

SFNUU Briefing and comments on Scottish Interim Report for the review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women.

BAUS would recommend members review [the interim report](#). The terms of reference and scope are explained in the initial pages.

The document is a thorough review of the current practice in Scotland and also draws a number of conclusions.

A major recommendation for Scotland involves the functioning of their expert review to oversee the working and organisation of services. NHS England has just published their interim report, which complements the Scottish report. The link to this report is available on <https://www.england.nhs.uk/ourwork/qual-clin-lead/mesh/>

In England, the working and organisation of services is likely to be dictated by the NHS England CRG document (E10) on commissioning services for recurrent urinary incontinence and recurrent prolapse. It is anticipated this will come into force next April.

The final report is due out after the results of the PROSPECT trial and SCENIER report when they are published.

Conclusion 1:

Robust clinical governance must surround treatment, the decision to use mesh and the surgical approach used. To support decision making, management of the individual patient should take place in the context of multi-disciplinary team assessment, audit and review. The use of a comprehensive information system will underpin this.

BAUS would highlight to members that all new procedures should be introduced with approval of their Trust's governance for new procedures. This should include the routine selection of outcome data and interim reports back as per local policy. BAUS would also highlight NICE guidance on female incontinence (CD141) to stress the importance of multi-disciplinary teams in decision making. The entry of data into the BAUS audit for stress urinary incontinence is strongly recommended. This audit was carried out in 2014 and it is recommended that all data for 2015 and subsequent years is entered. When the new database is available, then data should be entered within this. BAUS would recommend any increased resources to facilitate multi-disciplinary team meetings and allow data collection, entry and analysis.

Conclusion 2:

Evidence of involvement in multi-disciplinary team working, engagement in audit activity and recording and reporting of adverse events should be an important part of consultant appraisal and thus statutory revalidation of medical staff.

BAUS supports this and would prefer the use of the stress urinary incontinence audit prospectively to achieve this.

Conclusion 3:

Informed consent is a fundamental principle underlying all healthcare. There has been extensive work done by the Expert Group which preceded the establishment of the Independent Review, with leadership by both patients and clinicians. This has resulted in an SUI information leaflet and consent form.

BAUS supports this and has had representation on both the NHS Scotland and NHS England working parties, developing information leaflets. The new information leaflets for stress urinary incontinence and prolapse will be available on the BAUS website from 1st January 2016. All information sheets relevant to the practice of urology will be updated in due course and on a two yearly basis. BAUS have encouraged surgeons to reference their own data from the stress urinary incontinence audit where applicable.

Conclusion 4:

The Independent Review does not consider that current research studies on safety and effectiveness will provide evidence on long term impact of mesh surgery. The lack of extended long term follow up and related outcome data, including information on quality of life and activities of daily living, should be addressed.

BAUS agrees with this and would support the universal rather than unilateral approach across many areas of urological surgery to improve knowledge of longer term outcomes for implants and reconstructive surgery. However, BAUS would advise caution as this information is going to be difficult to collect.

Conclusion 5:

Good information, as stated before, is essential to good patient care. The experience of the Independent Review has been that there are many gaps although there is information both in a professionally led database (the BSUG database) and routine NHS information (SMR01 and SMR00). I

Conclusion 6:

The Independent Review expressed serious concern that some women who had adverse events found they were not believed, adding to their distress and increasing the time before any remedial intervention could take place. Improving awareness of clinical teams of the possible symptoms of mesh complications together with good communication skills, (including good listening and empathy) is an essential part of good clinical care.

BAUS acknowledges this point. BAUS would also comment that robust data on mesh removal is also lacking and the role of this is yet to be completely defined. Likewise, there is no specific training programme or qualification in mesh removal currently available; however, the sub speciality training programme should include the management of complications and a voluntary register of centres performing this surgery will soon become available. This should be addressed via the specialist commissioning process with NHS England.

Conclusion 7:

A review of the different sources of evidence available to and considered by the Independent Review (patient experience, clinical expert opinion, research evidence and epidemiological evidence from routine information) has led us to express concern in this Interim Report at the use of the transobturator rather than the retropubic approach for routine surgery for stress urinary incontinence using mesh. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views.

BAUS have stressed that current NICE guidance recommends all individuals being considered for stress urinary incontinence surgery to be reviewed through multi-disciplinary team meeting and all options including the use of the transobturator tape be discussed

Conclusion 8:

Similar concern is expressed, both for effectiveness and adverse events, at the use of transvaginal mesh in surgery for pelvic organ prolapse. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views.

BAUS would highlight the points to conclusions and points 3 and 4 above. BAUS would also highlight that it is mandatory to report adverse outcomes to the MHRA. Further data is available at <https://yellowcards.mhra.gov.uk/>.