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BRIEFING PAPER

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Surgical mesh implants

By Sarah Barber

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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 complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

These complications can include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England mesh working group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

There have been a number of recent reviews looking at the use of mesh. Departments of Health in both England and Scotland have undertaken work in this area, as have the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Commission. The Welsh Government have set up a group to review the use of mesh implants.

NHS England have led the most recent review on the use of mesh implants in urogynaecological surgery, with the Mesh Oversight group publishing its final report of the review 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.

Concerns have been raised about the safety of the mesh implants themselves and the regulatory process used to assess them. There has been disappointment that the recent NHS England review did not looked at this issue. In response to concerns relating to mesh implants, new EU regulations have changed the medical device classification of mesh implants. This will mean that they will be subject to greater scrutiny during the pre-approval process. These changes will come into force in 2020.

The Under-Secretary of State for Health, Jackie Doyle-Price, responded to a Westminster Hall debate on the risk of surgical mesh implants in October 2017. She said that the issues with mesh implants were related to clinical practice and not to the devices themselves and that the Government needed to ensure that clinicians have the most up to date advice. Ms Doyle Price also set out that it was important that women were given the information to make an informed choice, and that the evidence on mesh implants would be reviewed to keep guidance up to date.

It has been reported that a number of UK patients are pursuing legal action against the mesh implant manufacturers and the NHS. There has also been legal action on this issue in other countries.

There has been some international regulatory activity in this area. Recent announcements by medicines and device regulators in Australia and New Zealand have meant that certain mesh products will be removed from sale there and producers are being required to provide safety information on their products.

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.[1] Guidance now states that the use of mesh implants in primary procedures for POP is not supported by current evidence.[2]

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[3]

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.

1 RCOG, Pelvic Organ Prolapse, March 2013
2 NHS England, Mesh Oversight Group Report, July 2017
3 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.[4]

1.3 Clinical guidelines

The National Institute for Health and Care Excellence (NICE) provides evidence-based information for the NHS on the effectiveness and cost-effectiveness of healthcare interventions. It publishes mandatory technology appraisal guidance stipulating clinical interventions (mainly medicines) which must be funded by NHS commissioners, as well as advisory clinical guidelines and public health guidance.

NICE guidance on procedures using mesh implants have been updated following concerns relating to mesh implants and a recommendation from the NHS England mesh working group.

Recently published NICE guidance

NICE has recently published interventional procedures guidance for a number of procedures using surgical mesh. It explains that, with regard to interventional procedure guidance "there is no legal requirement to comply with the recommendations we make, although it is considered best clinical practice for the NHS to do so.[5]

The most recent guidance on the use of mesh in the surgical repair of vaginal wall prolapse was published in December 2017. At this time, NICE provided an overview on the new pieces of guidance on the use of surgical mesh:

> NICE has published eight pieces of interventional procedure guidance (IPG) on mesh. They give advice on the use of mesh as a treatment for stress urinary incontinence (SUI), or pelvic organ prolapse (POP).
>
> This publication focuses on the use of mesh for vaginal wall prolapse, which is a type of POP. It is the last of eight IPGs to be updated.
>
> **Sir Andrew Dillon, NICE chief executive said:** "Our updated advice on surgical procedures using mesh is based on the latest evidence available, which has been considered in the light of the serious concerns expressed by individual patients and patient groups. We emphasise the importance of patient consent and data collection and we are confident that our advice will give patients and health professionals the right information to make treatment decisions."
>
> IPGs look at possible risks and benefits of procedures. More details on the recommendations NICE makes is here.[6]

It also responded to suggestions from media reports that the recommendations in the guidance constituted a ban on the use of this procedure:

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4 NHS Choices, Urinary incontinence - Surgery and procedures
5 NICE, Interventional procedures recommendations (accessed 20 December 2017)
6 NICE, Mesh for vaginal wall prolapse should only be used in the context of research, says NICE, 15 December 2017

> The evidence for long term efficacy is inadequate in quality and quantity. Therefore, the procedure should only be used in the context of research. This does not constitute a ban on the use of the procedure, as has been suggested in some media reports.[7]

Links to the new interventional procedures guidance are included below:

- Single-incision short sling mesh insertion for stress urinary incontinence in women (October 2016)
- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse (March 2017)
- Extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women (March 2017)
- Sacrocolpopexy using mesh to repair vaginal vault prolapse (June 2017)
- Infracoccygeal sacropexy using mesh to repair uterine prolapse (June 2017)
- Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse (June 2017)
- Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse (June 2017)
- Transvaginal mesh repair of anterior or posterior vaginal wall prolapse (December 2017)

Stress urinary incontinence guidelines

A December 2017 Parliamentary Question response sets out that the NICE guidance on urinary incontinence is due for publication in 2019:

> Departmental officials have had a number of discussions with the National Institute for Health and Care Excellence (NICE) about the development of guidance on vaginal meshes. NICE has published seven out of eight pieces of Interventional Procedure guidelines; with the final piece due to be published in 15 December 2017. The NICE Clinical Guidance on urinary incontinence is due to be published in 2019, with a consultation on the draft guidance planned for 2018.
>
> Ministers and officials have met with NHS England on a number of occasions to discuss the recommendations that were set out in the NHS England Mesh Oversight Group final report that was published in July 2017. The recommendations included an e-learning resource for general practitioners and the production of information leaflets outlining the benefit and risks of all treatment options available for both patients and clinicians.[8]

More information on the update to the *Urinary incontinence (update) and pelvic organ prolapse in women: management* guidance is available on the NICE website.

1.4 Mesh implant complications

All medical procedures may carry risks and it is important that the patient and their doctor weigh 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

7 NICE, Mesh for vaginal wall prolapse should only be used in the context of research, says NICE, 15 December 2017

8 HC Written Question 116359: Surgical mesh implants, 7 December 2017

> decide to go ahead with a procedure using mesh, the operation should only be performed by a specialist with expertise in this technique.[9]

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.[10]

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

- 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 (section 3.2), 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.

9 RCOG, Mesh (accessed 9 January 2018)
10 NHS Choices, Pelvic organ prolapse, February 2015

2. Statistics on mesh complications

The frequency of complications due to the use of mesh in urogynaecological 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.[11]

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

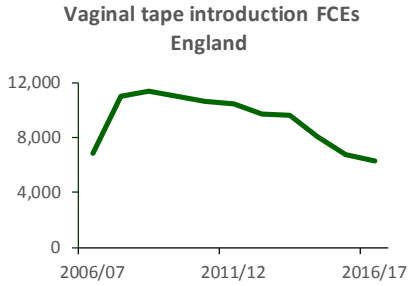
	Introduction of tension-free vaginal tape	Introduction of transobdurator tape	Total
2006/07	4,894	1,997	6,891
2007/08	7,015	3,971	10,986
2008/09	6,859	4,506	11,365
2009/10	6,682	4,275	10,957
2010/11	6,451	4,191	10,642
2011/12	6,580	3,872	10,452
2012/13	6,156	3,580	9,736
2013/14	6,149	3,494	9,643
2014/15	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

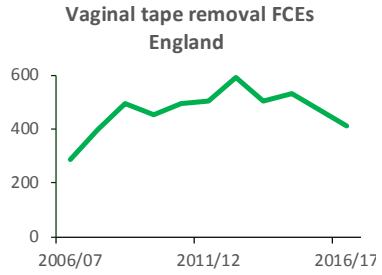
Source: NHS Hospital Episodes Statistics

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.

[11] 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

Source: NHS Hospital Episodes Statistics

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.

Overall, the proportion of patients experiencing a complications at any stage - ie peri-procedural, within 30 days or within 5 years, was 9.8% in the unconfounded cohort and 12.8% in the confounded cohort.

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 argued 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 approval process.

Scrutiny of the 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 recently published study examined marketing clearance of vaginal mesh devices through the US Food and Drug Administration and concluded that trans-vaginal mesh products for pelvic organ prolapse have been approved on the basis of weak evidence over the last 20 years. The authors argue that current systems for ensuring patient safety are inadequate for medical devices and that clinical trial evidence should be mandatory for gaining marketing authorisation for implantable devices

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.[12]

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. [13] 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[14] and can be marketed and sold anywhere in the EU.

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

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

14 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

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.[15]

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 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 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 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. […][16]

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.[17] 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.[18]

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.

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15 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

16 European Parliament, Question for written answer to the Commission: Surgical mesh erosion and risk classification, 8 September 2017

17 FDA, FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks, January 2016

18 Ibid.

> See how to *report a non-compliant medical device* if you notice any issue with a medical device placed in the UK market.[19]

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
>
> 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).[20]

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.

3.2 Concerns about mesh device regulation

Patient groups and others have criticised recent reviews on the use of mesh implants because they have not considered the safety of the devices themselves.

The regulation of mesh implants was the subject of a December 2017 study published in BMJ Open. Heneghan et al (2017) examined marketing clearance of vaginal mesh devices through the US Food and Drug Administration and concluded that trans-vaginal mesh products for pelvic organ prolapse have been approved on the basis of weak evidence over the last 20 years. The authors argued that current systems for ensuring patient safety are inadequate for medical devices and that clinical trials evidence should be mandatory for gaining marketing authorisation for implantable devices. They recommended the setting up of a patient registry to enable long term follow up and surveillance.[21]

An accompanying analysis article in the BMJ reports that, as mesh implants were regulated as class II devices, they were able to be licensed on the basis of equivalence to existing products, despite there being important differences between some devices:

> In our linked *BMJ Open* paper we traced marketing clearance for 61 mesh devices back through a chain of equivalence claims to only two unique originating devices approved in 1985 and 1996. We found no evidence of any new clinical trial data at

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19 MHRA, Guidance: Medical devices: how to comply with the legal requirements, 2013

20 RCOG, Mesh

21 Heneghan CJ, Goldacre B, Onakpoya I, *et al*. Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process. *BMJ Open* 2017;7:e017125. doi:10.1136/bmjopen-2017-017125

> the time of device approval for all of these 61 devices, with empirical evidence of effectiveness from randomised trials emerging on average five years after approval (range 1 to 14 years).
>
> However, changes in design should have alerted regulators to important differences in the technological characteristics of the mesh that should have negated the use of equivalence. As an example, one of the early devices, the Protegen sling, which was made from polyester, continued to be used as a predicate for more modern devices even though they were made from polypropylene, and despite the Protegen sling being removed from the market.[22]

As noted above, the European Commission and the FDA (in the case of mesh used in POP procedures) have both reclassified mesh implants as class III devices. However, the change in classification in the EU will not come into force until 2020. The study authors argue that the "changes are insufficient, and the long delay in implementation does not represent a timely response to patients' needs."[23]

Professor Carl Heneghan at the Centre for Evidence Based Medicine at Oxford University has also produced an online timeline on transvaginal mesh safety concerns from the launch of the protegen sling implant in 1996 through to the present.

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22 Heneghan Carl, Aronson Jeffrey K, Goldacre Ben, Mahtani Kamal R, Plüddemann Annette, Onakpoya Igho et al. Transvaginal mesh failure: lessons for regulation of implantable devices BMJ 2017; 359 :j5515

23 Ibid.

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.[24]

There has also been international action in this area. The medicines regulator in Australia, the Therapeutic Goods Administrator has undertaken a review of the use of mesh which has led to a number of mesh implants being removed from use in Australia. New Zealand has also taken action in this area, asking companies not to market mesh implants in the country until they are proved as safe.[25]

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.

[24] BMJ, Patients harmed by mesh implants address emotional parliamentary meeting, 25 July 2017
[25] http://www.health.govt.nz/news-media/media-releases/medsafe-introduces-surgical-mesh-restrictions

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.[26]

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.[27] 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;

26 NHS England, Mesh working group: Interim Report, December 2015
27 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 early 2018.

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 oversight group report

MHRA response

The Director of Devices at the MHRA, John Wilkinson, responded to the oversight group report:

> Patient safety is our highest priority and we sympathise with women who have suffered complications after surgery.
>
> We are committed to helping address the serious concerns raised by some patients. We have undertaken work to assess the findings of studies undertaken by the clinical community over many years, as well as considering the feedback from all sources in that time.
>
> What we continue to see is that evidence supports the use of these devices in the UK for treatment of the distressing conditions of incontinence and organ prolapse in appropriate circumstances. This is supported by the greater proportion of the clinical community and patients.
>
> In common with other medical device regulators worldwide, none of whom have removed these devices from the market, we are not aware of a robust body of evidence which would lead to the conclusion these devices are unsafe if used as intended.
>
> We actively encourage patients and healthcare professionals to report complications associated with these implants through the Yellow Card Scheme.[28]

Patient groups

[28] MHRA, MHRA response to the final report of the Mesh Oversight Group, 26 July 2017

Patient groups have expressed disappointment with the findings of the final working group report, and some campaigners have branded the review a 'whitewash.'[29] It has also been reported that patient representatives had resigned from the group prior to publication.[30]

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. [31]

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 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." [32]

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.

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

> "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." [33]

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.
>
> 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. [34]

The MHRA went 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 urogynaecological surgery.

The SCENIHR published its opinion on the use of mesh in urogynaecological 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.

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[33] RCOG, RCOG and BSUG response to NHS Mesh report, 25 July 2017
[34] MHRA, A summary of the evidence on the benefits and risks of vaginal mesh implants, 2014

- 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.[35]

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 urogynaecological 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 Mesh 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 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.*"[36]

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.

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

36 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

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 had accepted all of the recommendations of the review group.[37]

In response to a December 2017 parliamentary question, Shona Robison said that the Chief Medical Officer had written to the MHRA about the regulation of mesh implants. She said that until the review's recommendations had been put in place, the Chief Medical Officer had requested that the ban on the routine use of mesh stay in place:

> Following the debate in the chamber last week, and in light of the BBC's Panorama programme earlier this week, both the Chief Medical Officer and I have written to the MHRA to express concerns about the role of the MHRA in relation to transvaginal mesh. Furthermore, given the concerns, I have also written to the Secretary of State for Health, Jeremy Hunt given his overall responsibility for the MHRA asking for a meeting to discuss these concerns.
>
> In her letter, the Chief Medical Officer also raised the recent decision about the future use of mesh in Australia and is seeking some clarification on what evidence informed the Australian decision and confirmation that it is being considered by the Regulator.
>
> Healthcare Improvement Scotland continue to progress plans for the first two meetings of the mesh Oversight Group and, in addition, Scottish Government officials continue to liaise with other UK nations about the options for a mesh registry.
>
> Members will be aware that NICE undertook a public consultation on revised mesh guidance, and we expect that guidance to be published tomorrow. NICE IPP guidance applies across the UK, including in Scotland, and the Chief Medical Officer has therefore written to all Health Boards, alerting them to the fact that new guidance will shortly be published, and stressing that it must be implemented.
>
> As ever, the Scottish Government's overriding concern is quality of care and, until the Chief Medical Officer is satisfied that the Review's recommendations have been implemented, and all necessary procedures, approvals and restrictions are in place, the request that routine use of mesh be suspended will continue.[38]

4.5 International action

United States

As discussed in section 3, The Food and Drug Administration (FDA) changed the classification of mesh implants for use in POP procedures to class III devices in 2014 following reports of increased numbers of complications.[39]

In 2012, the FDA had also 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.[40]

However, a recently published study on the FDA approvals process for mesh implants (as discussed in section 3.2) has reported that whilst there were 119 orders in 2012 for post marketing surveillance studies, this resulted in only 7 studies being undertaken; some

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37 Scottish Parliament OR Public Petitions Committee, 18 May 2017, c24
38 SP WA 14 December 2017, s50-01581
39 FDA, FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks, January 2016
40 Ibid.

manufacturers responded by ceasing the marketing the product, or changing the indication. As set out in the BMJ:

> In 2012, the FDA asked 33 manufacturers of surgical meshes to conduct 119 new safety studies. Our linked *BMJ Open* study shows that in response, the manufacturers instead ceased market distribution in 79 (66%) cases and changed the indication in 26 (22%) cases. In two orders the manufacturer reported it was no longer in business and one reported the device was not a mesh. In four orders the manufacturer requested their multiple orders should be consolidated into one leaving seven studies under way to assess the risks of harms. The FDA reclassified vaginal mesh for pelvic organ prolapse repair from a class II device to a class III device in 2016, requiring more stringent testing in trials before clearance.[41]

Australia

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is the organisation responsible for regulating medicines and medical devices in Australia. The TGA conducted a review of urogynaecological surgical mesh implants in 2013. As a result of this review, the TGA has conducted assessments of each mesh product and has made decisions on these.[42]

In November 2017, the TGA announced that following the review and later assessments, it was "of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients."[43] It had decided to remove mesh implants used in POP procedures from the Australian Register of Therapeutic Goods. It also reported that a certain type of mesh implant used in Stress urinary incontinence procedures, single incision mini-slings would also be removed from the register, but mid-urethral slings would not be removed. These changes came into force on 4 January 2018.

The TGA report that since the 2013 review "45 devices have been removed from urogynaecological use by the TGA – 43 cancelled from the ARTG and a further two have been limited to non-urogynaecological procedures."[44]

More information on this removal of mesh implants from the registry is provided on the TGA webpage.

Australian Senate

The Australian Senate's Community Affairs References Committee is also currently undertaking an Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters. More information on the Inquiry is provided on the Inquiry webpage, and in a September 2017 Guardian article.

New Zealand

Following the publication of the TGA review on surgical mesh used in urogynaecological surgery, in December 2017, Medsafe (the New Zealand regulatory authority for medicines and medical devices) announced that it is requiring suppliers of mesh implants to provide safety information about their products.

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41 Heneghan CJ, Goldacre B, Onakpoya I, *et al*. Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process. *BMJ Open* 2017;7:e017125. doi:10.1136/bmjopen-2017-017125

42 TGA, TGA actions after review into urogynaecological surgical mesh implants, 18 December 2017

43 Ibid.

44 Ibid.

More information is provided in a New Zealand Ministry of Health press release, which explains that this action will effectively limit the supply of mesh for POP and stress incontinence surgical procedures. [45]

[45] Ministry of Health New Zealand, Medsafe introduces surgical mesh restrictions, 11 December 2017

5. Parliamentary debate

The subject of complications from mesh implants used in surgical procedures for POP and SUI has been the subject of debate in parliament recently.

5.1 Westminster Hall debate

On 18 October 2017 there was a Westminster Hall debate on the risk of surgical mesh implants tabled by Emma Hardy MP. In her speech, Ms Hardy highlighted the experiences of women who had suffered complications following the use of mesh in surgery. She said that this had meant women had been left in persistent pain, with impacts on their ability to work, mobility and their sex lives.[46]

She also stated that campaign groups had expressed concerns about the mesh implants themselves, and that there was disappointment that this had not been looked at as part of the reviews:

> Building an evidence base is not the only issue. Many people, most notably the Sling the Mesh campaign, have raised concerns about the fact that previous reviews, especially in England, of surgical mesh have focused solely on the procedural failures of mesh surgery and not looked into the safety of the product itself. That is in line with the findings of a report issued by the EU's Scientific Committee on Emerging and Newly Identified Health Risks, which said that when 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.
>
> I completely agree with my hon. Friend the Member for Pontypridd (Owen Smith), the chair of the all-party parliamentary group on surgical mesh implants—he was of great help to me in preparing this speech—when he says that the fact that many companies have already taken their mesh product off the market should tell us that something is not right with these devices. We have to go to the core of the issue and investigate the fundamental safety of the products. Will the Minister commit to doing all she can to ensure that any future reviews of mesh products look at product safety as well as procedural issues?[47]

Ms Hardy asked for four actions from the Government:

> I call on the Government to do four things. First, they must commit to a full retrospective and mandatory audit of all interventions that involved mesh, followed by a full public inquiry. Secondly, they must suspend prolapse and incontinence mesh operations while the audit is being carried out. Thirdly, they must bring the NICE guidelines for mesh in stress-related urinary incontinence forward from 2019 to 2018. Fourthly, they must raise awareness among the general public and GPs.
>
> Mesh implants have affected thousands of people all over the country. For some, the consequences of operations will be life-changing and devastating. A Government commitment to taking these actions will not undo the suffering and pain that these people have endured, but would go a long way to making sure that nothing like this happens again.[48]

A number of MPs contributed to the debate, the majority of whom provided accounts of how their constituent's had been affected following a surgical procedure using mesh. There were repeated calls for an inquiry into the use and safety of mesh, and some MPs called for a ban/suspension on the use of these products. Sarah Wollaston, Chair of the

46 HC Deb 18 October 2017 c294WH
47 HC Deb 18 October 2017 c297WH
48 HC Deb 18 October 2017 C299WH

Health Committee, said that whilst she did not believe there should be a ban, there should be consultation with women, so they can make decisions about procedures.[49]

She also called for better collection of data on this issue, and a focus on improving clinical trials:

> A fundamental absence of data is at the heart of the issue. There has been cavalier practice, and we cannot allow that to continue. The women who have been affected deserve an apology and recognition of the extent of the problem and the delays in recognising and dealing with it. I welcome the findings of the mesh oversight group report, which describes pragmatic and practical recommendations, but clear failings have been allowed to continue for so long. At the heart of those failings is the inadequacy of clinical trials, recording and consent. Finally, we know that the devices are regulated by the European Union. I hope the Minister will comment on how the Government propose to take this issue forward after we leave the European Union. At the heart of it is the need to ensure that the safety of women is prioritised at all times.[50]

Sharon Hodgson, shadow spokesperson for Public Health said that the Opposition were calling for an "urgent inquiry into the number of women adversely affected by vaginal mesh implants and into why the safety of so many women was disregarded." Alongside other Members she also urged NHS England and NICE to update the clinical guidelines "immediately."[51]

The Parliamentary Under-Secretary of State for Health, Jackie Doyle-Price responded to the debate. She said that the issue with mesh implants was with clinical practice and not with the devices themselves, and that the Government needed to ensure that clinicians have the most up to date advice:

> Obviously, many hon. Members would like an immediate ban on mesh products. From my perspective, the issue is not with the product but with clinical practice. That is what is going wrong. That is where we need to be much clearer, ensuring that women are treated properly by their clinicians, given proper advice and risk assessments, and given the opportunity to report any complications and the ability to complain and challenge. The Government also need to ensure that all clinicians have the most up-to-date and appropriate advice.[52]

She also said that it was important women had the information to make an informed choice, and said that the evidence on mesh implants would be reviewed to keep guidance up to date:

> The women are the most important aspect of this debate. We should be focusing on them. We must make sure that they are fully supported to make informed decisions about the surgery, and I have heard from many hon. Members that in many cases they were not. This is a risky process and, as my hon. Friend the Member for Totnes (Dr Wollaston), the Chair of the Health Committee, said, many women have benefited from this surgery but there is a risk to it, and those risks were not properly communicated to allow women to make an informed choice. That is not acceptable and we must make sure that does not happen in the future.
>
> To do all of that, we are working with patients, NHS England and the MHRA, to come together with the mesh oversight group. The most recent report was published in July and its recommendations are being implemented. The updated guidelines will be published before the end of 2017. It is important that regulators ensure that advice

49 HC Deb 18 October 2017 c307WH
50 Ibid.
51 HC Deb 18 October 2017 c315WH
52 HC Deb 18 October 2017 c316WH

> and guidance keep up with developments in clinical technology and practice. We will constantly review evidence as it comes in to keep advice and guidance up to date.[53]

She also highlighted the Yellow Card scheme and urged women to report any complications to this scheme.

Following the debate, the Department of Health clarified that the guidelines referred to in the Minister's response were the interventional guidelines (for further information on clinical guidelines see section 1.3).[54] The clinical guidance on *Urinary incontinence (update) and pelvic organ prolapse in women: management* is due for publication in February 2019.

5.2 Parliamentary Questions

Since the Westminster Hall debate on this subject, there have been a number of Parliamentary Questions on the subject of mesh implants. On 6 December 2017 Jackie Doyle-Price responded to a question as to whether the Government would ban the use of mesh implants. She said that the MHRA supported the use of these devices as part of an appropriate treatment pathway:

> The Medicines and Healthcare products Regulatory Agency has considered all evidence available to them, both here in the United Kingdom and worldwide, and their view is that both the evidence and the greater proportion of the clinical community supports the use of these devices as part of an appropriate treatment pathway.
>
> The NHS England mesh oversight group's final report, published in July 2017, recommended that surgical mesh should not be routinely offered as the first surgical intervention when treating prolapse which is in alignment with the recommendations of the Scottish Independent Review.
>
> The report also sets out a number of actions which improve the support available for women who have suffered with complications including being able to be referred to 18 trusts in England that have the specialist multidisciplinary teams and experience to assess complications and offer the highest quality support.[55]

In another Parliamentary question response in December 2017, Ms Doyle-Price highlighted recently published NICE guidelines on the use of mesh, and stated that ministers are working with the All Party Parliamentary Group to consider additional action:

> The National Institute for Health and Care Excellence (NICE) is the independent body that provides authoritative, evidence-based guidance for the National Health Service on whether interventional procedures are sufficiently safe and efficacious for routine use in clinical practice, or whether special arrangements should apply to their use. NICE's guidance is developed through an established process that entails a thorough consideration of the available evidence and public consultation.
>
> NICE's interventional procedures guidance represents best clinical practice and we expect NHS organisations and healthcare professionals to take it fully into account in the treatment of NHS patients. The recommendation of NHS England's oversight group's reports ensures mesh is only used in appropriate situations with clear consent and understanding about the balance of benefit and risks. Ministers are also working with the All Party Parliamentary Group and considering a range of additional actions to ensure the evidence and data collected on these procedures is current and robust[56]

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53 HC Deb 18 October 2017 c317WH
54 Mesh campaigners are dismayed by minister's blunder over NICE guidance, BMJ, 20 October 2017
55 HC Written Question 116248: Surgical mesh implants, 6 December 2017
56 HC Written Question 119987: Surgical mesh implants, 22 December 2017

6. Legal action

It has 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.[57]

There have been legal cases relating to mesh implants 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.[58] Johnson and Johnson has said it will appeal the case. Bloomberg report that the company are facing over 54,000 lawsuits over mesh implants.[59]

[57] BBC News, Vaginal mesh implants: Hundreds sue NHS over 'barbaric' treatment, 18 April 2017
[58] The Guardian, Revealed: Johnson & Johnson's 'irresponsible' actions over vaginal mesh implant, 29 September 2017
[59] Bloomberg News, J&J to Pay $20 million in vaginal-mesh case as other trials loom, April 2017

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