area that had not been completed or published yet.

Mesh Oversight group report

The Mesh Oversight group published its final report in July 2017.[21] This reports on what actions have been taken to implement the recommendations of the 2015 report, and further action that may need to be taken in this area.

Key measures

The final report sets out a number of actions taken in response to the recommendations of the interim report, and further action to be taken:

- a resource guide has been developed for GPs to provide information about the complications associated with the use of mesh and referral options;

[20] NHS England, Mesh working group: Interim Report, December 2015
[21] NHS England, Mesh Oversight Group Report, July 2017

- Surgeons are required to show appropriate training and experience in SUI surgery and these surgical procedures are reported on a national database. The report also states that the use of mesh in primary procedures for POP is not supported by current evidence.
- NICE has reviewed and updated a number of clinical guidelines, and more are due for publication in 2019;
- A number of hospital trusts have been identified as providing multi-disciplinary services suitable for providing support and treatment for women with mesh complications.
- Professional organisations have worked with clinicians to improve adverse event reporting rates.
- The MHRA has been working on improving awareness of the yellow card scheme for reporting complications with mesh implants for clinicians and patients.
- There is ongoing work on the development of a registry to track mesh devices and complications. The sub group is due to report back on this issue in November 2017.

The following leaflets providing information for patients were published alongside the report:

- Surgical Procedures for Treatment of Pelvic Organ Prolapse in Women
- Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women

The BAUS website provides further information about the mesh review centres across the UK.

Responses to the working group report

Patient groups

Patient groups have expressed disappointment with the findings of the final working group report, and some campaigners have branded the review a 'whitewash.'[22] It has also been reported that patient representatives had resigned from the group prior to publication.[23]

The Sling the Mesh campaign group has said that women are "outraged" that the review does not look at the safety of the mesh devices themselves:

> Women are outraged after realising the NHS never intended to investigate mesh implant safety despite undertaking a three-year mesh review costing thousands of pounds.
>
> A long-awaited report was never given funding to look at the mesh product itself. The review began in 2014 and involved experts and patient representatives. It only commissioned to look at patient leaflets, under-reporting and how to deal with women who suffer mesh complications. [24]

Parliament

Owen Smith, Chair of the new All Party Parliamentary Group on mesh, also responded to the report:

> Labour MP Owen Smith, who has set up an All Party Parliamentary Group into mesh, said: "Mesh-injured women will be deeply disappointed by the outcomes of the final

22 BMJ, Patients cry "whitewash" as NHS refuses to halt use of mesh implants, 26 July 2017
23 Sling the mesh, Thousands suffer in silence, 24 July 2017
24 Sling the mesh, Thousands suffer in silence, 24 July 2017

> NHS England review, which seems to have made little progress since its interim report came out over a year ago.
>
> "This was an opportunity for the NHS to take a lead and recommend a pause in the use of mesh until we know precisely how many women have been adversely affected by the product. Instead, they appear content to allow mesh to be widely used despite growing, international concerns about its potential ill effects.
>
> "The only people pleased with this report will be the medical device companies who marketed mesh so diligently and who now fear mass litigation. Many companies have already taken their mesh products off the market that alone should tell us something is not right with these devices."[25]

Professional groups

The RCOG and BSUG joint response to the NHS England final report welcomed changes that mean that women with complications from surgical mesh can now be seen in specialist units and that women will have access to consistent information in order to make decisions about their care:

> Professor Jonathan Duckett, vice chair of the British Society of Urogynaecology (BSUG) and member of the MESH oversight group, said**:**
>
> "We are aware that women may experience complications following mesh surgery many years after the procedure, therefore primary care is likely to be the first place they raise their concerns. We are pleased that a learning resource for GPs has been created so that women with mesh complications receive the appropriate support and are swiftly referred to specialist centres.
>
> "We are also pleased that women will now have access to consistent information to enable and support them have a structured discussion with their clinician about all the treatment options and ensure the risks are fully explored and understood. The leaflets will also ensure that clinicians can be responsive to the worries of their patients and can address concerns with guidance in a consistent, high quality and person centred manner.
>
> "We will continue to promote the BSUG database to clinicians as a way of collecting more data that tells us about complications and we encourage clinicians and patients to report adverse incidents to the MHRA."[26]

4.2 MHRA review 2014

The MHRA is the body that regulates medicines and medical devices across the UK. Following a request from the Chief Medical Officer the MHRA undertook a review of the evidence from the regulatory system on the benefit and risks of vaginal mesh implants. The results of this review were published in October 2014.

The MHRA concluded in the review that in the case of vaginal mesh implants, for the majority of women the use is safe and effective, but there is an element of risk to individual patients:

> MHRA's current position is that, for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the individual patient. This conclusion is entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks.

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25 Sling the mesh, Thousands suffer in silence, 24 July 2017
26 RCOG, RCOG and BSUG response to NHS Mesh report, 25 July 2017

> Other issues associated with the use of these devices such as informed patient consent and suitable patient selection, are being taken forward by the NHS England led working group on vaginal mesh implants.[27]

The MHRA goes on to report that it will keep vaginal mesh implants under enhanced scrutiny, and that they are awaiting the outcomes of other reviews of the evidence in this area.

4.3 European Commission review 2015

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) announced in March 2014 that the European Commission had requested they undertake an investigation into the safety of the use of transvaginal mesh in uro-gynaecological surgery.

The SCENIHR published its opinion on the use of mesh in uro-gynaecological procedures in December 2015:

> Today, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) publish the final Opinion on the safety of surgical meshes used in urogynaecological surgery. The Opinion looks at the risks associated with the use of surgical meshes for various conditions, how to identify high risk patient groups and further assessment needs.
>
> A key conclusion is that in assessing the risk associated with mesh application, it is important to consider the overall surface area of material used, the product design and the properties of the material used. In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP) than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.
>
> SCENIHR's recommendations include:
>
> - Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects to consider when choosing appropriate therapy.
> - The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery.
> - For all procedures, the amount of mesh should be limited where possible.
> - A certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.[28]

An easy to read factsheet on the opinion has also been published.

4.4 Scottish Government review 2013-2017

The issue of adverse effects relating to the use of mesh in uro-gynaecological procedures has been the subject of attention and a recent independent review in Scotland. In 2013, the then Cabinet Secretary for Health and Wellbeing, Alex Neil, set up the Transvaginal Meshes Working Group. The group was established to look at the issues affecting women who developed complications from surgery using mesh implants.

An expert group was also established in December 2013, to "*look at ways of improving clinical practice, including developing pathways of care for women experiencing*

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27 MHRA, A summary of the evidence on the benefits and risks of vaginal mesh implants, 2014

28 European Commission, Safety of surgical meshes used in urogynaecological surgery: final Opinion, 17 December 2015

complications and to improve the consent process to ensure women are better informed of the risks and benefits of all procedures available to treat these conditions."[29]

A public petition was lodged on behalf of a patient group called the Scottish Mesh Survivors (SMS) in May 2014. The petitions called on the Government to undertake a number of actions including suspending the use of mesh in surgical procedures.

In June 2014, Alex Neil, announced in a Parliamentary Statement that the Chief Medical Officer would write to all health boards to ask them to consider suspending routine mesh implant use, and that there would be an independent review established.

The Independent review published its final report in March 2017 and made a number of recommendations. More information is provided in a Scottish Government press release:

> Scotland's Chief Medical Officer (CMO) has accepted the recommendations of the final independent report into the use of transvaginal mesh implant procedures.
>
> The report, published today, sets out a number of conclusions to improve the safeguards available. These include:
>
> - Mesh must not be offered routinely to women with pelvic organ prolapse.
> - Reporting of all procedures and adverse events to be mandatory, in line with the guidance from the General Medical Council.
> - Extra steps to ensure that patients have access to clear, understandable advice to help them make informed choices.
> - In the case of surgical treatment for stress-urinary incontinence, all appropriate treatments should be available, subject to informed choice and assessment.
> - Improved training for clinical teams involved in transvaginal mesh.
> - Improved research into the safety and effectiveness of the products.
>
> A new oversight group will be established to ensure the conclusions are implemented.

It was reported that there had been resignations of three members of the review group prior to the publication of the final report and that patient groups had expressed concerns about the report.

At a Petitions Committee meeting in May 2017, the Cabinet Secretary for Health and Wellbeing, Shona Robison confirmed that she was commissioning Professor Allison Britton of Glasgow Caledonian University to examine and report on the processes of the review group. She also confirmed that the Scottish Government has accepted all of the recommendations of the review group.[30]

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[29] Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women: Final report, March 2017

[30] Scottish Parliament OR Public Petitions Committee, 18 May 2017, c24

5. Parliamentary discussion

The subject of complications from mesh implants used in surgical procedures for POP and SUI has been the subject of a number of Parliamentary questions recently.

The most recent Government response on this issue, in October 2017, from the Under-Secretary of State for Health, Jackie Doyle-Price, set out that there are ongoing discussions between Ministers, the NHS and the Medicines and Healthcare products Regulatory Agency on the support for patients, and continuing work to assess the risks of the mesh implants. However, the Minister also said that these procedures are effective for a number of women, a good review of the evidence was needed to make sure the procedures are used appropriately and that women are aware of the potential risks involved.[31]

An All Party Parliamentary Group on surgical mesh implants has been established in 2017. This is chaired by Owen Smith MP.

A Westminster Hall debate has been tabled for 18 October 2017 on the risk of surgical mesh implants. The debate will be opened by Emma Hardy MP.

[31] HC Deb 10 October 2017 c148

6. Legal action

It has also been reported in the last year that over 800 women in the UK are pursuing legal cases against the NHS and the makers of the mesh implants, the largest of which is Johnson and Johnson.[32]

There have already been similar legal cases in other countries. In one September 2017 US example, Ethicon, a subsidiary of Johnson and Johnson, was ordered by a court in Philadelphia to pay $57.1 million in damages after a trial over allegations that its transvaginal mesh product was defective.[33] Johnson and Johnson has said it will appeal the case. Bloomberg report that the company are facing over 54,000 lawsuits over mesh implants.[34]

[32] BBC News, Vaginal mesh implants: Hundreds sue NHS over 'barbaric' treatment, 18 April 2017
[33] Law.com, Jury Hits J&J With Record $57.1M Verdict in Pelvic Mesh Case, 7 September 2017
[34] Bloomberg News, J&J to Pay $20 million in vaginal-mesh case as other trials loom, April 2017

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