



NHS Improvement and NHS England

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To: Acute trust CEOs and medical directors

www.england.nhs.uk
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Dear colleague

VAGINAL MESH: HIGH VIGILANCE RESTRICTION PERIOD: Immediate action required, all cases should be postponed if it is clinically safe to do so.

1. We understand that the Government will be announcing on Tuesday 10 July a national 'pause' in the use by the NHS of surgical mesh/tape to treat stress urinary incontinence (SUI) and for urogynaecological prolapse where the mesh is inserted through the vaginal wall, and that this pause will take the form of a high vigilance restriction.
2. This decision followed a recommendation from Baroness Cumberlege, chair of the Independent Medicines and Medical Devices Safety Review. Baroness Cumberlege's recommendation came after meetings held with women and families adversely affected by surgical mesh procedures. There is no concurrent change in the evidence base.

Background

3. Surgery for stress urinary incontinence with tape has provided successful relief of symptoms in many cases – however, some patients have experienced severe and debilitating complications following mesh and tape surgery. There has already been guidance to the NHS that vaginally inserted mesh for the treatment of vaginal prolapse should no longer be the primary surgical option.
4. Approximately 7,245 tape procedures for SUI were performed in NHS hospitals (or funded by the NHS in private hospitals) in England in 2016/17. This had reduced by 48% since 2008/9. In 2016/17, approximately 2,680 patients had a mesh procedure for prolapse – this figure includes those inserted vaginally but also those inserted via an abdominal surgical approach. This data does not include privately funded procedures in private facilities, or procedures carried out abroad.
5. The Mesh Working Group identified a series of actions to optimise care for women undergoing treatment for stress urinary incontinence and pelvic organ prolapse in their report in 2015, which have since been implemented by the Mesh Oversight Group. The final report of this group was published in July 2017 and can be found [here](#).

6. The high vigilance restriction will 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.

Implementation

7. This period will be implemented as a period of restricted practice and high vigilance.
8. For the majority of patients, a delay until the 'high vigilance restriction' ceases will be the preferred position.
9. We are clear that for some patients, mesh procedures may be the only viable treatment option for a debilitating condition. However, this treatment should only be used for a group of carefully selected patients who understand the risks. For such patients, the period of 'high vigilance restriction' will include:
 - a. a strict adherence to the recently published IPGs (Interventional Procedure Guidance) published by NICE for these procedures
 - b. an MDT assurance at trust levels to support the necessity of the procedure without delay
 - c. full supported patient choice and sign off in advance of that process
 - d. evidence of the competence of the surgeon.
10. It should be noted that we have been advised that non-tape surgical procedures for SUI (eg culposuspension) are more technically complex, may have a higher rate of complication than tape procedures and many surgeons will not have the training and skills to perform these procedures.
11. A Clinical Advisory Group has been established including members from Specialised Commissioning and clinical expertise from The British Society of Urogynaecologists (BSUG) and the British Association of Urological Surgeons (BAUS). The group will:
 - a) define procedures and scope for the high vigilance restriction
 - b) advise on appropriate confirmation process to ensure appropriateness of any mesh procedures intended
 - c) recommend a process for provider trust Medical Director sign off of the surgeon's competence for those mesh procedures required and any alternate operations

- d) advise on best options to ensure patient information and consenting processes are in place in a trust.

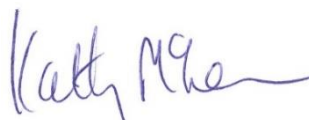
Further communication will follow in the coming days with the outcome of this work.

- 12. Pending the agreement of these high vigilance protocols, all cases should be postponed if it is clinically safe to do so. This excludes cases in which clinicians judge that there is clinical urgency to carry out the procedure, and no suitable alternative exists. Surgery should proceed if a delay would risk harm to the patient (such as for procedures involving cancer), based on a multidisciplinary team decision and informed consent.
- 13. Trusts will need to provide support to patients affected by this high vigilance restriction, including:
 - a. those already on the waiting list for mesh surgery
 - b. those for whom there is no alternative treatment
 - c. those who are appropriate for an alternative procedure (eg culposuspension). For this group, the skills may not be available in the trust they are currently being treated by and secondary referral would be required
 - d. those who have previously had treatment that involved vaginal mesh, who may become concerned and seek medical advice.
- 14. The high vigilance restriction will result in an unavoidable impact on waiting list performance (RTT) following enforced delays in surgery. Such cases will need to be coded appropriately.
- 15. NHS England and NHS Improvement will continue, and accelerate where possible, the work to meet the conditions set out in paragraph 6 and secure the cessation of the restriction. This includes:
 - a. working with NICE as part of their consultation to strengthen patient information by developing patient decision support tools
 - b. through Specialised Commissioning completing the consultation of the new service specification for complex SUI and prolapse procedures, mesh removal and procure a small number of designated specialist removal services that will also support urogynaecological/female urology networks
 - c. continue to pursue the commissioning of a national clinical audit/registry for urogynaecological procedures for SUI and prolapse.

Yours sincerely



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National Medical Director, NHS England



Dr Kathy McLean
**Executive Medical Director and Chief
Operating Officer, NHS Improvement**

Annex A

Pause in use of vaginal mesh: Q&A

1. Q: On what grounds will the use of mesh be paused?

A: Baroness Cumberlege has recommended that there is a 'pause' in the use of vaginally inserted mesh to treat prolapse and synthetic tape/sling used to treat stress urinary incontinence, until it can be assured that the conditions set out below are adequately met.

- Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly.
- Surgeons report every procedure to a national database.
- A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery.
- Reporting of complications via MHRA is linked to the register.
- 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.
- NICE guidelines on the use of mesh for SUI are published.

Much of this work has already been in progress following the report of the Mesh Working Group.

For many mesh procedures, the new NICE Interventional Procedures Guidance stipulates that they should only be used if special arrangements are in place for clinical governance, consent, and audit or research. This pause will allow us to establish that these special arrangements are in place across the NHS.

2. Q: How will the pause be implemented?

A: A pause in the use of vaginally inserted mesh to treat prolapse and synthetic tape/sling used to treat stress urinary incontinence will be implemented through a high vigilance programme of restricted practice. This is not a blanket ban; for some patients this is a debilitating condition for whom a delay or alternative treatment would not be appropriate. Operations will therefore be available under the high vigilance programme for carefully selected patients who understand the potential risks.

3. Q: Which procedures will be included in the pause and which will be exempt from it? How has this decision been made?

A: NHS England is now working with other agencies in the system to implement the pause quickly and safely. A Clinical Advisory Group has been established – with membership from NHSE, BSUG, BAUS and RCOG – to define procedures and scope for the high vigilance restriction, advise on a confirmation process to ensure the appropriateness of any mesh procedures intended, recommend a process for provider trust Medical Director sign-off of the surgeon's competence for those mesh procedures required and any alternative operations, and advise on the best options to ensure appropriate patient information and consenting processes are in place in a trust.

4. Q: How will clinical staff be made aware of this decision, and how will you ensure it's being adhered to?

A: NHS England will work with NHS England and NHS Improvement Regional Directors and Medical Directors to ensure the cascade of information around the high vigilance restriction of practice to services. NHS England will also work jointly with NHS Improvement's Medical Director to write to trusts, outlining the requirements of Medical Directors and surgeons to follow the direction, approval process for procedures and competence confirmations.

Additionally, NHS England will work jointly with NHS Improvement's Medical Director to communicate with provider trust Medical Directors and Nursing Directors to ensure patient support is in place for those already on the waiting list for mesh or tape surgery, those for whom there is no alternative and those who are appropriate for an alternative procedure (eg culposuspension) where the skills are not available in that trust and require secondary referral.

5. Q: What about the women who have already suffered – what support is available?

A: There are ongoing efforts to increase the support available to women who are suffering from complications following a mesh procedure. There are 19 specialist mesh centres across the UK where women can seek support and care if they should experience complications following a mesh procedure. We want to ensure that these centres offer the highest quality of care.

Primary stress urinary incontinence surgery is commissioned by Clinical Commissioning Groups (*that's the majority of mesh related treatment*) and NHS England is responsible for the commissioning of complex and revision surgery for complex surgery for urinary incontinence and vaginal and uterine prolapse, including vaginal mesh removal through Specialist Centres.

NHS England, through the Specialised Women's Clinical Reference Group, has reviewed the existing specialist **Urogenital and Anorectal Conditions** and **Recurrent Prolapse and Urinary Incontinence** service specifications and amalgamated them into a single service specification that now covers **Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse**; and developed a new specification for women with **Complications Of Mesh Inserted For Urinary Incontinence and Vaginal Prolapse**. Both service specifications have been subject to stakeholder testing and will be going to three months formal public consultation in July 2018.

Following consultation, NHS England Commissioning Teams and NHS England's Quality Surveillance Team will be assessing all specialist hospitals against the standards set in the complex surgery for urinary incontinence and vaginal and uterine prolapse service specification alongside an assessment of the full suite of other complex gynaecology service specification standards published by NHS England. The assessments will commence in April 2019 and conclude in June 2019. The assessment of hospitals against

the service specification standards may mean that fewer hospitals in the future will be designated to offer these complex treatments, but this will ensure the outcome for each and every patient is the best it can be.

Following the three month consultation of the Complications Of Mesh Inserted For Urinary Incontinence and Vaginal Prolapse Service Specification, NHS England will be procuring a new service to meet the standards set. The procurement will lead to the commissioning of probably up to 4 centres across the country who will provide a new multi-disciplinary team management and complex vaginal mesh removal surgery for women who have complex vaginal mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse. The multi- disciplinary team (MDT) and surgery will be provided by a designated Specialised Mesh Removal Service (Mesh Service). This new service will commence in April 2019.

Patients – past and future surgery

6. Q: I recently had mesh inserted to treat SUI and I am experiencing complications - what should I do?

A: If you have any symptoms that are worrying you, seek advice from your doctor.

Your GP will be aware of an information pack, available at <http://elearning.rcgp.org.uk/mod/page/view.php?id=8254>

7. Q: I recently had mesh inserted to treat SUI but am not experiencing complications – should I get it removed?

A: Many patients have had successful mesh and tape surgery without complications. If you are not experiencing complications, there is no need to take any action.

8. Q: I am on a waiting list to have surgery – am I still able to have this? What support will be offered?

A: It is likely that for the majority of women, a delay until the pause ceases will be the most appropriate option. A Clinical Advisory Group has been convened by NHS England, which will advise on how patients should be supported during the pause. In certain selected patients for whom a delay or alternative treatment would not be appropriate, some such surgery may proceed during the pause under conditions of high vigilance. If you are already on the waiting list or have been given a date for your surgery, your hospital will discuss with you a plan for your ongoing care.

9. Q: What alternatives are available to women who were due to have a tape procedure to treat SUI?

A: Treatment options vary between individual patients depending on the nature of their condition, and should be guided by medical consultation. It should be noted that non-tape surgical procedures for stress urinary incontinence are often more invasive and technically complex, and carry their own risk of complications. It is likely that for the majority of women, a delay until the pause ceases will be the most appropriate option.

10.Q: What alternatives are available to women who were due to have vaginally inserted mesh to treat POP?

Treatment options vary between individual patients, and should be guided by medical consultation.

11.Q: How will services cope with a greater demand if the use of mesh is paused?

A: NHS England is establishing plans to quickly and safely implement this period of high vigilance, while providing appropriate support to patients whose treatment will be affected.

12.Q: For some patients a mesh procedure is the only option – what will they do?

A: In certain selected patients for whom a delay or alternative treatment would not be appropriate, some such surgery may proceed during the pause under conditions of high vigilance. Assurance will be required from hospitals to ensure appropriate patient selection, informed choice, and strict adherence to NICE's Interventional Procedure Guidelines have taken place.

13.Q: Will I still be able to have a mesh procedure if I understand and accept the risks?

A: It is likely that for the majority of women, surgery will be delayed until the pause ceases when all recommendations have been put into place. In certain selected patients for whom a delay or alternative treatment would not be appropriate, some such surgery may proceed during the pause under conditions of high vigilance. Assurance will be required from hospitals to ensure appropriate patient selection, informed choice, and strict adherence to NICE's Interventional Procedure Guidelines.