HOUSE OF COMMONS LIBRARY

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 complications that can occur with the use of this mesh in urogynaecology 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. It is acknowledged by NHS England, NICE and others that there is limited evidence on the long-term adverse effects following these procedures.

A halt on the use of mesh procedures for stress urinary incontinence and pelvic organ prolapse

In February 2018, the then Secretary of State for Health and Social Care, Jeremy Hunt announced the establishment of a medicines and medical devices safety review in February 2018. This review is being led by Baroness Cumberlege and has taken evidence from patients, patient groups, and clinicians on three areas of concerns in relation to medicines and medical devices – Sodium valproate, primodos (the hormone pregnancy test) and surgical mesh.

In July 2018, following the evidence it had heard, the Independent Medicines and Medical Devices Safety Review called for the immediate halt of the use of surgical mesh in stress urinary incontinence procedures. The use of mesh in procedures to treat pelvic organ prolapse had only been undertaken as part of research following NICE guidance in 2017.

The Government accepted this recommendation and said the pause should also apply to vaginally inserted mesh to treat pelvic organ prolapse. This high vigilance restriction period means that for most women, there will be a delay in having procedures or alternative treatment would be offered but does not mean that a blanket ban is in place. Halts in the use of mesh in Scotland, Wales and Northern Ireland are also currently in place.

This halt in procedures remains in place at the time of writing

The regulation of mesh implants

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 2017 NHS England review did not look at this issue.

Mesh implants are regulated as medical devices, under EU legislation. 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 Government have said when the UK leaves the EU, it will still implement the new EU Medical Devices Regulations.

In response to a debate on medical devices in February 2019, the then Under-Secretary of State for Health, Jacqui Doyle-Price acknowledged that improvements were needed to the existing system of regulation for devices. She said that the Government would implement the changes introduced by the EU regulations and were confident that this would drive system-wide improvement. She also said, that in advance of this the Government were taking actions to ensure the existing legislation is working as effectively as possible.

There has also been international action on the regulation of mesh devices.

The use of mesh for hernia repair

Another use of mesh that has received recent attention is in hernia repair procedures. Complications due to this mesh use were raised in a BBC investigation in September 2018. This briefing paper mainly focuses on mesh procedures for stress urinary incontinence and pelvic organ prolapse but hernia repair using mesh is discussed in Section 8. There is a Westminster Hall debate on hernia mesh in men on 5 September 2019.

1. The use of mesh implants in stress urinary incontinence and pelvic organ prolapse

Concerns have been raised over procedures where mesh is used in surgery to treat pelvic organ prolapse and stress urinary incontinence. These procedures are currently subject to a high vigilance restriction period during which they will not be used for most women (for more information on this see section 5).

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:

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

- **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.
- **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 Mesh implant complications

There are some 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, nerve damage, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel.[5]

These sources provide more information about these complications:

- NHS, Pelvic organ prolapse, August 2019
- NHS England, Mesh complications, June 2017
- Royal College of Obstetricians and Gynaecologists, Mesh, April 2019

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.

4 NHS Choices, Urinary incontinence - Surgery and procedures, October 2016
5 NHS Choices, Pelvic organ prolapse, August 2015

2. Statistics on mesh complications for pelvic organ prolapse and stress urinary incontinence

The frequency of complications due to the use of mesh in urogynaecology procedures has been the subject of ongoing discussion. It has been 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. This lack of data on long term complications was also noted by NICE in its 2019 clinical guidance (see section 3).

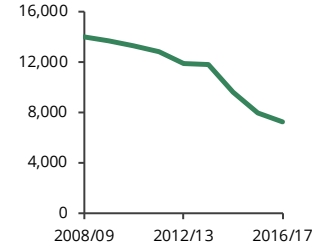
Patient groups, campaigners and some academics have said that complications are more common than the official figures.[6]

2.1 How many women have had mesh implant procedures?

NHS Digital have published experimental statistics on procedures involving surgical mesh or tape to treat stress urinary incontinence (SUI) and urogynaecology prolapse from 2008/09 to 2016/17[7].

Overall, a total of 100,516 patients had a tape insertion procedure for SUI. The number of procedures has fallen year on year from 13,990 in 2008/09 down to 7,245 in 2016/17.

SUI TAPE INSERTION PROCEDURES
England



Over the same period a total of 3,012 of these tapes were removed. The table below shows the number of removals in each year that can be linked back to the year the procedure was performed, highlighting those performed within 30 days of insertion and those after 30 days.

TAPE INSERTION PROCEDURES FOR STRESS URINARY INCONTINENCE (SUI)
England

		Subsequent removals			Removal rate		
	Procedures	Within 30 days	Over 30 days	Total removals	Within 30 days	Over 30 days	Total removals
2008/09	13,990	23	548	571	0.16%	3.9%	4.1%
2009/10	13,679	24	472	496	0.18%	3.5%	3.6%
2010/11	13,276	20	442	462	0.15%	3.3%	3.5%
2011/12	12,804	18	455	473	0.14%	3.6%	3.7%
2012/13	11,864	18	319	337	0.15%	2.7%	2.8%
2013/14	11,786	16	302	318	0.14%	2.6%	2.7%
2014/15	9,606	12	182	194	0.12%	1.9%	2.0%
2015/16	7,929	10	104	114	0.13%	1.3%	1.4%
2016/17	7,245	10	37	47	0.14%	0.5%	0.6%

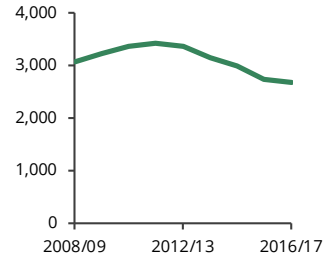
[6] The Guardian, Senior doctors call for public inquiry into use of vaginal mesh surgery in UK, 18 July 2017
[7] NHS Digital Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh: Hospital Episode Statistics (HES), Experimental Statistics, April 2008 - March 2017

Source: *Retrospective Review of Surgery for Urogynaecological Prolapse and SUI using Tape or Mesh*

A total of 27,016 patients had a mesh insertion procedure for orgynaecological prolapse between 2008/09 and 2016/17. The number of procedures increased from 3,073 in 2008/09 to 3,413 in 2011/12 but has since has fallen year on year down to 2,680 in 2016/17.

Over the same period a total of 247 mesh implants were removed. The table below shows the number of removals in each year that can be linked back to the year the procedure was performed.

MESH INSERTION FOR PROLAPSE
England



MESH INSERTION PROCEDURES FOR UROGYNAECOLOGICAL PROLAPSE
England

		Subsequent removals			Removal rate		
	Procedures	Within 30 days	Over 30 days	Total removals	Within 30 days	Over 30 days	Total removals
2008/09	3,073	1	53	54	0.03%	1.7%	1.8%
2009/10	3,219	0	51	51	0.00%	1.6%	1.6%
2010/11	3,356	0	52	52	0.00%	1.5%	1.5%
2011/12	3,413	2	35	37	0.06%	1.0%	1.1%
2012/13	3,353	0	30	30	0.00%	0.9%	0.9%
2013/14	3,141	0	8	8	0.00%	0.3%	0.3%
2014/15	2,993	0	8	8	0.00%	0.3%	0.3%
2015/16	2,738	0	7	7	0.00%	0.3%	0.3%
2016/17	2,680	0	0	0	0.00%	0.0%	0.0%

Source: *Retrospective Review of Surgery for Urogynaecological Prolapse and SUI using Tape or Mesh*

It is also possible to analyse the removal rate over time from the year of the initial procedure. The tables below show that for both conditions the removal rate (for removals over 30 days from insertion) is highest in the two years following the insertion.

REMOVAL RATE PER 1,000 TAPE INSERTION PROCEDURES FOR STRESS URINARY INCONTINENCE (SUI)
England

	Removal rate per year per 1,000 insertions that occurred within initial insertion year								
	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
2008/09	8.2	10.2	4.4	3.9	3.3	2.2	2.4	2.8	1.8
2009/10	_	7.4	10.3	5.0	2.9	2.4	2.4	2.3	1.8
2010/11	_	_	6.8	9.9	6.3	2.9	3.6	2.0	2.0
2011/12	_	_	_	7.7	13.1	6.1	3.4	2.4	2.8
2012/13	_	_	_	_	6.2	9.4	5.1	3.2	3.0
2013/14	_	_	_	_	_	5.9	10.9	5.2	3.6
2014/15	_	_	_	_	_	_	7.1	7.7	4.2
2015/16	_	_	_	_	_	_	_	5.8	7.3
2016/17	_	_	_	_	_	_	_	_	5.1

Source: *Retrospective Review of Surgery for Urogynaecological Prolapse and SUI using Tape or Mesh*

REMOVAL RATE PER 1,000 MESH INSERTION PROCEDURES FOR UROGYNAECOLOGICAL PROLAPSE
England

	Removal rate per year per 1,000 insertions that occurred within initial insertion year								
	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
2008/09	1.3	3.9	2.3	3.6	2.3	1.6	0.7	1.0	0.7
2009/10	_	2.2	3.1	2.2	1.9	1.2	2.2	2.5	0.6
2010/11	_	_	2.1	5.1	3.9	2.1	1.5	0.3	0.6
2011/12	_	_	_	2.3	2.6	2.9	0.9	0.9	0.6
2012/13	_	_	_	_	1.5	2.1	1.8	2.4	1.2
2013/14	_	_	_	_	_	0.6	0.3	1.3	0.3
2014/15	_	_	_	_	_	_	0.3	1.0	1.3
2015/16	_	_	_	_	_	_	_	0.7	1.8
2016/17	_	_	_	_	_	_	_	_	0.0

Source: *Retrospective Review of Surgery for Urogynaecological Prolapse and SUI using Tape or Mesh*

2.2 Comment on NHS statistics on mesh implant surgery and complications

Following the publication of the NHS digital statistics on mesh implant surgery, it was reported that the then Under-Secretary of State for Health, Lord O'Shaughnessy, said that he will ask the Chief Medical Officer, Professor Dame Sally Davies to discuss the statistics with relevant NHS bodies, surgical societies and patient groups and report back in a month. [8]

The Royal College of Obstetricians and Gynaecologists welcomed the review but said that it was difficult to make any clear conclusions from the data. It said it continued to call for mandatory data collection on surgical procedures using mesh implants through the BSUG database:

> "We welcome this retrospective review which provides some insight into the number of women who have undergone surgical procedures for the management of pelvic organ prolapse and stress urinary incontinence, including operations in which mesh or tape was utilised. However, the data contained within the report provide only a 'snap shot' from which it is difficult to extrapolate any clear conclusions relating to the number and severity of surgical complications.
>
> "The results of this report confirm findings from other published studies which show that mesh and tape removal has decreased significantly over the last decade, with less than 2% of patients requiring mesh or tape removal. These figures therefore provide support for the use of mesh in carefully selected patients. Unfortunately, retrospective data collection cannot inform us why patients underwent subsequent surgical procedures, including mesh removal.
>
> "The report also highlights a clear decline in the number of women who have undergone urogynacological surgery between 2008 and 2017. It is impossible for the review to show why this decrease has occurred - it may be because of alternative therapeutic interventions or better prevention.
>
> "Women with urinary incontinence or pelvic organ prolapse must be made aware of all the treatment options available and empowered with the information they need in order to make informed choices appropriate to their lifestyle. It is important that all women who experience complications relating to mesh devices are referred via their GP to a specialist unit with a multi-disciplinary team of professionals who can listen, advise and support them.
>
> "The RCOG and The British Society of Urogynaecology (BSUG) continue to call for mandatory prospective data collection through the BSUG database, a well-established method of collecting outcome data for all urogynaecological procedures, including mesh. This would give more accurate information regarding outcomes, including both success and complication rates, and provide comprehensive data to inform women and healthcare professionals about the benefits and risks of all urogynaecological procedures." [9]

It was reported that the founder of the Sling the Mesh campaign group, Kath Sansom, has said that the Government had "selectively used figures" in the review, and had not included private patients or women attending their GP with symptoms from mesh complications:

> Commenting on the report, Kath Sansom, founder of the Sling The Mesh campaign group, said: "The government has selectively used figures in a bid to make mesh risk

8 Scale of vaginal mesh problem confirmed by NHS review, The Guardian, 18 April 2018
9 RCOG, RCOG statement in response to NHS mesh review, 18 April 2018

> look low, and have presented it in such a confusing way that to a unexperienced reader they will think mesh is not a problem.
>
> "It has not included private patients or women going to GPs for pain medication or antibiotics to treat painful urinary infections, so there are thousands not included in this data.
>
> "This audit has no information on the devastating social and psychological impact on women – we ran a survey that shows one-in-three women in our group of 6,000 have had to stop work, and one in five reduced their hours due to disability or pain.
>
> "We demand a national recall urgently before hundreds more women are maimed by mesh." [10]

2.3 Adverse outcomes

There are some 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 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.

A recent metanalysis of 175 published studies on surgery for urinary incontinence, Imamura et al (2019), commented on the limited availability of good quality data on long term impacts of mesh implants. The authors called for standardised data collection regarding procedures and core outcomes in order to effectively evaluate surgery for stress urinary incontinence.

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[10] Hundreds of women each year need vaginal mesh implants removed, NHS audit finds, The Independent, 18 April 2018

3. NICE 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.

This section provides information on two different types of relevant NICE guidance:

- Interventional procedure guidance that provides specific guidance on procedures using mesh implants; and
- A NICE guideline, which provides evidence-based recommendations on the care and services suitable for individuals with a certain condition.

3.1 Interventional procedures guidance

NICE has published interventional procedures guidance for a number of procedures using surgical mesh. It explained 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.[11]

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.[12]

It also responded to suggestions at the time from media reports that the recommendations in the guidance constituted a ban on the use of this procedure, saying that the procedure should only be used in the context of research:

> 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.[13]

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11 NICE, Interventional procedures recommendations (accessed 20 December 2017)
12 NICE, Mesh for vaginal wall prolapse should only be used in the context of research, says NICE, 15 December 2017
13 NICE, Mesh for vaginal wall prolapse should only be used in the context of research, says NICE, 15 December 2017

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)

3.2 2019 NICE guidelines

NICE published guidance on Urinary incontinence and pelvic organ prolapse in women: management in April 2019. This provides recommendations on the assessment and treatment of women with these conditions and the treatment of mesh related complications.

The guidance notes that there are public concerns about mesh surgical procedures for these conditions. It states the following about evidence on long term adverse effects of all procedures in the guidance:

> For all of the procedures recommended in this section, including mesh procedures, there is evidence of benefit but limited evidence on the long-term adverse effects. In particular, the true prevalence of long-term complications is unknown.[14]

The guidelines advise that where a surgical procedure is being considered, clinicians use NICE patient decisions aids with patients in order to promote informed consent and shared decision making.[15]

> If a woman is thinking about a surgical procedure for stress urinary incontinence, use the NICE patient decision aid on surgery for stress urinary incontinence to promote informed preference and shared decision making. Discussion with the woman should include:
>
> - the benefits and risks of all surgical treatment options for stress urinary incontinence that NICE recommends, whether or not they are available locally
> - the uncertainties about the long-term adverse effects for all procedures, particularly those involving the implantation of mesh materials
> - differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period
> - any social or psychological factors that may affect the woman's decision

14 NICE, Urinary incontinence and pelvic organ prolapse in women: management, April 2019
15 NICE, Surgery for stress urinary incontinence: Patient decision aid, 2019

The public information section of the guidelines provides the following about mesh surgery:

> Surgery with mesh
>
> One type of surgery that is used to treat stress urinary incontinence and pelvic organ prolapse involves inserting a piece of synthetic mesh. For a few women, surgery with mesh has led to serious complications. Some, but not all, of these complications can also happen after other types of surgery for these conditions.
>
> NICE has recommended that doctors have an in-depth discussion with women about the risks and benefits of different types of surgery, including surgery with mesh, before they decide whether one of these could be an option for them. NICE has also said that doctors must keep detailed records about the surgery they do for these conditions, including any complications women develop after they've had their surgery. Doctors should give each woman a copy of her record. The guideline also includes advice on the best care for women who have complications after surgery with mesh.

The guidance also recommends the establishment of a national registry for women who have had surgery for stress urinary incontinence and pelvic organ prolapse. It advises that this should ensure that follow up data is collected on key short- and long-term outcomes. It states that the registry should report annually (see section 4.2).

Concerns about the guidelines

Following the publication of the 2019 NICE guidelines in April 2019, concerns were expressed that they had changed the previous recommendation about only using transvaginal mesh procedures in pelvic organ prolapse in research.[16] In response to these concerns, the Independent Medicines and Medical Devices review ((MDDR) see section 5) wrote to NICE to seek clarification. In June 2019, the MDDR reported that NICE had responded to their correspondence and confirmed that the research only restriction still applied and that the guidance had been updated:

> NICE have confirmed to us that the 'research only' restriction still stands in relation to vaginally inserted mesh (synthetic polypropylene or biological) surgery for the treatment of vaginal wall prolapse. They recognised that the wording of the latest guidelines did not convey this clearly.

[16] Harriet Pike, NICE guidance overlooks serious risks of mesh surgery, BMJ, 2 April 2019

4. Medicines and medical devices safety review

On 21 February 2018, the then Secretary of State for Health and Social Care, Jeremy Hunt, announced an independent review on medicines and medical device safety. He highlighted three issues of concern: the use of primodos (the hormone pregnancy test), use of the anti-epileptic drug sodium valproate in pregnancy; and the use of vaginal mesh.

With regards to vaginal mesh complications, Mr Hunt reported that the Government would be publishing a retrospective audit of complications and developing a database to improve clinical practice:

> […] I asked the chief medical officer for advice in the light of calls for a full ban. She has been clear that clinical experts here and abroad agree that, when used appropriately, many women gain benefit from this intervention, hence a full ban is not the right answer in the light of the current evidence available. However, this is not to minimise the suffering many women have experienced, which is why today I can announce that we will be publishing a retrospective audit to investigate the links between patient-level data to explore outcomes, and investing £1.1 million to develop a comprehensive database for vaginal mesh to improve clinical practice and identify issues.[17]

He said that the review, led by Baroness Cumberlege, would look at what had happened in the three cases above, and make recommendations on future action:

> To do better in the future, we need to ensure that patient voices are bought to the table as systematically and consistently as other voices in the system, so today I have asked Baroness Julia Cumberlege to conduct a review into what happened in each of these three cases, including whether the processes pursued to date have been sufficient and satisfactory, and to make recommendations on what should happen in future. She will assess, first, the robustness and speed the of processes followed by the relevant authorities and clinical bodies to ensure that appropriate processes were followed when safety concerns were raised; secondly, whether the regulators and NHS bodies did enough to engage with those affected to ensure their concerns were escalated and acted upon; thirdly, whether there has been sufficient co-ordination between relevant bodies and the groups raising concerns; and fourthly, whether we need an independent system to decide what further action may be required either in these cases or in the future. This is because one of the judgments to be made is whether, when there has been widespread harm, there needs to be a fuller, or even statutory, public inquiry. Baroness Cumberlege will make recommendations on the right process to make sure that justice is done and to maintain public confidence that such decisions have been taken fairly.[18]

The scope of the review sets out what it intends to do with regards to each of the issues set out above. It states that, with reference to mesh surgical procedures:

> Abdominal and vaginal pelvic mesh procedures[1]
>
> - whether the scientific evidence underpinning current regulatory and clinical practice fully and properly reflects:
>   - the long term quality of life impact where there are adverse complications following these pelvic mesh procedures;
>   - the innate properties of the polymeric material currently in use in the manufacture of pelvic mesh products and what is known about how

17 HC Deb 21 February 2018, c165
18 HC Deb 21 February 2018, c166

those properties change once the mesh has been implanted in the human body and over time; and

- the risks associated with the procedures themselves in comparison with the alternative available options.

- the circumstances of the synthetic pelvic mesh medical device regulation, approval and adverse effects reporting to date.[19]

4.1 Halt in the use of mesh in stress urinary incontinence

In July 2018, the Independent Medicines and Medical Devices Safety Review called for the immediate halt of the use of surgical mesh in stress urinary incontinence procedures.

The Chair of the Review, Baroness Cumberlege, said that the decision had made following the evidence heard by the review about the experiences of complications after these procedures:

> "We strongly believe that mesh must not be used to treat women with stress urinary incontinence until we can manage the risk of complications much more effectively. We have not seen evidence on the benefits of mesh that outweighs the severity of human suffering caused by mesh complications.
>
> "I have been appalled at the seriousness and scale of the tragic stories we have heard from women and their families. We have heard from many women who are suffering terribly. Their bravery and dignity in speaking out is deeply moving, and their sadness, anger, pain and frustration at what has happened to them and others has been compelling. We had to act now.
>
> "My team and I are in no doubt that this pause is necessary. We must stop exposing women to the risk of life-changing and life-threatening injuries. We must have measures in place to mitigate the risk, and those are sadly lacking at the moment.
>
> "At this stage in our Review we are not recommending a ban, but a halt to procedures until the conditions we have laid down are met. I am pleased that both the Department of Health & Social Care and NHS England support our recommendation, and I look forward to its quick implementation."
>
> This follows NICE's 2017 guidance that mesh for vaginal wall prolapse should only be used in the context of research. In 2014 the Scottish government put in place a suspension in the use of mesh for SUI[20]

The Department of Health and Social care accepted this recommendation. On 17 July, it stated that the pause included all procedures where mesh is inserted vaginally to treat stress urinary incontinence and pelvic organ prolapse.[21]

A letter from NHS England to all acute NHS trusts set out that a high vigilance restriction period would apply to these procedures. This would mean that for most women, there would be a delay in having the procedures until the pause was ended, or an alternative procedure may be used. However, the high vigilance restriction would not mean a blanket ban on these surgeries. For some patients, mesh procedures would be the only viable treatment but this would only be used for a "group of carefully selected patients who understand the risks."[22]

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19 The Independent Medicines and Medical devices Safety review, Terms of Reference, 2018
20 The Independent Medicines and Medical devices Safety review, News: Independent Review calls for immediate halt of the use of surgical mesh for stress urinary incontinence, 10 July 2018
21 Department of Health and Social Care, Government announces strict rules for the use of vaginal mesh, 11 July 2018
22 NHS England, Letter to Acute trusts: Vaginal mesh: High vigilance restriction period, 9 July 2018

The letter sets out that the restrictions would remain in place until the following conditions are met:

> a. Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly.
>
> b. Surgeons report every procedure to a national database.
>
> c. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery.
>
> d. Reporting of complications via MHRA is linked to the register.
>
> e. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh.
>
> f. NICE guidelines on the use of mesh for SUI are published.[23]

In response to the recommendations from the MDDR, the Welsh Cabinet Secretary for Health and Social Services, Vaughne Gething said that the evidence was of a significant reduction in the use of vaginal mesh procedures in Wales already but that the Chief Medical Officer would be writing to health boards in Wales to ensure that medical directors were aware of the Baroness Cumberlege's recommendations and that these were consistent with the Wales review panels recommendations.[24]

The Chief Medical Officer in Northern Ireland, Dr Michael McBride also wrote to NHS trusts in July 2018 asking them to implement a pause in the use of surgical mesh and tape in stress urinary incontinence.[25]

In September 2018, the Cabinet Secretary for Health and Sport in Scotland, Jeane Freeman, announced a halt in the use of transvaginal mesh surgical procedures.[26] She said that mesh implants should only be used in the most exceptional circumstances, and the instruction to halt was a proportional measure whilst a high vigilance 'restrictive use Protocol' was put in place.[27]

The halt on the use of mesh remains in place at the time of writing.

4.2 National device registry

There have been a number of calls for a national register of mesh devices which would collect information on procedures and complications. This has been raised by the MDDR, and is one of the requirements prior to the restrictions being lifted on procedures. It has also been recommended by NICE in its 2019 guidelines, and by patient groups, clinicians and academics.

In February 2018, Jeremy Hunt announced Government funding to develop a comprehensive database for vaginal mesh. In response to a debate on medical devices in February 2019, the then Under-Secretary of State for Health, Jacqui Doyle-Price said that this issue was under consideration by the Department of Health and Social Care:

> The hon. Gentleman and the right hon. Member for Cynon Valley (Ann Clwyd) mentioned the issue of the national devices registry. I will say, up front, that I can assure them that this matter is already under consideration by the Department and it

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23 ibid.
24 Welsh Government, Written Statement - Baroness Cumberlege's announcement on the use of surgical mesh, 11 July 2018
25 Northern Ireland Department of Health, Letter from Chief Medical officer, 11 July 2018
26 Scottish Government, Halt in use of transvaginal mesh, 12 September 2018
27 Scottish Government, Halt in use of transvaginal mesh, 12 September 2018

> is linked to our wider digitisation agenda for the NHS. We have the technology and we should use it, in the interests of patient safety. We will be implementing that under new EU regulations to trace medical devices through unique device identifiers. I would be more than happy to meet him at a later date as we progress these proposals. As we depart from the European Union, we have an opportunity to alter our regulatory system. I am not sure that all my Conservative colleagues, in pushing Brexit, see it as an opportunity to tighten regulation, but that opportunity remains, so I look forward to that dialogue.[28]

[28] HC Deb 12 February 2019 C862

5. 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 December 2017 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 group of BMJ articles published in October 2018 provide commentary on the development, use and regulation of mesh implants. These raise a number of concerns, from conflicts of interest and industry funding in the initial research on the use of mesh implants in the treatment of stress urinary incontinence to a failure by the medical profession to ensure the collection of data on mesh operations and complications.[29]

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.[30]

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. [31] 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[32] and can be marketed and sold anywhere in the EU.

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29 Jonathan Gornall, The trial that launched millions of mesh implant procedures: did money compromise the outcome? BMJ, 10 October 2018

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

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

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

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.[33]

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. […][34]

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.[35] 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.[36]

The Government has said that, following the UK leaving the EU, that it intends to fully align the UK with the new EU Medical devices regulations.[37] The MHRA has reported that its preparations to implement both medical devices regulations continue.[38]

- 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

33 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

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

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

36 Ibid.

37 Commons Written Question 278523, 25 July 2019, and HL Deb 28 February 2019 c357

38 MHRA, MHRA and making a success of Brexit, updated January 2019

5.1 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.[39]

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).[40]

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.

5.2 Concerns about mesh device regulation

Patient groups and others have criticised reviews on the use of mesh implants, such as that undertaken by NHS England, 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

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39 MHRA, Guidance: Medical devices: how to comply with the legal requirements, 2013
40 RCOG, Mesh

for gaining marketing authorisation for implantable devices. They recommended the setting up of a patient registry to enable long term follow up and surveillance.[41]

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 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.[42]

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."[43]

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 2019.

A group of BMJ articles published in October 2018 provide commentary on the development, use and regulation of mesh implants.[44] These raise a number of concerns, from conflicts of interest and industry funding in the initial research on the use of mesh implants in the treatment of stress urinary incontinence to a failure by the medical profession to ensure the collection of data on mesh operations and complications.[45] In an editorial, the BMJ editor in chief, Fiona Godlee, and Carl Heneghan, Professor of Evidence Based Medicine at Oxford University describe the post marketing assessment of vaginal mesh as "a shameful episode in the history of implantable devices." They state that a mandatory device registry is long overdue.[46]

Government response

In response to a debate on medical devices in February 2019, the then Under-Secretary of State for Health, Jacqui Doyle-Price said that it was fair to say that in the past regulation

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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 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

43 Ibid.

44 BMJ, Investigation exposes vaginal mesh "scandal" that has left thousands of women irreversibly harmed [accessed 4 September 2019]

45 Jonathan Gornall, The trial that launched millions of mesh implant procedures: did money compromise the outcome? BMJ, 10 October 2018

46 Carl Heneghan and Fiona Godlee, Editorial: Surgical mesh and patient safety, BMJ, 10 October 2018

had perhaps "focused excessively on what is in the commercial interests of businesses to maintain competition rather than having patient safety at its heart:"

> The hon. Gentleman has highlighted some of the weaknesses. It is fair to say that perhaps in the past regulation has focused excessively on what is in the commercial interests of businesses to maintain competition, rather than having patient safety at its heart; I think that, when it comes to medical regulation, it should have that at its heart. Naturally, he referred to mesh, which he and I have discussed many times before. There is no doubt that mesh has transformed the lives of some women when they were living with the debilitating consequences of stress incontinence, but it is becoming clear that mesh was deployed far too insensibly—far too many women were given this treatment, often at comparatively young ages, given that this was going to stay in their body for a long time.
>
> I do not want to pre-empt what will come out of the Cumberlege review, but I have discussed some of the findings with Baroness Cumberlege. On the whole issue of how our medical establishment have dealt with this, the conversations that have taken place with women who were having this treatment were utterly inadequate and we will learn many lessons. I say to those women who have suffered badly at the hands of mesh treatment that there are clear medical criteria relating to that product and, if they have any complaint about the treatment they have received, they should be pursuing claims for clinical negligence against their practitioners. We look forward to the conclusions of Baroness Cumberlege's review.[47]

She went on to state that the existing system of regulation needed to be improved and highlighted the new EU Regulations. She said that the Government would implement the changes introduced by the EU regulations and were confident that this would drive system-wide improvement. She also said that, in advance of this, the Government were taking actions to ensure the existing legislation is working as effectively as possible.

47 HC Deb 12 February 2019 C862

6. Previous reviews of vaginal 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. A recent one 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 May 2018, a Welsh Task and Finish Group published its report on the use of synthetic tape and mesh sheets for stress urinary incontinence and pelvic organ prolapse in Wales. This made a number of recommendations which it states seek to introduce a new innovate pathway for the care of patients with stress urinary incontinence and pelvic organ prolapse in Wales.

Patient groups have expressed concerns about the findings of 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.[48]

6.1 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.

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.

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

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.[49]

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.[50] 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;
- 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

49 NHS England, Mesh working group: Interim Report, December 2015
50 NHS England, Mesh Oversight Group Report, July 2017

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.[51]

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.'[52] It has also

[51] MHRA, MHRA response to the final report of the Mesh Oversight Group, 26 July 2017
[52] BMJ, Patients cry "whitewash" as NHS refuses to halt use of mesh implants, 26 July 2017

been reported that patient representatives had resigned from the group prior to publication.[53]

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. [54]

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." [55]

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." [56]

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

6.2 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.[57]

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.

6.3 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.
> - 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.

[57] MHRA, A summary of the evidence on the benefits and risks of vaginal mesh implants, 2014

- 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.[58]

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

6.4 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.*"[59]

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.

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

59 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

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.[60]

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. [61]

6.5 Welsh Government review 2018

In October 2017, the Cabinet Secretary for Health and Social Services in Wales requested that a Task and Finish Group be established to review the use of synthetic tape and mesh sheets for stress urinary incontinence and pelvic organ prolapse in Wales. The group consisted of clinicians and academics working in urogynaecology, pain management, physiotherapy and continence.

The report was published in May 2018. It notes a limitation to the data on the complications associated with mesh procedures. It makes a number of recommendations which it states seek to introduce a new innovate pathway for the care of patients with stress urinary incontinence and pelvic organ prolapse in Wales:

> This incorporates the principles of increased promotion of specialist services for continence, physiotherapy and chronic pain as a preventative, out of hospital care approach for incontinence and prolapse, with surgery as a last resort. This could be part of a new 'pelvic health and wellbeing' pathway. Also, the group believes that proposed improvements to patient information for patients in Wales will lead to better decision making and a more robust consent process.
>
> The group further recognised the need for improvements to data capture of procedures performed, devices used, complications reported and access to specialist support for patients in the event that they experience problems or have concerns. The report includes some short term clinical coding initiatives and an opportunity to ensure all professionals have knowledge of services available that could quickly improve this situation whilst a longer term solution is pursued.[62]

Following the publication of the report, in a Statement to the Welsh Assembly, the Cabinet Secretary, Vaughne Gething said that a fundamental change was needed to the way in which the NHS supports women with pelvic health problems. He said he was establishing a ministerial directed implementation group to implement the recommendations of the task and finish group.[63]

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60 Scottish Parliament OR Public Petitions Committee, 18 May 2017, c24
61 SP WA 14 December 2017, s50-01581
62 Report of the Welsh Task and Finish Group to Review the Use of Vaginal Synthetic Mesh Tape and Sheets for Stress Urinary Incontinence and Pelvic Organ Prolapse, May 2018
63 Statement by the Cabinet Secretary for Health and Social Services: The Report of the Welsh Task and Finish Group to Review the Use of Vaginal Synthetic Mesh, 8 May 2019

7. International action

This section provides some examples of international action on mesh implants used in stress urinary incontinence and pelvic organ prolapse.

7.1 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.[64]

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.[65]

However, a 2017 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 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.[66]

The deadline for submissions of applications for premarket approval of mesh devices used in POP procedures was July 2018. All companies that had not submitted this information by this time were required to remove their products from the market.

In April 2019, the FDA asked the manufacturers of all remaining surgical mesh implants used in transvaginal repair of POP to remove these from the market. It stated that it had determined that the manufacturers "have not demonstrated a reasonable assurance of safety and effectiveness for these devices, which is the premarket review standard that now applies to them since the agency reclassified them in class III (high risk) in 2016."[67]

7.2 Australia

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.[68]

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

65 Ibid.

66 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

67 FDA, FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices, 16 April 2019

68 TGA, TGA actions after review into urogynaecological surgical mesh implants, May 2019

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."[69] 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."[70]

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

7.3 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.

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. [71]

[69] Ibid.
[70] Ibid.
[71] Ministry of Health New Zealand, Medsafe introduces surgical mesh restrictions, 11 December 2017

8. The use of mesh in hernia repairs

8.1 Hernias

A hernia is where an internal part of the body protrudes through a weakness in the muscle or surrounding tissue wall.

There are a number of different kinds of hernia, including:

- Inguinal hernia: where tissue/bowel protrudes through into the groin at the top of your thigh. This is the most common type of hernia and mainly affects men.
- Femoral hernia: where tissue/bowel protrudes through into the groin, similar to inguinal hernias but are less common and affect more women than men. Both femoral and inguinal hernias are called groin hernias.
- Umbilical hernia: where tissue or bowel protrudes through the abdomen near the umbilicus (tummy button/navel). These can affect babies as well as adults.
- Incisional hernia: where tissue protrudes through a surgical wound in the abdomen that has not fully healed

For more information on these and less common types of hernia, see the NHS website.

8.2 Treatment for hernias

When a hernia has been diagnosed, it will be determined whether this should be repaired surgically. In some cases, whilst the hernia will not get better without treatment, it will not get any worse.

An assessment will be made about the benefits and risks of any surgery. The NHS website lists the following factors that may be considered as part of this assessment:

- the type of hernia – some types of hernia are more likely to become strangulated or cause a bowel obstruction than others
- the content of your hernia – if the hernia contains a part of your bowel, muscle or other tissue, there may be a risk of strangulation or obstruction
- your symptoms and the impact on your daily life – surgery may be recommended if your symptoms are severe or getting worse, or if the hernia is affecting your ability to carry out your normal activities
- your general health – surgery may be too much of a risk if your general health is poor[72]

When a decision is made to proceed with a surgical repair, this can be done using a laparoscopic (Keyhole) approach which can be less invasive but more difficult, or an open surgery.

8.3 The use of mesh in hernia repair surgery

The British Hernia Society provides a 2018 information leaflet for patients on the use of mesh in hernia repair surgery. This states that hernia can be repaired using a technique that uses mesh, or one where the defect in the abdominal wall is repaired using stitches.

It provides the following information on the use of mesh in groin hernia repairs:

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72 NHS, Hernia, 19 June 2019

Surgical mesh, regulations and safety

The use of mesh to repair the majority of hernias has been the preferred method in the UK and worldwide for over 25 years. There is a large volume of data on the outcome of various hernia operations and different meshes. Indeed when surgeons themselves have hernias they opt for mesh repairs. Meshes used in surgery are tightly regulated and require a CE-mark to be used in patients in the European Union. Patient safety is a critical component of this regulation and regulatory compliance is subject to periodic reviews by authorities in the EU.

Is a repair with mesh a 'gold standard?'

Many patients who develop a hernia, have a 'tissue weakness' which doesn't hold stitches well. This explains why repairs with stitches have a higher failure rate than those with additional mesh. For the vast majority of patients, mesh poses little if any additional risk, and coupled with a lower recurrence rate, has resulted in the use of mesh becoming the gold standard in hernia repairs.

Are there disadvantages to a mesh repair?

Mesh is foreign material, like any synthetic implant (dentures, crowns, heart valves etc). It can become infected but this is a rare event. Some patients can develop chronic pain after surgery. There is no firm relationship with the use of mesh and chronic pain, and non-mesh repairs can equally result in this problem.[73]

Clinical guidelines

There are National Institute of Health and Care Excellence (NICE) clinical guidelines on hernia repair. The most recent guidance on this, Laparoscopic surgery for inguinal hernia repair was published in 2004. The guidance comments on the different methods of repair for inguinal hernias but looks at the evidence on laparoscopic vs open repair rather than focusing on mesh vs non-mesh approaches.

International guidelines on hernia repair surgery were published by the HerniaSurge group (An expert group of international surgeons with specific experience in hernia-related research) and endorsed by international hernia societies and surgical organisations in 2018. These guidelines discuss a number of different surgical approaches to hernia repair. However, they state that there was a consensus for a 'strong' recommendation, based on the evidence, to use a mesh-based technique.[74]

8.4 Statistics on hernia procedures.[75]

In England, over 80% of hernia procedures each year involve prosthetic materials (including all mesh implants). The table below shows a brief time series of the number of these procedures carried out for different types of hernia.

Overall, the number of procedures peaked in 2014/15 at just under 99,300 and has since fallen to the most recent figure of around 91,700 in 2017/18.

[73] British Hernia Society, Mesh and your Hernia Repair, November 2018
[74] The HerniaSurge Group, International guidelines for groin hernia management, Hernia (2018) 22:1–165
[75] Details of the OPCS-4 codes used to compile the statistics in the section are lists in Appendix 1

HERNIA PROCEDURES INVOLVING PROSTHETIC MATERIAL
England

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Primary repair of inginal hernia	62,362	61,280	65,760	65,813	62,745	63,388	60,350
Repair of recurrent inginal hernia	5,287	5,176	5,610	5,538	5,295	5,256	5,185
Primary repair of femoral hernia	1,490	1,491	1,586	1,641	1,629	1,720	1,571
Repair of recurrent femoral hernia	124	136	143	106	151	147	142
Primary repair of umbilical hernia	10,338	10,518	11,000	11,484	11,192	11,270	10,491
Repair of recurrent umbilical hernia	1,001	1,016	1,073	1,105	1,067	1,139	1,053
Primary repair of incisional hernia	6,617	6,587	6,988	6,722	6,470	7,351	6,962
Repair of recurrent incisional hernia	1,334	1,281	1,297	1,334	1,298	1,477	1,365
Primary repair of ventral hernia	4,506	4,677	4,833	4,878	4,900	4,130	4,047
Repair of recurrent umbilical hernia	417	533	572	645	654	530	507
Total	**93,476**	**92,695**	**98,862**	**99,266**	**95,401**	**96,408**	**91,673**

Source: NHS Digital Hospital Episode Statistics

Figures are also available on the number of removals of prosthetic materials used in previous hernia procedures. The table below shows that the number of removals fell from 437 in 2011/12 down to 342 in 2017/18. Please note that these removals do not necessarily relate to the procedures shown in the table above. The date of the initial procedure is not recorded and it is possible that removals may relate to procedures carried out in earlier years.

REMOVAL OF PROSTHETIC MATERIALS FROM HERNIA PROCEDURES
England

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Inguinal hernia	111	115	110	104	106	84	96
Femoral hernia	10	9	6	9	2	5	5
Umbilical hernia	101	107	106	90	142	106	99
Incisional hernia	138	135	118	101	100	123	101
Ventral hernia	77	55	63	63	46	46	41
Total	**437**	**421**	**403**	**367**	**396**	**364**	**342**

Source: NHS Digital Hospital Episode Statistics

Other hernia procedures involve the use of natural materials or sutures as shown in the tables below.

HERNIA PROCEDURES INVOLVING NATURAL MATERIAL
England

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Primary repair of inginal hernia	320	296	157	153	150	182	154
Repair of recurrent inginal hernia	26	44	39	24	34	27	22
Primary repair of femoral hernia	30	21	29	17	16	10	8
Repair of recurrent femoral hernia	3	2	4	2	1	3	3
Primary repair of umbilical hernia	107	86	70	82	81	81	66
Repair of recurrent umbilical hernia	13	9	10	10	14	13	8
Primary repair of incisional hernia	87	81	99	129	119	143	124
Repair of recurrent incisional hernia	28	32	23	51	39	61	41
Primary repair of ventral hernia	71	67	70	68	74	42	47
Repair of recurrent umbilical hernia	12	17	15	23	18	10	11
Total	**697**	**655**	**516**	**559**	**546**	**572**	**484**

Source: NHS Digital Hospital Episode Statistics

HERNIA PROCEDURES INVOLVING SUTURES
England

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Primary repair of inginual hernia	2,374	2,303	2,380	2,517	2,564	2,572	2,402
Repair of recurrent inginual hernia	283	260	250	260	274	242	229
Primary repair of femoral hernia	1,429	1,403	1,471	1,536	1,412	1,471	1,486
Repair of recurrent femoral hernia	43	59	68	54	62	67	65
Primary repair of umbilical hernia	8,811	8,957	9,750	10,185	10,254	11,002	10,994
Repair of recurrent umbilical hernia	240	255	294	327	293	363	341
Primary repair of incisional hernia	1,230	1,343	1,377	1,579	1,620	1,935	2,016
Repair of recurrent incisional hernia	160	148	175	165	198	221	243
Primary repair of ventral hernia	2,564	2,722	3,003	2,931	2,993	3,180	3,146
Repair of recurrent umbilical hernia	72	108	111	122	113	122	120
Total	**17,206**	**17,558**	**18,879**	**19,676**	**19,783**	**21,175**	**21,042**

Source: NHS Digital Hospital Episode Statistics

8.5 Investigation into hernia mesh complications

In September 2018, a BBC Victoria Derbyshire investigation reported that up to 170,000 individuals could have been affected by hernia mesh complications following surgery in the last 6 years.[76]

It reported that NHS digital figures showed that 570,000 hernia mesh repairs had taken place during that time, and that leading surgeons believe the complication rate is 12-30%- meaning that 68,000 to 170,000 people could be affected.

The article stated that NHS trusts in England have no consistent policy for guidelines on treatment or follow-up with patients.

In response to these concerns, the Royal College of Surgeons published a statement about hernia mesh complications.[77] This stated that it was tragic if even one person experiences a complication, but that surgery carries with it a risk of complications:

> "It is clearly tragic if even a single patient suffers horrible complications from any type of surgery, not just hernia operations. Unfortunately the nature of surgery in general, not just mesh surgery, carries with it an inherent risk of complications which surgeons will always seek to assess, and will discuss with patients according to their individual clinical circumstances before surgery takes place.[78]

The statement also said it was important to distinguish between groin hernias and repairs for other abdominal wall hernias where complications rates may be higher. It also stated that it was important to stress that complications can range from minor to more serious and can occur in surgery where mesh is not used.:

> "It is important to make a distinction between groin hernia, the most commonly carried out repair and other forms of abdominal wall repair where a hernia has arisen, for example, in an incision or scar after a previous operation. These are more difficult and the complications rates are much higher.
>
> "A recent 2018 study found that both mesh and non-mesh hernia repairs were effective for patients and are not associated with different rates of chronic pain. The Victoria Derbyshire programme is right to point out how a minority of hernia mesh operations are associated with complications. However, it is also important to stress that such complications range dramatically from minor and correctable irritations to the more serious complications highlighted in its programme. Complications can also occur with non-mesh hernia repairs, and by not operating on a hernia at all. It is

[76] Anna Collinson and Jessica Furst, Hernia mesh complications 'affect more than 100,000', BBC News, 26 September 2018
[77] Royal College of Surgeons, RCS statement on hernia mesh complications, 26 September 2018
[78] Ibid.

> extremely important that patients are given the full picture by surgeons, regulators, and the media.[79]

The statement sets out that there have already been a number of scientific reviews in this area, and it is important to keep reviewing the evidence on this issue:

> "There have already been a number of scientific studies looking at the use of different types of mesh in hernia and we should continue to review the evidence and patients' experiences to make sure the right advice is given and the right action is taken. Along with the regulatory authorities, we will continue to listen to patients' experiences. Patients suffering complications or pain need help, not silence. There must also be an ongoing review of the data to make sure that previous studies have not missed any serious, widespread issue. It remains vital that surgeons continue to make patients aware of all the possible side effects associated with performing a hernia repair."

A BMJ article on the investigation reported that Kath Samson, founder of the campaign group, Sling the Mesh, had said that a lot of the studies looking at the complications "were flawed or had short follow-up times."

The BMJ also quoted the following response from the MHRA on the BBC findings:

> In a statement, the MHRA said: "We have not had any evidence that would lead us to alter our stance on surgical mesh for hernia repairs or other surgical procedures for which they are used. The decision to use mesh should be made between patient and clinician, recognising the benefits and risks in the context of the conditions being treated and in line with NICE guidance."
>
> An MHRA spokesperson added, "We encourage anyone—patient, carer, or healthcare professional—who is aware of a complication after a medical device is implanted, to report to us via the yellow card scheme, regardless of how long ago the implant was inserted."[80]

8.6 Reviews of complications associated with mesh hernia repairs

Cochrane review

A Cochrane review on the outcomes of surgical groin hernia repair with or without mesh was published in September 2018.[81]

The authors concluded that overall, both repairs with and without mesh were effective in the treatment of groin hernias but that mesh repairs "demonstrated fewer hernia recurrences, a shorter operation time and faster return to normal activities:"

> Mesh and non-mesh repairs are effective surgical approaches in treating hernias, each demonstrating benefits in different areas. Compared to non-mesh repairs, mesh repairs probably reduce the rate of hernia recurrence, and reduce visceral or neurovascular injuries, making mesh repair a common repair approach. Mesh repairs may result in a reduced length of hospital stay and time to return to activities of daily living, but these results are uncertain due to variation in the results of the studies. Non-mesh repair is less likely to cause seroma formation and has been favoured in low-income countries due to low cost and reduced availability of mesh materials. Risk of bias in the included studies was low to moderate and generally handled well by

79 Ibid
80 Jacqui Wise, Hernia mesh complications may have affected up to 170 000 patients, investigation finds, BMJ, 27 September 2018
81 Cochrane, Comparing surgical groin hernia repair performed with or without mesh, 13 September 2018

> study authors, with attention to details of allocation, blinding, attrition and reporting.[82]

Welsh Chief Medical Officer review

In January 2019, a Welsh Deputy Chief Medical Officer (DCMO) review of the use of mesh hernia repair was published.[83] This followed a request from the Cabinet Secretary for Health and Social Services, Vaughne Gething.

The review looked at the Welsh data on hernia repairs, clinical guidelines and undertook a literature review looking at complications from hernia repairs. It concluded that, in contrast to the findings related to the use of vaginal mesh, "the available statistical and clinical evidence does not support the view that the routine use of mesh in hernia repair is a serious problem for the population of Wales." The DCMO stated that:

> There are risks of complications associated with these operations, as there is with any interventional medical procedure, but the current evidence and available statistics do not support the concern the complications are in excess of what would be expected.
>
> My recommendation is that there is presently no evidence to suggest that further work is necessary but of course, the situation needs to be observed and would need a further review if the evidence changes or in any way suggests the need.
>
> I therefore advise we follow the cautionary approach proposed by the Royal College of Surgeons.

[82] Ibid.
[83] Welsh Government, Deputy Chief Medical Officer Review: Use of Hernia Mesh, January 2019

Appendix 1: OPCS Classification of Interventions and Procedures (OPCS-4) codes used in statistical tables

T20.1	Primary repair of inguinal hernia using insert of natural material
T20.2	Primary repair of inguinal hernia using insert of prosthetic material
T20.3	Primary repair of inguinal hernia using sutures
T21.1	Repair of recurrent inguinal hernia using insert of natural material
T21.2	Repair of recurrent inguinal hernia using insert of prosthetic material
T21.3	Repair of recurrent inguinal hernia using sutures
T21.4	Removal of prosthetic material from previous repair of inguinal hernia
T22.1	Primary repair of femoral hernia using insert of natural material
T22.2	Primary repair of femoral hernia using insert of prosthetic material
T22.3	Primary repair of femoral hernia using sutures
T23.1	Repair of recurrent femoral hernia using insert of natural material
T23.2	Repair of recurrent femoral hernia using insert of prosthetic material
T23.3	Repair of recurrent femoral hernia using sutures
T23.4	Removal of prosthetic material from previous repair of femoral hernia
T24.1	Repair of umbilical hernia using insert of natural material
T24.2	Repair of umbilical hernia using insert of prosthetic material
T24.3	Repair of umbilical hernia using sutures
T24.4	Removal of prosthetic material from previous repair of umbilical hernia
T25.1	Primary repair of incisional hernia using insert of natural material
T25.2	Primary repair of incisional hernia using insert of prosthetic material
T25.3	Primary repair of incisional hernia using sutures
T26.1	Repair of recurrent incisional hernia using insert of natural material
T26.2	Repair of recurrent incisional hernia using insert of prosthetic material
T26.3	Repair of recurrent incisional hernia using sutures
T26.4	Removal of prosthetic material from previous repair of incisional hernia
T27.1	Repair of ventral hernia using insert of natural material
T27.2	Repair of ventral hernia using insert of prosthetic material
T27.3	Repair of ventral hernia using sutures
T27.4	Removal of prosthetic material from previous repair of ventral hernia
T97.1	Repair of recurrent umbilical hernia using insert of natural material
T97.2	Repair of recurrent umbilical hernia using insert of prosthetic material
T97.3	Repair of recurrent umbilical hernia using sutures
T98.1	Repair of recurrent ventral hernia using insert of natural material
T98.2	Repair of recurrent ventral hernia using insert of prosthetic material
T98.3	Repair of recurrent ventral hernia using sutures

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