

Mesh Working Group

Interim Report

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Mesh Working Group

Interim Report

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it, to:

- ensure that NHS England can: demonstrate having due regard to the need to eliminate discrimination, harassment and victimisation; advance equality of opportunity; and promote good relations in exercising its functions (the public sector equality duty). Also to ensure NHS England demonstrates that it has given regard to the need to reduce health inequalities in all decision making processes and has evidence of compliance with the legal duties.
- prevent: failure to demonstrate compliance with the public sector equality duty, especially in relation to eliminating discrimination and other prohibited conduct on grounds of age, disability, gender, gender reassignment, marriage and civil partnerships, pregnancy and maternity, race, religion or belief, and sexual orientation. Also to prevent a failure to: act within our legal duties; prevent avoidable health inequalities across the life course; and act in line with NHS England's core values.

Throughout the development of the policies and processes cited in this document, we have also given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services, and in securing that services are provided in an integrated way where this might reduce health inequalities.

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Foreword

Synthetic mesh devices have been used for some time now in the surgical repair of the pelvic area to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

Women suffering from SUI and POP deserve the best possible advice and care. It has become clear to me that the health system has not delivered that level of care consistently and has been working with an insufficiency of information for patients, clinicians, regulators and commissioners.

I became involved in this work because I recognised the system needed to do something to deal with a set of issues that have remained unresolved for too long. I thank the patient groups for their tireless work in bringing these to the fore.

It has been my role as Chair of the Mesh Working Group to bring a degree of independence to proceedings and broker the frank exchange of views from patient and clinical members, regulators and policymakers necessary to inform our approach. It has not been NHS England's role to set the direction of the work: the expertise and experience in this field lie with the clinicians and patients. I am determined to see the system respond to the recommendations of this group.

What is certain is that our current knowledge is insufficient. We must not be complacent and assume current evidence on risk and benefit tells the whole story. This report and these recommendations can therefore only be interim. Encouragingly, we know much better evidence is on the horizon. Clinicians are already changing practice in response to the issues highlighted and patients voices have definitely resonated at all levels in ensuring future patients are better informed. We must continue to improve our knowledge and monitor emerging international evidence and safety reporting, always keeping an open mind as to the appropriate course of action on the appropriateness and role of implanted artificial mesh and slings. The adoption of these issues by NICE and their guidance is most welcomed and will be important in driving best practice.

The purpose of this Working Group was ostensibly to look at surgical procedures using mesh, but it rapidly became clear that we needed to look at all forms of treatment across the system. These wide-ranging recommendations reflect that approach. I believe they will mobilise the health system to bring about significant improvements in care and outcomes for women, and place prominently until satisfied, the as yet unresolved concerns of patients and clinicians.



Professor Keith Willett, NHS England



1 Introduction and background

Use of implantable medical devices is commonplace in surgery. Devices can and do improve patient outcomes in a range of surgical areas, from hip replacements to pacemakers and artificial heart valves. Devices have been used for many years in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). These devices are commonly known as meshes. This is a broad term that covers a number of different types of manufactured biological and synthetic device. They are used in a variety of surgical procedures such as hernia repair, breast reconstruction, vascular repair and the above mentioned urogynaecological procedures.

SUI is the condition where urine leaks with coughing, sneezing or laughing, or with lifting and exercise. A woman's bladder and urethra (water pipe/outlet of urine) are supported by pelvic floor muscles and ligaments. If the support is weakened, for example by childbirth, stress urinary incontinence may occur. The problems can be mild, moderate or severe and can lead to a considerable loss in quality of life. There is a range of non-surgical and surgical treatment options for women with SUI.

POP is the condition where the pelvic organs bulge (prolapse) from their natural position into the vagina. The organs within a woman's pelvis (uterus, bladder and rectum) are normally held in place by ligaments and muscles known as the pelvic floor and these support structures can be weakened by overstretching. Sometimes a prolapse may be large enough to protrude outside the vagina.

Surgical mesh is used in the treatment of SUI and 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 is being 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. They argue that the evidence cited to justify use of mesh is flawed and incomplete, and it is their belief that there is a growing body of evidence painting a less positive picture.

It is important at the outset to differentiate between surgery using mesh for SUI and that for POP. Evidence points to better outcomes and fewer, less serious complications for SUI than POP. Clinical guidance suggests that surgery using mesh for POP should only be carried out by surgeons with specialist expertise, with appropriate patient selection and strong clinical governance arrangements in place. Indeed, the numbers of patients receiving mesh implants in the NHS for POP continues to fall.

Many medical professionals share a number of the patients' concerns. NHS England and the Government have recognised the need to take action in order to assess the extent of any issues and what should be done to tackle them.

As a result, NHS England set up the Mesh Working Group (the Working Group), with the support of the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA), the medical device regulator in the United Kingdom. Both these organisations are standing members. The Working Group's role has been to identify issues causing concern in the treatment of SUI and POP, particularly surrounding use of mesh devices, and make recommendations to the health system to address them.

The Working Group consists of a broad range of organisations and individuals (full membership list, by organisation, at Appendix A) with an interest in improving care and outcomes for women with SUI and POP, particularly related to surgery using mesh devices. There has been strong patient representation from women who have had adverse outcomes from surgery and also a patient liaison member not affected by mesh-related complications. Their experiences and knowledge have been invaluable to the Working Group in determining exactly what the system needs to do to improve care. The medical profession has also been strongly represented. The two relevant specialist societies, British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons (BAUS) have played a central role, and the Royal College of Obstetricians and Gynaecologists (RCOG) has also been represented.

This report will explain the context in which this work has been undertaken, present the debate surrounding ongoing use of mesh and set out recommendations for the activity necessary to optimise care for women undergoing treatment for SUI and POP.

2 Framing the debate

Although some evidence suggests the risk of complications from surgery using mesh falls within accepted limits, there appears to be an increasing number of women who are reporting complications. The Working Group has endeavoured to establish the extent of these complications and ascertain why they have been occurring.

There is evidence that complications, when they do arise, can be very severe and life-altering. There is a lack of comprehensive data on complications, due to issues relating to data coding and incomplete data recording. This is coupled with a lack of data from safety reporting of adverse incidents (AIs) and long term population level surgical outcomes, meaning we do not currently know the true complication rates and cannot use data to gauge severity.

Some of the complications women are reporting are occurring several years after the implant. Studies have not, in the main, been conducted over longer time periods. This means there is insufficient evidence to determine the extent of longer term complications, information that would, if available, be used by clinicians and patients in the consent process. In addition, it is not possible to identify which complications are a result of surgery and which are a natural progression of the underlying condition.

2.1 View from patient members

The patient members of the Working Group adversely affected by mesh have understandably cited the severity of complications as a reason firmly to believe that mesh should not be used at all for this purpose. It is the opinion of those patient members that mesh devices should be suspended pending establishment of a clearer case for their safety and efficacy. If such a case cannot be established, they would want to see procedures using mesh to treat SUI and POP banned.

These members also argue that, because of data inaccuracies, there is a lack of basis for fully informed consent. Furthermore, they have strongly criticised the consenting process itself. They state that they were not given choice, or the time to consider treatment options, and were not given full information on the possible degree of severity of complications.

They do not support the view that non-mesh surgical procedures have worse outcomes as they believe there is not adequate data and evidence to support such a comparison.

They question implantation of mesh devices through what is considered to be a clean contaminated area of the pelvis. It is the view of these patient members that this allows bacteria to travel into the body which subsequently becomes resistant to antibiotic treatment.

They state that there is evidence that mesh implantation procedures (blind insertion of trocars) can seriously damage nerves, causing permanent disability. They also state that evidence suggests mesh is not inert in the body, that it can erode, shrink (tighten) with the formation of scar tissue, fragment and embed into organs causing chronic pain. They also state there is evidence that mesh can cause chronic inflammation and infection. The ultimate outcome of chronic mesh-induced inflammation is unknown, which is of great concern to this community of patients.

Furthermore, there is growing patient concern that there is a possible link between mesh complications and developing an auto immune condition such as lupus or a secondary condition such as fibromyalgia.

These patient members want a thorough scientific study to establish exactly what happens when mesh is implanted in the pelvic region. This, they say, should include: a comprehensive analysis of the composition of the polypropylene mesh; whether chemicals can leach from it into the body once implanted; and what happens to an implanted mesh over time.

2.2 View from clinical members

Clinical members recognise the limitations of current data, but do not agree that mesh use should be discontinued. They cite studies that suggest acceptable risk profiles for these procedures, particularly when compared to the surgical alternatives. This is especially true for SUI. For POP, clinical members recognise clinical guidance that suggests surgery using mesh should only be carried out by surgeons with specialist expertise, with appropriate patient selection and strong clinical governance arrangements in place.

The broad clinical view is that women should not be denied effective surgical options because there is some degree of risk associated with them. They argue that all surgery carries risk and that we need to move forward with new techniques and technology. This is especially true where outcomes from the surgical alternatives are felt to be disappointing and likely to lead to further surgery for recurrence of symptoms. The key to this for clinicians is the consenting process, where prospective surgical patients must be given the information they need to make an informed choice as to the nature of their

treatment. There is broad recognition amongst clinical members of the Working Group that the consent process must be improved.

2.3 Regulatory considerations

It is important to recognise that these mesh devices have to comply with the European Medical Device Regulations that apply to any medical device before it can be sold in Europe. Manufacturers have to declare conformity with the regulations and need to demonstrate that their device meets essential requirements, including those specific to its design and construction. These also include the clinical data, chemical, physical and biological properties, with particular attention paid to: the choice of materials used; toxicity; and compatibility between the materials used and biological tissues, cells and body fluids. Evidence of compliance with the regulations is assessed by a third party called a Notified Body before it can be CE marked and placed on the market in Europe.

This means manufacturers have to ensure the design and construction of mesh conform to safety principles taking account of the generally acknowledged state of the art.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been actively investigating reported issues with SUI and POP mesh implants since 2011 when first brought to its attention by affected patient groups. Although the number of adverse incidents reported was relatively small compared to the number of devices understood to be in use, the severe nature of some of the reported complications was a concern.

However, MHRA's investigations with mesh manufacturers, professional clinical organisations and Notified Bodies, and reviews of published research literature have not found evidence to show that the POP and SUI mesh did not comply with the Regulations. Such evidence would be necessary to justify taking enforcement action against manufacturers such as suspending or removing their devices from the market. Regular consultation with other European and worldwide regulatory authorities has provided similar views.

2.4 Points of agreement

While there has been much debate and some disagreement amongst members, there is consensus between patients, clinicians, policymakers and regulator 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.

3 Why an interim report?

We can be certain that our current knowledge is insufficient. There is a great deal of information to come, in the form of studies and evidence yet to report. (For further information, see *Studies yet to report* section, p.29.) This will significantly enhance that knowledge and clarify the picture over the course of the next two years.

We are already witnessing changes and improvement in the system as a result of this work, in terms of clinical practice change, improved reporting of adverse incidents, and the patient voice being heard and acted upon.

This report and these recommendations are therefore interim, whilst we continue closely to monitor the situation. We believe the steps are now in place to help ensure we will soon be in a better place to make the right decisions, in conjunction with patients, on the appropriateness of mesh use.

4 Approach of the Working Group

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 for his ability to maintain the requisite level of independence to broker open and honest debate in an environment where there are some understandable tensions. Professor Willett has been determined to derive firm recommendations from that debate and ensure the system responds to them.

4.1 Three areas of focus

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**

4.2 Conducting the work

A sub group was set up for each of these areas, consisting of members from the Working Group and selected other people with relevant expertise or experience (membership lists at Appendix B). These sub groups each met initially to define their terms of reference and scope, and then at regular intervals to discuss issues within that scope and formulate draft recommendations. The three sub groups regularly reported their progress to the Working Group at full meetings.

Each sub group has devised a number of recommendations that its members believe will have a positive impact on care for SUI and POP. These draft recommendations have been presented to the Working Group at full meetings to be ratified.

Each sub group's work is described in separate sections of this report, followed by a recommendations log which records the recommendations and the organisation(s) tasked with leading on them. Where there was disagreement, this has been documented.

5 Clinical quality

The purpose of this strand of work was to consider whether clinical practice is currently of sufficient quality to achieve good outcomes consistently. The group was asked to reflect on the areas of clinical practice and process that might need to be improved and the means of bringing that about.

This led the group to make recommendations in the following areas:

- Surgeon practice and training
- Clinical guidance and standards
- GP awareness of post-operative problems and appropriate care pathways
- Support for women with post-operative problems
- Reporting of consultant level outcomes data

After careful consideration of various options, it was agreed that the most effective way to ensure surgeon practice is current and adheres to clinical guidelines is to use the medical appraisal process. If concerted effort is made in this area, this is the strongest lever we have in the system to effect improvement.

The recommendations for the National Institute for Health and Clinical Excellence (NICE) to review its current clinical guidance and create new

guidance were strongly supported by the group and have met with support from NICE. An updated and unified set of Clinical Guidelines for SUI and POP was seen as necessary for promoting best practice. This will be coupled with a number of measures designed to encourage greater adherence to NICE guidance.

Raising awareness amongst GPs of complications and how to address them was a strong theme in the group. Patient members felt their concerns had not been listened to when reported to their GP. Getting help was therefore made very difficult. There was strong consensus that it is vital to raise awareness amongst GPs of possible complications and the care pathways for dealing with them.

Patient members of the group felt that insufficient consideration had been given to whether the devices were safe to implant in the pelvic area. They have called for scientific study to establish exactly what happens when mesh is implanted in the pelvic region.

One patient member, Teresa Hughes, representing Meshies United, does not support the use of appraisal alone to ensure surgeons are recording procedures on a national database. The member would only support this recommendation if a national registry was developed which would effectively mandate the recording of procedures. The subject of a national registry is addressed in Recommendation 4 of the data and information sub group, which recommends the undertaking of a cost benefit analysis of such a registry.

5.1 Recommendations log: Clinical quality sub group

Ref	Description	Lead organisation(s)	Status
CCREC 1	<p>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.</p> <p>The appraisal must ask surgeons performing these procedures if they are:</p> <ul style="list-style-type: none"> • appropriately trained and current in their practice • adhering robustly to NICE guidance (including that for informed consent, and advice on and means of recording any derogation from NICE guidance) • reporting the procedure on a national database e.g. the BSUG and BAUS databases • reporting adverse incidents (AIs) to MHRA* <p>NHS Trust Responsible Officers (RO) should be responsible for ensuring that these things are happening as well as requiring surgeons to explain any non-compliance and for taking action to address it. Any independent providers commissioned to provide services for the NHS should be subject to the same rigour.</p> <p>All surgeons undertaking surgery for both primary and recurrent stress incontinence should submit their data to the BAUS SUI Audit and/or BSUG database. This data should then be submitted as an index procedure for their yearly appraisal. All trust ROs will be informed of this.</p> <p>The RO should inform all appraisers/appraisees who undertake this surgery of this requirement and the need to submit this data for their trust appraisal.</p> <p>*All additional reporting requirements for individual cases also apply, e.g. reporting to local incident systems, the National Reporting and Learning System (NRLS) and serious incidents to Strategic Executive Information System (StEIS).</p>	<p>NHS Trust Development Authority (NTDA)</p> <p>Monitor</p>	Agreed

CCREC 2	<p>National Institute of Health and Care Excellence (NICE) to produce a Clinical Guideline that describes, holistically, care for women with Pelvic Organ Prolapse (POP)</p> <p>Current NICE guidance for POP takes the form of a number of Interventional Procedures Guidelines (IPG). These are focused on specific surgical procedures. A broader, more holistic approach is needed to ensure guidance encompasses the entire pathway of care for POP, to include both surgical and non-surgical treatments. This should take the form of the current NICE Clinical Guideline for Urinary Incontinence (CG171).</p> <p>NICE is recommended to produce a Clinical Guideline that encompasses the whole range of treatment for POP, from conservative, non-surgical interventions to the surgical procedures currently described by IPGs.</p>	NICE	Agreed
CCREC 3	<p>NICE to review current Clinical Guideline for Urinary Incontinence (CG171)</p> <p>The current NICE Clinical Guideline for Urinary Incontinence is recent (September 2013), but it has become necessary to revisit its content due to ongoing concerns related to mesh procedures and evidence from recent studies and those yet to report.</p> <p>CG171 should be reviewed in light of the current context and emerging evidence, with timescales for completion that permit such evidence to be taken into account, where possible.</p>	NICE	Agreed

CCREC 4	<p>NICE to review guidance on complications arising from surgery for Stress Urinary Incontinence (SUI) and POP.</p> <p>A lack of knowledge remains among some clinicians about what to do when complications arise from SUI and POP surgery. As a result, clinicians are not consistently providing sufficient and timely care for patients with complications.</p> <p>NICE is recommended, in its review of the current SUI Clinical Guideline and development of recommended new POP clinical guideline, to include advice to clinicians on managing complications. This should include guidance on the degree of severity of the complication and therefore whether women should be referred to a specialist centre for further surgery.</p> <p>The new Clinical Guidelines should include a comprehensive list of possible complications with an explanation of the possible extent of those complications. This should take the form of a risk profile for each complication.</p>	NICE	Agreed
CCREC 6	<p>A nurse helpline service for mesh-injured women to be established, modelled on a service being piloted in Scotland.</p> <p>Discussions in Scotland with patient and clinician representatives indicated the need for a support service specifically for mesh-injured women that would provide necessary information on how to get support to manage their complications.</p> <p>A helpline service should be set up in England to provide clear, locally tailored advice to mesh-injured women on how to get help (e.g. through mesh-injured units) that actively directs women to other clinical services required (e.g. psychological support services and pain management services) as appropriate and provides information on how patients can report post-operative complications/adverse incidents through MHRA.</p> <p>Information on this service should be placed on NHS Choices and other appropriate channels considered.</p> <p>The service should be well publicised, with a leaflet, poster and screen/video poster campaign for GP practices and other relevant care settings considered. Promotional materials should be reviewed by patient groups before publication.</p>	NHS England	Agreed

CCREC 7	<p>GP awareness of treatment options for SUI and POP to be improved through the introduction of an e-learning package, to include:</p> <ul style="list-style-type: none"> • mesh procedures and their alternatives • how to deal with possible complications • non-surgical interventions • alternative surgical options and their possible complications • information on continence nurse service for mesh injured women <p>Discussions with patient and public voice representatives and clinicians have highlighted that GPs often have little awareness of the issues related to SUI and POP, particularly surgical complications, the impact these can have on patients and how best to refer patients who present with specific health complaints.</p> <p>An e-learning package should be developed under the leadership of the Royal College of Obstetricians and Gynaecologists (RCOG) and BAUS to improve GP awareness of mesh-related clinical issues, and that leads to improved clinical outcomes for patients and ensures patients feel empowered by their GPs to raise any concerns.</p>	Royal College of Obstetricians and Gynaecologists (RCOG) BAUS	Agreed
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6 Data and information

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. The data and information sub group was set up to look at this issue and try to identify any barriers which might exist to ascertaining a true understanding of complication rates for vaginal mesh implant procedures. It considered what action might be taken to remove such barriers.

The sub group considered the data and information currently available on the outcomes and complications following mesh implant procedures and found that there is currently a strong disparity between the types of experience patients are reporting and the published evidence. The sub group concluded that there are several issues around current data collection and reporting of adverse events. These are contributing to the difficulty in establishing an accurate picture of how effective or otherwise treatment using vaginal mesh implant is and of the adverse incidents reported. The issues are:

- Underreporting to MHRA of adverse incidents relating to these procedures
- Hospital Episode Statistics (HES) codes relating to vaginal mesh procedures and salvage procedures being too general to be of use in this context
- Although national databases exist for recording surgical procedures (the BSUG and BAUS databases), completion rates are currently too low
- Patients are not always aware of the options for reporting adverse incidents themselves
- Not enough is being done to collect information on patient experience of these procedures

The recommendations the information and data sub group has developed aim to address these issues by:

- strengthening clinical leadership and, in doing so, improving rates of reporting of adverse events to MHRA, and submissions to the BSUG and BAUS databases
- improving HES coding
- raising awareness amongst patients of their option to use MHRA reporting procedures for adverse incidents
- making more and better use of the information patients themselves can provide.

One of the issues which has been challenging to address is how to capture information on complications when they have occurred after several years (in some cases, complications have not occurred until 10 years or more after the mesh has been implanted). A further challenge is linking it with relevant data which may help identify patterns or trends which could then be interrogated. This could help to establish whether improvements could be made to avoid similar complications in the future. The sub group concluded that there is a potential case to be made for a national registry of vaginal mesh implant procedures which would go some way towards addressing this. However, it also recognised that establishing and maintaining such a registry would be a resource intensive undertaking. Therefore the sub group recommended as a first step that a cost benefit analysis of such a registry should be carried out.

6.1 Recommendations log: Data and information sub group

Ref	Description	Lead organisation(s)	Status
I&DREC1	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>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 for taking action to address such non-compliance. All independent providers commissioned to provide these services for the NHS should be subject to the same rigour. Ideally, private practices should also adhere to the procedures above.</p> <p>These recommendations reflect those made by the clinical quality sub group.</p> <p><i>Rationale for recommendation:</i></p> <p>To ensure that we have an accurate picture of how effective or otherwise this treatment is and of</p>	<p>NHS England</p> <p>RCOG and Royal College of Surgeons (RCS)</p> <p>BSUG</p> <p>BAUS</p>	Agreed

	<p>adverse events, it is essential that clinicians:</p> <ul style="list-style-type: none"> • complete HES data with the appropriate codes especially with potential introduction of new codes for full or partial removal of mesh (see I&DREC2) • fully participate in existing clinical audits • report every case of an adverse incident to the MHRA. 		
I&DREC2	<p>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. A small working group should be established to look at this issue for both POP and SUI and advise on what requests need to be made to HSCIC to introduce new codes in future versions of the OPCS to address this.</p> <p><i>Rationale for recommendation</i></p> <p>Working with the HSCIC and HES, the Data and information group ascertained that the following OPCS-4.7 codes classify vaginal tape procedures for SUI:</p> <p>M53.3 Introduction of tension-free vaginal tape M53.4 Total removal of tension-free vaginal tape M53.5 Partial removal of tension-free vaginal tape M53.6 Introduction of transobturator tape M53.7 Removal of transobturator tape</p> <p>Whilst the following OPCS-4.7 codes classify vaginal mesh procedures:</p> <p>P23.6 Anterior colporrhaphy with mesh reinforcement P23.7 Posterior colporrhaphy with mesh reinforcement P24.5 Repair of vault of vagina with mesh using abdominal approach P24.6 Repair of vault of vagina with mesh using vaginal approach</p> <p>However, there are no specific OPCS-4.7 codes to classify full or partial removal of vaginal mesh</p>	<p>Health and Social Care Information Centre (HSCIC)</p> <p>NHS England</p> <p>Welsh Government to take forward for Patient Episode Data for Wales (PEDW) data</p>	Agreed

	<p>for POP, although there are two codes which include but are not limited to the removal of vaginal mesh:</p> <p>P23.8 Other repair of prolapse of vagina: Other specified Y26.4 Removal of repair material from organ NOC.</p> <p>There are also no specific codes for salvage surgery for POP and SUI. There are no specific codes that specifically classify the above terms.</p> <p>It is clear that there is a gap in OPCS coding which needs to be addressed. Collection of these data will allow for more accurate complication rates to be calculated across POP and SUI procedures.</p> <p>The current coding does not allow the identification of the reason why the tape/mesh has been removed. If codes could be developed which indicate the type of removal and indicate the reason why, this would provide more information via HES about these procedures. However, this is a technical area and so would need experts in the field to develop these codes. HSCIC should form a small expert working group to consider this issue.</p>		
I&DREC3	<p>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. The following actions are needed to address these issues:</p> <p>A. MHRA should continue to raise awareness amongst clinicians about the mechanisms that are in place for reporting/registering adverse events relating to mesh procedures. Emphasis should be placed on the fact that reports can be made retrospectively</p> <p>B. Patient support groups and MHRA, liaising where appropriate, should work to:</p> <ul style="list-style-type: none"> • encourage those women who have experienced adverse events to report them, 	<p>3A: Medicines and Healthcare products Regulatory Agency (MHRA)</p> <p>3B: MHRA and patient support groups</p> <p>3C: NHS England and patient support</p>	Agreed

	<p>ensuring they understand that adverse events can be reported retrospectively</p> <ul style="list-style-type: none"> ensure women are aware that patient identifying details will only be passed on to manufacturers if women give permission for this to be done. <p>C. A one-off information gathering exercise on patient outcomes should be conducted. This exercise should be independent, retrospective, take full account of patient experience and have buy-in from patient groups. It should include a sufficient time frame to detect the long term complications which may not arise for years after the surgery</p> <p><i>Rationale for recommendation:</i></p> <p>Despite extensive efforts, the Data and information group has found it difficult to gather information on mesh-related adverse incidents other than peer-reviewed publications in the medical literature which the group feels does not tell the whole story with regard to adverse incidents. Barriers include lack of codes for mesh salvage surgery referred to in I&DREC1. This contributes to the inability to quantify complications that are widely reported by patients but not contained in published series which also does not tally with the surgeon reported adverse incidents via organisations such as MHRA.</p> <p>The Data and Information Group explored a number of ways of setting up a survey of patient experience of pelvic surgery using mesh, but was not able to establish a way forward. The Group feels investment is needed if there is to be an accurate estimate of the scale of the problem.</p>	<p>groups</p>	
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I&DREC4	<p>A cost/benefit analysis of establishing a registry for these procedures should be undertaken at the earliest opportunity.</p> <p><i>Rationale for recommendation:</i></p> <p>As set out in the rationale for I&DREC3, it is very difficult to ascertain the true rate of adverse incidents for these procedures. Ideally, the group would like to see the establishment of a registry to provide this as well as data on the longer term outcomes of these procedures. The registry would need to differentiate between products. However, recognising the financial implications of establishing such a registry, a cost/benefit analysis should be undertaken in the first instance to inform discussions on whether such a registry would be viable and the scope for using and building on existing data sources.</p>	NHS England Department of Health (DH)	Agreed
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7 Informed consent

The consent process is a vital aspect of any consideration, by patient and clinician, of the risk and benefit of surgery. If a patient is fully informed about the known consequences of surgery, both beneficial and potentially harmful, the responsibility then rests with the patient, aided by the clinician, to make a decision. The same is true for high risk surgery as for low risk. The General Medical Council has provided best practice guidance on this in 'Consent: patients and doctors making decisions together', which clinicians should follow. More information on consent can be found at Appendix C.

The exchange of information between doctor and patient is central to good decision-making. The Informed consent sub group therefore considered the information currently available and where improvements could be made. It found that there was scope to develop information leaflets on mesh implant procedures for both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) which provided consistent and understandable information to be used in the consenting process. Working in collaboration with clinicians, professional bodies and patient support groups in Scotland, England, Wales and Northern Ireland, it has produced two information leaflets. In developing these leaflets, it discussed the following points:

- Making the use of the leaflets mandatory: whilst current policy does not allow NHS England to mandate activities for NHS Trusts or NHS Foundation Trusts, other significant levers can be deployed, through clinical leadership and the backing of professional bodies, to ensure that the leaflets are used in clinical practice
- The implications for the professional bodies of reviewing the leaflets every two years and whether this was too ambitious without funding
- The merits and practicality of attaching a consent form to the information leaflets or to include instead a space for both the patient and health professional to sign, indicating they had received and understood the contents of the information leaflet.
- Whether the leaflets produced by the group would mean more time would be needed for the consent procedure. Additional time might be needed given the comprehensiveness of the information leaflets and subsequently allowing patients sufficient time to absorb the information and come to a conclusion (possibly involving an additional appointment). This could have possible wider implications across the NHS if all surgical procedures were adopt a similar approach in providing information to patients, which would need to be reflected in the commissioning agreements. However, if clinicians were currently undertaking a thorough consent process, the use of these leaflets may not require significantly more time.

7.1 Recommendations log: Informed consent sub group

Ref	Description	Lead organisation(s)	Status
ICREC1	<p>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.</p> <p><i>Rationale for recommendation</i></p> <p>The consent sub group recognises that the information currently given to patients on SUI and POP procedures using mesh is inconsistent. It is important that all patients are given consistent and up to date information so that they can give informed consent based on the best available information that is evidence based.</p>	<p>NHS England</p> <p>RCOG</p> <p>BSUG</p> <p>BAUS</p>	Agreed
ICREC2	<p>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.</p> <p><i>Rationale for recommendation</i></p> <p>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.</p>	<p>NHS England</p> <p>RCOG</p> <p>BSUG</p> <p>BAUS</p>	Agreed

	The key steps in providing information with the aim of obtaining informed consent are: discussing with the procedure with the patient; alternatives including to do nothing; risks; and questions (PARQ). Records should show evidence that the patient understands the information given to them.		
ICREC3	<p>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.</p> <p>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.</p> <p><i>Rationale for recommendation</i></p> <p>It is not possible to mandate the use of the leaflets. Clinical leadership is crucial to ensure their uptake. The former Parliamentary under Secretary of State for Health Dr Dan Poulter MP wrote to David Richmond on 24 March 2015 highlighting this:</p> <p><i>'As discussed, we also seek your leadership with the profession on the issue of informed consent. Providing understandable and meaningful information to patients is at the heart of this and I hope that RCOG and BAUS will feel able to recommend and promote to its members the information leaflets being developed by the NHS England sub group on consent.'</i></p>	RCOG BSUG BAUS	Agreed

ICREC4	<p>The professional bodies should take ownership and aim to have regular and timely (every two years) review of the SUI and POP mesh leaflets through collaboration and coordination with the four UK nations. The review will take into account further evidence as it is made available, to ensure that it is a reflection of best practice in the UK.</p> <p><i>Rationale for recommendation</i></p> <p>As new evidence emerges it is important regularly to review the SUI and POP leaflets to ensure that they reflect any new evidence. It is important that all nations are coordinated to avoid a situation where one nation updates information in isolation from the other nations.</p>	RCOG BSUG BAUS	Agreed
ICREC5	<p>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.</p> <p><i>Rationale for recommendation</i></p> <p>The consent sub group agreed that it would be best if the four nations had separate but coordinated SUI and POP leaflets each carrying their own NHS logo and the professional society logos. The individual nations' NHS logo is important so that each nation has some flexibility. For example, if Scotland wished to have the leaflets presented with the Scottish Government logo then it is free to do so without having to consult with the other nations.</p> <p>RCOG, BAUS and BSUG have agreed that their logos can be used and RCS will be approached.</p>	NHS England RGOG BSUG BAUS	Agreed
ICREC6	<p>BSUG and BAUS will aim to review their information leaflets for all SUI and POP procedures and update them in due course.</p> <p><i>Rationale for recommendation</i></p> <p>BSUG and BAUS recognise the benefits of reviewing all their leaflets for all SUI and POP procedures including those that do not use mesh. BAUS and BSUG are looking into how this update can be implemented.</p>	BSUG BAUS	Agreed

8 Complications surgery

Women who experience problems with their mesh will need the expert help of an experienced doctor. This may be the surgeon who originally implanted their mesh. Women with serious complications will require treatment at a specialist centre by surgeons specifically trained and experienced in dealing with such complications.

NHS England develops service specifications and policies centrally for specialist and highly specialist treatments carried out by care providers. These service specifications are essentially descriptions of the treatment and its aftercare. They also include things like the intended outcomes of the treatment, and accreditation and training of surgeons. NHS England specialised commissioning teams work with providers to ensure these requirements are met in order for them to be able to deliver the service.

The specifications associated with this area are E10: Recurrent Incontinence and E10: Recurrent Prolapse. These specifications lay out the training and accreditation for all gynaecological and urology surgeons working in this area. These specifications will be available from April 2017.

NHS England specialised commissioning teams should ensure that their units include surgeons who undertake mesh removal (salvage) or that their unit has a network arrangement with units that do. Patients undergoing this procedure should be made fully aware of the risks associated with mesh salvage.

All women who are contemplating removal of mesh for clinical or personal reasons should be aware of the risks and complications associated with this procedure. These should be explained to them by their General Practitioner (who will refer them) or by the surgeon performing the operation. The British Association of Urological Surgeons (BAUS) and British Society of Urogynaecology (BSUG) currently hold lists of centres and surgeons who can undertake this work, and will be working together to publicise these lists.

9 Governance and accountability

It is envisaged that an Oversight Group (OG) consisting of selected members of the Mesh Working Group will remain to oversee recommended activities and request lead organisations to report back on their delivery. This group will meet every six months, to monitor progress and provide steer and challenge to the work as necessary.

It will be for the lead organisations for each recommendation to determine timescales for implementing the related activities, in agreement with the OG. Each lead organisation will be expected to submit a plan to the OG for delivery of the recommendation, specifying milestones and the completion date. This will allow effective progress tracking and risk management.

Lead organisations will be expected to work independently of the OG to appoint delivery teams from relevant organisations. They will manage activities without the need for recourse to the OG, except at agreed reporting intervals. However, the OG will be available as a point of reference for lead organisations seeking guidance on delivering their recommendations.

10 Experiential evidence

The experiences of women undergoing surgery have been central to the Working Group's approach to tackling the issues within its scope. Patient members' direct experiences of the procedures themselves, the pathway that led to surgery and the outcomes of surgery have directly informed this work.

However, we know that capturing women's experiences in a formal way is an important part of ensuring we learn from them and that women have been listened to. Finding an effective means of doing so should be an ongoing consideration for the Oversight Group and the partner organisations involved.

11 The Scottish Independent Review

The Mesh Working Group in England has been aware of the work taking place in Scotland in this area and has noted the findings of the Scottish Independent Review's Interim Report. Members of the English and Scottish policy teams have regularly discussed how the respective work aligns and will continue to identify opportunities to work together where this is appropriate.

The Mesh Working Group thanks colleagues in Scotland for their cooperation, in particular in the sharing of informed consent leaflets developed in Scotland, and looks forward to continuing to work closely together in the future.

12 Studies yet to report

There are further studies yet to report that this group must be cognisant of in order for it to improve knowledge to desired levels. The following is a selection of the most prominent pieces of work that will inform ongoing recommendations and consideration of the activity required to improve care and outcomes of SUI and POP surgery.

Web links to information on these studies are at Appendix D.

12.1 PROSPECT study

PROSPECT is a study of women who have had surgery to treat POP. The following text is taken directly from the PROSPECT study webpage:

Around one in 10 women will need prolapse surgery at some point in their lives. There is not enough evidence from research to identify which operation is best. New techniques have been introduced which use mesh to reinforce the surgery, but these have not been properly evaluated, especially in terms of how well they improve prolapse symptoms. In particular, a recent review by NICE (the National Institute for Clinical Excellence) has found that there is insufficient information on the efficacy and safety of mesh used in prolapse surgery in women.

The study will be carried out in at least 15 hospitals in the UK. We will randomise women having an anterior and/or posterior vaginal wall prolapse operation to one of two trials:

Woman having first repair operation

A woman who is having her first repair operation will be randomised to one of: a) a standard anterior or posterior prolapse repair, b) a standard repair with a biological graft inlay to support the stitches; or c) a standard repair with a non-absorbable mesh inlay to support the stitches

Woman having second or subsequent repair

A woman who is having a second or subsequent repair will be randomised to: d) a standard anterior or posterior prolapse repair, e) a standard repair with a non-absorbable mesh inlay to support the stitches, or f) a new mesh repair using an introducer (mesh kit). This last option will only be available for women having a secondary operation for prolapse as it is thought that it is more

invasive than the other options and so should be reserved for such women, because they have a higher risk of failure

Women will have a routine gynaecological examination before surgery and they will complete questionnaires both before and after their operation. Further symptom questionnaires will also be filled in 6, 12 and 24 months later. The women will be examined and reviewed in outpatients at 4 to 6 months after surgery. Our primary outcome is the cure or improvement of prolapse symptoms, as reported by the women themselves

12.2 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 early 2016.

12.3 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.

12.4 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 is now analysing and replying to comments received during the public consultation. The final opinion will be sent for adoption during the plenary meeting on 3 December 2015.

13 Declaration of interest: BSUG database

A patient member of the Working Group, Teresa Hughes, representing Meshies United, has asked BSUG to confirm whether it received funding from mesh manufacturers for developing the BSUG database.

BSUG's full response is as follows:

"The BSUG database was established by and continues to be managed by members of the Society who are practising clinicians. Its primary aim is the recording of all operative information relating to urogynaecology so that

individuals and organisations, including industry, can learn from our own and others experiences and so improve the services we offer our patients.

Setting up and running a database of this sort entails significant time and costs which we as a society do not have. Members give up their time to run the database without recompense because we believe that the collecting and sharing of this information is in the public interest and will improve patient care. The initial costs were met by the acceptance of several unrestricted educational grants from a number of companies that operate within the field of urogynaecology. This included a number of the companies that manufacture tapes for stress urinary incontinence and mesh for prolapse surgery. These companies had no say in the way the database was designed or run.

No other method exists for collecting information on this type of surgery and we would hope that the public would feel reassured and support this BSUG initiative to enable better care for the patients that we treat.”

It is Teresa Hughes' view that this is a conflict of interest. BSUG's view is that unrestricted educational grants do not represent a conflict of interest and that it has declared the interest appropriately by including the information in this report.

14 Appendix

14.1 A: List of Mesh Working Group members organisations

(Individual members named by request)

- British Association of Urological Surgeons (BAUS)
- British Society of Urogynaecology (BSUG)
- Department of Health (DH)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Meshies United, Patient campaign group (represented by Teresa Hughes, Founder)
- National Institute for Health and Care Excellence (NICE)
- NHS England (Acute Care Policy and Strategy Unit; Patient Safety team; Complex Gynaecology Clinical Reference Group)
- Patient Representative for the Mesh Injured Community
- Royal College of Obstetricians and Gynaecologists (RCOG)
- RCOG Women's Network (represented by a lay member of the Network)
- Scottish Government
- Dr Sohier Elneil, Consultant Urogynaecologist, University College London Hospitals NHS Foundation Trust and member of NICE Interventional Procedures Advisory Committee
- TVT MUM (Messed Up Mesh), Patient campaign group (represented by Lorraine Evans, Founder and Researcher, TVT MUM; Hayley Martin – MBACP FdA, Counsellor/Psychotherapist, TVT MUM)
- Welsh Government

14.2 B: List of members of the three sub groups

Clinical quality

- BAUS
- BSUG
- DH
- Meshies United, Patient campaign group (represented by Teresa Hughes, Founder)
- MHRA
- NHS England (Acute Care Policy and Strategy Unit; Complex Gynaecology Clinical Reference Group)
- Patient Representative for the Mesh Injured Community
- RCOG
- Scottish Government
- Dr Sohier Elneil, Consultant Urogynaecologist, University College London Hospitals NHS Foundation Trust and member of NICE Interventional Procedures Advisory Committee

Data and information

- BAUS
- BSUG
- DH
- Health and Social Care Information Centre (HSCIC)
- MHRA
- NHS England (Acute Care Policy and Strategy Unit)
- RCOG
- TVT MUM (Messed Up Mesh), Patient campaign group (represented by Lorraine Evans, Founder and Researcher; Hayley Martin, MBACP FdA, Counsellor/Psychotherapist)
- Welsh Government

Informed consent

- BAUS
- BSUG
- DH
- Ingrid Hardacre, Patient member
- RCOG
- Wael Agur, Consultant Urogynaecologist, NHS Ayrshire and Aran, representing Scottish Government
- Welsh Government

14.3 C: Information on informed 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
- the key steps in providing information with the aim of getting informed consent are discussing with the patient the procedure, alternatives including do nothing, risks and questions (PARQ)
- 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

14.4 D: Web links to studies yet to report

PROSPECT study:

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

SIMS trial:

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

SCENIHR:

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihc_consultation_27_en.htm