



29/03/2019

NHS Improvement and NHS England

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To: Regional Directors, Trust Medical Directors, and clinicians involved in the care of patients with stress urinary incontinence and pelvic organ prolapse

Dear Colleagues,

EXTENSION OF PAUSE TO THE USE OF VAGINAL MESH

In July 2018 we wrote to you regarding concerns that some patients had experienced significant adverse effects after operations using synthetic mesh to treat stress urinary incontinence (SUI) or urogynaecological prolapse. In that letter (Appendix A) we asked you to comply immediately with a national 'pause' in the routine use of mesh for these purposes and introduce a period of high vigilance restriction pending the introduction of certain conditions designed to improve the safety of the use of synthetic mesh. At that time the pause was set to last until the end of March 2019.

We are now writing to confirm that the pause and period of high restriction is being extended. The initial high vigilance letter outlined that the restriction will remain in place until the following conditions outlined in section A and B below are met:-

Section A

- 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.

Section B


- Work with NICE as part of their consultation to strengthen patient information by developing patient decision support tools.
- Specialised Commissioning to complete 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.
- Continue to pursue the commissioning of a national clinical audit/registry for urogynaecological procedures for SUI and prolapse.

NHS England and NHS Improvement are progressing the areas outlined in section A and B and continue to work with the Clinical Advisory Group that has been established including members from Specialised Commissioning and clinical experts from the British Society of Urogynaecologists (BSUG) and the British Association of Urological Surgeons (BAUS).

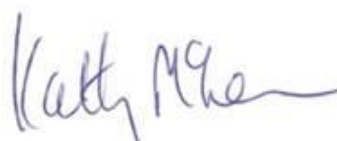
The vast majority of cases linked to the original restriction period will have been postponed. However, there will have been a number of excluded cases in which clinicians judged that there was a clinical urgency to carry out the procedure, and that no suitable alternative exists. In these cases, surgery would have proceeded if a delay would have meant a risk or harm to the patient (such as for procedures involving cancer), based on a multidisciplinary team decision and informed consent. This arrangement is also still in place as part of this extended restriction notification and Trusts will need to continue to provide support to patients affected by this high vigilance restriction.

We will write to you again later this year to update you on progress towards meeting the conditions and when the period of pause can end.

Yours Sincerely,



Stephen Powis
National Medical Director
NHS England



Kathy McLean
Executive Medical Director
and Chief Operating Officer
NHS Improvement

20/07/2018

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To: Regional Directors, Trust Medical Directors, and clinicians involved in the care of patients with stress urinary incontinence and pelvic organ prolapse

From: Professor Keith Willett and Dr Kathy McLean

Dear Colleagues,

On 10th July 2018, the Secretary of State for Health and Social Care and the Chief Medical Officer announced a 'pause' in the use of synthetic mesh/tape to treat stress urinary incontinence (SUI) and urogynaecological prolapse where the mesh is inserted through the vaginal wall. This 'pause' will be operationalised as a 'RESTRICTION OF USE', and a 'HIGH VIGILANCE RESTRICTION PERIOD' for any exceptions to this restriction and for a wider group of related procedures.

We established a Clinical Advisory Group comprising subject matter expert members representing NHS England Medical Directors and Specialised Commissioning CRG, BSUG (British Society of Urogynaecologists), BAUS (British Association of Urological Surgeons), ACPGBI (Association of Coloproctology of Great Britain and Ireland), The Pelvic Floor Society (TPFS) and the Royal College of Obstetrics and Gynaecology (RCOG), who provided recommendations to CMO with the following scope:

- A. Recommend the mesh/tape procedures to be included in the restriction of use.
- B. Recommend and justify any mesh/tape procedures that should be excluded from the restriction, with or without increased vigilance.
- C. Recommend any alternative non-mesh procedures that should be subject to increased vigilance, given the change in practice caused by the restriction on mesh/tape use.
- D. Advise on high vigilance processes which must be followed by NHS and private hospitals for any mesh/tape surgery defined in (A) but deemed clinically essential during the restriction, and for the procedures defined in (B) and (C). This requires

provider trust/hospital Medical Directors to be accountable for ensuring that procedures are in place to:

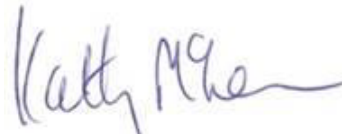
- i. Ensure the necessity and appropriateness of any procedure covered by the restriction of use and high vigilance period.
 - ii. Ensure that all appropriate surgical options have been offered, including where secondary referral would be required.
 - iii. Ensure that appropriate information and consenting processes are in place in all cases.
 - iv. Provide assurance of a surgeon's competence for any procedure offered.
 - v. Ensure there is documenting and registering of included procedures.
- E. Recommend how Trusts and GPs should support patients with advice, including patients newly referred or diagnosed, patients on the waiting list, and patients who have had previous mesh surgery who may have concerns.

The CMO has accepted the recommendations of this group in full and with immediate effect. The attached document describes the actions to be taken.

Yours Sincerely,



Keith Willett
Medical Director for Acute Care and
Emergency Preparedness
NHS England



Kathy McLean
Executive Medical Director
and Chief Operating Officer
NHS Improvement

Appendix: Support for Medical Directors in assuring the competence of surgeons to carry out procedures from the 'high vigilance scrutiny' group

The Clinical Advisory Group guidance requires that the surgeon's competence in the procedure must be signed off in advance by the trust/hospital Medical Director as part of the high vigilance procedure. This should include a 'critical interview' exploring the surgeon's practice and supported by regular performance review, assessing evidence that the surgeon:

- i. has been appropriately trained
- ii. has actively maintained their skills
- iii. has a record of their practice of the procedure, follow-up, and documented complications including mesh/tape removals
- iv. is recording every procedure on the specialty database (BSUG, BAUS or TPFS) or any subsequently developed national recording system

The responsibility for this process lies with the trust Medical Director (MD). The MD may choose to deputise the practicalities of the process to the Clinical Director or a Consultant responsible for governance, who would then report back to the MD. As the MD is ultimately responsible, they must determine the exact methodology within their trust.

The following provides some suggested sources of information and evidence that Medical Directors may wish to take into account in order to support this process.

The surgeon has been appropriately trained (i)

1. Consultants who have completed subspecialty (specialist) training should have documented evidence of procedures that have been formally assessed.
2. Senior Consultants active in training and assessing trainees as competent to perform these procedures can be considered de facto to be evidenced as trained.
3. Some Consultants will have evidence of training outside of a training programme (such as letters confirming competency from a Consultant active in training).
4. In rare circumstances where none of the above applies, if the Medical Director is uncertain in making a judgement, they may ask a specialist society to recommend a recognised expert in the procedure to advise them.

The surgeon has actively maintained their skills (ii)

5. A record of the number of procedures performed is present in the surgeon's logbook, and in the procedure-coded HES data that trusts submit centrally.
6. Surgeons will have documentation of their annual appraisal.
7. Evidence of CPD collected as part of the appraisal process will demonstrate teaching performed, teaching received, and meetings attended. At least every 3 years, this CPD activity should include the subspecialty area in question.

8. Records of the surgeon's attendance for at least 70% of appropriate MDT meetings evidences active involvement in this process.
9. Again, in the event of uncertainty the Medical Director may request the name of a recognised expert from the specialist societies to advise them.

The surgeon has a record of their practice of the procedure, follow-up, and documented complications including mesh/tape removals (iii)

10. Surgeons will maintain a logbook of relevant procedures and of other procedures involving generic skills pertinent to the surgery in question.
11. Records of the procedures performed should also be held by the trust.
12. Significant complications should be discussed at 'Morbidity and Mortality' meetings.
13. All significant complications now require a duty of candour, and hence reporting to the local governance group - as such this data will be available for review.
14. We recommend that each unit should now submit 3-monthly returns to the Responsible Officer.
15. As above, if there are concerns as to whether a surgeon's evidence is sufficient for MD sign-off, then guidance could be sought through a specialist society.

The surgeon is recording every procedure on the specialty database (BSUG, BAUS or TPFS) or any subsequently developed national recording system (iv)

16. This is a new requirement. Surgeons who did not record procedures on these databases previously are not excluded from practice, but all procedures should be recorded from the initiation of the pause onwards.
17. Each surgeon may be asked to provide written assurance to the Responsible Officer committing that data for all patients will be entered onto a national database, except where the patient withholds consent. Trusts should provide administrative support to surgeons for this process.
18. Surgeons should collect summaries of audit data, both for their annual appraisal and at local level 3-monthly. This should correlate with records of activity to confirm 100% data entry compliance.

Recommendations of the Mesh Pause Clinical Advisory Group to Medical Directors and Surgical Teams

The scope of this advice

2. The RESTRICTION OF USE of synthetic tape and mesh in women applies only to procedures for stress urinary incontinence (SUI) and vaginally inserted mesh for pelvic organ prolapse.
3. In addition, a process of HIGH VIGILANCE SCRUTINY should apply:
 - i. to procedures described in 1) where there is no alternative and delay is unacceptable;
 - ii. to procedures offered as alternatives to mesh and tape for SUI or prolapse as a result of the change in practice;
 - iii. to procedures involving abdominally-inserted mesh (see B below).
4. Mesh and tape procedures to be excluded from the restricted practice and high vigilance scrutiny are:
 - i. Mesh used in other types of surgery, such as abdominal wall hernia and inguinal hernia repairs.
 - ii. Mesh used in obstetric practice for cervical sutures.
5. Male urological sling incontinence procedures are not within the remit of this advice. However, these procedures should only be performed as part of a well-conducted randomised controlled trial, in line with existing NICE guidance.
6. The restriction in practice should also not apply to patients enrolled in NIHR portfolio clinical trials. Such trials comprise rigorous patient selection, detailed information and consent, and close monitoring and follow-up. However, researching clinicians should review their trial protocols against the processes below to ensure that the vigilance applied is at least as high as that described in this document, and they must inform participating patients about the context of the pause.

It is noted that this pause will compromise the ability of doctors in training to achieve the expected case numbers of tape procedures for SUI. This should not prevent them from completing training (through award of CCT), provided their competence in the overall management of incontinence is maintained. When practice resumes following the pause if the mesh and tape procedures are reintroduced, these surgeons will require mentorship in the early stages of their consultancy to ensure they are competent in these techniques.

A. Recommendation A: The mesh and tape procedures to be included in the restriction of use

7. The restricted practice should apply only to:
 - i) Insertion of synthetic tape as a surgical intervention in SUI.
 - ii) Vaginally inserted synthetic mesh as a treatment for prolapse.
The consequences of this for the treatment of vaginal prolapse are expected to be very limited as vaginal insertion of synthetic mesh should already have all but ceased as a result of earlier NHSE recommendation and NICE guidance.

8. It is expected that the vast majority of cases covered in 6) will be delayed, or an alternative non-mesh procedure performed if appropriate. Non-surgical interventions should continue to be offered where possible.
9. Where procedures in 6 i) or ii) are considered necessary, i.e. the procedure cannot be delayed and there is no reasonable alternative, then the high vigilance scrutiny criteria should apply, as defined in section D.

B. Recommendation B: Mesh procedures that should be excluded from the restriction but should be subject to high vigilance scrutiny

10. Abdominally-inserted mesh for prolapse (such as for sacrocolpopexy, hysteropexy, and rectopexy) should be excluded from the restriction but included in the high vigilance scrutiny (see section D).
These are complex reconstructive procedures, established in use since the 1980s. Clinical advice is that there are few viable alternatives. It is critical that they are subject to appropriate patient selection, consent and surgical technique – as such, the use of these procedures must be recorded and scrutinised.

C. Recommendation C: Alternative non-mesh procedures that should also be subject to increased vigilance given the change in practice that may result from the restriction of synthetic mesh and tape use.

11. The restriction in practice should not apply to non-tape/mesh alternative procedures for SUI – periurethral injectables, colposuspension and fascial sling procedures.
12. However, it must be recognised that few surgeons now have the skills for open or laparoscopic colposuspension – a complex procedure with recognised complications and failures. (That is why colposuspension was largely replaced by tape procedures, which are less invasive and easier to perform, and the practice expanded). While tape procedures are restricted in use it is possible that more colposuspension procedures may be performed, which intrinsically carry higher risk and therefore could generate a new harm.
13. It will therefore be essential to mitigate this by including non-tape procedures for SUI in the high vigilance scrutiny: e.g. colposuspension, fascial sling procedures, and periurethral injectable treatments. This should apply for the duration of the pause.
14. Biological mesh should not be used as a substitute for synthetic mesh for the treatment of SUI or vaginal prolapse – there is insufficient evidence to support its routine use.