HOUSE OF COMMONS LIBRARY

DEBATE PACK

Number CDP 2018/0089, 5 April 2018

Surgical mesh

By Dr Sarah Barber
Nikki Sutherland

This pack has been produced ahead of the debate to be held in the Commons Chamber on Thursday 19 April 2018 on surgical mesh. The subject for the debate has been selected by the Backbench Business Committee and the debate will be opened by Emma Hardy MP.

The motion to be debated is:

> That this House commends the recent announcement of a retrospective audit into surgical mesh for pelvic organ prolapse and stress urinary incontinence; notes that vaginal mesh has been banned in other jurisdictions such as New Zealand; further notes that NICE guidance recommends against the use of surgical mesh for pelvic organ prolapse and that no NICE recommendations have been made for stress urinary incontinence; reports that Sheffield University recently announced the development of a new mesh material and calls on the Government to suspend prolapse and incontinence mesh operations while the audit is being carried out, bring forward the NICE guidelines for mesh in stress related urinary incontinence from 2019 to 2018, and to commit to a full public inquiry into mesh if the audit suggests that this is the best course of action.

Please see also the Library's newly updated briefing paper in Surgical Mesh Implants for further information.

Contents

The House of Commons Library prepares a briefing in hard copy and/or online for most non-legislative debates in the Chamber and Westminster Hall other than half-hour debates. Debate Packs are produced quickly after the announcement of parliamentary business. They are intended to provide a summary or overview of the issue being debated and identify relevant briefings and useful documents, including press and parliamentary material. More detailed briefing can be prepared for Members on request to the Library.

1. News items

Independent

Hundreds of women each year need vaginal mesh implants removed, NHS audit finds

Campaigners say the official review uses 'selective' data and does not reflect the full extent of harm from the implants

17 April 2018

https://www.independent.co.uk/news/health/vaginal-mesh-implant-removal-nhs-audit-numbers-women-a8309276.html

Guardian

Jeremy Hunt launches review into handling of vaginal mesh scandal

21 February 2018

https://www.theguardian.com/society/2018/feb/21/jeremy-hunt-launches-review-into-handling-of-surgical-mesh-scandal

BMJ

Vaginal mesh procedures need compulsory register, says royal college

BMJ 2018; 360 doi: https://doi.org/10.1136/bmj.k586 Cite this as: BMJ 2018;360:k586

6 February 2018

https://www.bmj.com/content/360/bmj.k586

Independent

Government to review thousands of harmful vaginal mesh implants

NHS England estimates 100,000 women are fitted with the device

30 January 2018

https://www.independent.co.uk/news/health/vaginal-mesh-implants-audit-government-thousands-women-health-risk-scandal-latest-a8185061.html

Guardian

New Zealand bans vaginal mesh implants

12 December 2017

https://www.theguardian.com/science/2017/dec/12/new-zealand-bans-vaginal-mesh-implants

BBC News Online

Mesh risks not passed on to doctors

11 December 2017

http://www.bbc.co.uk/news/uk-scotland-42307953

BBC News Online

Vaginal mesh ban 'a retrograde step', surgeons say

8 December 2017

http://www.bbc.co.uk/news/health-42280544

Guardian

Women harmed because vaginal mesh regulation 'not fit for purpose

6 December 2017

https://www.theguardian.com/society/2017/dec/06/woman-great-harm-due-loopholes-vaginal-mesh-regulation

Guardian

'Scandal' of vaginal mesh removal rates revealed by NHS records

15 August 2017

https://www.theguardian.com/society/2017/aug/15/scandal-of-vaginal-mesh-removal-rates-revealed-by-nhs-records

2. Press releases

Royal College of Obstetricians and Gynaecologists

RCOG statement in response to NHS mesh review

17 April 2018

NHS Digital has published a review of patients who have had a urogynaecological procedure for prolapse or stress urinary incontinence including those where mesh, or tape or their equivalents were used.

Between 2008 and 2016, a total of 100,516 patients had a reported tape insertion procedure for stress urinary incontinence and 27,016 patients had a reported mesh insertion procedure for prolapse.

In 2016, there were 7,245 patients who had an insertion for tape insertion procedure, a reduction of 48% from 2009 when 13,990 patients were recorded. Meanwhile, there were 2,680 patients in 2017 who had a reported mesh insertion procedure for prolapse, a reduction of 13% from 2008 when 3,073 patients were recorded.

Professor Linda Cardozo, spokesperson for the Royal College of Obstetricians and Gynaecologists (RCOG), said:

> 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.

Department of Health and Social Care

Review launched to respond to patient concerns about NHS treatments

22 February 2018

The review will focus on 3 NHS treatments: Primodos, vaginal mesh implants and the anti-epilepsy drug sodium valproate.

Health and Social Care Secretary Jeremy Hunt has announced a review into how the health system responds to reports from patients about side effects from treatments.

The review comes after patient-led campaigns on 3 NHS treatments:

- the hormone pregnancy test Primodos, which was used up until 1978
- the anti-epileptic drug sodium valproate
- the use of vaginal mesh

Mr Hunt said that the response these groups of patients received from the NHS and its regulators was "not good enough".

Baroness Julia Cumberlege will lead the review. She will consider:

- whether any further action is needed relating to the complaints around Primodos, sodium valproate and vaginal mesh
- the processes followed by the NHS and its regulators when patients report a problem
- how to make sure communication between the different groups involved is good

Mr Hunt has asked the review to set up an independent committee to help ministers decide on the best approach to resolving these issues.

He said:

> Over the years, there have been significant concerns raised by individuals and campaign groups about the potentially harmful effects of 3 products used by the NHS. The response they have received from those in positions of authority has not always been good enough.
>
> From Primodos to mesh and sodium valproate, patients and their families have had to spend too much time and energy campaigning for answers in a way that has added insult to injury for many. I want to see if we can establish a fairer and quicker way of resolving these concerns both now and in the future.

Chair of the review, Baroness Cumberlege, said:

> I look forward to undertaking this tremendously important review and in particular to working with patients to ensure that our health system learns from those it may have failed. It's essential that voices aren't just listened to, but properly heard, and that whenever appropriate, the system promptly learns lessons and makes changes.

National Institute for Health and Clinical Excellence

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

15 December 2017

Updated advice says current evidence on the safety of the procedure shows there are serious, but well-recognised safety concerns.

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.

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.

Royal College of Obstetricians and Gynaecologists and British Society of Urogynaecology

RCOG and BSUG response to NICE guidance on transvaginal mesh repair for prolapse

15 December 2017

This NICE IPG refers only to the use of mesh to reinforce pelvic organ prolapse repair for anterior and posterior wall prolapse. It does not refer to the use of mesh or tape for stress urinary incontinence or vaginal vault surgery which are subject to different NICE IPG's. The NICE Clinical

Guideline on Urinary Incontinence and Pelvic Organ Prolapse is due to be published in 2019.

Mr Edward Morris, vice president for clinical quality at the Royal College of Obstetricians and Gynaecologists, said:

> This guidance from NICE recommends that vaginal placement of mesh to repair prolapse should only be used in the context of research. Current evidence does not recommend the routine use of mesh to treat prolapse as the first surgical intervention, due to higher complication rates when compared to non-mesh repairs. Therefore this guidance is consistent with the majority of UK current clinical practice.
>
> However, there is a small subset of women for whom other surgical interventions are not appropriate for their prolapse and the use of mesh may be of benefit to them, provided they have appropriate information and counselling about the risks and benefits, and have explored all other treatment options. We are concerned that this guidance may leave these women without an effective option to manage their condition.
>
> This step also means that there is a risk further research in this area could cease – we therefore urge NICE to recommend this as a priority area in order to ensure we have the optimal surgical approach to care for women with prolapse.
>
> It is paramount that women with pelvic organ prolapse are made aware of all the treatment options available, and empowered with information about the risks associated with any procedures, to enable them to make an informed decision about the right treatment for their condition. Specialist training, surgical experience and appropriate patient selection are all crucial factors in ensuring current and future patients receive the highest quality care.

Professor Jonathan Duckett, Chair of the British Society for Urogynaecology (BSUG), said:

> The recent NHS England report outlined the ongoing work taking place across the NHS to ensure good outcomes for all women undergoing procedures involving mesh and reduce the number of those experiencing complications.
>
> BSUG are aware there is currently an incomplete picture of the long-term recording of outcomes and the incidence of complications following all pelvic surgery, not just mesh surgery, due to insufficient reporting and published data. We strongly recommend that all data relating to mesh procedures are recorded on the BSUG database and that any complications are similarly recorded and reported to the MHRA via the Yellow Card scheme. It is only by the routine use of such systems that we will can track trends and better inform both patients and surgeons.
>
> We are also urging reporting authorities to make a clear distinction between the vaginal mesh for prolapse which is the subject of this NICE IPG and the incontinence mesh devices or the abdominal mesh for prolapse to which this document does not relate.

Royal College of Obstetricians and Gynaecologists and British Society of Urogynaecology

RCOG and BSUG response to NHS Mesh report

25 July 2017

NHS England has today published a new report setting out progress to improve information about treatment options and support for women with stress urinary incontinence and pelvic organ prolapse.

The report outlines the ongoing work taking place across the NHS to reduce the number of women experiences complications as a result of vaginal mesh surgery and puts in place the necessary care and support for women who do.

An interim report in 2015 recognised three key areas of action and made recommendations on what should be done to tackle them. These focussed on improving clinical quality and practice to achieve good outcomes consistently, better data and information and informed consent. Today's report describes how those recommendation are being delivered.

Clinical representatives from the Royal College of Obstetricians and Gynaecologists (RCOG) and British Society of Urogynaecology (BSUG) sat on the oversight group which produced the report, and a lay representative from the RCOG's Women's Voices Involvement Panel sat on the working group that developed the new patient information leaflets.

Commenting on today's report, Mr Eddie Morris, vice president for clinical quality at RCOG, said:

> It is absolutely right that women who experience complications relating to mesh devices can now be referred to specialist units that have a multi-disciplinary team of professionals who can listen, advise and support them. 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. For many women suffering from these conditions, mesh devices can be an effective form of treatment which is less invasive than alternative surgical procedures.

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.

Lesley Briggs, a lay representative on the MESH working group and member of RCOG's Women's Voices Involvement Panel, said:

> This report is the culmination of a concerted effort by clinicians and patients to put into place changes so that current and future patients can expect high quality care when undergoing procedures involving mesh. Crucially there is now consistent and accurate information enabling each woman to enter into a dialogue with her doctor so she understands her condition, the treatments available – and the alternatives, what the treatment will entail and the risks associated with these procedures, enabling them to make an informed decision about their condition.

The RCOG has created a Mesh webpage bringing together a number of resources to help support decision-making by women and healthcare professionals about the use of mesh.

Notes to editors:

There are several treatment options available for both pelvic organ prolapse and stress urinary incontinence. These will depend on the severity of symptoms, a woman's age and health, and whether she is planning to have children in the future.

Treatment options for both conditions include pelvic floor exercise and lifestyle changes, such as losing weight, eating a high-fibre diet, cutting down on caffeine and alcohol, and avoiding heavy lifting and standing for long periods.

If other treatments for urinary incontinence (including bladder training and medication) are unsuccessful, surgery may be recommended. Healthcare professionals may also suggest surgical repair, vaginal mesh and hysterectomy for women with pelvic organ prolapse, if local hormone treatment and vaginal pessaries don't work.

Transvaginal mesh is one of several treatment options available for pelvic organ prolapse and stress urinary incontinence. Surgical procedures using mesh devices may be appropriate and can be far less invasive that alternative surgical produces.

Evidence from the recently published UK PROSPECT study in *The Lancet* shows that mesh is a successful treatment for prolapse in most cases, and the majority of women treated with mesh respond well to this treatment. Unfortunately, there is also a risk of possible complications which include mesh erosion, infection and bleeding, and the strain of future pregnancies may cause the prolapse to recur. Pain and dyspareunia (painful sex) also occur after native tissue (non-mesh) prolapse surgery.

As part of the regular update programme, NICE is currently revising its guidelines on female urinary incontinence on pelvic organ prolapse and these are due to be published in 2019.

Medicines and Healthcare products Regulatory Agency

MHRA response to the final report of the Mesh Oversight Group

26 July 2017

NHS England set up the Mesh Working Group to address the concerns of a number of patients and clinicians.

John Wilkinson, Director of Devices at MHRA, said:

> 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.

The final report of the NHS England-led Mesh Working Group can be found on the NHS England website.

In 2014 MHRA also produced a summary report of the evidence on the benefits and risks of vaginal mesh implants as part of ongoing research.

3. Parliamentary material

Statement

Commons statement followed by Questions – Medicines and Medical Devices Safety Review

HC Deb 21 February 2018 | Vol 636 cc165-7

https://hansard.parliament.uk/Commons/2018-02-21/debates/7DA2E2F3-E1E6-40CB-8061-680E0399CA97/MedicinesAndMedicalDevicesSafetyReview#contribution-2CB27B27-ED1B-44BD-9EB4-12102BFD4FEA

Lords statement followed by Questions – Medicines and Medical Devices Safety Review

HL Deb 22 February 2018 | Vol 789 cc272-5

https://hansard.parliament.uk/Lords/2018-02-22/debates/8AC6EABF-6C48-4888-8911-9C6A0C23782F/MedicinesAndMedicalDevicesSafetyReview#contribution-0A8D9375-123F-4941-8C0F-5C58912DA954

Debate

Westminster Hall debate: Surgical Mesh Implants

Motion that this House has considered the risks of surgical mesh implants.

HC Deb 18 October 2017 | Vol 629 cc293-319WH

https://hansard.parliament.uk/Commons/2017-10-18/debates/B546B1F1-099F-442C-AD71-0185D1B3F69C/SurgicalMeshImplants

PQs

Surgical Mesh Implants

Asked by: Hardy, Emma

To ask the Secretary of State for Health and Social Care, how many and what proportion of surgical mesh implants have shrunk after being inserted.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

Between 2013 and 2017, the Medicines and Healthcare products Regulatory Agency (MHRA) received 18 adverse incident reports including the terms "shrunk" or "shrink" (or similar) relating to surgical mesh to treat stress urinary incontinence or pelvic organ prolapse.

It should be noted that these figures include a range of recognised complications related to this type of surgical procedure and do not necessarily indicate a fault with any particular device.

These figures include reports from manufacturers, healthcare professionals and members of the public and therefore may not necessarily represent an individual patient. As there is no limiting time on reporting, people can make multiple reports at any time after the mesh has been implanted and on the same issue.

HC Deb 08 March 2018 | PQ 130437

Surgical Mesh Implants: Females

Asked by: Hardy, Emma

To ask the Secretary of State for Health and Social Care, what steps his Department is taking to collect data on the number of women who have had vaginal mesh surgery who experienced (a) pain, (b) a reduction in the quality of sex life, (c) constant urinary infections and (d) a reduction in the quality of life.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

On 21 February, my Rt. Hon. Friend the Secretary of State announced the establishment of a prospective registry covering urogynaecological pathways for stress urinary incontinence and prolapse, including procedures using mesh implants. Registry data will support the understanding of comparable benefits, risks and patient outcomes over time.

NHS Digital is in the process of undertaking a retrospective audit (secondary analysis of existing data) of surgery for stress urinary incontinence and vaginal prolapse, which will help the National Health Service to better understand complications related to surgery using vaginal mesh. Analysis will include the number of patients who have undergone an operation and will investigate in part their subsequent interactions with the NHS through hospital outpatient appointments.

The Medicines and Healthcare products Regulatory Agency's (MHRA's) Yellow Card Scheme allows patients to report any adverse outcomes experienced from the use of a medical device, no matter how long ago the surgery took place. The MHRA is continuing to enhance awareness of the Yellow Card reporting system for adverse outcomes to increase reporting rates among both clinicians and patients.

HC Deb 08 March 2018 | PQ 130435

Medicines and Medical Devices Safety Review

Asked by: Moran, Layla

To ask the Secretary of State for Health and Social Care, for what reason Baroness Cumberlege's review of vaginal mesh implants will not include an audit of ventral mesh rectopexy surgery.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

Using Hospital Episodes Statistics (HES), NHS Digital is already in the process of undertaking a retrospective audit (secondary analysis of existing data) of surgery for stress urinary incontinence and vaginal prolapse, which will help the National Health Service to better understand complications related to surgery using vaginal mesh. Analysis will include the number of patients who have undergone an operation and will investigate in part their subsequent interactions with the NHS through hospital outpatient appointments. This approach to the analysis of HES is novel and the results will be classified as experimental statistics.

The retrospective audit will not include patients that have undergone rectopexy, as this is a procedure used to treat rectal prolapse rather than stress urinary incontinence or vaginal prolapse (although on occasion, rectopexy may be undertaken with stress urinary incontinence or vaginal prolapse procedures).

Adding the entirety of the rectal prolapse patient cohort to this particular data set may distort the results and therefore impact the ability to draw conclusions specifically for stress urinary incontinence and vaginal prolapse. The focus at this point is on stress urinary incontinence and vaginal prolapse.

HC Deb 06 March 2018 | PQ 130679

Medicines and Medical Devices Safety Review

Asked by: Eagle, Maria

To ask the Secretary of State for Health and Social Care, if he will take steps to ensure that women affected by taking Primados as a hormone pregnancy test are consulted about the terms of reference for Baroness Cumberlege's Review of the Safety of Certain Medicines and Medical Devices.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Secretary of State for Health and Social Care has asked Baroness Cumberlege to finalise the terms of reference for the Medicines and Medical Devices Review and to consult on those terms of reference with stakeholders.

Baroness Cumberlege will engage with patient groups and other stakeholders throughout the course of the review.

Baroness Cumberlege will also involve patient groups representative of people concerned by the use of Primodos, Sodium Valproate and

vaginal mesh from the early stages of the Medicines and Medical Devices Review.

HC Deb 28 February 2018 | PQ 129481

Surgical Mesh Implants

Asked by: Lefroy, Jeremy

To ask the Secretary of State for Health and Social Care, if he will immediately suspend the use of medical procedures involving vaginal mesh implants.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Government does not support a suspension or ban of the use of surgical mesh devices. The view of the Medicines and Healthcare products Regulatory Agency (MHRA) is that surgical mesh devices are acceptably safe when used as intended and as part of an appropriate treatment pathway where the associated risk and benefits are considered, and where surgical mesh devices conform to the requirements of the current legislation in the European Union.

As a Department we are committed to improving the outcomes for all patients involved. We continue to work closely with MHRA, NHS England, the National Institute for Health and Care Excellence and professional bodies. MHRA continue to review available evidence to ensure our regulatory position is up to date, liaising with EU partners and non-EU regulators.

HC Deb 26 February 2018 | PQ 127530

Health: Pelvic Mesh Implants

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government whether they intend to review the safety of the use of pelvic mesh implants.

Answered by: The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord O'Shaughnessy)

My Lords, NHS England's mesh working group report outlined recommendations to optimise care when surgical mesh is used to treat stress urinary incontinence and pelvic organ prolapse. We continue to implement those recommendations. NICE has now published eight pieces of updated interventional procedure guidance related to vaginal mesh. Updated clinical guidance covering urinary incontinence and mesh will be published in February 2019. The MHRA continues to review available evidence to make sure that our regulatory position is up to date, liaising with EU and non-EU partners.

Lord Hunt of Kings Heath

My Lords, I thank the Minister for his personal involvement in the decision to conduct a retrospective audit into vaginal mesh surgery, but will he go a little further? He will be aware that an increasing number of women have reported suffering from complications that include debilitating pain, infection, inflammation, the loss of sex life and mobility issues. A number of countries have now banned the use of mesh implants completely. On the precautionary principle, will he suspend the use of mesh until the audit that he has announced has been completed and new guidelines issued by NICE?

Lord O'Shaughnessy

I am grateful to the noble Lord for raising this issue, because there is certainly a complication rate. I know that a lot of women are suffering as a result of complications from this procedure. As he will know, we have asked the MHRA, NICE and NHS England to have a look at the correct use of this kind of mesh. They have all concluded that they do not support a complete ban. They propose a range of restrictions on usage. Indeed, the most recent interventional procedure from NICE on prolapse said that it should be used only for research purposes and not as a front-line treatment. However, I am aware that Australia and New Zealand are implementing bans for particular usage. I have asked NICE and MHRA to investigate why they have done that and to report to me urgently so that I can see the grounds for the ban. We have different regulatory systems, but I want to know what is happening there.

Baroness McIntosh of Pickering

My Lords, will my noble friend explain to the House what the alternative might be if pelvic mesh implants were to be stopped? Is it not appropriate to be absolutely sure that any alternative is fool-proof and that there are no consequences?

Lord O'Shaughnessy

My noble friend makes an excellent point. This is one procedure, and for some women it can be positive and life-enhancing. But we also know that it carries a risk of complications. That is one reason why we wanted to carry out the audit, because it will look not only at areas and procedures where there have been problems and complications but where it has been successful, so that we can have a proper understanding of what the complication rate is and therefore what the safety concerns are.

Baroness Jolly

My Lords, the NICE guidelines that the Minister just referred to conclude that,

"Evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research",

as he said. But will he tell the House how confident we can now be that that is the case and that the information has been effectively

disseminated? What is the mechanism for informing clinicians and women about this NICE guidance?

Lord O'Shaughnessy

The noble Baroness is quite right to say that it is not just about having the guidelines but making sure that clinicians follow them. Professional standards demand that clinicians do follow them, and indeed a clinician would need to be strongly justified in using mesh implants outside of the guidelines. They include things like gaining consent, providing information and registering operations that have been carried out. The guidelines are very strict and we expect clinicians to follow them.

Lord Patel

My Lords, does the noble Lord agree that, while we cannot be sure why New Zealand and Australia have suddenly announced total bans on the use of mesh implants, the evidence suggests that of the 20% of women who suffer from complications, most of them had been treated for pelvic floor prolapse, not stress incontinence? Banning their use completely at this stage for women with certain conditions who may benefit from them would, without further evidence, be completely wrong.

Lord O'Shaughnessy

The noble Lord speaks with great experience. Obviously, a number of procedures are involved, and NICE is now looking at extra procedures to provide the guidance. It does look like it is not the right thing to do in cases of prolapse, but it can be a very successful course of treatment for other conditions. It is important to take a differentiated approach.

Baroness Tonge

My Lords, does the Minister share with me a sense of puzzlement that this subject was brought to the House in the first place? I find it very odd given that we have royal colleges and NICE with people to assess the efficacy of particular treatments. Many treatments, both medical and surgical, carry a risk of complications. Are they all going to be brought to the House of Lords for discussion?

Lord O'Shaughnessy

Our job in this House is to scrutinise the decisions that are made in our publicly funded health services. I think that it is absolutely right that we do scrutinise these issues and make sure that the care being provided in this country adheres to the highest and safest standards.

HL Deb 06 February 2018 | Vol 788 cc1907-9

Health: Pelvic Mesh Implants

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government whether they intend to review the safety of the use of pelvic mesh implants.

Answering member: The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord O'Shaughnessy

My Lords, NHS England's mesh working group report outlined recommendations to optimise care when surgical mesh is used to treat stress urinary incontinence and pelvic organ prolapse. We continue to implement those recommendations. NICE has now published eight pieces of updated interventional procedure guidance related to vaginal mesh. Updated clinical guidance covering urinary incontinence and mesh will be published in February 2019. The MHRA continues to review available evidence to make sure that our regulatory position is up to date, liaising with EU and non-EU partners.

06 February 2018 | Vol 788 c1907

Surgical Mesh Implants: Males

Asked by: Stone, Jamie

To ask the Secretary of State for Health and Social Care, what steps his Department is taking to investigate the causes of pain and suffering to male patients by mesh implants; and what corrective procedures are being developed by Government health experts.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The main reported complication following abdominal and hernia repair and urogynaecological procedures for both men and women identified by the the Medicines and Healthcare products Regulatory Agency Yellow Card Scheme, is post-operative pain, which may be temporary, but may become a chronic complication and this can happen even in the absence of a repair using a synthetic implant.

The National Institute for Health and Care Excellence (NICE) has produced a number of guidance documents regarding mesh implants for both men and women. These include the technology appraisal guidance on laparoscopic surgery for inguinal hernia repair which was last reviewed in February 2016 and is available at:

https://www.nice.org.uk/guidance/ta83

The medical technologies guidance on the PolySoft hernia patch used with ONSTEP technique to treat inguinal hernias which was published in August 2014 is available at:

https://www.nice.org.uk/advice/mib9

NICE is also currently producing guidance relating to 'Persistent pain: assessment and management', with a draft guidance consultation due between 22 July -3 September 2019 and the final publication date currently being projected for 20 January 2020, and guidance into laparoscopic ventral mesh rectopexy for internal rectal prolapse which will include men and is expected to be published on 20 June 2018.

HC Deb 16 January 2018 | PQ 122252

Surgical Mesh Implants

Asked by: Moran, Layla

To ask the Secretary of State for Health, what steps he is taking to ensure that publicly funded research into transvaginal mesh repair of anterior or posterior vaginal wall prolapse includes (a) details of patient selection, (b) long-term outcomes including complications, (c) type of mesh used, (d) method of fixation and (e) quality of life as recommended by NICE.

Answering member: Jackie Doyle-Price | Department: Department of Health

The Department's National Institute for Health Research (NIHR) welcomes funding applications for research into any aspect of human health. Applications are subject to peer review and judged in open competition, with awards being made on the basis of the importance of the topic to patients and health and care services, value for money and scientific quality. The NIHR would expect researchers applying for funding through NIHR research programmes to be aware of the National Institute for Health and Care Excellence guidelines.

HC Deb 22 December 2017 | PQ 119984

Surgical Mesh Implants

Asked by: Clwyd, Ann

To ask the Secretary of State for Health, if he will ban vaginal mesh operations.

Answering member: Jackie Doyle-Price | Department: Department of Health

The Medicines and Healthcare products Regulatory Agency has considered all evidence available to them, both here in the United Kingdom and worldwide, and their view is that both the evidence and the greater proportion of the clinical community supports the use of these devices as part of an appropriate treatment pathway.

The NHS England mesh oversight group's final report, published in July 2017, recommended that surgical mesh should not be routinely offered as the first surgical intervention when treating prolapse which is in alignment with the recommendations of the Scottish Independent Review.

The report also sets out a number of actions which improve the support available for women who have suffered with complications including being able to be referred to 18 trusts in England that have the specialist multidisciplinary teams and experience to assess complications and offer the highest quality support.

HC Deb 06 December 2017 | PQ 116248

4. Useful links and further reading

Royal College of Obstetricians and Gynaecologists resource page – *mesh*

https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/

Mesh Oversight Group report July 2017

https://www.england.nhs.uk/wp-content/uploads/2017/07/mesh-oversight-group-report.pdf

Healthcare Improvement Scotland - Transvaginal Mesh Implants Oversight Group

http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/transvaginal_mesh_implants.aspx

Scottish Government *Independent Review of transvaginal mesh implants* – final report published 27 March 2017

http://www.gov.scot/About/Review/Transvaginal-Mesh-Implants

Links to NICE Interventional Procedures Guidances on mesh

https://www.nice.org.uk/news/article/mesh-for-vaginal-wall-prolapse-should-only-be-used-in-the-context-of-research-says-nice

Sling the Mesh campaign

https://slingthemesh.wordpress.com/

Scottish Mesh Survivors

http://www.scottishmeshsurvivors.com/

The Voices Today on Messed up Mesh (TVT Mum)

http://www.tvt-messed-up-mesh.org.uk/

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