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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:

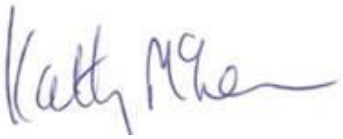
A. **Recommend the mesh/tape procedures to be included in the restriction of use.**
B. **Recommend and justify any mesh/tape procedures that should be excluded from the restriction, with or without increased vigilance.**
C. **Recommend any alternative non-mesh procedures that should be subject to increased 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,



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

The scope of this advice

1. 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.

2. 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).

3. 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.

4. 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.

5. 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

6. The restricted practice should apply only to:

    1. Insertion of synthetic tape as a surgical intervention in SUI.
    2. 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*.

7. 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.

8. 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

9. 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.

10. The restriction in practice should not apply to non-tape/mesh alternative procedures for SUI – periurethral injectables, colposuspension and fascial sling procedures.

11. 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.

12. 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.

13. 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.

Summary table of procedures and level of restriction/scrutiny

PROCEDURE	LEVEL OF RESTRICTION / SCRUTINY
Tape procedures for SUI	Restricted; any clinically essential exceptions to follow high vigilance scrutiny criteria
Mesh procedures for POP	Restricted; any clinically essential exceptions to follow high vigilance scrutiny criteria and NICE guidance
Abdominally-inserted mesh for pelvic organ prolapse (e.g. sacrocolpopexy, hysteropexy, rectopexy)	Not restricted; but subject to high vigilance scrutiny
Complex gynaecological mesh reconstructions, e.g. following cancer surgery	Not restricted; but subject to high vigilance scrutiny
Colposuspension (non-tape procedure for SUI)	Not restricted; but subject to high vigilance scrutiny
Injectable treatments for SUI (non-tape)	Not restricted; but subject to high vigilance scrutiny
Fascial sling (non-tape procedure for SUI)	Not restricted; but subject to high vigilance scrutiny
Mesh used in hernia repair	No change in practice – in line with NICE guidance
Mesh used in cervical sutures in Obstetrics	No change in practice – in line with NICE guidance
Male urological sling procedures	In line with NICE guidance - only to be performed as part of a well-conducted RCT
Biological mesh procedures for SUI and vaginal prolapse	Not to be substituted for synthetic mesh – insufficient evidence for routine use

D. Recommendation D: High vigilance procedures must be in place and followed by NHS and private hospitals for any mesh/tape surgery defined in (A) but deemed clinically necessary during the pause, and for the procedures defined in (B) and (C). <u>The high vigilance process must ensure the necessity and appropriateness of any procedure, and ensure that all appropriate treatment and surgical options have been fully explained and offered, including where secondary referral would be required.</u>

14. The trust/hospital Medical Director is accountable for ensuring that the appropriate high vigilance processes have been followed for each case performed. They may deputise a named clinician to carry out the monitoring of the process on their behalf (but with the Medical Director retaining overall accountability). The affirming clinician must be independent of the patient's clinical care and MDT decision, i.e. not part of their treating team, and need not be of that clinical specialty.

15. A critical element of the high vigilance process must be assurance that the patient has been fully informed of the natural history of the condition, the risks and benefits of conservative, non-surgical and surgical treatment options and any consequence of postponing surgery until a later date. The process must demonstrate that the responsible clinicians have secured and documented the agreement and consent of the patient. The BAUS options leaflet may be used to support this - https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/SUI%20options.pdf

16. The high vigilance process must provide assurance to the Medical Director that a multidisciplinary team (MDT) has agreed the appropriateness of the procedure for that patient, and the need to proceed within this pause period.

    i. The multidisciplinary team must include at least 2 Consultant Surgeons appropriate to the condition (urology, urogynaecology, gynaecology, colorectal surgery).
    ii. The full range of potential techniques for the patient's condition must be known and comprehensively understood by the MDT surgeons (i.e. for SUI – colposuspension, fascial slings, and periurethral injectables). Likewise for prolapse the clinicians within the MDT must have sufficient knowledge and understanding to fully discuss the range of available techniques offered for the patient's condition (i.e. for uterine prolapse – mesh hysteropexy, sacrospinous hysteropexy, hysterectomy and colpocleisis and for vault prolapse - sacrocolpopexy, sacrospinous fixation and colpocleisis)
    iii. It is likely that the frequency of these MDTs will need to increase. Trusts should put into place the necessary administrative support, and factor in the impact on clinicians' job plans.

17. The capability of the local unit should not restrict the patient's treatment options. This may require secondary referral and the formation of local surgical networks. Units performing alternative procedures may require additional resource.

Ensuring that appropriate information and consenting processes are in place in all cases

18. For any mesh procedures necessarily carried out under high vigilance scrutiny, as a minimum the patient information and consenting process must adhere to the recommendations of the NHS England Mesh Working Group and Oversight Group, and use the information agreed with patient representatives in that process and published through NHS England, BAUS and BSUG - https://www.england.nhs.uk/mesh/

19. Equivalent standards must apply to non-mesh procedures under high vigilance scrutiny, using patient information resources from a recognised organisation such as BAUS, BSUG or IUGA (International Urogynaecological Association), and the BAUS options leaflet:
    - https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/SUI%20options.pdf
    - https://www.baus.org.uk/patients/information_leaflets/
    - https://bsug.org.uk/pages/information-for-patients/111

20. Patients must be informed that the procedure is subject to high vigilance scrutiny.

21. As with all data collection, any patient data entry to a register must comply with the GDPR requirements and consent.

A process for Medical Director's assurance of the surgeon's competence

22. 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 - The Pelvic Floor Society) or any subsequently developed national recording system

    NOTE: Further guidance to support the Medical Director's assurance process will be an appendix to this document.

A process for documenting and registering procedures

23. Evidence of adherence to the high vigilance process described above must be included in the medical notes.

24. The Medical Director must ensure that each procedure is recorded on the specialty database (BSUG, BAUS, TPFS) or any subsequently developed national recording system.

E. Recommendation E: Trusts/hospitals and GPs should support patients with advice, including patients newly referred or diagnosed, patients already on the waiting list, and patients who have had previous mesh surgery who may have concerns.

The following are considered appropriate sources of information to support local patient advice processes. Initial patient contact is likely to be through their General Practitioner. Patients on waiting lists for surgery should be contacted and offered advice, and for most that will be through an out-patient review**.**

25. An information pack for GPs is available at: http://elearning.rcgp.org.uk/mod/page/view.php?id=8254
26. The British Association of Urological Surgeons (BAUS) website contains information for patients at: https://www.baus.org.uk/patients/sui_mesh_complications.aspx
27. Information for health professionals, including specialised centre referral information, is available at: https://www.england.nhs.uk/publication/information-for-health-professionals-on-mesh-implants/
28. Patient information from The Pelvic Floor Society (TPFS) is available at: http://thepelvicfloorsociety.co.uk/pages.php?t=Patient-Information&s=Patient-Information&id=92

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.

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

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.

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

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.