



DEBATE PACK

Number CDP 2019/0206, 29 August 2019

Hernia mesh in men

A general debate will be held in Westminster Hall on Thursday 5 September 2019. The debate will be opened by Jim Shannon MP.

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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 and RCS statement

BMJ

Hernia mesh complications may have affected up to 170 000 patients, investigation finds

27 September 2018

<https://www.bmj.com/content/362/bmj.k4104>

BBC News Online

Hernia mesh complications 'affect more than 100,000'

26 September 2018

<https://www.bbc.co.uk/news/health-45604199>

Royal College of Surgeons

RCS statement on hernia mesh complications

26 September 2018

Commenting on the Victoria Derbyshire programme's claim that hernia mesh complications 'affect more than 100,000' people, a Royal College of Surgeons spokesperson, said:

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.

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

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.

2. Parliamentary material

Debates

Commons debate: [Licensing of Medical Devices](#)

HC Deb 12 February 2019 | Volume 654 c857-

Commons debate: [Surgical Mesh](#)

HC Deb 19 April 2018 | Vol 639 c 493-

PQs

[Hernias: Surgery](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government, further to the Written Answer by Baroness Blackwood of North Oxford on 25 March (HL14391), how they ensure that all consultant general surgeons are fully trained to maintain their skills in carrying out non-mesh hernia repair treatments.

**Answering member: Baroness Blackwood of North Oxford |
Department: Department of Health and Social Care**

Consultant surgeons go through a standardised training and education process and must pass examinations and have confirmation of their surgical competence by their supervisors before they can join the General Medical Council's (GMC) Specialist Register.

Unless they are on this Specialist Register they cannot practise as consultant surgeons in England. As practising surgeons, they are expected to maintain a Licence to Practise through the GMC's process of revalidation that must be renewed by application every five years and which is associated with annual appraisal. This includes reflection on their performance, continuing professional development, any involvement in serious incidents or complaints, feedback from multi professional colleagues and patients and quality improvement activities.

Typically, the Medical Director of a hospital trust employing surgeons will ensure that numbers and outcomes of surgical procedures carried out by a consultant surgeon are included in their appraisal reflection and discussion. Consultants and their appraisers have a professional responsibility to inform the Medical Director if they have concerns about surgical performance including for non-mesh hernia repair treatments.

HL Deb 10 April 2019 | HL15007

[*Hernias. Surgical Mesh Implants*](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government what consideration they have given to establishing a national registry of patients who have received mesh hernia repair treatments.

**Answering member: Baroness Blackwood of North Oxford |
Department: Department of Health and Social Care**

In February 2018, the Government announced the establishment of the Independent Medicines and Medical Devices Safety (IMMDS) Review, led by Baroness Cumberlege. The Review is evaluating what happened in each of the cases of primodos, sodium valproate and surgical mesh, including whether the processes pursued to date have been sufficient and satisfactory. The Review will make recommendations for future change to the United Kingdom healthcare system which the Government will consider in full.

At this time, there is no specific intention to develop a separate national registry of patients who have received mesh hernia repair treatments. The Government remains committed to driving system and regulatory change where required in the interests of patient safety. Recent Parliamentary debates have considered the scope of the IMMDS Review and the wider issues of safety and innovation within medical devices regulation and their use.

The Department funds research through the National Institute for Health Research (NIHR). The NIHR welcomes funding applications for research into any aspect of human health, including hernia repair; it is not usual practice to ring-fence funds for particular topics or conditions.

The Government is committed to making additional improvements to the system of medical device regulation including in response to the IMMDS Safety Review once it has reported.

HL Deb 25 March 2019 | HL14392

[*Hernias. Surgery*](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government what assurances they have received that surgeons in England continue to maintain their skills in non-mesh hernia repair treatments.

**Answering member: Baroness Blackwood of North Oxford |
Department: Department of Health and Social Care**

Hernias are some of the most common operations carried out in the National Health Service. Consultant general surgeons are fully trained to perform these operations and are expected to follow National Institute for Health and Care Excellence guidance when discussing appropriate procedures for individual patients. Surgeons are expected to maintain their skills and to review the outcomes of their treatments to confirm their competence.

HL Deb 25 March 2019 | HL14391

[Hernias: Surgical Mesh Implants](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government what assessment they have made of NHS Digital statistics on the number of patients adversely affected by hernia mesh operations.

**Answering member: Baroness Blackwood of North Oxford |
Department: Department of Health and Social Care**

NHS Digital does not hold statistics on the number of patients adversely affected by hernia mesh operations.

HL Deb 25 March 2019 | HL14389

[Hernias: Surgical Mesh Implants](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government whether they will ask the National Institute for Health and Care Excellence to produce guidance on hernia mesh operations which covers all the types of hernia that are treated by surgeons.

**Answering member: Baroness Blackwood of North Oxford |
Department: Department of Health and Social Care**

The Department has no current plans to ask the National Institute for Health and Care Excellence (NICE) to produce guidance on this topic. However, NHS England is now the lead commissioner of NICE clinical guidelines, and would be responsible for deciding whether this is a priority for NICE guidance.

NICE has published guidance on laparoscopic surgery for inguinal hernia repair, which makes reference to open mesh operations. NICE has also published a MedTech Innovation briefing on the PolySoft hernia patch used with the ONSTEP technique to treat inguinal hernias.

HL Deb 25 March 2019 | HL14388

[Surgical Mesh Implants](#)

Asked by: Lord Hunt of Kings Heath

To ask Her Majesty's Government whether they plan to commission new guidelines from NICE in relation to hernia mesh.

**Answering member: Lord O'Shaughnessy | Department:
Department of Health and Social Care**

The National Institute for Health and Care Excellence (NICE) has not been asked to develop any new guidelines in relation to hernia mesh.

NICE has developed technology appraisal guidance on *Laparoscopic surgery for inguinal hernia repair* published on 22 September 2004. A copy of the guidance is attached. The guidance states that laparoscopic surgery is recommended as one of the treatment options for the repair of inguinal hernia, but it should only be performed by appropriately trained surgeons who regularly carry out the procedure. NICE reviewed the evidence in February 2016 and found no new evidence which would lead to a change in the existing recommendations. However, if NICE is notified of a significant change to the evidence base at any stage in the future, this could trigger a formal review proposal.

HL Deb 09 May 2018 | HL7279

[Hernias: Surgical Mesh Implants](#)

Asked by: Smith, Eleanor

To ask the Secretary of State for Health and Social Care, if he will respond to the recommendations made in the Hernia Outcomes Campaign's report, *Inguinal Hernia Surgery: Improving Patient Outcomes and Reducing Variation* published in November 2017, and will he make a statement.

To ask the Secretary of State for Health and Social Care, what assessment his Department has made of the potential merits of the recommendation made by Hernia Outcomes Campaign on the introduction of a watchful waiting policy for inguinal hernia surgery in that organisations report, *Inguinal Hernia Surgery: Improving Patient Outcomes and Reducing Variation*, published in November 2017.

To ask the Secretary of State for Health and Social Care, what criteria is used by Clinical Commissioning Groups to determine commissioning policies for inguinal hernia repair.

To ask the Secretary of State for Health and Social Care, what guidance NHS England has issued to Clinical Commissioning Groups for the development of commissioning policies for inguinal hernia repair.

To ask the Secretary of State for Health and Social Care, what assessment has his Department made of the effect of removing the Patient Reported Outcome Measure on hernia repair on the commissioning policies used by Clinical Commissioning Groups.

Answering member: Steve Brine | Department: Department of Health and Social Care

NHS England has advised that the Patient Reported Outcome Measure (PROM) on hernia repair did not demonstrate significant improvements in quality of outcomes for many patients and was not implemented very widely.

The Hernia Outcomes Campaign team are in discussion with the Royal College of Surgeons of England, with the British Hernia Society, the Getting It Right First Time team and NHS England about potentially constructing and testing a more useful PROM for hernia outcomes.

NHS England has advised that no specific guidance is issued to clinical commissioning groups (CCGs) regarding the development of commissioning policies for inguinal hernia repair.

It is up to CCGs to decide how services are delivered at a local level and to decide the criteria that they use to determine their commissioning policies for hernia repair. In doing so, they are expected to take account of any National Institute for Health and Care Excellence Quality Standards that are relevant to this.

Individual surgeons have a responsibility for assessing the outcomes of their operations and should make this information available in summary form to prospective patients to help them make effective decisions about whether or not to choose surgical treatment.

A representative of NHS England has met with members of the Hernias Outcomes Campaign and discussed the contents of their 2017 report. NHS England concur that for patients with few symptoms an effective process of shared decision-making between patient and surgeon may well result in a choice not to opt for immediate surgery.

HC Deb 09 May 2018 | PQ139589; PQ 139587; PQ 139586; PQ 139585; PQ139583

3. Useful links and further reading

The Independent Medicines and Medical Devices Safety Review

<http://immdsreview.org.uk/index.html>

National Institute for Health and Care Excellence (NICE) technology appraisal guidance *Laparoscopic surgery for inguinal hernia repair*

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

National Institute for Health and Care Excellence (NICE) medtech innovation briefing *The PolySoft hernia patch used with the ONSTEP technique to treat inguinal hernias*

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

Welsh Government Deputy Chief Medical Officer Review *Use of Hernia Mesh* January 2019

<https://gov.wales/sites/default/files/publications/2019-05/deputy-chief-medical-officer-review-use-of-hernia-mesh.pdf>

Cochrane review *Comparing surgical groin hernia repair performed with or without mesh* September 2018

https://www.cochrane.org/CD011517/COLOCA_comparing-surgical-groin-hernia-repair-performed-or-without-mesh

Sling the Mesh campaign

<https://slingthemesh.wordpress.com/>

British Hernia Society

<https://www.britishherniasociety.org/>

British Journal of Surgery Vol 106 Issue 7 June 2009 *In support of mesh for hernia repair*

<https://onlinelibrary.wiley.com/doi/full/10.1002/bjs.11240>

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