

# APPENDIX – Information for Health Professionals on Mesh Implants

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## MESH IMPLANTS

Surgical mesh is used in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) to provide extra support when repairing weakened or damaged tissue.

For many women suffering the distressing effects of SUI and POP, surgical procedures using mesh devices have provided an effective form of treatment which can be far less invasive than alternative surgical procedures. Some evidence also suggests improved outcomes for procedures using mesh, over the periods studied. However, the safety and efficacy of surgery for SUI and POP using mesh devices has been questioned. A community of patients has campaigned to raise the profile of concerns surrounding the serious complications that can arise when these devices are implanted in the body.

## MESH WORKING AND OVERSIGHT GROUP

NHS England set up the Mesh Working Group with the support of the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA) in response to concerns raised about the safety of mesh for the treatment of SUI and POP by this community of patients. The Working Group's role was to identify issues causing concern in the treatment of SUI and POP using of mesh devices. It made recommendations to the health system to address them in the Interim Report which can be read [here](#).

Following the publication of the interim report the Mesh oversight group was formed to oversee the implementation of the recommendations made. These recommendations have been successfully

implemented of which one was the creation of this resource. A summary of the work of the oversight group can be seen in the final report of the mesh oversight group and can be read [here](#).

This resource aims to guide GPs on:

- Symptoms and complications that women may present with that may be caused by mesh implants.
- Raise awareness of referral options
- Sign post to good quality patient information approved by the working group and its patient representatives..

## REPORTING

Any adverse incident involving a device should be reported to the MHRA, especially if the incident has led, or might have led to: deterioration in health or permanent impairment of body structure or function; the necessity for medical or surgical intervention (including implant revision); hospitalisation or prolongation of existing hospitalisation; death; life-threatening illness or injury.



<https://yellowcard.mhra.gov.uk/>

### BSUG Audit Database

BSUG Audit Database is an online database tool provided for the membership to gather data for the purposes of audit with statistical reports which aim to raise the standards of care and understanding for this field.

For registration, please contact BSUG Secretariat at [bsug@rcog.org.uk](mailto:bsug@rcog.org.uk)

For BSUG members with an NHS N3 internet connection, the BSUG Audit Database is available here: <https://nww.bsug.nhs.uk>

## PATIENT INFORMATION AND INFORMED CONSENT

Pre-operative patient information leaflets are available for:

- Surgical Procedures for the Treatment of Pelvic Organ Prolapse in Women;
- Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women.

These include an explanation of terms, details on surgical and non-surgical treatment options, possible risks, useful resources, expectations from surgery and information checklists.

The leaflets are not mandatory, but they provide consistent and understandable information for patients and will ensure that GPs can provide the necessary information regarding the proposed procedure.

A consent form is attached to each of these leaflets which include a space for both the patient and health professional to sign, indicating they had received and understood the contents of the information leaflet.

The Patient Information Leaflets can be found here: <http://bsug.org.uk/pages/information-for-patients/111>

## INFORMATION ON CONSENT

It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care for a person. This principle reflects the right of patients to determine what

happens to their own bodies, and is a fundamental part of good practice.

The General Medical Council (GMC) guidance on consent highlights the following process:

- Consent must be obtained from the surgeon doing the operation except in exceptional circumstances.
- The timing of the consent must allow adequate time for the patient to reflect on the information given and reaffirming consent where necessary
- Patients can indicate their consent either orally or in writing; however their consent needs to be recorded in their notes and on their consent form.
- Consent does not legally have to be written on a particular form. It is evidence pertaining to the process and documentation of that process which is important.
- Informed consent should be gained by discussing the following with the patient:
  - The proposed procedure.
  - Alternatives including doing nothing.
  - Risks of the procedure, alternatives and doing nothing.
  - Patient questions.
- Records should show evidence that the patient understands the information given to them.

The GMC guidance can be found at:

[www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)

## EXISTING NICE GUIDANCE

Updated NICE clinical guidance on the use of mesh for the treatment of POP and SUI is expected to be published in 2019. This resource will be updated with the guidance once published.

The following NICE guidelines specifically cover interventional procedures using surgical mesh

- [Sacrolpopexy with hysterectomy using mesh to repair uterine prolapse - guidance \(IPG577\)](#)
- [Single-incision short sling mesh insertion for stress urinary incontinence in women - guidance \(IPG566\)](#)
- [Insertion of mesh uterine suspension sling \(including sacrohysteropexy\) for uterine prolapse repair - guidance \(IPG282\)](#)
- [Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair - guidance \(IPG281\)](#)
- [Surgical repair of vaginal wall prolapse using mesh - guidance \[IPG267\]](#)
- [Sacrolpopexy using mesh for vaginal vault prolapse repair - guidance \(IPG283\)](#)

## INFORMATION FOR MEDICAL DIRECTORS

The NHS England Mesh Working Group recommends that 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.

NHS Trust Medical Directors/Responsible Officers should be responsible for ensuring that these three things are happening as well as requiring surgeons to explain any non-compliance and demonstrate action to address such non-compliance. All independent providers commissioned to provide these services for the NHS should be subject to the same rigor.

## RESEARCH - IN PROGRESS AND EXISTING

Women who have experienced complications following surgical procedures using vaginal mesh implants have expressed concern for some time that the true extent of complications may be higher than currently reported. 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 rigor brought to discussions. Abstracts from the key research papers have been included below.

### PROSPECT study

The PROSPECT study was carried out in 35 hospitals in the UK. Between 2010 and 2013, 1,352 women undergoing primary transvaginal anterior or posterior compartment prolapse surgery were randomly allocated to one of:

- a) a standard anterior or posterior prolapse repair using native tissue alone
- b) a standard repair with a biological graft inlay to support the stitches
- c) a standard repair with a non-absorbable mesh inlay to support the stitches

The primary outcomes, measured at 1 year and 2 years, were participant-reported prolapse symptoms (i.e. the Pelvic Organ Prolapse Symptom Score [POP-SS]) and prolapse-related quality-of-life scores.

The results indicate that augmentation of a vaginal repair with mesh or graft material did not improve women's outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term. However, more than one in ten of the women exposed to synthetic mesh had a mesh complication.

The authors concluded that follow-up is vital to identify any longer-term potential benefits and serious adverse effects of mesh or graft reinforcement in vaginal prolapse surgery.

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31596-3/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31596-3/fulltext)

### MHRA report

*The Use of Polypropylene Mesh In Stress Urinary Incontinence And Pelvic Floor Reconstructive Surgery: a review of biocompatibility*

Polypropylene is the predominant material in mesh devices used to treat pelvic floor conditions such as POP and slings to treat SUI. Due to the nature of complications experienced by some patients implanted with these devices, the biocompatibility of polypropylene has recently come into question. This review of the literature explores the in vivo response to polypropylene used in animal models to determine its suitability as an implantable material. The effects of structure, weight and

size of polypropylene mesh have been considered as well as the impact of anatomical location. Polypropylene based meshes have also been compared to alternative materials including biologically derived meshes and other polymers in terms of the host's response.

This article is currently in the process of being presented to scientific and medical journals for publication with the view to be freely available by 2019.

### SIMS trial:

SIMS is a Health Technology Assessment (HTA) funded randomised control trial evaluating surgical treatment of urinary incontinence in women. It will compare the standard vaginal mesh implant for SUI with a smaller vaginal mesh implant, known as a mini-sling and will have a three year follow-up.

The following text is taken directly from the SIMS webpage:

Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension-Free Mid-Urethral Slings in the Surgical Management Of Female Stress Urinary Incontinence; A Pragmatic Multicentre Non-Inferiority Randomised Controlled Trial

Urinary incontinence (UI) is a common and distressing condition for women particularly over the age of 40 years. In the UK, it is estimated that 6 million (40%) of this age group have clinically significant UI symptoms, 1 million (6.2%) are bothered by symptoms and 0.33 million (2.2%) find them socially disabling. UI has a negative impact on a woman's social, physical and psychological wellbeing; leading to embarrassment, low self-esteem and social isolation.

The aim of this pragmatic multicentre RCT [randomised control trial] is to determine the clinical effectiveness and cost-effectiveness of adjustable anchored Single Incision Mini-Slings (SIMS) compared to tension-free Standard Mid-Urethral Slings (SMUS) in the surgical management of female stress urinary incontinence (SUI).

The hypothesis being tested is that patient-reported success rate following surgical treatment with adjustable anchored SIMS procedures is non-inferior to tension-free SMUS while the former is associated with less post-operative pain, shorter hospital stay, earlier recovery and consequently earlier return to usual activities/work and is more cost effective than SMUS

<https://w3.abdn.ac.uk/hsru/sims/>

### Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

In January 2014, the European Commission asked the SCENIHR to provide an opinion on the safety of surgical meshes used in urogynaecological surgery. The SCENIHR published its preliminary opinion in June 2015 and launched a public consultation on the draft report which closed in July 2015.

The SCENIHR considers three factors as being important when assessing the risks associated with mesh application: the overall surface area of material used, the product design and the properties of the material used. In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP)

than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.

The body of evidence suggests that, when assessing the health risks of synthetic meshes, there is a need to clearly separate the smaller risks associated with stress urinary incontinence sling surgery from those of pelvic organ prolapse mesh surgery.

The final opinion can be read here:

[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/emerging/docs/scenihr\\_049.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_049.pdf)

There are further studies yet to report that will go some way to improve knowledge to desired levels. The most prominent pieces of work will inform future clinical practice, specialised commissioning arrangements and patient choices.

## KEEPING UP TO DATE

As a better understanding of the true nature and extent of complications associated with mesh devices is developed, healthcare professionals should keep up to date by familiarising themselves with the relevant literature and completing relevant continuing professional development. Link to BAUS, BSUG and RCOG as ways to keep up to date.

At the time of publication, NICE guidance on complications with surgical mesh is in development, with publication expected in 2019. Information on guidance in development is available here:

<https://www.nice.org.uk/guidance/indevelopment>