

Mesh Oversight Group Report

July 2017

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Mesh Oversight Group Report

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Executive Summary

This Mesh Oversight Group Report follows on from the Mesh Working Group Interim Report of December 2015. Both reports are about vaginal mesh implants used to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in women.

The use of mesh to treat women with SUI and POP is a safe option for women. However, the diligent campaigning of some women who experienced complications from mesh surgery has highlighted the need for better information for women experiencing SUI and POP, better data and a multi-disciplinary approach to caring for women.

During 2016/17 the Mesh Oversight Group ensured that the recommendations of the interim report were implemented working alongside the British Society of Urogynaecology (BSUG); British Association of Urological Surgeons (BAUS); the Royal College of Obstetricians and Gynaecologists (RCOG), and the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), the Department of Health (DH) and of course our patient members. The Mesh Oversight Group report sets out the actions that have been taken to fulfil those recommendations including improvements to:

- The clinical quality of the care women receive including improvements to surgical practice and training, updating of clinical guidance and standards, raising awareness of post-operative problems amongst GPs and offering improved and swifter access to clinical expertise for women with post-operative problems.
- The quality and amount of data and information available to support informed decision making by patients and clinicians. This includes improving the reporting of adverse incidents and improving procedure coding in Hospital Episode Statistics so that a more complete picture of the level and seriousness of complications is established.
- The consent process so women are more aware of the pros and cons of the treatment option they have chosen or agreed to. For example through the provision of high quality standardised information for patients and a more consistent consent process.

The report also summarises the recent research about vaginal mesh implants and the implications of this. It further summarises the development of a GP resource and comprehensive patient information leaflets. Further work will be taken forward to fully deliver the recommendations set out in the interim report. Where this is required the action and action owners are clearly identified.

Foreword by Professor Keith Willett

It is right and proper for those who deliver, lead and regulate health care to listen to patients' concerns and work with all parties to resolve them. A programme of work was initiated in response to concerns from women who developed complications following surgery using vaginal mesh devices to treat stress urinary incontinence (SUI) and treat pelvic organ prolapse (POP)¹. These women felt their concerns had been ignored. I recognised there were issues to be addressed.

The Mesh programme was developed and implemented in partnership with women², specialist societies; the British Society of Urogynaecology (BSUG); British Association of Urological Surgeons (BAUS); the Royal College of Obstetricians and Gynaecologists (RCOG), and the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), the Department of Health (DH) and NHS England. The programme's role has been to consider the use of vaginal mesh in the treatment of SUI and POP and the related standards of care. The programme has adopted an intentionally pragmatic and practical approach to make change happen on the ground and achieve impact quickly for patients. It has focused on the all-important patient-doctor consultation on SUI and POP treatment options, post treatment follow-up and the management of complications if they arise.

I previously chaired the Mesh Working Group which explored the issues with patients and made recommendations to the system in its [interim report](#). I also chaired the Mesh Oversight Group to oversee implementation of those recommendations by the responsible bodies, as described in this final report. I am pleased to be able to say that there has been significant progress since this work began. Information available to women and clinicians is now better and more consistent. Comprehensive information leaflets on treatment options for SUI and POP have been developed. A learning resource for GPs has also been created that uses what we have learned from our patient members about seeing and treating women who have received mesh implants.

In addition, we have made changes to the way surgery is recorded by hospitals and surgeons, which has allowed us to collect more of the data that tells us about complications. There has also been a rise in the number of women and surgeons reporting complications to MHRA, with numbers peaking in 2016. We think this is due to increased awareness and identification, as well as reporting of mesh complications, rather than a rise in the number of complications themselves.

Also, women can now be referred to named units that have declared they have a multi-disciplinary team of health professionals with the experience necessary to advise women who are experiencing complications from mesh surgery on their treatment options.

¹ This report relates only to mesh used to treat stress urinary incontinence (for example, mid-urethral tapes) and vaginally inserted mesh for the treatment of pelvic organ prolapse. This report does not relate to all use of mesh to treat prolapse.

² Where this report refers to 'women' this also includes any patient with gynaecological issues of SUI or POP, regardless of gender identification.

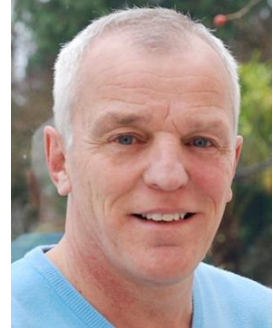
The [Independent Review of Transvaginal Mesh Implants in Scotland](#) reported earlier this year (March 2017). This covered the research base for different procedures and the legal issues both in the UK and USA. I strongly recommend the Review be read in conjunction with this report for those who would like a more in-depth, technical understanding of mesh.

I thank the members of the NHS England Joint Oversight Group for their diligent pursuit of the objectives we were set in the interim report and add special thanks to our patient representatives who have unswervingly kept the group focussed on the patient.

The momentum created by the interim and final report must continue into the future. I am reassured that this will happen by the commitment of NICE to review and develop new guidance related to the care of women with SUI and POP that will impact across the NHS and wider. Our collective vision is that future patients recognise they have been part of a shared decision-making process, experience fewer complications and where complications do occur they are recognised and treated promptly.



Professor Keith Willett, NHS England



Introduction

Use of implantable medical devices is commonplace in surgery. Devices ranging from hip replacements to pacemakers and artificial heart valves can and do improve patient outcomes in a variety of surgical areas. 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 common hernia 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 for urine) are supported by pelvic floor muscles and ligaments. If the support is weakened, for example by childbirth, SUI 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 internal pelvic organs bulge (prolapse) from their natural position into the vagina. The organs within a woman's pelvis, (the 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 artificial support when repairing weakened or damaged tissues.

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. There is published evidence to suggest improved outcomes for procedures using mesh, over the periods studied, but complications are also recognised. Most studies, however, had limited follow-up.

1 Revisiting the issues

The progress detailed in this report was driven by concerns about the effectiveness and safety of mesh implants for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). In 2015 it was recognised that knowledge and data in this area was insufficient and that some women were experiencing complications following surgery.

Although some published research suggested the risk of complications from surgery using mesh falls within accepted limits, an increasing number of women have reported complications, sometimes many years after their surgery. The shared personal experience from patients told us that complications can, for some, be very severe and life-altering.

Patient groups questioned the safety and efficacy of surgery for SUI and POP using mesh devices. They considered the evidence cited to justify use of mesh to be flawed and incomplete. Women felt that medical professionals were insufficiently aware of the potential complications following surgery and that insufficient information was provided for women.

Clinicians also recognised the limitations of data at the time and that information for patients was not good enough. They were clear that the consent process needed to be improved. The broad view of clinical members was that women should not be denied effective surgical options because there is some degree of associated risk (as there is with all surgery), but rather they should be fully informed so they can make the right decision with their doctors.

NHS England and the Department of health (DH) recognised the need to take action to better understand these issues and what should be done to tackle them. This led to the formation of the Mesh Working Group. The purpose of the Working Group was to bring together patient representatives, clinicians, regulatory organisations and stakeholder organisations to participate in open dialogue, identify key issues and make recommendations for a way forward.

The Mesh Working Group published its early findings and recommendations in an interim report in December 2015. The interim nature of the report reflected the insufficiency of evidence available at the time. It also gave an opportunity for patients, clinicians and stakeholder organisations to work together and understand each other's experiences. Since then there has been a continued effort to better understand the implications of using mesh implants, improve services and information for women with mesh implants for SUI and POP, increase the reporting of complications and take account of further published evidence.

2 A focus on quality, information and consent

The Working Group agreed there were three overlapping areas that needed specific improvements in order to address both patient and clinicians concerns.

These are detailed in the interim report and cover the following areas:

Clinical Quality

(CCREC 1, 2, 3, 4, 6, 7 of the interim report)

The purpose of this strand of work was to consider whether clinical practice was 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.

Recommendations were made in the following areas:

- Surgical 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.

Data and Information

(I&DREC 1, 2, 3, 4 of the interim report)

It was agreed there was an incomplete picture of the incidence of complications following mesh surgery due to insufficient reporting and published data. It was recommended that better data collection and better linking of relevant data could track trends and better inform both patients and surgeons.

The following recommendations were made to address these issues.

- Strengthening clinical leadership and, in doing so, improving rates of reporting of adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA), and submissions to the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) databases.
- Improving Hospital Episode Statistics (HES) procedure coding so clinicians can more accurately report what kind of mesh surgery took place and why.
- Raising patient's awareness of self-reporting adverse incidents to MHRA using the [website](#).

Informed Consent

(ICREC 1, 2, 3, 4, 5, 6 of the interim report)

The group considered the information that was commonly available to women and concluded that improvements must be made. Informed discussion and consent is a vital aspect of any discussion between patient and doctor when considering use of mesh. A patient, their GP and surgeon must be fully informed about the potential benefits and risks of surgery. This allows the patient, aided by the clinician, to make an informed decision about the care they wish to have, along with the option of alternatives. This is a fundamental basis of all medical treatment whether it is a relatively minor, low risk treatment or complex surgery with higher associated risks.

Recommendations were made to:

- Provide more consistent information to patients through [information leaflets](#).
- Improve the consent process so it is clearer that all women have given informed consent.

3 Oversight Group

Following the interim report a Mesh Oversight Group was convened to progress those recommendations and hold the responsible bodies to account. This is the final report of the Mesh Oversight Group and should be considered in conjunction with the Mesh Working Group Interim Report of December 2015. This report summarises the action taken to address the recommendations of the interim report. It details how the work was carried out, any work that is ongoing and planned further actions.

The Oversight Group had standing members and associate members.

Standing members were people from organisations with operational responsibility for mesh surgery, those with a policy function and those with a role in regulating medical devices. This included representatives of the two specialist urology and gynaecology societies the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons (BAUS), the Medicines and Healthcare products Regulatory Agency (MHRA), the Royal College of Obstetricians and Gynaecologists (RCOG), National Institute for Health and Care Excellence (NICE), the Department of Health (DH) and NHS England.

Associate membership created a space for women affected by mesh surgery complications to be involved in and influence implementation of the recommendations. The skills, knowledge and experience of all members was recognised as crucial in ensuring the recommendations were achieved and improvements addressed the concerns and issues identified by the Working Group.

A membership list can be found in [appendix 3](#).

The role of the Oversight Group included the following.

- Ensure the Interim Report's recommendations are implemented in a timely manner, according to the project plan.
- Consider opportunities and risks in order to influence successful implementation of the recommendations.
- Have an overview of progress reporting in order to support and facilitate high quality, timely work.
- Ratify and validate the project plan, final report and key documents as they arise.

3.1 Approach of the Oversight Group

The Oversight Group, although chaired by Professor Keith Willett (Medical Director for Acute Care in NHS England), was a group in which the identified lead organisations for each of the interim report's recommendations could come together to ensure progress was being made towards implementation. Each organisation involved in the group had responsibility for actions on their area of influence. The group met every three months to monitor progress, resolve issues and agree how to deal with any hold ups. The expertise of organisations and individuals not represented on the Oversight Group has been sought as necessary.

We did not take a sub-group approach with the Oversight Group as we did with the Working Group. However, a group was set up to conduct a cost benefit analysis of a registry for mesh procedures. This is a complex area of work involving potential system wide change that required expertise of a wide range of people including: NHS England; the Department of Health (DH); the British Society of Urogynaecology (BSUG); British Association of Urological Surgeons (BAUS); the Scottish Government; the Welsh Government; the Medicines and Healthcare products Regulatory Agency (MHRA) and clinicians.

4 Progress in implementing the recommendations

Clinical quality

Surgeon practice and training (CCREC1)

The interim report recommended:

The established hospital doctors' appraisal systems in each hospital trust should be used to ensure surgeons undertaking mesh procedures are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data submission requirements; and report complications.

NHS Improvement (NHSI) (previously NTDA/Monitor) has written to all trust Responsible Officers (ROs) asking them to ensure this is implemented (see [appendix 5](#)). Trust ROs are responsible for ensuring these elements of appraisal are happening in their trusts, requiring surgeons to explain any non-compliance and taking action to address it.

Appraisals now require surgeons to confirm they are:

- Appropriately trained and current in their practice.
- For surgeons undertaking SUI surgery, they are able to demonstrate they are performing these operations regularly through national databases and the appraisal system.
- Reporting the procedure on a national database e.g. the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) databases and reporting adverse incidents (AIs) to the Medicines and Healthcare products Regulatory Agency (MHRA).

The future

Although this recommendation has been delivered it is incumbent upon trust ROs and individual clinicians to ensure these practices become embedded and are sustained long term. NHS England will write to NHSI on behalf of the working group to share the final report and this message of local ownership.

Clinical Guidelines and Standards (CCREC 2, 3, 4)

The interim report recommended:

NICE produce a clinical guideline that describes, holistically, care for women with pelvic organ prolapse (POP), review the current clinical guideline for SUI and the guidance on complications arising from surgery for stress urinary incontinence (SUI) and POP.

After considering all the new evidence, views of topic experts and the NHS England Mesh Working Group Interim Report, NICE agreed to update the clinical guideline for SUI (CG171) and extend the scope to include POP. NICE has engaged in a programme of public consultation. The new guidance is due to be published in early

2019. It will become the reference point for all clinicians, their clinical directors, hospital trusts and commissioners.

NICE also produces Interventional Procedures Guidance (IPG) which is concerned with safety and how well a procedure works. It allows new treatments to be introduced in the NHS in a responsible way. A full list is included in [appendix 4](#).

NICE is updating all IPG about SUI and POP. This guidance will be an additional way to protect the safety of women who are treated with mesh.

The future

The combined SUI and POP guideline is planned for publication in 2019. NICE guidelines are reviewed on a regular basis, at intervals that are influenced by the publication of new evidence and the capacity of the guidelines programme. Any updates after 2019 will be guided by this principle. IPG can be reviewed at any time in the future as new evidence becomes available or every three years.

Support for women with post-operative problems (CCREC 6)

The interim report recommended:

The establishment of a nurse-led helpline for mesh injured women, to be modelled on a service being piloted in Scotland.

The Scottish helpline is available on Mondays between 4.30 pm and 6.30 pm and Thursdays from 9 am to 11 am. The helpline telephone number is 07824537938.

Since this recommendation was made, feedback from the Scottish pilot showed the number of women using the helpline is small³. In order to reach more women in a cost efficient and sustainable way that improves continuity, the Oversight Group agreed a different approach. Currently 18 hospital trusts have identified themselves as having the right multi-disciplinary teams and experience to provide advice and treatment or onward referral for women with mesh complications. Clinical leads in those centres have confirmed they will comply with the criteria set by their specialty, including discussing all patients at a joint meeting to help determine the best treatment options. A list of these units has been published ([BAUS](#) and [BSUG](#) websites) and awareness raised among hospital clinical directors and GPs.

The inclusion of a centre on the list does not confer any accreditation by BAUS or BSUG: the list has been compiled using information submitted by the centre themselves.

All centres offer a multi-disciplinary team (MDT) approach with urology, urogynaecology, specialist radiology, specialist pain management and specialist diagnostic medical / allied health professional team members. If surgery to treat mesh complications is advised by the MDT, and this surgery is felt to be beyond the remit of the unit guided by expert advice, onward referral will be made to an appropriately experienced centre.

³ Initially there were 40 calls in the first two months of the help-line but this dropped to between zero and 15 call per two months.

The future

The national specialised commissioning team will develop, consult on, and publish a service specification for the centres providing an experienced team for mesh removal. This will include advice on referral, multidisciplinary assessment to consider mesh removal, and surgery by expert teams. There will be a procurement of a limited number of centres providing the balance between geographical access and maximising centre activity to rapidly build expertise. These centres will be linked by a national network to report their treatment outcomes.

NHS England's Complex Gynaecology Specialised Commissioning Team is also revising the service specifications of nationally commissioned services for complex gynaecology. These will ensure that NHS England commissions only those services able to demonstrate they meet the defined treatment and quality requirements. As experience develops in the specialised centres for mesh removal, as defined above, and evidence of treatment outcomes are reported, the commissioning team will consider the formation of national clinical policy supporting the pathway of care.

GP awareness of post-operative problems and appropriate care pathways (CCREC 7)

It is now accepted that women may experience complications following mesh surgery many years after the procedure. For these women, primary care is likely to be the first place they raise their concerns. The interim report therefore recommended:

GP awareness of treatment options for SUI and POP must be improved. A learning resource for GPs was commissioned by NHS England so women who see their GP with mesh complications receive the appropriate support and are swiftly referred to self-declared centres where necessary.

The resource includes information covering:

- Signs and symptoms of mesh complications.
- How and where to refer women with suspected mesh complications.
- Reporting of mesh complications.
- Links to patient information leaflets that detail mesh procedures and their alternatives, non-surgical interventions, alternative surgical options and risks and complication.
- Informed consent.
- Current research.
- Clinical guidelines.
- Clinical coding.

Although the resource is primarily aimed at raising awareness among GPs, it is also available to patients and other health professionals. The resource is included in [appendix 4](#). It can also be found [here](#).

As well as the learning resource, awareness will be raised through the usual professional CPD routes for GPs. Ultimately we expect as with other NICE Guidance,

GP electronic records will automatically alert doctors if relevant history and symptoms are entered at a consultation.

The future

The GP resource has been shared with practices across the country and their commissioners. This will provide GPs with the knowledge to identify and holistically support and care for women who present with mesh complications. GPs and their commissioners should ensure this resource continues to be used in general practice going forward.

4.2 Data and information

Improving rates of reporting (I&DREC 1)

The interim report recommended that clinical leaders:

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.

Organisations have worked together to make progress towards capturing accurate complication rates. This work is closely linked to CCREC 1 as Medical Directors/Responsible Officers have been asked to make sure surgeons discuss complications reporting during their appraisal.

BSUG have worked on improving the reporting rate by emailing its membership and highlighting this in several newsletters. BSUG also have a tab on the [website dedicated to MHRA reporting](#).

BAUS has e-mailed all members about MHRA reporting process. BAUS has included a direct link to the reporting tool in their on-line audit of surgery for SUI.

The Royal College of Obstetricians and Gynaecologists (RCOG) has emailed all members regarding the MHRA reporting process. The RCOG also has a page about mesh within the 'Patient safety' section of its website which includes information about the reporting process.

The future

The effects of this drive on reporting should be seen as MHRA data is released on reporting rates. MHRA will continue to evaluate ways to raise awareness of the yellow card system. Reporting will become common practice as an essential component of self-declared mesh complication treatment centres and eventually specialist commissioning arrangements.

Improving Hospital Episode Statistics coding (I&DREC 2)

The interim report recommended:

New Operating Procedure Codes (OPCS) should be developed to reflect complications which result in full or partial mesh removal and the reason for this.

To allow for more accurate complication rates to be calculated for POP and SUI, surgical procedure codes (OPCS codes) have been updated to include the type of procedure and implant and the type of secondary surgery carried out, including total and partial removal of mesh. The updated codes will give us a more detailed picture of why mesh is used, the types of complications occurring and when and why removals take place. A full list of codes can be found in [appendix 4](#).

It is acknowledged the usefulness of information generated from clinical code relies on accurate clinical reporting. That will be promoted through the annual appraisal of individual surgeons as described in CCREC 1.

The future

As well as increased reporting, increased accuracy of reporting, with clearer categories, will empower women and clinicians to deepen their understanding of the impact of mesh procedures for SUI and POP. This work will underpin the work of the self-declared centres and specialised commissioner ultimately improving outcomes for women.

Raising Awareness and Improving Reporting (I&DREC 3A&B)

The interim report recommended a:

Better understanding is needed of the true nature and extent of the complications with these devices.

With the support of stakeholders, MHRA continues to enhance awareness of the Yellow Card Scheme for both clinicians and patients to report complications for urogynaecological mesh devices.

MHRA's work is designed to generate behaviour change by raising awareness of reporting through the following:-

- Education - Informing clinicians, health care practitioners and patients there is a system to report complications.
- Clarity - Providing clarity of how to report, when to report, what to report and what happens as a result of the report.
- Impact - Being able to demonstrate that reporting makes a positive difference by allowing MHRA to understand more about the issues related to these devices, and to determine if any regulatory action is required in the interests of public safety.

The future

Once its communication activities have taken place, MHRA will conduct evaluation to assess whether awareness of the Yellow Card Scheme has increased. MHRA will continue to protect public health by analysing and monitoring adverse incident reports for mesh devices and taking regulatory action if necessary.

(I&DREC 3C)

The Interim report recommended:

A one-off information gathering exercise on patient outcomes should be conducted.

The Oversight Group explored this recommendation at length and agreed that an information gathering exercise would not be feasible. Existing information sources could not provide this type of information and the challenges of collecting this type of new data outweighed the potential benefits when considering the changes to OPCS codes, increase in reporting levels and the creation of self-declared mesh complication centres. Also, the creation of a data dashboard by the specialist commissioning team will meet this requirement and more.

In addition, NICE will collect patient questionnaires as part of their consultation on Clinical Guidelines and IPG. Summaries of these data are not publically available although NICE do recognise the value of publishing anonymised summaries, and will ask the patient involvement team to specifically ask patients for consent to do this in the future.

Developing a Registry (I&DREC 4)

The interim report recommended:

A cost/benefit analysis of establishing a registry for mesh surgeries should be undertaken.

A working group was formed to take forward that recommendation and:

- Look at the current data capture.
- Decide what is needed and how existing data capture can be used and linked together.
- Carry out a cost/benefit analysis of options if necessary.

The registries sub group continues to work to develop a way of allowing the tracking of the mesh device that women receive. The aim is to gain a complete picture of complications and when they occur. The group is examining options to see if there is now a straightforward solution that uses new technology and ways of gathering information. The group is looking at the potential of existing databases and of linking up with the Scan4Safety barcoding initiative. Scan4Safety uses unique barcodes on every medical device and can track the devices over a long period of time. Scan4Safety is currently being adopted in six demonstrator sites.

The Future

The registries subgroup will continue to meet to consider the best way to capture accurate data on the use of mesh and mesh complications. The sub group will report on its findings and make recommendations by November 2017, the original date for publication of this Oversight Groups final report.

4.3 Informed consent

Patient information leaflets (ICREC 1, 2, 3, 4, 5, 6)

The interim report recommended:

Comprehensive patient information leaflets about stress urinary incontinence (SUI) and treat pelvic organ prolapse (POP) be produced, used to improve the consent process, be promoted and branded by senior leaders and stakeholders and reviewed regularly.

Two comprehensive patient information leaflets have now been produced in collaboration with the Independent Review of Transvaginal Mesh Implants working group for Scotland. The leaflets provide information about SUI and POP procedures, surgical alternatives to mesh, non-surgical alternatives to surgery and risk and complications of procedures. The leaflets carry the NHS logo and were made available for use in June 2017. Working with the Scottish group has meant that information is consistent across NHS England and the NHS in Scotland.

The leaflets include an information checklist to be signed by both the patient and surgeon to ensure the patient has read and understood all of the information. The leaflet also makes clear that consent must be obtained from the patient by the surgeon.

These leaflets can be found here for [POP](#) and here for [SUI](#).

BSUG, BAUS and RCOG, have committed to promoting the use of these leaflets to their members. BSUG and BAUS will promote the use of the information leaflets in its next member's newsletter.

The RCOG will promote the use of the patient information leaflets in its next e-newsletter to members and by linking to the leaflets from relevant areas of its website. The RCOG will also promote these resources to women and the public via the 'Patients' section of its website and via its Women's Network and Women's Voices Involvement Panel.

The future

The mesh working group has championed the creation and dissemination of the SUI and POP patient information leaflets. It will now be for the collective authors and champions of the leaflets to ensure they remain up to date. The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.

4.4 Commissioning

For women with gynaecological problems, their first point of contact will often be their GP, who will provide basic advice, treatment and onward referral for specialist input as required. This specialist input can be provided by a range of different providers in different settings depending on how the Clinical Commissioning Group (CCG) has commissioned services, based on its local population's needs.

CCGs commission primary surgical treatment for urinary incontinence, primary surgery for stress urinary incontinence and primary surgery for pelvic organ prolapse.

NHS England commissions:

- The investigation and management of women whose primary surgery for urinary incontinence has failed or who have complications such as mesh exposure following insertion of a tape
- The investigation and management of women whose primary surgery for stress urinary incontinence has failed or who have recurrence of the condition
- The investigation and management of women whose primary surgery for pelvic organ prolapse has failed or who have recurrence of the condition

NHS England Specialised Commissioning Directorate is currently working with the members of the Specialised Women's Services Clinical Reference Group (CRG⁴) on the review of the complex gynaecology service specifications. The service specification review will consider the progress made by the Mesh Oversight Group, NICE guidance and the updated NICE IPG.

Once the group have finalised their recommendations to NHS England, the specifications will go out for a period of public consultation prior to being agreed as the new service specification for commissioning complex gynaecology services.

Regional specialised commissioning teams will then work with their local hospitals to consider if they are able to meet the requirements of the revised service specifications. They will also consider the best way to design services to meet the needs of local women. The regional teams will also ensure that there is a joined up approach to the commissioning of high quality specialised gynaecology services and the delivery of care to women across the whole mesh pathway.

Information generated from a registry could be used to ensure that complex gynaecology services commissioned by NHS England Specialised Commissioning are of good quality. The provision of accurate data to a mesh registry can be considered for inclusion as a 'must do' activity in the contract for mesh services. A Quality Dashboard could then be developed for NHS England commissioned complex gynaecology services to enable ongoing monitoring of the quality of the services. This will include information from professional organisations around complication rates as well as external assessments of providers by regulators such as Care Quality Commission (CQC).

⁴ Clinical Reference Groups (CRGs) to provide clinical advice and leadership to the Specialised Commissioning directorate. These groups of clinicians, commissioners, public health experts, patients and carers use their specific knowledge and expertise to advise NHS England on the best ways that specialised services should be provided.

5 Summary

This report sets out clear and achievable steps to improve the care of women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP). It is a direct and practical response to the serious issues raised by patients and the recommendations published in the interim report in 2015. It describes how improvements will be met in patient information and consent, shared decision-making, procedure recording and complication reporting as part of professional clinical practice. It also describes measures to address the knowledge level in general practice where the majority of initial consultations occur and patients may later present with complications. This report also has a particular focus on those women who have developed complications and their referral and access to self-declared specialist centres with multidisciplinary teams able to advise on and treat complications and post-operative problems. The intention is for those to become specialised commissioned hospital services.

This report also sets out processes to improve the reporting of complications. General Medical Council guidance is clear: adverse events involving mesh as a medical device must be reported and clinicians must bear this responsibility. The Yellow Card Scheme also allows patients to report problems. For the future, barcoding will facilitate the tracking and tracing of mesh implants back to individual patients which will place the NHS hospitals, private hospitals, and the public they serve in a more safety alert environment.

These measures will all contribute to providing best practice care choices for women suffering SUI and POP. Inherent in this is that all appropriate treatments (non-surgical, mesh and non-mesh) should be offered to patients in fully informed consultations. Care should be delivered by a multidisciplinary team of appropriately trained and experienced specialists. All cases should be registered on an appropriate database such as those provided by BSUG and BAUS.

The current NICE clinical guidance on the management of SUI (CG171 updated November 2015) recommends that surgeons should be performing a minimum of 20 sub-urethral sling procedures each year.

'An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than 5 cases of any procedure annually should do so only with the support of their clinical governance committee'.

The contributors to this report strongly suggest surgeons undertaking SUI surgery must be able to demonstrate they are performing these operations regularly through national databases and the appraisal system. Commissioners of gynaecology services that provide treatment for SUI should ensure the services commissioned by them are able to demonstrate compliance with this standard. Where this is not the case, appropriate action must be taken to ensure women have access to quality services nationwide.

The use of vaginal mesh in primary procedures to treat POP is not supported by the current evidence and this should not be offered routinely for the first

surgical intervention. The Chief Medical Officer (CMO) for Scotland, reflecting on the Scottish Independent Report has advised hospital chief executives to consider specifying that surgeons performing POP procedures should complete a minimum number of procedures per year. This report is at one with the CMO that this represents reasonable advice. The issues raised by patients, the increased awareness of late complications amongst surgeons and the more recent research have resulted in a major reduction in the number of such procedures.

Consideration will need to be given as to who is the responsible commissioner for this procedure in the treatment of POP in light of the emerging evidence and revised Interventional Procedural Guidance from NICE once this is published. Once established, the commissioning organisation will need to ensure any competency and quality requirements are reflected in their service specifications and managed through the contracts held with providers of NHS services.

Appendix

1 Research

The following research papers have been published since the interim report was published. Below are abstracts and summaries taken from the source material.

1.1 Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)

Published in *The Lancet* 20 December 2016

“Interpretation of findings

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, but more than one in ten women had a mesh complication. Therefore, 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)

1.2 Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study

Published in *The Lancet* 20 December 2016

“Interpretation of findings

Our results support the use of mesh procedures for incontinence, although further research on longer term outcomes would be beneficial. Mesh procedures for anterior and posterior compartment prolapse cannot be recommended for primary prolapse repair. Both vaginal and abdominal mesh procedures for vaginal vault prolapse repair are associated with similar effectiveness and complication rates to non-mesh vaginal repair. These results therefore do not clearly favour any particular vault repair procedure.”

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32572-7/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32572-7/abstract)

1.3 Synthetic midurethral slings redeemed

Published in *The Lancet* 20 December 2016

“Using data abstracted from the Scottish hospital discharge dataset, Joanne Morling and colleagues¹ have undertaken the Herculean task of evaluating the safety and efficacy of vaginal mesh procedures to treat stress urinary incontinence and pelvic organ prolapse. The most relevant and important take-home message of this study published in *The Lancet*,¹ is that mesh midurethral slings are equally effective as colposuspension, with fewer immediate and similar late complication rates up to 5 years later.”

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32597-1/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32597-1/abstract)

1.4 Mesh, graft, or standard repair for prolapse surgery?

Published in *The Lancet* 20 December 2016

“As reconstructive pelvic surgeons sought to reduce anatomical and symptomatic recurrence of transvaginal prolapse, the concept of incorporating an augmenting material was adopted. With this idea, similar to mesh-based hernia repair, health-care professionals aim to decrease anatomical recurrence of prolapse and thereby decrease the need for reoperation. In the PROSPECT study in *The Lancet*, Chiaris Glazener and colleagues¹ have made progress in answering a clinically relevant question: using two parallel-group randomised controlled trials, the investigators assessed augmentation of transvaginal prolapse surgery with synthetic absorbable or non-absorbable mesh (type 1 monofilament macroporous polypropylene) or biological grafts (porcine acellular collagen matrix, porcine small intestinal submucosa, or bovine dermal).”

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32595-8/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32595-8/abstract)

1.5 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

This trial has been postponed.

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

1.6 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion on The safety of surgical meshes used in urogynecological surgery 2015

“Based on the available scientific evidence, the SCENIHR recommends:

- The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery,
- That due to increased risks associated with the use of synthetic mesh for POP repair via a trans-vaginal route, this option should only be used when other surgical procedures have already failed or are expected to fail.
- Limiting the amount of mesh for all procedures where possible. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for POP surgery.
- The introduction of a certification system for surgeons based on international guidelines and established in cooperation with the relevant European Surgical Associations.
- Appropriate patient selection and counselling, which is of paramount importance for the optimal outcome for all surgical procedures, particularly for the indications discussed. This should be based on the results of further clinical evidence, which should be collected in a systematic fashion for all of these devices.”

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf

1.7 In vivo response to polypropylene following implantation in animal models: a review of biocompatibility

Published in the *International Urogynecology Journal*, February 2017, Volume 28, Issue 2, pp 171–180

“Introduction and hypothesis

Polypropylene is a material that is commonly used to treat pelvic floor conditions such as pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Owing to the nature of complications experienced by some patients implanted with either incontinence or prolapse meshes, the biocompatibility of polypropylene has recently been questioned. This literature review considers the in vivo response to polypropylene following implantation in animal models. The specific areas explored in this review are material selection, impact of anatomical location, and the structure, weight and size of polypropylene mesh types.

Methods

All relevant abstracts from original articles investigating the host response of mesh in vivo were reviewed. Papers were obtained and categorised into various mesh material types: polypropylene, polypropylene composites, and other synthetic and biologically derived mesh.

Results

Polypropylene mesh fared well in comparison with other material types in terms of host response. It was found that a lightweight, large-pore mesh is the most appropriate structure.

Conclusion

The evidence reviewed shows that polypropylene evokes a less inflammatory or similar host response when compared with other materials used in mesh devices”

<https://www.gov.uk/government/news/interrogating-research-to-protect-public-health>

The Cochrane Review has published new questions:

1.8 Open retropubic colposuspension for urinary incontinence in women

Lapitan MCM, Cody JD, (2016). Cochrane Database of Systematic Reviews 2016. DOI: 10.1002/14651858.CD002912.

http://www.cochrane.org/CD002912/INCONT_open-retropubic-colposuspension-urinary-incontinence-women

1.9 Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse

Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J, (2016a). Cochrane Database of Systematic Reviews 2016. DOI: 10.1002/14651858.CD012079;

http://www.cochrane.org/CD012079/MENSTR_transvaginal-mesh-or-grafts-compared-native-tissue-repair-vaginal-prolapse

1.10 Surgery for women with apical vaginal prolapse

Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J, (2016b). Cochrane Database of Systematic Reviews 2016. DOI:10.1002/14651858.CD012376;

http://www.cochrane.org/CD004014/MENSTR_surgical-management-pelvic-organ-prolapse-women

2 Declarations of interest

The BSUG representative on the Mesh Oversight Group is an officer of the British Society of Urogynaecology and has received funding for studies involving the use of mesh for both prolapse repairs and sub-urethral slings.

3 List of Mesh Oversight Group members organisations

Standing members

- British Association of Urological Surgeons (BAUS)
- British Society of Urogynaecology (BSUG)
- Department of Health (DH)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Health and Care Excellence (NICE)
- NHS England (Acute Care Policy and Strategy Unit; Clinical Policy and Operations; Specialised Commissioning)
- Royal College of Obstetricians and Gynaecologists (RCOG)

Associate members

- British Health Care industries
- Meshies United
- RCOG's women's network
- TVT Messed up Mesh (MUM)
- Independent patient members

4 Summary table of recommendations and actions taken

CCREC 1		
Interim report recommendation	Actions taken	Future
<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</p>	<p>NHS Improvement has written to all trust Responsible Officers (ROs) for medical staff appraisal asking them to ensure that this is done.</p>	<p>This recommendation has been delivered.</p> <p>It is incumbent upon trust ROs and individual clinicians to ensure that these practices become embedded and are sustained long term.</p> <p>NHS England will write to NHSI on behalf of the working group to share the final report and this message of local ownership.</p>

<p>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>		
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CCREC 2 & 3		
Interim report recommendation	Actions taken	Future
<p>CCREC2 National Institute of Health and Care Excellence (NICE) to produce a Clinical Guideline that describes, holistically, care for women with Pelvic Organ Prolapse (POP) Current NICE guidance for POP takes the form of a number of Interventional Procedures Guidelines (IPG). These are focused on specific surgical procedures.</p> <p>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</p>	<p>The NICE Centre for Guidelines has commissioned an update and extension of the scope of the clinical guideline for Urinary Incontinence to include Pelvic Organ Prolapse.</p> <ul style="list-style-type: none"> • Review of evidence completed March 2016. (Surveillance report 2016 – Urinary Incontinence (2013) NICE guideline CG171). • NICE consulted on the scope of the review of CG171 in January 2017. 	<p>The combined SUI and POP guideline is planned for publication in 2019.</p> <p>Any updates after 2019 will be guided by this principle.</p>

<p>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> <p>CCREC3 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>	<ul style="list-style-type: none"> • NICE decided that a partial update with an extended scope is necessary for this guideline. • Decision made to extend the scope of CG171 to include pelvic organ prolapse. 	
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CCREC 4		
Interim report recommendation	Actions taken	Future
<p>NICE to review guidance on complications arising from surgery for Stress Urinary Incontinence (SUI) and POP. 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>	<p>The NICE Interventional Procedures Guidance (IPG) programme has updated the following MESH related IPG.</p> <ul style="list-style-type: none"> • Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair - NICE interventional procedure guidance (IPG284) – Published as IPG577 on 22 March 2017. Please find the published guidance here: https://www.nice.org.uk/guidance/ipg577 • Extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women- NICE interventional procedure guidance (IPG133) – Published as IPG576 on 22 March 2017, please find the published guidance here: https://www.nice.org.uk/guidance/ipg576 • Single-incision sub-urethral short tape insertion for stress urinary incontinence in women (2008) NICE interventional procedure guidance IPG262 – published as IPG566 in October 2016 please find the published guidance here: https://www.nice.org.uk/guidance/ipg566 	<ul style="list-style-type: none"> • Surgical repair of vaginal wall prolapse using mesh (2008) NICE interventional procedure guidance IPG267 – publication date: September 2017 • Insertion of biological slings for stress urinary incontinence (2006) NICE interventional procedure guidance IPG154 – publication date: TBC • Intramural urethral bulking procedures for stress urinary incontinence in women (2005) NICE interventional procedure guidance IPG138 - publication date: TBC <p>IPG can be reviewed at</p>

	<ul style="list-style-type: none">• Surgical repair of vaginal wall prolapse using mesh (2008) NICE interventional procedure guidance (IPG267) – the anticipated publication date 27 September 2017• Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair (2009) NICE interventional procedure guidance IPG282 - published as IPG584 in June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg584• IP728/2 Infracoccygeal sacropexy using mesh for uterine prolapse repair (2009) NICE interventional procedure guidance IPG280 – published as IPG582 in June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg582• IP268/3 Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair (2009) NICE interventional procedure guidance IPG281 - published as IPG581 in June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg581	any time in the future as new evidence becomes available or every three years.
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	<ul style="list-style-type: none">• IP311/3 Sacrocolpopexy using mesh for vaginal vault prolapse repair (2009) NICE interventional procedure guidance (IPG283) – published as IPG583 in June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg583 <p>Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair (2009) NICE interventional procedure guidance IPG281 was published as IPG581 on 28 June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg581</p> <p>Infracoccygeal sacropexy using mesh for uterine prolapse repair (2009) NICE interventional procedure guidance IPG280 was published as IPG582 on 28 June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg582</p> <p>Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair (2009) NICE interventional procedure guidance IPG282 was published as IPG584 on 28 June 2017. Please find the guidance here: https://www.nice.org.uk/guidance/ipg584</p>	
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CCREC 6		
Interim report recommendation	Actions taken	Future
<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>	<p>The focus of this recommendation has changed following feedback from the Scottish pilot.</p> <p>18 hospital trusts have identified themselves as having the right multidisciplinary teams and experience to provide advice and treatment or onward referral for women with mesh complications.</p> <p>http://www.baus.org.uk/patients/sui_mesh_complications.aspx</p>	<p>NHS England's Complex Gynaecology Specialist Commissioning Team will consider commissioning named centres for treating women with complications.</p>

CCREC 7		
Interim report recommendation	Actions taken	Future
<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>	<p>A learning resource has been produced. It can also be found here https://www.england.nhs.uk/ourwork/qual-clin-lead/mesh/</p>	<p>The GP resource has been shared with practices across the country and their commissioners.</p> <p>GPs and their commissioners should ensure that this resource continues to be used in general practice going forward.</p>

I&DREC 1		
Interim report recommendation	Actions taken	Future
<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</p>	<p>MHRA continue to raise awareness of the Yellow Card Scheme to increase awareness of reporting of adverse incidents among clinicians and patients.</p> <p>NHS Improvement has written to all trust Responsible Officers (ROs) for medical staff appraisal asking them to ensure that this is done.</p> <p>BSUG have enhanced awareness by emailing the membership, including this in several newsletters and adding a tab on the website dedicated to MHRA reporting.</p> <p>BUAS have raised awareness of reporting with all members.</p> <p>The RCOG has raised awareness by emailing its membership and including a page dedicated to mesh on its website.</p>	<p>MHRA will continue to evaluate ways to raise awareness of the Yellow Card Scheme.</p> <p>Reporting will become common practice as an essential component of self-declared mesh complication treatment centres and eventually specialist commissioning arrangements.</p>

<p>the procedures above.</p> <p>These recommendations reflect those made by the clinical quality sub group.</p> <p>Rationale for recommendation: To ensure that we have an accurate picture of how effective or otherwise this treatment is and of 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. 		
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I&DREC 2		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation Working with the HSCIC and HES, the Data and information</p>	<p>Codes from Final Summary of Changes OPCS 4.7 – OPCS 4.8 - published October 2017</p> <p>M53 Vaginal operations to support outlet of female bladder Note: Principal category, extended at M57 M53.7 Total removal of transobturator tape M57 Other vaginal operations to support outlet of female bladder Note: Principal M53 M57.1 Introduction of vaginal tape NEC</p>	<p>As well as increased reporting, increased accuracy of reporting with clearer categories will empower women and clinicians to deepen their understanding of the impact of mesh procedures for SUI and POP. This work will underpin the work</p>

<p>group ascertained that the following OPCS-4.7 codes classify vaginal tape procedures for SUI: 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 Whilst the following OPCS-4.7 codes classify vaginal mesh procedures: 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 However, there are no specific OPCS-4.7 codes to classify full or partial removal of vaginal mesh for POP, although there are two codes which include but are not limited to the removal of vaginal mesh: 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</p>	<p>M57.2 Total removal of vaginal tape NEC M57.3 Partial removal of vaginal tape NEC M57.4 Partial removal of transobturator tape M57.8 Other specified M57.9 Unspecified</p> <p>P23 Other repair of prolapse of vagina Note: Principal category, extended at P28 Use a supplementary code for concurrent excision of uterus (Q08) P24 Repair of vault of vagina Excludes: Operations to support female bladder (M51-M55) Note: Principal category, extended at P30 P27.4 Endoscopic examination of vagina Includes: Vaginoscopy NEC P28 Repair of prolapse of vagina Note: Principal P23 Use a supplementary code for concurrent excision of uterus (Q08) P28.1 Total removal of prosthetic material from previous repair of vaginal prolapse P28.2 Partial removal of prosthetic material from previous repair of vaginal prolapse P28.8 Other specified P28.9 Unspecified P30 Other repair of vault of vagina Excludes: Operations to support female bladder (M51-M55) Note: Principal P24 P30.1 Total removal of prosthetic material from previous repair of vaginal vault</p>	<p>of the self-declared centres and specialised commissioner ultimately improving outcomes for women.</p>
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<p>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>	<p>prolapse P30.2 Partial removal of prosthetic material from previous repair of vaginal vault prolapse P30.8 Other specified P30.9 Unspecified</p> <p>Q54 Operations on other ligament of uterus Note: Principal category, extended at Q57 Q54.7 Total removal of prosthetic material from previous suspension of uterus Q57 Other operations on other ligament of uterus Note: Principal Q54 Q57.1 Partial removal of prosthetic material from previous suspension of uterus Q57.8 Other specified Q57.9 Unspecified</p>	
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I&DREC 3		
Interim report recommendation	Actions taken	Future
<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</p>	<p>A&B - MHRA has a communications plan outlining the approach to meet its recommendations.</p> <ul style="list-style-type: none"> • MHRA has started phase 1 to engage with key stakeholder organisations. • The aim is to gain each stakeholder organisation's support in raising awareness, 	<p>Once its communication activities have taken place, MHRA will conduct evaluation to assess whether awareness of the</p>

<p>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, ensuring they understand that adverse events can be reported retrospectively • 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>Rationale for recommendation: 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</p>	<p>amongst their constituents, of using the Yellow Card Scheme to report adverse incidents involving mesh.</p> <ul style="list-style-type: none"> • MHRA is also obtaining further insight into, and will benchmark, the clinicians current understanding and use of the Yellow Card Scheme. • MHRA included some information about the Yellow Card scheme in NHS England’s POP leaflet. <p>C – A one off information gathering exercise was found not to be feasible.</p>	<p>Yellow Card Scheme has increased.</p>
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<p>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>		
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I&DREC 4		
Interim report recommendation	Actions taken	Future
<p>A cost/benefit analysis of establishing a registry for these procedures should be undertaken at the earliest opportunity.</p> <p>Rationale for recommendation: 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>	<p>A sub-group has been formed to look at options about a registry.</p> <p>The potential of existing databases and Scan4Safety is also being examined.</p>	<p>The registries subgroup will continue to meet to consider the best way to capture accurate data on the use of mesh and mesh complications. The sub group will report on its findings and make recommendations by November 2017, the original date for publication of this Oversight Groups final report.</p>

ICREC 1		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation 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>A comprehensive patient information leaflet about SUI has been produced in collaboration with Independent Review of Transvaginal Mesh Implants working group for Scotland.</p> <p>A comprehensive patient information leaflet about POP has been produced in collaboration with Independent Review of Transvaginal Mesh Implants working group for Scotland.</p>	<p>The mesh working group has championed the creation and dissemination of the SUI and POP patient information leaflets. It will now be for the collective authors and champions of the leaflets to ensure that they remain up to date.</p> <p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

ICREC 2		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation</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. 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.</p>	<p>Both leaflets include a page for patients and clinician to sign to confirm the patient has read and understood the information in the leaflet and discussed risks with their surgeon. This is not a consent form but does check the patients understanding.</p> <p>I confirm that I have read and understood, to the best of my ability, all the information in the booklet including:</p> <ul style="list-style-type: none"> • The details of the procedure proposed and the desired outcome • All available alternatives of this procedure and their advantages and disadvantages • All information on possible risks including my own • All my questions were answered' <p>There is a page to write down questions for their surgeon and expectations from surgery.</p>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

ICREC 3		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation 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: '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.'</p>	<p>BSUG will include information about the leaflets in their newsletter. BSUG have included the leaflets on its website.</p> <p>BAUS have included the leaflets on its website.</p> <p>The RCOG has included the leaflets on its website and will promote these resources in its member e-newsletter and via its lay networks.</p> <p>NHS England wrote to NHS Improvement (formally NTDA) in January 2017 to ask them to ensure that the leaflets are being used.</p>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

ICREC 4		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation 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>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG.</p>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

ICREC 5		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation 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</p>	<p>The SUI leaflet carries the NHS logo. It has been made clear where there are differences between Scottish and English recommendations.</p>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

<p>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>		
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ICREC 6		
Interim report recommendation	Actions taken	Future
<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>Rationale for recommendation</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>	<p>The English Oversight Group have worked with the Scottish Review to create the information leaflets.</p>	<p>The leaflets will be reviewed in 2019 by BAUS and BSUG who will update the leaflets to include the latest information and guidelines.</p>

4 Letter from NHSI to trust ROs

Provider bulletin: 16 March 2016


Please implement the urologist and gynaecologist surgeon appraisal system

NHS England's ['Mesh working group interim report'](#) recommends that all medical directors/responsible officers use the urologist and gynaecologist surgeon appraisal system to focus on improving clinical practice and reporting in this surgical area. To help with this, please can you ensure that surgeons within your organisation:

- are appropriately trained in their practice
- adhere to NICE clinical guidance
- comply with national data requirements (by recording procedures on either the British Society of Urogynaecology (BSUG) or British Association of Urological Surgeons (BAUS) database)
- report complications/adverse incidents to the Medicines and Healthcare products Regulatory Agency (MHRA)
- explain any non-compliance and take action to address it

5 Mesh resource for GPs

Mesh complications

SYMPTOMS	SIGNS of mesh complications on examination	ACTIONS																		
<p>Patients may present with any of the following symptoms:</p> <ul style="list-style-type: none"> <input type="radio"/> Irregular vaginal bleeding or discharge <input type="radio"/> Pelvic pain or swelling <input type="radio"/> Discomfort during intercourse <input type="radio"/> Recurrent or new bladder or bowel symptoms <input type="radio"/> Prickling feeling or pain in the vagina, which may be exacerbated by exercise <input type="radio"/> Buttock or leg pain: a searing pain <p>These symptoms are more likely to be mesh-related if there was recognised damage to the bladder, urethra or bowels during the original mesh procedure.</p> <p>If a problem with a mesh device is suspected then the patient will need to be physically examined for any of the following signs of a mesh related problem.</p> <p style="text-align: center;">1</p>	<ul style="list-style-type: none"> ! Tenderness on palpating the mesh ! Graft / mesh exposure (erosion) into the vagina ! Mesh erosion into the bladder, urethra or bowel ! Failure of the procedure and recurrence of prolapse ! Vaginal adhesions and/or scarring <div style="border: 1px solid yellow; padding: 5px; margin-top: 10px;"> <p>REPORTING YellowCard</p> <p>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.</p> <p>https://yellowcard.mhra.gov.uk/</p> </div> <p>The Patient Information Leaflets can be found here: bsug.org.uk/pages/information-for-patients/111</p> <p style="text-align: center;">2</p>	<p>Patients with mesh complications will likely require referral to a gynaecology or urology team.</p> <p>Patients with significant mesh problems after Stress Urinary Incontinence or Pelvic Organ Prolapse surgery can be seen by the units below. Please click on the city for a link to referral information on the relevant unit.</p> <p>These units are self-selected and this list will be updated so please check the link below for the most comprehensive list. Work is underway to commission mesh complication services through NHS England specialised commissioning.</p> <div style="display: flex; align-items: center;">  <table border="0"> <tr> <td><input type="button" value="Glasgow"/></td> <td><input type="button" value="Cambridge"/></td> </tr> <tr> <td><input type="button" value="Newcastle"/></td> <td><input type="button" value="Stevenage"/></td> </tr> <tr> <td><input type="button" value="Middlesbrough"/></td> <td><input type="button" value="Oxford"/></td> </tr> <tr> <td><input type="button" value="Manchester"/></td> <td><input type="button" value="London UCLH"/></td> </tr> <tr> <td><input type="button" value="Wakefield"/></td> <td><input type="button" value="London Imperial"/></td> </tr> <tr> <td><input type="button" value="Sheffield"/></td> <td><input type="button" value="London Guys & St Thomas"/></td> </tr> <tr> <td><input type="button" value="Birmingham"/></td> <td><input type="button" value="Bristol"/></td> </tr> <tr> <td><input type="button" value="Leicester"/></td> <td><input type="button" value="Epsom"/></td> </tr> <tr> <td><input type="button" value="Norwich"/></td> <td><input type="button" value="Eastbourne"/></td> </tr> </table> </div> <p>A list of all the units is available here: baus.org.uk/patients/sui_mesh_complications.aspx#return</p> <p style="text-align: center;">3</p>	<input type="button" value="Glasgow"/>	<input type="button" value="Cambridge"/>	<input type="button" value="Newcastle"/>	<input type="button" value="Stevenage"/>	<input type="button" value="Middlesbrough"/>	<input type="button" value="Oxford"/>	<input type="button" value="Manchester"/>	<input type="button" value="London UCLH"/>	<input type="button" value="Wakefield"/>	<input type="button" value="London Imperial"/>	<input type="button" value="Sheffield"/>	<input type="button" value="London Guys & St Thomas"/>	<input type="button" value="Birmingham"/>	<input type="button" value="Bristol"/>	<input type="button" value="Leicester"/>	<input type="button" value="Epsom"/>	<input type="button" value="Norwich"/>	<input type="button" value="Eastbourne"/>
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For more information see the attached appendix

APPENDIX – Information for Health Professionals on Mesh Implants

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1 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

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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.

2 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..

3 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/>

4 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

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

5 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>

6 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

7 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

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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 \(IPG283\)](#)

8 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.

9 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.

10 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

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- 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)

11 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.

12 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-

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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/>

13 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_0049.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.

14 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>

