BAUS Section of Female, Neurological & Urodynamic Urology response to the NHS England, Mesh Working Group – Interim report, December 2015

The purpose of the Working Group was to gather opinion from a wide range of interested parties from the clinical and patient communities, policymakers and regulators on what needed to change, and recommend measures to bring that change about.

Professor Keith Willett was appointed chair.

While there has been much debate and some disagreement amongst members, there is consensus between patients, clinicians, policymakers and regulators that there is significant scope for improving care. This can be achieved by focusing on clinical practice, improving data and information, and reviewing procedures for obtaining informed consent.

The Working Group recognised a need to focus on three broad areas which encompass the identified issues. These are:

- **Clinical Quality**
- **Data and Information**
- **Informed Consent**

Recommendations : Clinical quality sub group

Use trust appraisal system to ensure surgeons: are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data requirements and report complications.

BAUS supports this recommendation but urges caution as appraisal systems are variable and a QOF would ensure that this happens.

National Institute of Health and Care Excellence (NICE) to produce a Clinical Guideline that describes, holistically, care for women with Pelvic Organ Prolapse (POP)

BAUS supports this recommendation.

NICE to review current Clinical Guideline for Urinary Incontinence (CG171)

BAUS supports this recommendation.

NICE to review guidance on complications arising from surgery for Stress Urinary Incontinence (SUI) and POP.
BAUS supports this recommendation.

A nurse helpline service for mesh-injured women to be established, modeled on a service being piloted in Scotland.

BAUS supports this recommendation but additional resource will be required to sustain and manage this, and data from this pilot would be necessary before giving full support to identify how successful this is.

GP awareness of treatment options for SUI and POP to be Improved through the introduction of an e-learning package

BAUS supports this recommendation but additional resource will be required to sustain and manage this and both BAUS and BSUG should be involved.

Recommendations : Data and information sub group

Stronger clinical leadership is needed to promote awareness amongst all health care professionals/surgeons undertaking procedures which involve implanting mesh of the importance of returning all the necessary data associated with their activities. The relevant Royal Colleges should be asked to consider identifying an individual or individuals to provide this leadership.

BAUS supports this recommendation and the specialist section will inform all surgeons undertaking these operations of their responsibility, but additional resource will be required to sustain and manage this through managing the ongoing audit and also in the development of a database so that all relevant operations can be recorded. The Medical Director, through the trust appraisal process, should then ensure that evidence of this data entry is recorded.

NHS (Trust) employee appraisal systems should ensure surgeons adhere to clinical guidance, comply with national data requirements and report complications. A section of the appraisal should ask surgeons performing these procedures if they are:

- **following NICE guidance**
- **reporting the procedure on a national database e.g. BSUG/BAUS database**
- **reporting adverse incidents to MHRA, including reporting retrospectively, regardless of whether they carried out the original procedure.**

BAUS supports this recommendation but additional resource will be required to sustain and manage this through managing the ongoing audit and also in the development of a database so that all relevant operations can be recorded. The Medical Director, through the trust appraisal process, should then ensure that evidence of this data entry is recorded.

At present there is considerable lack of resource in trusts to support data entry unlike cancer data, and many trusts do not have the required software to support data entry into a modern web based system. We would recommend funding be made available for a data entry coordinator in all trusts.

There are no specific HES OPCS-4.7 codes to classify full or partial removal of vaginal mesh for POP. Therefore the group recommends that new OPCS codes should be developed to reflect complications which result in full or partial mesh removal and the reason for this

BAUS supports this recommendation.

There is considerable disparity between published evidence in academic/medical literature and experiential evidence from patients on the nature and extent of problems with these devices. A better understanding of the true nature and extent of the complications with these devices needs to be established and more independent rigour brought to discussions

BAUS supports this recommendation but additional resource with support for *prospective* data entry to a database/registry is needed and to also support complications are entered into the MHRA reporting system.

BAUS also supports that future evidence from patients also includes evidence from those that have also had good experiences from mesh implants.

A cost/benefit analysis of establishing a registry for these procedures should be undertaken at the earliest opportunity.

BAUS supports this recommendation but if recommended additional resource with support for data entry would be required.

Recommendations : Informed consent sub group

Consistent information should be given to patients on mesh procedures for treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) through the use of leaflets that have been developed in line with national guidance in collaboration with clinicians, professional bodies and patient support groups in Scotland, England and Wales and Northern Ireland.

BAUS supports this recommendation and will make available to all surgeons and clinical staff the new information sheets that have been developed.

Good practice in obtaining legally informed consent is for discussions between the clinician and patient to take place about: the procedure; the alternatives; recommendations; and questions/understanding. This should be recorded. Reasonable time should be allowed once the patient has been given the information leaflet, and the opportunity to ask questions before signing a consent form. The information leaflet can provide the opportunity for the patient to sign to say this has been completed, by additional text at the end. The consent form to be kept separate from the information leaflet and not to follow a predetermined template. The GMC guidance should be followed when obtaining consent.

BAUS supports this recommendation.

Once finalised RCOG, BSUG and BAUS should recommend the use of these SUI and POP leaflets by all their members, including those operating in the private sector. A letter to be written by Sir Bruce Keogh, Medical Director, NHS England to the NHS Trust Development Authority (NTDA) and Monitor to ask them to ensure Trusts are using the leaflets.

BAUS supports this recommendation.

The SUI and POP leaflets should carry the relevant national NHS logo along with logos from RCOG, RCS, BSUG and BAUS, with a statement that the other nations will be using the same information.

BAUS supports this recommendation.

BSUG and BAUS will aim to review their information leaflets for all SUI and POP procedures and update them in due course.

BAUS supports this recommendation but additional resource will be required to ensure these are completed in a timely fashion.