THE USE OF URO-GYNAECOLOGICAL MESH IN SURGICAL PROCEDURES

Report to the Minister for Health
Mr. Simon Harris T.D

From the Chief Medical Officer

21st November 2018

How to use this Report

Readers should note that for ease of navigation, report findings and recommendations are presented in the body of the report as follows:

Finding

Findings are presented as white font in a dark blue box

Recommendation:
Recommendations are presented in light blue boxes

Weblinks are included to direct the reader to sources of further information or resources where relevant. These are presented in blue text as a hyperlink e.g. https://health.gov.ie/

Table of Contents

Glossary of Terms and Abbreviations

ARTG	Australian Register of Therapeutic Goods
BAUS	British Association of Urological Surgeons
BSUG	British Society of Urogynaecology
CFI	Continence Foundation of Ireland
CMO	Chief Medical Officer
DH	Department of Health (England)
DOH	Department of Health (Ireland)
EU	European Commission
FDA	Food and Drug Administration (US)
GP	General Practitioner
HPRA	Health Products Regulatory Authority
HSCNI	Health and Social Care Board, Northern Ireland
HSE	Health Service Executive
INOR	Irish National Orthopaedic Registry
IOG	Institute of Obstetricians and Gynaecology
IVDR	Regulation 2017/746 on *In-Vitro* Diagnostic Devices
MDR	Regulation 2017/745 on Medical Devices
MDT	Multi-Disciplinary Team
MHRA	Medicines and Healthcare Regulatory Authority (UK)
MUS	mid-urethral sling
NHS	National Health Service (England and Scotland)
NICE	National Institute for Health and Care Excellence (UK)
NIMS	National Incident Management System
NOCA	National Office for Clinical Audit
NtH	Notice to Hospitals
NWHIP	National Women and Infants' Health Programme
POP	Pelvic organ prolapse
PTBs	Professional training bodies
RANZCOG	Royal Australia and New Zealand College of Obstetricians and Gynaecologists
RCOG	Royal College of Obstetricians and Gynaecologists (UK)
RCPI	Royal College of Physicians in Ireland
RCSI	Royal College of Surgeons in Ireland
SCA	State Claims Agency
SCENIHR	European Scientific Committee on Emerging and Newly Identified Health Risks
SUI	Stress urinary incontinence
TD	Teachta Dála
TGA	Therapeutic Goods Administration (Australia)

CE mark: A mark of quality applied to medical devices in accordance with the Medical Devices Directive 93/42/EEC (as amended) which was transposed into Irish law by S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations (as amended). A CE marked medical device can then be freely placed on the entire EU market.

Executive Summary

Introduction

Synthetic mesh devices have been widely used in the surgical treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in women over the past two decades. For many women suffering the distressing symptoms of SUI and POP, surgical procedures using synthetic mesh devices have provided a more effective and less invasive form of treatment than traditional surgical procedures. However, controversy about the safety of mesh devices has arisen in many countries because of concerns about the frequency and severity of complications associated with their use.

Background

In November 2017, in response to public and patient concern about the ongoing safety of mesh devices and recognising the complexity of the issues involved, the Minister for Health, Mr. Simon Harris T.D. requested the Chief Medical Officer (CMO) to prepare a report for him on the clinical and technical issues involved in ensuring both:

a) the safe and effective provision of mesh procedures in uro-gynaecology and

b) an appropriate response to women who suffer mesh complications.

Methodology

Preparation of this report has involved consultation and engagement with national and international bodies, including the Health Products Regulatory Agency (HPRA); the relevant professional training bodies, the Institute of Obstetricians and Gynaecology (IOG) and the Royal College of Surgeons in Ireland (RCSI); the Continence Foundation of Ireland (CFI) and the Health Service Executive (HSE), as well as colleagues in other jurisdictions. The report has also been informed by review of international reports and safety reviews of mesh surgery which have been published in recent years, as summarised in Appendix 1.

The report has also been informed by the personal experiences of women who have suffered complications following mesh surgery, as described through representations made by them and by politicians on their behalf to the Minister and the Department of Health; and from a meeting of the Minister with representatives of the Mesh Survivors Ireland group at which women described distressing and painful complications which were severe and life-altering. The bravery, commitment and dignity shown by these women in sharing what were harrowing, deeply personal experiences are acknowledged and appreciated. The telling of their stories makes public what heretofore was often a private suffering.

However, it is important to note that the views of the many women who have undergone mesh procedures and have had satisfactory outcomes, with minor or no complications, could not be reflected in this report. Also, following the implementation of a pause in mesh procedures by the HSE in July 2018, as described in Section 2, a number of women whose procedures were postponed made representations to the Department expressing concern at the impact that this had on them personally as they awaited treatment for the distressing symptoms of SUI.

The report provides a brief background description of mesh implant devices, including the complications associated with their use; and summarises international best practice in the use of mesh procedures in the clinical management of SUI and POP. A range of recommendations for action by the

HSE is identified, to provide assurance that the use of mesh implants and the care of women requiring aftercare in Irish hospitals is in line with emerging evidence and best practice internationally, based on expert advice received and review of international experience.

Several important interim system actions to address the safety and effectiveness of mesh implant use have been progressed in advance of completion of the report and these are described in the report.

Actions to date

On July 24th, 2018, the HSE was requested by the CMO to pause all uro-gynaecological mesh procedures, in cases where it is clinically appropriate and safe to do so, pending confirmation by the HSE of the implementation of recommendations relating to (i) professional training requirements, (ii) patient information and consent and (iii) the development and maintenance of a national data set for all mesh procedures carried out in HSE funded hospitals. The request to institute a pause in vaginal mesh procedures was considered proportionate and necessary to address public and patient concern about the ongoing safety of mesh devices as comprehensively as possible. The request followed consideration by the Department of the announcement by health authorities in the United Kingdom earlier that month to institute a similar pause, which arose because of a lack of certainty or confidence that critical clinical governance measures to assure the safety of mesh procedures were demonstrably in place. The Department considered that similar concerns about the visibility and consistency of such measures apply equally in the public health system here.

Prior to this request, in May 2018, the HSE had been requested to begin work immediately on the development of national standardised patient information and informed consent materials and the clarification and development of treatment pathways and appropriate referral services for women suffering serious complications.

A Synthetic Mesh Devices Advisory Group has been convened by the National Women and Infants' Health Programme (NWIHP) which includes three patient representatives, as well as representatives of the HPRA, the IOG, the RCSI, the CFI and all Hospital Groups, to advise on and progress all the interim recommendations as advised to the HSE in May 2018 and in July 2018.

Report Findings

Overall Findings

- Mesh implant devices are certified as compliant with relevant European Union (EU) legislation and no market action against mesh devices for the treatment of SUI or POP has been taken by any of the European device regulatory competent authorities.
- There is an extensive evidence base supporting (i) the use of the mid-urethral sling (MUS) devices in the treatment of SUI and (ii) the use of abdominally placed mesh in the management of POP. A significant majority of patients benefit greatly from these procedures, with reduced long-term complications and improved functional outcomes compared to non-mesh procedures.
- Mesh procedures should be performed by trained personnel, in patients who are appropriately selected and counselled and when appropriate multidisciplinary expertise and clinical governance mechanisms are in place.

- Transvaginal placement of mesh for the treatment of POP is no longer regarded as appropriate first line treatment. Its use is restricted by clinical guidance in some jurisdictions. Regulatory restrictions on its use are in place in Australia and New Zealand.
- Mesh devices are associated with significant and severe complications in a minority of women, which are of concern given the difficulties of mesh implant removal.
- Many other health systems, including the United Kingdom (UK), Australia and the Netherlands have implemented specific measures in recent years to ensure appropriate use of mesh procedures in the treatment of SUI and POP and to ensure appropriate aftercare for women suffering mesh complications.

Informed Consent

- As would be usual with many surgical conditions, standardised information resources were not available at national level to ensure that all patients receive consistent information about the benefits and risks of mesh devices, to advise of other treatment options and to support informed consent processes.
- Many women reported that they were not informed of other treatment options; they had not been informed that their surgeries involved the use of mesh; they were not informed of mesh complications; and they were not made aware of the difficulties associated with mesh removal or with the treatment of long-term mesh complications.

Aftercare of Women with Complications

- Structured treatment or referral pathways were not evidently in place for the minority of women requiring specialist, multidisciplinary care for serious complications following mesh surgery.
- Some women reported considerable difficulty in accessing timely, compassionate and appropriate specialist aftercare for complications.
- Some women reported that individual clinicians responded to their personal concerns in an inappropriate manner which greatly added to their distress. Women also reported feeling that they were not believed, or that their clinicians minimised or did not understand the severity of their complications.

Clinical and Professional Issues

- Governance mechanisms are not in place at national level to provide assurance that mesh surgeries are carried out in accordance with agreed international best practice and clinical guidance.
- There is no mandated professional clinical guidance at national level to guide the use of mesh implants in the management of SUI or POP or to guide the management of women with complications.
- Communication mechanisms currently in place at national level between the HPRA, healthcare providers and professional bodies do not provide assurance that the findings and recommendations of safety reviews such as those circulated by the HPRA in recent years regarding mesh implants are systematically analysed and acted upon where appropriate.

Information

- There are significant gaps in knowledge about current practice in Ireland regarding the use of urogynaecological mesh implants.
- Routinely collected clinical information at national level does not provide the capacity for monitoring or audit of mesh surgeries for the treatment of SUI and POP.
- Based on international experience, there is under-reporting of adverse events relating to mesh surgeries by clinicians to both the HPRA and to the National Incident Management System (NIMS) operated by the State Claims Agency (SCA).

Recommendations

A range of recommendations are identified throughout the report in response to the findings above. These include recommendations about patient information and informed consent, patient selection and counselling, clinical and professional standards of practice, including clinical guidance, professional training and the appropriate multidisciplinary expertise in units carrying out mesh procedures, the development of information resources to permit long-term research and audit of practice, ensuring the reporting of mesh related complications, and ensuring timely, appropriate arrangements for the management of women with complications.

Full implementation of the report's recommendations will provide significant assurance that all patients presenting for treatment for SUI and POP and all women who develop mesh-related complications receive high quality, patient centred care in accordance with accepted evidence and supported by robust clinical governance mechanisms.

A programme of work to advance several of the report's recommendations has already commenced in the HSE.

Section 1: Introduction

1.1 Background

Synthetic mesh devices have been widely used in the surgical treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in women over the past two decades. It is widely accepted that for many women suffering the distressing symptoms of SUI and POP, surgical procedures using synthetic mesh devices have provided a more effective and less invasive form of treatment than traditional surgical procedures. However, controversy about the safety of mesh devices has arisen owing to concerns about the frequency and severity of complications associated with their use. For some women, these complications are reported to be severe and life-altering.

The safety of mesh devices has been the focus of considerable regulatory, policy, clinical, and political scrutiny in many jurisdictions in recent years including the United States of America (USA), England, Scotland, Northern Ireland, Australia and other European countries, resulting in several safety reviews by regulatory bodies and other national health systems. There are also reports of multiple litigations underway in a number of countries against relevant medical device manufacturers.

In late 2017, concerns arose about the frequency and severity of complications associated with the use of mesh devices in the surgical treatment of SUI and POP in women in Ireland; the regulation and audit of their use; the extent of use of these devices in Ireland and the availability of services for women affected by mesh-associated complications including through the tabling of several Parliamentary Questions to the Minister for Health.

In responding to these questions and in recognition of the complexity of the matters arising, the Minister requested the Chief Medical Officer (CMO) to prepare a report for him on the clinical and technical issues involved in ensuring both:

a) the safe and effective provision of mesh procedures in urogynaecology and

b) an appropriate response to women who suffer complications as a result of undergoing such procedures.

1.2 Methodology

Preparation of this report has involved consultation and engagement with a number of national bodies, including in particular the Health Products Regulatory Agency (HPRA); the relevant professional training bodies (PTBs), the Institute of Obstetricians and Gynaecology (IOG) and the Royal College of Surgeons in Ireland (RCSI); the Continence Foundation of Ireland (CFI) and the Health Service Executive (HSE). Information and advice was also provided by the National Office for Clinical Audit (NOCA) and the State Claims Agency (SCA). High quality, timely and comprehensive submissions of advice were received from all stakeholders, and the willingness of all to work together in the preparation of submissions was particularly welcome.

The report has been informed by the personal experiences of several women who have suffered complications following mesh procedures for SUI and POP, as described through representations made by individual women and politicians on their behalf to the Minister and the Department of Health in 2018; and from a meeting with representatives of the Mesh Survivors Ireland group which was held in June 2018.

The report has also been informed by examination of international reports and safety reviews of mesh surgery which have been published in recent years, including a report to the European Commission, reviews at national level by other countries including the National Health Service (NHS) in England and Scotland, and the recent report of a Parliamentary Inquiry in Australia. A summary of these reports, their findings and recommendations, is included at Appendix 1. Engagements were also made with colleagues in other jurisdictions for further information gathering and learning from their experiences of the problems associated with mesh implants and the measures adopted in response to these.

Finding

Many other health systems, including the United Kingdom (UK), Australia and the Netherlands have implemented specific measures in recent years to ensure appropriate use of mesh procedures in the treatment of SUI and POP and to ensure appropriate aftercare for women suffering mesh complications.

There were several developments in relation to transvaginal mesh devices while this report was being prepared, some of which received considerable media attention. These included regulatory actions in Australia and New Zealand in December 2017, which effectively removed transvaginal POP mesh devices and 'mini slings' for the treatment of SUI from the market in those countries, revised procedural guidance issued by the National Institute for Health and Care Excellence (NICE) (UK) in December 2017 restricting the use of transvaginal mesh in certain types of prolapse surgery to research purposes only; the publication in March 2018 of the report of a Parliamentary Inquiry in Australia on the 'Number of women in Australia who have had transvaginal mesh implants and related matters' and the widely reported decision by health authorities in the UK on July 10th 2018 to institute a pause in mesh procedures.

A programme of work to advance several of the report's recommendations has already commenced in the HSE. In advance of finalisation of the report, two sets of interim system recommendations were identified and conveyed to the HSE for action on an urgent basis, in May 2018 and July 2018. The HSE was requested to pause all mesh procedures on July 24th, 2018, pending implementation of recommendations relating to professional training, informed consent and the development of a national dataset for mesh procedures. A Synthetic Mesh Devices Advisory Group has been convened by the NWIHP which includes three patient representatives, as well as representatives of the HPRA, the IOG, the RCSI, the CFI and all Hospital Groups, to advise on and progress all of the interim recommendations. These interim actions are described in Section 2 of the report.

1.3 Issues for Consideration

The following issues were identified for consideration by this report:

- **the adequacy of current professional clinical guidance in Ireland**
- **professional training arrangements for surgeons undertaking mesh procedures,**
- **measures to ensure appropriate patient selection and counselling and informed consent,**
- **the requirement for ongoing audit of mesh implant surgery and**
- **the requirement for appropriate aftercare arrangements for women with complications.**

1.4 Stakeholder Consultation

In January 2018, the CMO wrote to the IOG and the RCSI, as the relevant gynaecological and urological professional training bodies for surgeons undertaking these mesh procedures, to advise them of the concerns about mesh implants which had been brought to the Minister's attention, to request that they jointly consider the issues set out at 1.3 above on an urgent basis and to advise him as to the steps required to ensure that clinical practice in Ireland in respect of mesh devices can be demonstrated to be in line with accepted best practice internationally.

The CMO also wrote to the Director General of the HSE seeking the observations and advice of the Executive in respect of the issues raised. The HSE was asked to provide any information that would assist in describing the magnitude and nature of problems associated with the use of mesh procedures. Pending that advice, the CMO requested the HSE on a priority basis to bring these concerns to the attention of relevant business units, clinicians and managers and also requested that existing practice in all units where mesh procedures were performed, including arrangements for patient counselling and informed consent, be reviewed.

In its response, the HSE advised that the Clinical Director of the National Women and Infants Health Programme (NWIHP) would lead the response on behalf of the HSE and work closely with the professional training bodies and other stakeholders at national level to advance this work.

1.5 Stakeholder Meeting

High quality, comprehensive submissions were received within a very short time frame in response to the requests above. A meeting of stakeholders, including the IOG, the RCSI, the CFI, the HPRA, the HSE and Department officials was convened in March 2018 to review the advice and submissions received.

It was agreed that current evidence supports (i) the use of the mid-urethral sling (MUS) devices in the treatment of SUI and (ii) the use of abdominally placed mesh in the management of complex POP in appropriately chosen cases when done by trained personnel. A range of recommendations were identified by stakeholders to ensure these two treatments could be progressed appropriately and to provide assurance that the use of mesh implants and the care of women requiring aftercare is undertaken in line with emerging evidence and best practice internationally. Stakeholders expressed their willingness to continued joint working and engagement to advance the recommendations agreed.

After the meeting, ongoing engagements between the Department and relevant stakeholders took place to clarify issues in relation to the detail of some recommendations.

The full list of recommendations is presented in Section 10 of the report.

Section 2 – Interim Recommendations and Pause on Mesh Procedures

2.1 Introduction

A significant programme of work to advance several of this report's recommendations has already been commenced in the HSE.

In advance of finalisation of the report, two sets of interim system recommendations were identified and conveyed to the HSE for action on an urgent basis, in May 2018 and July 2018. The HSE was also requested to pause all mesh procedures on July 24th, 2018, pending implementation of recommendations relating to professional training, informed consent and the development of a national dataset for mesh procedures.

2.2 Priority Recommendations – May 2018

The first set of priority recommendations were communicated to the HSE in May 2018. Following the process of stakeholder engagement already described, it was determined that two recommendations should be progressed in advance of the report's completion:

- the availability of patient information and informed consent materials and
- the provision of aftercare for women suffering serious complications.

These priority recommendations and the rationale for them are described in Section 6 of the report. The CMO wrote to the Acting Director General of the HSE on 28th May 2018 requesting that the Executive commence work on these actions, in conjunction with the IOG, the RCSI and the CFI.

2.3 Pause in Mesh Procedures and Associated Recommendations – July 2018

The CMO wrote to the Acting Director General of the HSE on 20th July 2018 to request that the HSE put immediate measures in place to:

1. Pause the use of all procedures involving uro-gynaecological/transvaginal mesh implants for the management of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP) in HSE funded hospitals, in cases where it is clinically appropriate and safe to do so.
2. Ensure that in situations where expert clinical judgment is that there is an urgency to carry out the procedure and no suitable alternative exists, surgery should proceed only if a delay would risk harm to the patient and should be based on a multidisciplinary team decision and fully informed patient consent.

This pause is to remain in place pending confirmation by the HSE, working in conjunction with the IOG and the RCSI, of the implementation of three recommendations in relation to:

(i) Professional training requirements
(ii) The development of appropriate patient information material and consent materials (This recommendation had already been conveyed to the Executive for implementation as one of the Priority Recommendations identified in May 2018).
(iii) The development and maintenance of a national data collection of all mesh procedures carried out in HSE hospitals.

These recommendations and the rationale for them are described further in Sections 6, 7 and 8 of the report.

The Department also wrote to the IOG, the RCSI and the CFI on 20 July 2018 requesting that they assist the HSE in progressing these recommendations on an urgent basis.

2.3.1 Pause in Mesh Procedures - Background

On Tuesday July 10th 2018, a decision to pause vaginal mesh procedures, until a set of conditions to mitigate the risks of injury are met, was announced by the National Health Service (NHS) in England. On Wednesday July 11th, a similar pause was instigated by health authorities in Northern Ireland.

This decision was reviewed by the Department, together with representatives of the HSE and the HPRA. It was noted that there was no concurrent change in the regulatory status of uro-gynaecological mesh implants at a European level or in the evidence base concerning these devices; instead the decision arose because of a lack of certainty or confidence that critical clinical governance measures to assure the safety of mesh procedures were demonstrably in place.

Arising from its engagements with stakeholders as part of the ongoing preparation of this report, the Department was aware that similar concerns about the visibility and consistency of such clinical governance measures also arose in the public health system in Ireland. There was understandable public and patient concern about the ongoing safety of mesh devices due to the considerable publicity that this issue has received, which was heightened by the announcement of a pause in procedures in the NHS. It was considered important that this be addressed as comprehensively as possible. A similar pause on the use of mesh procedures in publicly funded hospitals, pending confirmation by the Executive that the recommendations set out above have been implemented, was therefore considered proportionate and necessary to provide public assurance that these procedures are being carried out in accordance with internationally accepted good practice.

It is acknowledged that there may be concerns that restricting the availability of mesh procedures, particularly SUI mesh procedures, which are widely accepted to be less invasive and more effective than non-mesh alternatives will delay access to treatment procedures for distressing symptoms. Uro-gynaecological mesh procedures are largely elective procedures and it is not anticipated that a postponement of months will materially affect health outcomes for those women affected. It is anticipated that the HSE will be able to indicate to the Department that these recommendations have been implemented within months.

2.4 Interim Actions: Progress Update

The HSE has confirmed to the Department of Health that a pause has been instituted in the use of all procedures involving uro-gynaecological/transvaginal mesh implants for the management of SUI or POP in HSE funded hospitals, in cases where it is clinically appropriate and safe to do so.

A Synthetic Mesh Devices Advisory Group has been convened by the NWIHP which includes three patient representatives, as well as representatives of the HPRA, the IOG, the RCSI, the CFI and all Hospital Groups, to advise on and progress all the interim recommendations as advised to the HSE in May 2018 and in July 2018.

A Learning Notice concerning mesh devices in uro-gynaecological procedures was circulated by the NWIHP on 26th June 2018 to all maternity hospitals and acute hospitals with gynaecological services to highlight the importance of appropriate patient selection the provision of adequate information

and the securing of consent. Service providers were also informed that a Response Group has been convened to propose remedies for and address the provision of aftercare for complications. This learning notice is available on the NWIHP website.
https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/quality-and-safety/learning-notice-0518-transvaginal-mesh.pdf

Work to enhance aftercare services for women suffering complications is ongoing by the HSE and will include identifying the appropriate specialist clinical expertise and facilities required both at hospital group level and nationally to provide comprehensive aftercare services. It will also include an examination of the requirement for specialist diagnostic services. The outcome of this work will clarify if there is a need to look at sourcing services from abroad to address any shortfalls identified at national level, either through utilisation of the treatment abroad scheme or by commissioning services from abroad.

Pending finalisation of this work, the HSE advises that all patients who have experienced complications due to mesh devices should contact their consultant's clinic in the first instance. Each hospital group has nominated an individual to coordinate a response to this group of patients. If patients are having trouble accessing information they can contact the National Women & Infants Health Programme at smi.nwihp@hse.ie for help.

Section 3 - Context

3.1 Introduction

This section of the report provides background information about mesh implant devices and an overview of the complications associated with their use in the treatment of SUI and POP. It also outlines the experiences of women suffering complications, and the views of the clinicians and professional bodies engaged with in the writing of the report.

3.2 What is mesh?

Mesh is a broad term to describe a type of medical device which is permanently implanted in the body to provide additional support during the surgical repair of weakened or damaged tissue. Mesh can be made of synthetic material (e.g. polypropylene), biologic material (e.g. collagen) or a mixture of both. Mesh implants are commonly used in surgical procedures across a range of surgical specialties. The focus of this report is solely on the use of synthetic mesh implants in two types of uro-gynaecological procedures in women, specifically the surgical treatment of Stress Urinary Incontinence (SUI) and the surgical repair of Pelvic Organ Prolapse (POP).

The use of mesh implants in uro-gynaecological procedures has been standard clinical practice since the late 1990's. Urogynaecological mesh devices (also referred to as transvaginal mesh or vaginal mesh implants) are supplied in a variety of forms including 'slings', 'tapes', 'ribbons' and 'mesh'. Most surgical mesh materials currently used in urology-gynaecology procedures are made from synthetic, non-absorbable material that remains in the body indefinitely.

Pelvic floor dysfunction is a major health problem in women as they age and therefore demand for pelvic floor surgery is increasing as the population ages. It has been estimated that there is an 11-20% lifetime risk of a woman undergoing a single operation for SUI or POP by the age of 80.[1] A large proportion of repeat operations have also been documented.

There are significant differences between the use of mesh for SUI and for POP and it is important not to confuse the procedures and the risks and benefits involved. These are described in more detail in Section 4.

3.3 Mesh Complications

All surgical procedures have a risk of associated complications. There is an extensive international literature concerning complications associated with different types of urogynaecological mesh. A review and summary of the evidence concerning mesh complications was undertaken by the European Scientific Committee on Emerging and Newly Identified Health Threats in 2015[1] as part of its report on this topic. More recently, the Scottish Independent Review of the safety and efficacy of transvaginal mesh published in 2017 also provides a useful summary of the evidence from international safety reviews and systematic reviews[2].

[1] https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_049.pdf

[2] https://beta.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/

Mesh related complications include temporary and relatively minor short-term effects, as well as longer term complications. It has been reported in a number of international safety reviews that complications may be severe and life altering in a minority of women. Mesh complications can be extremely difficult to treat in some patients because of the unique characteristics of mesh devices, which are designed to be permanently implanted.

Finding

Mesh devices are associated with significant and severe complications in a minority of women, which are of concern given the difficulties of mesh implant removal.

Complications reported in association with mesh implants used in the treatment of SUI and POP include: pain, mesh erosion through the vagina and / or surrounding tissues, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. Apart from mesh erosion, all of the above complications can also occur following non-mesh surgical repair for SUI and/or POP.

Mesh erosion (for example through the vaginal wall) is one of the complications most highlighted in recent media reports. All synthetic meshes are associated with some risk of mesh erosion, reported by different studies in the reports in the footnotes below to occur in 2-4% of SUI procedures and 4-19% of POP procedures.

However, the reported data about the frequency and severity of mesh complications have been questioned. On one hand, some women and their advocates argue that many complications are not recognised or reported by clinicians and the severity of the associated symptoms is similarly un-recognised. It is also argued in a number of reports that the available data regarding the frequency of complications probably represents an under-estimate, as it is accepted that there is an absence internationally of comprehensive long-term follow-up data, particularly beyond the time period normally covered in clinical trials.

In contrast, clinicians and the professional training bodies who were engaged with in the preparation of this report stressed that in their experience the rate of serious mesh complications is very low and compares very favourably with equivalent non-mesh procedures in patients who are appropriately selected and where surgeons are appropriately trained. In practice, clinicians said they were aware of individual surgeons with specific expertise in MUS surgery who have inserted thousands of mesh implants with few if any patients suffering complications requiring further surgery. It is also argued that as many of the complications reported by women occur several years after the implant, they may be difficult to distinguish from the evolving symptoms of the underlying pelvic disease. Similar symptoms are often reported by women who have undergone non-mesh surgery or no surgery.

It is important to note also that the use of mesh has evolved over the years since its introduction, with many different individual products having been both placed on and removed from the market over

time. Some devices are no longer in use, particularly some of those used in the transvaginal repair of POP which were recognised to have been particularly problematic.

3.4 Views of Women

Safety concerns about mesh implants have been brought to the fore at national level largely through the actions of women who have suffered complications in sharing their experiences and bringing their concerns to public and political attention so that other patients might benefit. The bravery, commitment and dignity shown by these women in sharing what were often harrowing, deeply personal experiences were greatly appreciated.

However, it is important to note that the views of the many women who have undergone mesh procedures and have had satisfactory outcomes, with minor or no complications, could not be reflected in this report. Also, following the implementation of a pause in mesh procedures by the HSE in July 2018, as described in Section 2, a number of women whose procedures were postponed made representations to the Department expressing concern at the impact that this had on them personally as they awaited treatment for the distressing symptoms of SUI.

Representations in relation to mesh-associated complications were made to the Minister and to the Department by several individual women and/or politicians on their behalf, either individually or as members of the Mesh Survivors Ireland or the Mesh Ireland groups. A meeting was also held between the Minister and representatives of the Mesh Survivors Ireland group in June 2018 at which women described distressing and painful complications, many of which were severe and life-altering.

Both the Mesh Survivors Ireland and Mesh Ireland groups reported that they have several hundred members in their Facebook groups. MSI stated that the group is aware of many more women who have been affected by mesh who are not members, particularly older women who do not use social media. Members come from all over the country and across a wide age range. Women reported having their procedures in both public and private hospitals.

Women reported a range of complications following mesh surgery for SUI or POP, including chronic pain, incontinence and erosion of mesh causing sexual, bladder and bowel difficulties; with some women requiring significant additional surgical and other treatments. Individual women described their complications as life-altering, leaving them with chronic symptoms such as pain and incontinence, and resultant emotional, psycho-sexual and psychological difficulties which greatly reduced their quality of life and impacted on their family relationships. For some women, complications occurred immediately following surgery; with other women symptoms occurred months or years following the initial procedure.

Many women called for a total ban on mesh products to treat SUI and POP, stating that in their view the severity of complications outweighs the benefits.

Informed Consent and the quality of information provided to patients in advance of mesh procedures were identified as areas of particular concern. Many women suffering complications following mesh procedures for SUI or POP reported that they had not been specifically informed that their surgeries involved the use of mesh; and instead terms such as ‘ribbon’ or ‘tape’ or ‘gold-standard’ were used

pre-operatively, which the women considered misleading. They said they were not made aware of the potential risks involved in these procedures, which were presented to them as short and simple day case procedures; and they were not made aware of the possible difficulties associated with mesh removal or with the treatment of long-term mesh complications. Many women also reported that they were not informed of or given a choice in relation to other treatment options. Some women reported that they did not undergo recommended assessments such as urodynamic studies in advance of undergoing MUS surgery.

Finding

Many women reported that they were not informed of other treatment options; they had not been informed that their surgeries involved the use of mesh; they were not informed of mesh complications; and they were not made aware of the difficulties associated with mesh removal or with the treatment of long-term mesh complications

An extremely strong source of distress and dissatisfaction reported by many women was the difficulty experienced in accessing timely, compassionate and appropriate specialist aftercare. For some women, the response of clinicians to their concerns greatly added to their distress. Many women were of the opinion that they were not believed, that clinicians minimised or did not understand the severity of their complications, and there was a lack of confidence on the part of women that their treating clinicians had the expertise to assess and treat complications.

A strong view emerged that aftercare arrangements for the management of women with complications are not adequate at national level, with no clarity about referral pathways or means to access a second opinion where this is sought. Concerns were expressed about the availability of specialist diagnostic facilities such as translabial scanning, which many women regarded as essential to meet the needs of this patient group.

Finding

Some women reported considerable difficulty in accessing timely, compassionate and appropriate specialist aftercare for complications.

Some women reported that individual clinicians responded to their personal concerns in an inappropriate manner which greatly added to their distress. Women also reported feeling that

It was reported that many women have travelled abroad for translabial scanning and/or mesh removal surgeries at personal expense. Many women requested that access to funding or reimbursement mechanisms such as the Treatment Abroad Scheme should be clarified for this group where women considered they were unable to access suitable services in Ireland.

3.5 Views of Clinicians and Professional Bodies

The professional bodies and individual clinicians engaged with during preparation of this report acknowledge that mesh procedures are associated with a risk of complications in some women, but stressed that their experience is that serious complications are rare events when patients are appropriately selected and surgeons have appropriate specialist training; with individual surgeons citing complication rates less than 1%. Most women with complications have minor or short-term problems. Mesh procedures have transformed the treatment of SUI and POP in recent decades and have been of great benefit to most women treated. Clinicians stated that the views of women who have had a good outcome from mesh procedures are not publicly or readily available but should also be considered to ensure balance. Clinicians expressed strong concern that restrictions on the availability and use of mesh would ultimately have a very detrimental effect on the health of women through the removal of treatment options.

3.5.1 Advice of the Institute of Obstetricians and Gynaecologists (IOG) and the Royal College of Surgeons in Ireland (RCSI)

In their joint discussion paper submitted to the CMO during the preparation of this report, the IOG and the RCSI advise that:

All major National and International professional associations continue to recommend the use of urethral tape to treat SUI, and abdominally placed surgical mesh to treat complex POP (abdominal sacrocolpopexy) because a significant majority of appropriately selected patients benefit greatly from these procedures, with reduced long-term complications and improved functional outcomes compared to other operations. As for all surgery, surgeons must be appropriately trained, involved in audit and maintain their competence as part of a CPD programme. Appropriate patient selection for surgical intervention in complex cases should involve multidisciplinary team discussion.

3.5.2 Continence Foundation of Ireland (CFI) Position Statement on Mid-Urethral Slings

The CFI is a multi-disciplinary grouping of professionals with an interest in female incontinence and pelvic floor reconstructive surgery. The CFI has published a position statement on MUS on its website as follows:

(MUS) have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications. This has resulted in MUS becoming the operation of choice in Europe, Asia, North and South America and Australasia for treatment of SUI with several million procedures performed worldwide.

Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile irrespective of the operative route (more than 2000 publications, including women with obesity, prolapse and other types of bladder dysfunction). They are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. If you have any concerns or questions, please contact your doctor.

http://www.continence.ie/index.html

Section 4 - Regulation of Mesh Implants

4.1 Introduction

This section of the report provides background information about the regulatory status of mesh implants in Ireland, the EU, the USA, Australia and New Zealand.

4.2 Regulation of Mesh Implants – Ireland and the European Union

Medical devices are regulated for the entire European Union market place under EU Directives which specify the requirements that must be met before any device can be placed on the market. These requirements cover safety, performance, specification, design, manufacture and packaging of devices and the need for a medical device to be CE marked before it can be placed on the EU market. Any mesh device bearing a CE mark in accordance with the Medical Devices Directive 93/42/EEC (as amended) which was transposed into Irish law by S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations (as amended), can then be freely placed on the entire EU market.

The Health Products Regulatory Authority is the competent authority for medical devices regulation in Ireland. However, the HPRA has no direct involvement in the authorisation of any medical devices before they are brought to market. There is also no requirement for a manufacturer to inform the HPRA before placing a CE marked medical device on the market in Ireland, nor does the HPRA routinely maintain a list of all devices placed on the Irish market.

The HPRA has sought to identify manufacturers of vaginal mesh products as part of its vigilance and market surveillance activities. There is a range different mesh products placed on the market in Ireland, each with different indications for use. The HPRA understands that more than 6000 vaginal mesh implants have been placed on the Irish market.

To secure a CE mark for a medical device such as vaginal mesh implants the manufacturer must seek approval from a "Notified Body". The degree of detail of the assessment criteria and scrutiny applied is dependent on both the applicable Directive and the risk classification of the product concerned, Class III being the most stringent.

4.3 Advice of the Health Products Regulatory Agency

Transvaginal mesh devices are certified as compliant with relevant EU legislation. As such, it is considered that the benefits outweigh the risks for these devices and none have been removed from the market by any medical device regulators in Europe. The advice of the HPRA is that in order to ensure that the use of transvaginal mesh is appropriate and as safe as possible, in addition to it being necessary for the device to perform as intended, the healthcare system also needs to have appropriate measures in place to guide patient selection, treatment and follow-up.

Finding

Mesh implant devices are certified as compliant with relevant European Union (EU) legislation and no market action against mesh devices for the treatment of SUI or POP has been taken by any of the European device regulatory competent authorities.

4.4 HPRA Communications and Actions to date in relation to Mesh Implants

In 2009, 2011, and 2012, the HPRA wrote to relevant consultants in Ireland to inform them of notifications published by the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in relation to this topic. The HPRA requested that incidents related to the use of these products be reported to them.

In October 2012 the HPRA informed the DOH of the situation as it was understood at that time, highlighting that '**no conclusive generic device family related issue has been identified'.**

In January 2016 the HPRA circulated the European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion and the related fact sheet to The Royal College of Surgeons in Ireland (RCSI) and The Royal College of Physicians (RCPI) in Ireland for onward distribution to their members.

In December 2017, the HPRA published a webpage to provide members of the public with information regarding vaginal mesh implants: https://www.hpra.ie/homepage/medical-devices/special-topics/vaginal-mesh-implants

Over the period 2009 to mid-October 2018 the HPRA has received 121 incident reports relating to urogynaecological mesh implants, of which just two reports were received prior to November 2017. The HPRA continues to encourage those who have experienced a safety issue with a medical device, including transvaginal mesh devices or implants, to report it through its medical device adverse incident reporting system. The system is accessible to patients, healthcare professionals or any person who identifies a medical device safety issue. Issues or concerns about a medical device can be submitted through the HPRA website's online reporting system or by downloading and completing an incident report form which is also available from its website www.hpra.ie

In December 2017, a European Competent Authority taskforce met via conference call to further examine this topic. It was unanimously agreed that while market action is currently not required, discussing a common position across all member states would be beneficial. The HPRA continues to provide input to the European Competent Authority taskforce. In addition to its contribution to the European taskforce, the HPRA has advised that it is undertaking an ongoing review of all aspects of these devices incorporating the assessment of user reports in addition to all current and emerging scientific evidence. The outcome of these review processes will establish whether there are grounds for future regulatory action in relation to the use and/or status of these medical devices.

4.5 Future EU Regulation

Regulation 2017/745 on Medical Devices (MDR) and Regulation 2017/746 on *In-Vitro* Diagnostic Devices (IVDR) were formally published in the Official Journal *of the European Union* on 5th May 2017, and entered into force at the end of May 2017. The Regulations will have a staggered transitional period with some aspects becoming legally binding after 6 months, full application of the MDR after 3 years and full application of the IVDR after 5 years.

The MDR and IVDR represent a significant development and strengthening of the existing regulatory system for medical devices in Europe and will replace the original Directives which have been in place for over 25 years.

Under the new Regulations (EU 2017/745), the classification of mesh implants intended for long term or permanent use will change to the highest risk classification, Class III.

4.6 Regulatory Status of Mesh in Other Jurisdictions

4.6.1 United States of America

- In October 2008, the US Food and Drug Administration (FDA) issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement).
- In July 2011, the FDA published an updated communication ('*Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication'*) which stated that the FDA has "*identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of POP based on a review of adverse events reported to the FDA and an assessment of the scientific literature*". Based on the panel's deliberations, the FDA issued an order to "*reclassify meshes used to repair POP transvaginally from class II, which generally includes moderate-risk devices, to class III, which generally includes high-risk devices, and a second order that requires manufacturers to submit a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP".*
- *https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.*
- Since this time, the FDA has periodically updated their website to provide further information to patients and healthcare professionals. Details on the FDA website include the different surgical and non-surgical treatment options, recommendations for health care providers that treat women with POP and/or SUI, recommendations for patients who are considering surgery for these conditions and steps to report problems to the FDA.

4.6.2 Australia & New Zealand

- In November 2017, the Australian medical devices regulator, the Therapeutic Goods Administration (TGA) announced the removal of transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG). The TGA stated that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients. https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants#actions
- The TGA also considered that "*there is a lack of adequate scientific evidence before the TGA for it to be satisfied that the risks to patients associated with the use of mesh products as single incision mini-slings for the treatment of stress urinary incontinence are outweighed by their benefits*". These products were also removed from the ARTG in November 2017.
- In January 2018, the TGA announced that following post-market review of urogynaecological mesh implants, a number of manufacturers of mid-urethral tapes had updated their device instructions to include information about certain adverse events such as severe chronic pain, groin pain and bladder perforation.
- MedSafe (the Medical Device Regulator for New Zealand) has aligned its approach with the actions taken in Australia.
  http://www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp

Section 5 - The Clinical Use of Mesh in the Management of Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP)

5.1 Introduction

This section provides an overview of the current clinical use of mesh implants in the management of SUI and POP, based on the expert advice of the professional training bodies (PTBs) to this report and makes a number of recommendations concerning their use.

5.2.1 Stress Urinary Incontinence (SUI)

Stress Urinary Incontinence is a common and distressing symptom for women, particularly over the age of 40 years, where urine leaks involuntarily from the bladder on physical exertion, such as when coughing, laughing, sneezing or running. SUI has a negative effect on social, physical and psychological wellbeing, and can lead to embarrassment, low self-esteem and social isolation.

5.2.1 Treatment Options for SUI

Depending on severity, there are several treatment options for SUI, including the option of no treatment. These would include conservative, non-surgical measures such as pelvic floor muscle training and behavioural modifications e.g. engaging in a weight loss programme, refraining from smoking, administration of recommended medications and continence products, which are useful in alleviating symptoms in some women. If conservative measures and physiotherapy are unsuccessful, surgical treatment options would include both traditional non-mesh procedures as well as those involving mesh.

The joint advice of the PTBs to this report is that traditional surgical procedures for the treatment of SUI, which use the patient's own tissues as support (e.g. colposuspension, pubofascial slings) provide good results for many patients, but have the disadvantage of a large surgical incision, long duration of hospital admission (3 to 5 nights) and a prolonged post-operative recovery period (6 weeks to 3 months, depending on occupation). They are also associated with a significant incidence of short term complications. In a minority of patients, significant long-term problems may be difficult if not impossible to treat, including bladder emptying symptoms and recurrent urinary tract infection, chronic pelvic and bladder pain, painful sexual intercourse (dyspareunia) and wound related problems.

5.2.2 Mesh procedures for SUI

The use of synthetic surgical mesh devices, known as mid-urethral tapes or slings (MUS), was introduced into clinical practice in the late 1990's. A small strip of mesh tape is used to support the urethra or bladder neck and so stop leakage from the bladder. Sling procedures are minimally invasive procedures which are usually done as day cases.

MUS mesh devices have been extensively studied in multiple clinical trials. The research base consistently indicates that the outcomes of MUS surgery are at least comparable to or better than traditional surgical approaches, with the major advantages of shorter operating and admission times, and a quicker return to normal activities, together with a lower incidence of early post-operative and longer term wound complications. This has resulted in the MUS becoming the operation of choice for treatment of SUI in Europe, the United Kingdom, Australasia and the USA.

5 2.3 Complications associated with SUI Mesh Procedures

All surgeries for SUI, both mesh and non-mesh, have a risk of associated complications. These include pain, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. Many of these complications can be dealt with by the clinician who provided the patient's original care on an outpatient basis. More serious complications require additional medical intervention, and sometimes require surgical treatment and/or hospitalisation.

The use of mesh in transvaginal SUI repair introduces the risk of mesh erosion which is not present in traditional non-mesh surgery for SUI repair. The FDA website states that '*the average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent*'. Audits in the UK and elsewhere have indicated that approximately 4% of women undergo mesh removal procedures following SUI vaginal mesh tape insertion; however, it is important to stress that many of these are partial rather than total mesh removals.

5.2.4 SUI Mesh Procedures – Advice from Professional Training Bodies

The IOG and RCSI in their submission to this report pointed to the extensive evidence base supporting the use of MUS and ongoing emerging evidence from international and Irish studies which provide reassuring evidence about the safety and efficacy of MUS procedures. One such study is a shortly to be published review paper from Limerick of 300 cases of tape procedures with median follow up of four years, which reports an 85% objective cure rate, 4% improved rate and only one tape exposure (mesh erosion) case. No patient reported chronic pain, infections or bladder exposure. Individual clinicians in their advice to this report said that surgeons with specialist expertise in MUS surgery see very few patients with complications requiring mesh removal.

The PTBs further recommended that operations using mesh are only performed by specialists with expertise in this technique, and only after a full discussion about the benefits and risks of such surgery with the woman who should be given detailed information about all treatment options to help with her decision-making.

This advice aligns with the findings of several international safety reviews which are summarised in Appendix 1.

Finding

There is an extensive evidence base supporting the use of the mid-urethral sling (MUS) devices in the treatment of SUI. A significant majority of patients benefit greatly from these procedures, with reduced long-term complications and improved functional outcomes compared to non-mesh procedures. Mesh procedures should only be performed by trained personnel, in patients who are appropriately selected and counselled and when appropriate multidisciplinary expertise and clinical governance mechanisms are in place.

5.3 Pelvic Organ Prolapse (POP)

Pelvic organ prolapse is a condition where there is weakness in the ligaments and muscles in the pelvic floor and the internal pelvic organs bulge into the vagina. After the menopause, approximately 50% of women will describe symptoms of POP, which can cause significant quality of life problems. Causes of prolapse include pregnancy and childbirth, aging, chronic cough, chronic constipation and heavy lifting or following hysterectomy and other pelvic surgeries. Prolapse is categorised into different types of varying complexity, severity and difficulty to treat, depending on the organs affected.

5.3.1 Treatment Options for POP

There are several treatment options for POP, depending on complexity, severity and other patient factors, including the option of no treatment.

Conservative, non-surgical treatment options include lifestyle changes e.g. losing weight, avoiding heavy lifting, physiotherapy and vaginal pessaries. Surgical options include traditional (non-mesh) surgical procedures and surgical procedures involving the use of mesh. Up to 15% of women will have surgery for POP.

Traditional surgical techniques use the patient's own tissues to repair the prolapse. Native tissue repair has a higher risk of recurrent prolapse compared with synthetic mesh: 25% of patients require re-operation within three years of the original repair with up to 70% recurrence rates after anterior prolapse repair. As with all types of prolapse repair, there is a risk of development of pelvic pain in the short and long term which can be difficult to treat.

5.3.2 Mesh procedures for POP

Because of this very high recurrence risk, grafts or implants have been developed to give long term support to the site of surgical repair to reduce prolapse recurrence rates. Grafts used for POP repair may be biological (grown from animal cells) or synthetic (mesh). Complex POP repair utilising mesh is commonly referred to as a 'mesh repair'. A variable quantity of mesh, tailored for each individual patient, is used to reinforce the weak vaginal wall tissues.

Mesh implants for POP can be placed through the vagina (transvaginal placement) or through the abdomen (abdominal placement).

5.3.3 Abdominal placement of Mesh for POP Repair– Advice from Professional Training Bodies

The advice of the PTBs is that abdominal placement of mesh (abdominal sacrocolpopexy) is used to treat vaginal vault prolapse, one of the most difficult types of POP to treat. Abdominal sacrocolpopexy has been considered the gold standard procedure for management of this condition. Using an abdominal approach, a graft or mesh is placed on the anterior and posterior vaginal wall and then attached to the sacral promontory. The complication rate for this procedure is lower than with vaginally placed mesh. Evidence from a recent Cochrane Review (September 2016) is that compared to various vaginal procedures, abdominal sacralcolpopexy was associated with better objective and subjective outcomes, a lower requirement for repeat surgery for prolapse, and lower rates of complications such as SUI and painful intercourse.

Finding

There is an extensive evidence base supporting the use of abdominally placed mesh in the management of POP. A significant majority of patients benefit greatly from these procedures, with reduced long-term complications and improved functional outcomes compared to non-mesh procedures. Mesh procedures should only be performed by trained personnel, in patients who are appropriately selected and counselled and when appropriate multidisciplinary expertise and clinical governance mechanisms are in place.

5.4 Transvaginal placement of mesh for POP

Evidence about the rate of long-term complications has given rise to concerns about the use of transvaginally placed mesh implants for POP repair over the past several years and this is the area of urogynaecological mesh surgery which has been most contentious.

The PROSPECT study (2016) was a major randomised controlled trial across 35 centres in the UK comparing transvaginal mesh repair of POP with traditional surgical procedures. It found that 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. www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31596-3/abstract. The study concluded that more long-term follow-up is needed to determine if there are long-term benefits to the use of mesh in prolapse repairs.

Guidance and practice internationally in relation to vaginally placed mesh in the management of POP has been changing and the use of transvaginal mesh procedures for POP has declined globally in recent years.

Some of the key changes in guidance and practice which have occurred internationally include:

- In October 2008, the US Food and Drug Administration (FDA) issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement).
- In July 2011, the FDA published an updated communication ('*Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication*') in relation to this matter. The FDA has "*identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of POP based on a review of adverse events reported to the FDA and an assessment of the scientific literature*". Based on the panel's deliberations, the FDA issued an order to "*reclassify meshes used to repair POP transvaginally from class II, which general includes moderate-risk devices, to class III, which generally includes high-risk devices, and a second order that requires manufacturers to submit a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP".* *https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm*
- The advice from the SCENIHR to the European Commission in 2016 stated that '*implantation of any mesh for the treatment of POP through the vaginal route should only*

be considered in complex cases in particular after failed primary repair surgery.' http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en

- The Scottish Independent Review (March 2017) recommended that '*the use of polypropylene mesh or biological graft* (for POP) *should not be offered routinely but may be considered in complex conditions – only after discussion at an appropriately constituted MDT*) https://beta.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/
- Procedural guidance from the National Institute for Health and Care Excellence (NICE) (UK) in December 2017 recommended that vaginal placement of mesh to repair prolapse should only be used in the context of research. '*the evidence for long term efficacy is inadequate in quality and quantity. Therefore, the procedure should only be used in the context of research. This does not constitute a ban on the use of the procedure, as has been suggested in some media reports.*' https://www.nice.org.uk/guidance/ipg599
- In November 2017, the medical device regulatory body in Australia, the Therapeutic Goods Administration (TGA) decided to remove those transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG). The TGA considered that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients. The medical device regulatory body in New Zealand (MedSafe) has aligned with the actions taken in Australia.

5.4.1 Transvaginal placement of Mesh for POP Repair – Advice from Professional Training Bodies

The advice of the PTBs to this report is that transvaginal placement of synthetic mesh is recognised as resulting in better long-term anatomical outcomes in POP repair than traditional mesh repairs, but emerging evidence indicates that it is also associated with a high risk of mesh erosion of approximately 10-12% , in addition to a higher risk of pelvic pain. It was reported that the routine use of transvaginal mesh for POP repair has been effectively discontinued in Ireland, and many of the relevant mesh device kits are no longer placed on the market here. However, individual clinicians support the option of transvaginal placement of mesh in certain cases.

In their submission to this report, the IOG and the RCSI drew attention to the response of the Royal College of Obstetricians and Gynaecologists (RCOG) to the publication of the NICE guidance of December 2017, referred to above. The RCOG responded: *'there is a small subset of women for whom other surgical interventions are not appropriate and the use of mesh may be appropriate to them, provided they have appropriate information and counselling about the risks and benefits and have explored all other treatment options. We are concerned that this guidance may leave these women without an effective treatment option…. It is paramount that women with pelvic organ prolapse are made aware of all the treatment options available and empowered with information about the risks associated with any procedures, to enable them make an informed decision about the right treatment for their condition. Specialist training, surgical experience and appropriate patient selection are all crucial factors in ensuring current and future patients receive the highest quality of care.'*

The Royal Australia and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) issued a statement on transvaginal mesh in prolapse repair which was reviewed in November 2016: '*The data*

are not supportive of the use of transvaginal mesh for any primary repair procedure. There is no robust data on its use in recurrent prolapse. However, patients at increased risk for recurrent prolapse such as the obese, the young, those with chronically raised abdominal pressure (severe asthma, constipation) and those with stage 3 and 4 prolapse may find the risk benefit profile of transvaginal mesh procedures acceptable. Ideally, transvaginal mesh procedures would be performed in the setting of a properly conducted clinical trial with appropriate ethical oversight. Therefore, referral to a centre with such a trial in process should be considered and discussed with these women. At the minimum, a detailed and exhaustive consent and audit process is required and consideration of a second opinion from an independent gynaecologist who is experienced in pelvic reconstructive surgery should also be discussed prior to surgery.'

In another statement, issued in response to the release of the report of a New Zealand Parliamentary Inquiry, RANZCOG also noted: '*Prolapse can be a difficult condition to treat successfully, and it is unhelpful to look only at the outcomes of Mesh surgery without simultaneously looking at outcomes of alternative approaches both with respect to both efficacy and complications. It is noteworthy that some women are in circumstances such that they will elect to have vaginal prolapse surgery with surgical mesh after they have carefully weighed the possible adverse effects against the lower success rates of native tissue repair.'*

In its most recent statement, following the decision by the TGA to remove transvaginal mesh products from the Australian register in December 2017, RANZCOG stated "*We understand the reasons that have prompted this decision by the TGA. It has become clear that the evidence underpinning the safety and usefulness of mesh used for prolapse is of questionable value. RANZCOG takes on board the decision made by the TGA as the regulatory body for Australian implants. Until such time that the evidence of scientific studies provides a more persuasive argument in favour of mesh kits in the treatment of vaginal prolapse, RANZCOG supports this cautious approach…. The health and wellbeing of women is absolutely paramount. There is an urgent need for good-quality research to guide us on the appropriate use of mesh for prolapse."*

Finding

Transvaginal placement of mesh for the treatment of POP is not regarded as appropriate first line treatment and its use is restricted through a number of mechanisms in some jurisdictions, for example through NICE clinical guidance in the United Kingdom or through regulatory restrictions in Australia and New Zealand.

Section 6 - Ensuring the Safe and Effective Use of Mesh Implants: Priority Recommendations

6.1 Introduction

As described in Section 2, it was identified in May 2018, in advance of completion of this report, that work should begin immediately on the following priority recommendations:

(i) the availability of patient information and informed consent materials and
(ii) the provision of aftercare for women suffering serious complications.

The CMO wrote to the Acting Director General of the HSE on 28th May 2018 requesting that the Executive commence work on these actions, in conjunction with the IOG, the RCSI and the CFI.

This section describes the rationale for these recommendations. An update on their implementation is provided in Section 2.

6.2 Patient Information and Consent

There was a shared understanding among the stakeholders consulted that the development of national, standardised patient information resources about mesh implants, including Patient Information and Consent Leaflets, should be developed as a priority.

6.2.1 Informed Consent

All patients have a right to expect that they are given consistent and up to date information, that they are informed of all the treatment options available to them and provided with adequate time for discussion, reflection and decision making in partnership with their clinicians so that they can give fully informed consent. As described in Section 3, many women suffering complications following mesh procedures for SUI or POP reported that they had not been informed that their surgeries involved the use of mesh; they were not made aware of the risks involved in these procedures; they were not informed of other treatment options and they were not made aware of the possible difficulties associated with mesh removal or with the treatment of long-term mesh complications.

It was identified through engagement with stakeholders that standardised information resources were not available at national level to ensure that all patients receive consistent information about the benefits and risks of mesh devices, to advise of other treatment options and to support informed consent processes. as would be usual with many surgical conditions.

Finding

As would be usual with many surgical conditions, standardised information resources were not available at national level to ensure that all patients receive consistent information about the benefits and risks of mesh devices, to advise of other treatment options and to support informed consent processes.

Informed consent is a fundamental principle underpinning all healthcare as outlined in the HSE National Consent Policy 2017 and the guidance of the Medical Council relating to informed consent:

https://www.hse.ie/eng/about/who/qid/other-quality-improvement programmes/consent/national-consent-policy-august-2017.pdf
https://issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606

Comprehensive patient information resources and consent leaflets about SUI and POP to support informed consent processes have been developed in several other jurisdictions as part of their response to national mesh safety reviews. Examples include the Patient Information Leaflets developed by NHS England, available at the links below:
https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/suimeshleaflet.pdf
https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/popmeshleaflet.pdf

6.2.2 Patient information Resources

There is understandable public and patient concern about the ongoing safety of mesh devices used in the management of SUI and POP in light of the considerable publicity that this issue has received. Comprehensive, evidence based educational materials need to be agreed between the major stakeholders and made publicly available on relevant websites which set out the essential facts concerning the effectiveness, benefits and complications of mesh implants and describing the treatment pathways and resources available to women and clinicians. Several countries have developed such resources in recent years, which provide useful models.

Examples include:
Mesh – Frequently Asked Questions resource developed by the Health and Social Care Board, Northern Ireland (HSCNI):
http://www.hscboard.hscni.net/our-work/commissioning/mesh-frequently-asked-questions/

Patient Information Resources developed by the RCOG and the British Society of Urogynaecology (BSUG) in England:
https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/
https://bsug.org.uk/pages.php/information-for-patients/111?id=11

Patient Information Resources developed by the Australian Quality and Safety Commission:
https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/

6.3 Patient Information and Consent Recommendations

Patient Information and Consent

Recommendation 1:
1. The HSE, working in conjunction with other stakeholders as appropriate, should develop Patient Information and Consent Leaflets on mesh procedures for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Information provided should include the benefits and risks of mesh procedures, including risks of failure and complications, as well as describing alternative treatment options, including no treatment.
Status: Priority recommendation – action commenced in May 2018

Patient Information Resources

Recommendation 2:
2. The HSE, working in conjunction with other stakeholders as appropriate, should develop comprehensive evidence-based information resources about mesh devices and the services in place for the management of mesh related complications for publication on the HSE and other stakeholder websites.
Status: Priority recommendation – action commenced in May 2018

**As described in Section 2 this is one of three urgent recommendations for which confirmation of implementation by the HSE has been sought. Pending this confirmation, the HSE has paused the use of all procedures involving uro-gynaecological/transvaginal mesh implants for the management of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP) in HSE funded hospitals, in cases where it is clinically appropriate and safe to do so.*

6.4 Aftercare for Women Suffering Complications

6.4.1 Introduction

As described in Section 3, difficulty in accessing timely, compassionate and appropriate specialist aftercare was an extremely strong source of distress and dissatisfaction reported by some women during the preparation of this report. It became apparent that there was a need for clarity at national level about the systematic provision of appropriate multidisciplinary care for women experiencing serious complications. Although it was reported by clinicians that a number of surgical units with the required multidisciplinary expertise and facilities provide tertiary referral services, information was not readily available about the location and composition of these units or the number of such referrals which have been made. Due to the lack of readily available data about the number of women affected, the precise level of demand for such specialist care in Ireland is unclear.

Finding

Structured treatment or referral pathways were not evidently in place for the minority of women requiring specialist, multidisciplinary care for serious complications following mesh surgery.

6.4.2 Management of Mesh Complications

It is recognised that all surgeries for SUI and POP, both mesh and non-mesh, have a risk of associated complications in a minority of women. For most women, complications following mesh surgery can be dealt with by the clinician responsible for the patient's original care. However, a minority of women suffer serious complications following mesh surgery requiring specialist, multidisciplinary care.

Mesh devices are designed to be permanently implanted in the body. However partial or complete removal of mesh may be required to address some complications and mesh removal is recognised to be very problematic in some circumstances.

The categorisation of mesh removal described by the Health and Social Commission (Northern Ireland) on its website provides a useful summary of the different types of mesh removal which may be necessary and their implications for the level of service provision needed:

The type of mesh removal depends on the reason for surgery and type of mesh. Some operations for removal involve a minor procedure (revision, trimming or partial release of tape) and others are more complex operations (complete removal/ partial removal of eroded mesh). The most common reason for revision or removal of mesh is mesh that has eroded into the vagina and less commonly for removal of a tight tape, which protrudes into the vagina leading to painful sex or vaginal pain. On rare occasions, mesh can erode into a neighbouring organ such as the urethra, bladder or bowel, which makes removal necessary. There are different types of 'removal':

1. *If a patient is unable to empty the bladder after a mesh tape has been used to treat stress urinary incontinence, it can be cut or released to reduce tension without removing any of it.*
2. *If a small piece of mesh has eroded into the vagina, the exposed part can be trimmed or partially removed. This is a simple day case procedure, which may be done under local or general anaesthesia.*
3. *If a piece of mesh has eroded into the urethra or bladder, then that part is removed (partial / total removal of eroded mesh), which may involve complex surgery and the need for further operations.*
4. *In rare cases of long term pain, complete removal of the vaginal portion of the mesh may be necessary, and in very rare cases, total removal of the entire mesh can be performed. This surgery is very complex and makes up less than 5% of the removals undertaken in mesh centres in the UK. It has its own risks, with little evidence on the benefits of entire mesh removal, so a careful balance needs to be struck between trying to relieve existing problems and the risk of causing new ones.*

http://www.hscboard.hscni.net/our-work/commissioning/mesh-frequently-asked-questions/

6.4.3 Specialist Aftercare for Women Suffering Complications – Advice from Professional Training Bodies

The advice of the IOG and the RCSI to this report is that*, 'in keeping with the Code of Practice for Surgeons (RCSI, 2018), any surgeon performing these procedures should be capable of managing most complications arising from these procedures and 'consult appropriately with other clinicians and transfer the care of the patient, when appropriate, to another colleague or unit where the required*

resources and skills are available.' …. For women with major clinical complications related to mesh surgery, the availability and input of a specialist urogynaecologist, urologist, colorectal surgeon, pain specialist, physiotherapist and psychologist may be required as part of a multidisciplinary approach. At present, each hospital group has this clinical expertise and thus, the capability of managing most of these cases in a holistic fashion. We also recommend that any woman who has experience complications or has concerns, is advised to contact the hospital where her procedure was performed, either directly or through her GP, and that she be given a prioritised appointment. If, for whatever reason, she does not wish to return to that unit, then a national helpline should be available where concerned women can be counseled by a trained allied health professional, and referred onwards to a multidisciplinary service if required.

6.4.4 Specialist Mesh Complications Referral Services: Examples from other jurisdictions

Criteria for specialist referral centres that treat women with complex mesh problems after SUI or POP surgery have been developed by professional organisations in a number of countries.

National Health Service (NHS), United Kingdom

Criteria for referral centres that see women with mesh problems after SUI or POP surgery have been developed jointly by the British Association of Urological Surgeons (BAUS) and the British Society of Urogynaecology (BSUG). Trusts that agree to see women with mesh problems after SUI or POP surgery are obliged to agree that they will comply with the criteria set for discussing all patients at a joint meeting, to help determine best treatment options. The essential requirements are that:

- a designated urologist, gynaecologist, colo-rectal surgeon and pain relief specialist are available;
- patient discussions are carried out in the setting of a multi-disciplinary team (MDT) meeting; and the application by the centre is agreed & signed-off by the Trust's Medical Director.

Details of these accredited centres are available on the relevant websites:
https://www.baus.org.uk/patients/sui_mesh_complications.aspx
https://bsug.org.uk/pages.php/information-for-patients/111?id=111

Australia

Following a request from state and territory health department representatives, the Australian Quality and Safety Commission developed resources for consumers, clinicians and health services on the use of transvaginal mesh products for the treatment of POP and SUI. The Guidance describes the experience and qualifications that senior medical practitioners need to be credentialed to implant and remove mesh for treatment of POP and SUI. It also includes recommendations on device specific training, requirements for maintaining skills, monitoring and reporting on patient outcomes, the types of specialty supports services hospitals should have if they offer implantation and removal of transvaginal mesh and requirements for post-operative follow-up.
https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/

6.4.5 Specialist Scanning Facilities for the Assessment of Mesh Complications

Difficulty in accessing specialist scanning facilities for the assessment and diagnosis of mesh-related problems was raised by many women as a particular concern. Many women were of the view that translabial scanning, a specialist type of ultrasound, is essential for diagnosing mesh related problems which they state has the advantage of being non-invasive, cheap and easy to perform.

The advice of the IOG and the RCSI to this report is that '*The facility to perform translabial ultrasound is available in units across the country. There is, however, no clinical evidence that it is as, or more useful, in assessing or diagnosing women with complications when compared to clinical examination, endoscopy or MRI.'*

Current advice in Northern Ireland in relation to scanning is that *'Belfast Trust has placed an order for a transvaginal scanner and it is expected to be fully operational in 2019. The centre when fully operational will offer enhanced patient services including transvaginal and translabial ultrasound.'*
http://www.hscboard.hscni.net/our-work/commissioning/mesh-frequently-asked-questions/

The HSE has confirmed that it will specifically examine the availability and location of specialist diagnostic services as part of its implementation of the recommendations below.

6.4.6 Aftercare for women suffering complications: Recommendations

Aftercare for Women Suffering Complications

Recommendations 3 - 7
The aftercare options/arrangements for women who require care for complications following the use of synthetic mesh devices in uro-gynaecological procedures should be clarified as a matter of urgency. The HSE should:
3. Identify a central contact point within the HSE for women who may require assistance to navigate the services and in terms of advice, treatment options, including options to seek a second opinion if necessary
4. Put in place a contact point and a referral pathway for women with no treating clinician or with severe complications at every Hospital Group level and a mechanism to communicate same to both women and clinicians
5. Establish the numbers of women requiring, and likely to require, specialist multidisciplinary aftercare services
6. Working together with the IOG and the RCSI, and having regard to examples of professional good practice elsewhere, to identify and put in place the specialist multidisciplinary services, including specialist diagnostic services, required to meet the specific care needs of women with complex and severe complications and to identify the appropriate locations at which these services will be provided.
7. Pending the full implementation of recommendations 1-4 above, to identify treatment options for women in urgent need of care, including if necessary the sourcing of services from abroad, either through existing mechanisms such as the treatment abroad scheme or through the commissioning of specialist diagnostic and treatment services
Status: Priority recommendation – action commenced in May 2018

Section 7 - Ensuring the Safe and Effective Use of Mesh Implants: Clinical and Professional Issues

7.1 Introduction

This section of the report discusses the system measures relating to clinical and professional practice required to ensure the safe and effective use of mesh devices and sets out recommendations to ensure that this approach is consistently adopted nationwide. Engagement with stakeholders at the outset of preparation of this report identified that governance mechanisms and information systems were not sufficient to demonstrate or provide assurance that practice at national level in relation to mesh implants is in accordance with agreed international best practice and clinical guidance.

Finding

Governance mechanisms are not in place at national level to provide assurance that mesh surgeries are carried out in accordance with agreed international best practice and clinical guidance.

Communication mechanisms currently in place at national level between the HPRA, healthcare providers and professional bodies do not provide assurance that the findings and recommendations of safety reviews such as the SCENIHR[1] report circulated by the HPRA in recent years regarding mesh implants are systematically analysed and acted upon where appropriate.

Professional Conduct and Ethics for Registered Medical Practitioners, Medical Council, 2016; Code of Practice for Surgeons, Providing a Good Standard of Surgical Practice and Care, RCSI, 2018). A consistent recommendation from national and international professional training bodies and international safety reviews is that mesh procedures should only be carried out by appropriately trained personnel.

7.2.1 Professional Surgical Training Requirements: Advice from Stakeholders

The advice of the IOG and the RCSI, in their joint submission to this report, is that surgeons should only undertake procedures that lie within the range of their competence and only if they have appropriate training and experience, consistent with Medical Council ethical and professional guidance and the RCSI Code of Practice for Surgeons.

Urethral mesh tape procedures and POP mesh repair should only be undertaken by appropriately trained surgeons who are on the relevant specialist registers and who have undertaken the relevant subspecialty training. Such specialists will have a declared interest in the treatment of urinary incontinence and/or POP. All surgeons treating patients with urinary incontinence and POP have an ongoing professional responsibility to maintain their competence in line with RCSI good surgical practice guidelines and Medical Council requirements in respect of competence assurance.

7.2.2 Recommendations: Professional Training Requirements

Professional Training Requirements

Recommendation 8:
8. Mesh surgery for the treatment of SUI and POP should only be carried out by appropriately trained surgeons who are on the specialist register and who have undertaken relevant subspecialty training as defined by the IOG and the RCSI. Such specialists will have a declared interest in the treatment of urinary incontinence and/or POP.
Status: In process – action commenced July 2018, linked to pause in mesh procedures

Recommendation 9:
9. The HSE should establish and maintain a list or registry of persons qualified to undertake SUI and/or POP mesh surgery procedures in HSE funded hospitals on foot of clear guidance from the relevant professional bodies, the IOG and the RCSI, re the sub-specialist training and ongoing competence requirements for surgeons undertaking these surgeries. *
Status: In process – action commenced July 2018, linked to pause in mesh procedures

**As described in Section 2 this is one of three urgent recommendations for which confirmation of implementation by the HSE has been sought. Pending this confirmation, the HSE has paused the use of all procedures involving uro-gynaecological/transvaginal mesh implants for the management of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP) in HSE funded hospitals, in cases where it is clinically appropriate and safe to do so.*

7.3 Mesh Surgical Unit Facilities

A consistent recommendation from national and international professional training bodies and international safety reviews is that mesh procedures should only be carried out in units with the necessary multidisciplinary expertise and facilities to ensure that patients with SUI and POP are fully and appropriately assessed, counselled and advised as to all their treatment options.

7.3.1 Mesh Surgical Unit Facilities: Advice from Professional Training Bodies

The advice of the IOG and the RCSI to this report is that surgeons who perform incontinence and prolapse surgery should have a regular specialist clinic where such patients are seen, assessed, and counselled for surgery. Such specialists should have appropriate access to physiotherapy and specialist nurses who can perform specialist assessments e.g. urodynamics. Regional multi-disciplinary teams should be developed to permit the discussion of specific patients with complex prolapse and incontinence, in keeping with the RCSI code of practice. Stakeholders also referred to the fact that benign gynaecology, of which urogynaecology is a recognised sub-specialty, is an area of practice that is currently under-resourced. Appropriate pathways, clinics, staffing, investigations and theatre time will be needed to ensure a coherent response to this group of patients.

7.3.2 Recommendations: Mesh Surgical Unit Facilities

Mesh Surgical Unit Facilities

Recommendation 10:
10. Mesh surgery should only be carried out in designated multidisciplinary specialist clinics with the appropriate facilities and with appropriate patient selection and strong clinical governance arrangements in place.
Status: In process– action commenced July 2018, linked to pause in mesh procedures

Recommendation 11:
11. The HSE should identify surgical locations meeting this requirement, for (i) SUI procedures and (ii) POP procedures, on foot of clear guidance from the relevant professional training bodies, the IOG and the RCSI, re the recommended multidisciplinary expertise and technical facilities required at units where each type of surgery takes place.
Status: In process– action commenced July 2018, linked to pause in mesh procedures

7.4 Clinical Guidance

It was identified in the course of preparation of the report that there is at present no clinical guidance mandated at national level to guide the use of mesh implants in the management of SUI or POP or in relation to the management of SUI and POP generally.

Finding

There is no mandated professional clinical guidance at national level to guide the use of mesh implants in the management of SUI or POP

Urinary Incontinence and Pelvic Organ Prolapse are complex, common conditions of significant public health importance, affecting a sizeable proportion of women as they age. Considering the ongoing concern about mesh complications, and the clear advice that mesh procedures should only be offered to appropriately selected women as one of a range of treatment options, there is a requirement for national clinical guidance addressing the entire pathway for these conditions, including the full range of treatment options, both surgical and non-surgical, as has been developed or is under development in other countries, such as the relevant guidance of NICE in the UK.

7.4.1 Clinical Guidance: Advice from Professional Training Bodies

The advice of the PTBs to this report is that a working group should be established to produce national guidance on the assessment and management of women with incontinence and prolapse.

7.4.2 Recommendation: Clinical Guidance

Clinical Guidance for the Management of Incontinence and Prolapse

Recommendation 12:
12. National clinical guidance to inform the development of evidence based care pathways for the assessment and management of women with (i) incontinence and (ii) prolapse should be developed as a priority by the HSE in accordance with the National Clinical Effectiveness Committee (NCEC) standards for clinical practice guidelines. Guidance should encompass the entire pathway of care for both conditions, including the full range of treatment options, both surgical and non-surgical.
Status: HSE to develop Implementation Plan

7.5 The Use of Transvaginally Placed Mesh in the Management of Pelvic Organ Prolapse:

As described in Section 5, there are concerns about the rate of complications associated with the use of transvaginally placed mesh implant devices in the management of POP. The advice of several international safety reviews and clinical studies is that transvaginal mesh should not be offered as a first line treatment in the management of POP. However, it is argued by some clinicians that the option of transvaginal placement of mesh is necessary for complex cases where other treatment options have failed or are not otherwise suitable and following assessment and discussion in an MDT setting, after detailed discussion with the patient about the associated risks and benefits. As of July 2018, the HSE has been requested to pause all transvaginal mesh procedures until certain conditions are met. In addition to these conditions, any future use of transvaginally placed mesh implant devices in the management of complex or recurrent POP cases, where other treatment options have failed or are not appropriate, should be restricted to settings where appropriate governance mechanisms are in place to ensure that patient health and wellbeing and patient safety considerations are paramount in all such treatment decisions.

7.5.1 Recommendations: The Use of Transvaginally Placed Mesh in the Management of Pelvic Organ Prolapse

The Use of Transvaginally Placed Mesh in the Management of Pelvic Organ Prolapse

Recommendation 13:
13. There are concerns about the rate of complications associated with the use of transvaginally placed mesh implant devices in the management of POP. Transvaginal mesh should not be offered as a first line treatment in the management of POP.
Status: Urgent – HSE to develop Implementation Plan

Recommendation 14:
14. To ensure that patient health and wellbeing and patient safety considerations are paramount in all treatment decisions, the use of transvaginally placed mesh implant devices in the management of complex POP cases, where other treatment options have failed or are not appropriate, should only be offered following assessment and discussion at MDT settings, and after detailed discussion with the patient about the associated risks and benefits.
Status: Urgent – HSE to develop Implementation Plan

Recommendation 15:
15. The HSE, on foot of clear guidance from the relevant professional training bodies, the IOG and the RCSI, should develop agreed protocols for the use of transvaginally placed mesh implant devices in the management of complex POP cases where other treatment options have failed or are not appropriate, which clarify multidisciplinary team (MDT) structures at regional and/or national level where such cases should be discussed.
Status: Urgent – HSE to develop Implementation Plan

Section 8 - Ensuring the Safe and Effective Use of Mesh Implants: Information Issues

8.1 Introduction

Good health information is a critical element to ensuring good quality, safe health care. The collection of robust, reliable health information to monitor health outcomes and complications of care is especially important in relation to the introduction of new technologies and new surgical techniques such as implantable devices.

This section of the report examines the information available at national level to monitor the safe and effective use of mesh implants and recommends measures for their improvement.

8.2 HSE Clinical Activity and Service Data

The HSE was requested to provide any information and clarification available that would assist in describing the magnitude and nature of any problems associated with the use of these devices to date in public hospitals and the arrangements that are in place for women suffering complications. The following information items in particular were sought:

(i) number of women to date who have had SUI or POP surgery involving insertion of mesh with a breakdown of procedure type or an estimate of these numbers
(ii) breakdown of these numbers between gynaecology and urology services
(iii) number of women reporting complications
(iv) number of women who have had mesh removal or revision procedures
(v) number of women awaiting mesh removal or revision procedures
(vi) number of units nationally at which these mesh procedures are performed
(vii) availability of standardised patient information leaflets / consent forms

8.2.1 Clinical Activity Data

The Hospital Inpatient Enquiry (HIPE) system is the principal source of national data on discharges from acute hospitals in Ireland. HIPE coding for the relevant surgical procedures does not specify if a mesh device was used therefore precise figures for the numbers of women who have had mesh implants for the repair of SUI and POP are not available, nor are figures available for the number of revision surgeries which may have involved the removal of mesh.

- HIPE figures indicate that 700-850 women per annum have undergone sling surgery for SUI in recent years. Based on the advice of clinicians about usual surgical practice, is estimated that the large majority of these procedures will have entailed the use of mesh.
- HIPE figures indicate that similar numbers of women have undergone prolapse repair procedures annually. Based again on the advice of clinicians, it is estimated that mesh is much less commonly used in these procedures.
- Figures from other jurisdictions with similar health systems support these estimates. There were 14,600 mesh procedures in Scotland in the period April 1997 – March 2016 of which 13,300 were for the treatment of SUI (79% of total SUI procedures) and 1,330 were POP primary mesh repairs (7% of total POP repairs)
- Data is not available as to the numbers of women who have been treated for complications or who are awaiting treatment for mesh complications in the public hospital system.

- A proportion of women will have had their surgery or received follow-up care in private sector hospitals for which data are not available.

8.2.2 Units at which Mesh Procedures are Performed

Information is not routinely collected about the number and location of surgical units nationally at which mesh insertion and removal procedures are carried out or of the facilities available at this units. The NWIHP undertook to obtain this information at Hospital Group level and a summary of the information compiled is provided below.

8.2.2.1 Mesh Insertions

All six Hospital Groups indicated that mesh insertion procedures are carried out by some hospitals within the Group.

19 hospitals of 46 reported that they carry out vaginal mesh insertion procedures. Many hospitals clarified that these were only SUI /sling /TVT mesh procedures but this information was not provided in respect of all hospitals / Groups.

8.2.2.2 Mesh Removals

Four Hospital Groups indicated that mesh removal procedures are carried out within the Group; one Hospital Group reported that mesh removal has not occurred and another Group reported that mesh removal was not 'routinely performed'.

In total of the 19 hospitals which carry out mesh procedures, nine hospitals reported that they also carry out removal procedures.

A small minority of these hospitals provided information indicating the number of mesh removal procedures which have been performed. Two hospitals indicated they have removed small portions of tape for tape exposure and pain (three occasions in total). One other hospital indicated that two mesh removal procedures were carried out over the past 10 years

All hospitals carrying out mesh procedures reported that they had the appropriate facilities and expertise to do so.

This information will need to be further reviewed and validated by the HSE in its progression of the recommendations of this report relating to Clinical and Professional Issues and Aftercare for Women with Complications after the advice of the IOG and RCSI in respect of surgical training criteria and unit facilities has been received.

8.2.3 Conclusion – Availability of information about mesh procedures carried out in HSE funded hospitals.

There are significant gaps in knowledge about current practice in Ireland concerning the use of mesh implants. Routine clinical activity data on the HIPE system does not identify the number of women who have received mesh implants, the numbers of women reporting complications or the numbers of women who have had or who are awaiting mesh removal procedures at clinician, hospital group or national level.

Finding

There are significant gaps in knowledge about current practice in Ireland regarding the use of urogynaecological mesh implants.

Routinely collected clinical information at national level does not provide the capacity for monitoring or audit of mesh surgeries for the treatment of SUI and POP.

As a minimum requirement, the HSE should put in place a data collection system to ensure that information about the numbers, locations and types of uro-gynaecological mesh procedures carried out in HSE-funded hospitals is routinely collected and centrally collated.

8.2.4 Recommendation – Develop and maintain a national data collection of all mesh procedures carried out in HSE funded hospitals.

National data collection of all mesh procedures carried out in HSE funded hospitals.

Recommendation 16:
16. The HSE should develop a data collection system to ensure that basic information about the numbers, locations and types of uro-gynaecological mesh procedures carried out in HSE-funded hospitals, including mesh revisions and removals, is routinely collected and centrally collated. *
Status: In process– action commenced July 2018, linked to pause in mesh procedures

**As described in Section 2 this is one of three urgent recommendations for which confirmation of implementation by the HSE has been sought. Pending this confirmation, the Executive has been requested to pause the use of all procedures involving uro-gynaecological/transvaginal mesh implants for the management of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP) in HSE funded hospitals, in cases where it is clinically appropriate and safe to do so.*

8.3 National Register of Implants used in the treatment of incontinence and prolapse in women.

As has been seen with safety concerns about other implantable devices such as breast implants and hip prostheses in recent years, there are specific concerns relating to implantable devices and a need to ensure adequate systems for long-term monitoring and traceability are in place.

A finding across many of the safety reviews of mesh which have been undertaken by regulatory bodies and national health systems internationally is that there is a lack of comprehensive, follow-up data in routine treatment settings beyond the time periods normally covered in clinical trials. The report of the NHS Mesh Oversight Group (2017) identified that '*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.*'

Other difficulties associated with long-term monitoring of mesh complications is that, apart from mesh erosion, some of the complications women report occur several years after the implant and may be difficult to distinguish from evolving symptoms of the underlying pelvic disease. As previously noted, the use of mesh has evolved over the years since its introduction, with many different individual products having been both placed on and removed from the market over time, and some devices are no longer in use, particularly those used in the transvaginal repair of POP which were recognised to have been particularly problematic.

The European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) opinion on the safety of surgical meshes used in urogynaecological surgery made a number of recommendations, including recommending the establishment of implant registries. The HPRA, the IOG and the RCSI all indicated support for the establishment of a national registry in their contributions to this report. This would permit sustainable national clinical audit of these devices.

Preliminary advice was sought from the National Office for Clinical Audit (NOCA) during the preparation of this report about this recommendation, based on its experience to date of establishing the Irish National Orthopaedic Registry (INOR). NOCA advice is that establishing a registry of this nature is a complex undertaking involving several stakeholders, and requires clinical leadership and detailed planning and consideration of the ethical and technical issues and resources involved. The INOR has taken several years to develop and roll-out. It is possible however that the system learning and technical expertise which has been gained in that process might yield efficiency and other benefits for the design of other implant registries in the future.

It is beyond the scope of this report to examine this issue in detail. It is recommended that the feasibility and business case for establishing a national registry with mandatory registration for all mesh implants (based on the existing model of the register of orthopaedic implants established by the National Office for Clinical Audit (NOCA)) should be examined further by the IOG, the RCSI, and the HSE.

8.3.1 Recommendation – National Register of Implants used in the treatment of Urinary Incontinence and Pelvic Organ Prolapse in Women

National Register of Implants used in the treatment of incontinence and prolapse in women.

Recommendation 17:
17. The business case for the establishment of a national register of implants used in the treatment of SUI and POP, with mandatory registration of implants (based on the existing model of the register of orthopaedic implants established by the National Office for Clinical Audit (NOCA)) and with scope for research and audit should be examined by the IOG, the RCSI, and the HSE.
Status: HSE to develop Implementation Plan

8.4 Adverse Event Reporting

Adverse event reporting is a critical element of monitoring the safety and quality of care associated with the use of mesh implant devices. There are two systems in place for reporting mesh-related adverse events:

- The HPRA operates the national system for recording and reporting details of suspected adverse reactions occurring in Ireland for all products which it regulates, including medical devices
- The National Incident Management System (NIMS) is the principal source of national data on incident and claim activity for the Irish health service.

8.4.1 HPRA Medical Device Adverse Incident Reports

The Health Product Regulatory Authority (HPRA) as the competent authority for medical device regulation has a role in monitoring the safety of medical devices in Ireland. Those who have experienced a safety issue with a medical device, including transvaginal mesh devices or implants, are strongly encouraged to report it to the HPRA medical device adverse incident reporting system, particularly if there is an incident which has occurred during use of the medical device which might lead to or might have led to death of a patient or user, or of other persons or to a serious deterioration in their state of health. HPRA also encourages reporting if there is an increase in the occurrence of events which are known complications. The medical device reporting system is accessible to patients, healthcare professionals or any person who identifies a medical device safety issue.

Over the period 2009 to mid-October 2018, the HPRA has received 121 incident reports relating to urogynaecological mesh implants, of which just two reports were received prior to November 2017 when this issue came to prominent public attention. The great majority of reports have come from members of the public or their legal representatives, with one report received from an implanting surgeon

8.4.2 State Claims Agency / National Incident Management System

The National Incident Management System (NIMS) hosted by the State Claims Agency (SCA) is the principal national source of data on patient / service user safety incidents and claims in the public sector. Information was sought from the SCA for this report about the number of incidents on NIMS related to mesh implants.

The SCA reported on 14th May 2018 that when the NIMS was searched using a number of terms related to mesh implants and reviewed for evidence of the commonly-reported side-effects of mesh implants, a total of 50 incidents were identified between 2005 and 2017 inclusive. There was evidence of incidents related to the initial post-operative period but a minority related to the mesh itself.

As of 27th July 2018, the SCA reported that it had received 11 claims in relation to trans-vaginal mesh implants, all of which were active .

8.4.3 Conclusion – Adverse Event Reporting

Based on the internationally reported complication rates; the information provided by the HSE in relation to mesh removal procedures and given the personal reports of complications received from women, these data suggest that there is under-reporting of mesh-related adverse events by clinicians to both the HPRA and the NIMS

Finding

Based on international experience, there is under-reporting of adverse events relating to mesh surgeries by clinicians to both the HPRA and to the National Incident Management System (NIMS) operated by the State Claims Agency (SCA).

HPRA should continue to raise awareness amongst clinicians about the mechanisms that are in place for reporting/registering adverse events relating to mesh devices. The HSE should also raise awareness of the requirement to report serious adverse events such as mesh erosion or chronic pain requiring complex mesh removal procedures.

8.4.4 Recommendations – Adverse Event Reporting

Adverse Event Reporting

Recommendation 18:
18. Information collection and adverse event reporting systems must be strengthened to ensure that the long-term safety of these devices is appropriately monitored.
Status: HSE to develop Implementation Plan

Recommendation 19:
19. Existing guidance and governance mechanisms in relation to adverse event reporting should be reviewed by the HSE in conjunction with the HPRA and the SCA to ensure appropriate reporting of device-related adverse outcomes to both the HPRA and the NIMS, with mandatory reporting of serious adverse events.
Status: HSE to develop Implementation Plan

8.4 Open Disclosure when things go wrong

Allied to the requirement for adverse event reporting is the professional duty of clinicians to engage in open disclosure and communication with patients when things go wrong in healthcare, which may or may not be the result of an error. Some women suffering complications following mesh procedures for SUI or POP reported that individual clinicians responded to their personal concerns in an inappropriate manner which greatly added to their distress. Women also reported feeling that they were not believed, or that their clinicians minimised or did not understand the severity of their complications.

Open disclosure is a consistent approach to openly communicating with patients and their families when things go wrong. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.

All clinicians currently have an individual, professional duty to support a culture of open disclosure as set out in the HSE National Open Disclosure Policy 2013 and the guidance of the Medical Council relating to Open Disclosure and Duty of Candour.
https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/opendiscfiles/opendiscpolicyoct13.pdf

https://issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606

One of the recommendations of the recent Scoping Inquiry into the CervicalCheck Screening Programme (2018) by Dr Gabriel Scally was that the Department of Health should engage with the Medical Council with the aim of strengthening the Council's ethical guidance for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure.

From a legislative perspective, Part 4 of the Civil Liability (Amendment) Act 2017 introduced important legal protections for open disclosure processes, to create a safe space for staff to be open and transparent with patients in order that they would be given as much information as possible, as early as possible, including an apology where appropriate. The apology itself, cannot be interpreted as an admission of liability and cannot be used in litigation against the provider.

The Minister for Health has committed to examining how legislation could be expedited to provide for mandatory open disclosure to patients of serious incidents. The General Scheme of the Patient Safety Bill which is currently being progressed will, for serious patient safety incidents, replace voluntary open disclosure with mandatory open disclosure. Voluntary open disclosure will continue to be used for all other unexpected and unintended patient safety incidents that are not prescribed by the Minister as serious patient safety incidents.

Section 9: Summary of Report Findings

Overall Findings

- Mesh implant devices are certified as compliant with relevant European Union (EU) legislation and no market action against mesh devices for the treatment of SUI or POP has been taken by any of the European device regulatory competent authorities.
- There is an extensive evidence base supporting (i) the use of the mid-urethral sling (MUS) devices in the treatment of SUI and (ii) the use of abdominally placed mesh in the management of POP. A significant majority of patients benefit greatly from these procedures, with reduced long-term complications and improved functional outcomes compared to non-mesh procedures.
- Mesh procedures should be performed by trained personnel, in patients who are appropriately selected and counselled and when appropriate multidisciplinary expertise and clinical governance mechanisms are in place.
- Transvaginal placement of mesh for the treatment of POP is no longer regarded as appropriate first line treatment. Its use is restricted by clinical guidance in some jurisdictions. Regulatory restrictions on its use are in place in Australia and New Zealand.
- Mesh devices are associated with significant and severe complications in a minority of women, which are of concern given the difficulties of mesh implant removal.
- Many other health systems, including in the United Kingdom (UK), Australia and the Netherlands have implemented specific measures in recent years to ensure appropriate use of mesh procedures in the treatment of SUI and POP and to ensure appropriate aftercare for women suffering mesh complications.

Informed Consent

- As would be usual with many surgical conditions, standardised information resources were not available at national level to ensure that all patients receive consistent information about the benefits and risks of mesh devices, to advise of other treatment options and to support informed consent processes.
- Many women reported that they were not informed of other treatment options; they had not been informed that their surgeries involved the use of mesh; they were not informed of mesh complications; and they were not made aware of the difficulties associated with mesh removal or with the treatment of long-term mesh complications.

Aftercare of Women with Complications

- Structured treatment or referral pathways were not evidently in place for the minority of women requiring specialist, multidisciplinary care for serious complications following mesh surgery.
- Some women reported considerable difficulty in accessing timely, compassionate and appropriate specialist aftercare for complications.
- Some women reported that individual clinicians responded to their personal concerns in an inappropriate manner which greatly added to their distress. Women also reported feeling that they were not believed, or that their clinicians minimised or did not understand the severity of their complications.

Clinical and Professional Issues

- Governance mechanisms are not in place at national level to provide assurance that mesh surgeries are carried out in accordance with agreed international best practice and clinical guidance.
- There is no mandated professional clinical guidance at national level to guide the use of mesh implants in the management of SUI or POP or to guide the management of women with complications.
- Communication mechanisms currently in place at national level between the HPRA, healthcare providers and professional bodies do not provide assurance that the findings and recommendations of safety reviews such as those circulated by the HPRA in recent years regarding mesh implants are systematically analysed and acted upon where appropriate.

Information

- There are significant gaps in knowledge about current practice in Ireland regarding the use of urogynaecological mesh implants.
- Routinely collected clinical information at national level does not provide the capacity for monitoring or audit of mesh surgeries for the treatment of SUI and POP.
- Based on international experience, there is under-reporting of adverse events relating to mesh surgeries by clinicians to both the HPRA and to the National Incident Management System (NIMS) operated by the State Claims Agency (SCA).

Section 10: Summary of Report Recommendations

Introduction

This section brings together all the recommendations which have been made throughout the body of the report.

Recommendations have been grouped as follows:

	Recommendation Numbers
#Patient Information and Consent	1 and 2
*Patient Information and Consent	
Patient Information Resources	
#Aftercare for Women Suffering Complications	3 to 7
Clinical and Professional Recommendations	8 to 15
*Professional Training Requirements	
Mesh Surgical Unit Facilities	
National Clinical Guidelines for the Management of Incontinence and Prolapse	
The Use of Transvaginally Placed Mesh in the Management of Pelvic Organ Prolapse	
Information Recommendations	16 to 20
*Develop and maintain a national data collection of all mesh procedures carried out in HSE funded hospitals.	
National Audit and Register of Implants used in the treatment of Urinary Incontinence and Pelvic Organ Prolapse in women.	
Adverse Event Reporting	

Key:

#These were identified as Priority Recommendations for immediate action in May 2018

*As of July 2018, the HSE has paused the use of transvaginal mesh procedures until these recommendations are confirmed to have been implemented.

Implementation of Recommendations

Responsibility for implementation of recommendations:
The HSE, working in conjunction with other stakeholders as appropriate and outlined below, are responsible for the implementation of the recommendations in this report.

Summary of Recommendations

Patient Information and Consent

Patient Information and Consent

Recommendation 1:
1. The HSE, working in conjunction with other stakeholders as appropriate, should develop Patient Information and Consent Leaflets on mesh procedures for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Information provided should include the benefits and risks of mesh procedures, including risks of failure and complications, as well as describing alternative treatment options, including no treatment.
Status: Priority recommendation – action commenced in May 2018

Patient Information Resources

Recommendation 2:
2. The HSE, working in conjunction with other stakeholders as appropriate, should develop comprehensive evidence-based information resources about mesh devices and the services in place for the management of mesh related complications for publication on the HSE and other stakeholder websites.
Status: Priority recommendation – action commenced in May 2018

Aftercare for Women Suffering Complications

Recommendations 3 - 7
The aftercare options/arrangements for women who require care for complications following the use of synthetic mesh devices in uro-gynaecological procedures should be clarified as a matter of urgency. The HSE should:
3. Identify a central contact point within the HSE for women who may require assistance to navigate the services and in terms of advice, treatment options, including options to seek a second opinion if necessary
4. Put in place a contact point and a referral pathway for women with no treating clinician or with severe complications at every Hospital Group level and a mechanism to communicate same to both women and clinicians
5. Establish the numbers of women requiring, and likely to require, specialist multidisciplinary aftercare services
6. Working together with the IOG and the RCSI, and having regard to examples of professional good practice elsewhere, to identify and put in place the specialist multidisciplinary services, including specialist diagnostic services, required to meet the specific care needs of women with complex and severe complications and to identify the appropriate locations at which these services will be provided.
7. Pending the full implementation of recommendations 1-4 above, to identify treatment options for women in urgent need of care, including if necessary the sourcing of services from abroad, either through existing mechanisms such as the treatment abroad scheme or through the commissioning of specialist diagnostic and treatment services
Status: Priority recommendation – action commenced in May 2018

Clinical and Professional Recommendations

Professional Training Requirements

Recommendation 8:
8. Mesh surgery for the treatment of SUI and POP should only be carried out by appropriately trained surgeons who are on the specialist register and who have undertaken relevant subspecialty training as defined by the IOG and the RCSI. Such specialists will have a declared interest in the treatment of urinary incontinence and/or POP.
Status: In process – action commenced July 2018, linked to pause in mesh procedures

Recommendation 9:
9. The HSE should establish and maintain a list or registry of persons qualified to undertake SUI and/or POP mesh surgery procedures in HSE funded hospitals on foot of clear guidance from the relevant professional bodies, the IOG and the RCSI, re the sub-specialist training and ongoing competence requirements for surgeons undertaking these surgeries.
Status: In process – action commenced July 2018, linked to pause in mesh procedures

Mesh Surgical Unit Facilities

Recommendation 10:
10. Mesh surgery should only be carried out in designated multidisciplinary specialist clinics with the appropriate facilities and with appropriate patient selection and strong clinical governance arrangements in place.
Status: In process – action commenced July 2018, linked to pause in mesh procedures

Recommendation 11:
11. The HSE should identify surgical locations meeting this requirement, for (i) SUI procedures and (ii) POP procedures, on foot of clear guidance from the relevant professional training bodies, the IOG and the RCSI, re the recommended multidisciplinary expertise and technical facilities required at units where each type of surgery takes place.
Status: In process – action commenced July 2018, linked to pause in mesh procedures

Clinical Guidance for the Management of Incontinence and Prolapse

Recommendation 12:
12. National clinical guidance to inform the development of evidence based care pathways for the assessment and management of women with (i) incontinence and (ii) prolapse should be developed as a priority by the HSE in accordance with the National Clinical Effectiveness Committee (NCEC) standards for clinical practice guidelines. Guidance should encompass the entire pathway of care for both conditions, including the full range of treatment options, both surgical and non-surgical.
Status: HSE to develop Implementation Plan

The Use of Transvaginally Placed Mesh in the Management of Pelvic Organ Prolapse

Recommendation 13:
13. There are concerns about the rate of complications associated with the use of transvaginally placed mesh implant devices in the management of POP. Transvaginal mesh should not be offered as a first line treatment in the management of POP.
Status: Urgent – HSE to develop Implementation Plan

Recommendation 14:
14. To ensure that patient health and wellbeing and patient safety considerations are paramount in all treatment decisions, the use of transvaginally placed mesh implant devices in the management of complex POP cases, where other treatment options have failed or are not appropriate, should only be offered following assessment and discussion at MDT settings, and after detailed discussion with the patient about the associated risks and benefits.
Status: Urgent – HSE to develop Implementation Plan

Recommendation 15:
15. The HSE, on foot of clear guidance from the relevant professional training bodies, the IOG and the RCSI, should develop agreed protocols for the use of transvaginally placed mesh implant devices in the management of complex POP cases where other treatment options have failed or are not appropriate, which clarify multidisciplinary team (MDT) structures at regional and/or national level where such cases should be discussed.
Status: Urgent – HSE to develop Implementation Plan

Information Recommendations

National data collection of all mesh procedures carried out in HSE funded hospitals.

Recommendation 16:
16. The HSE should develop a data collection system to ensure that basic information about the numbers, locations and types of uro-gynaecological mesh procedures carried out in HSE-funded hospitals, including mesh revisions and removals, is routinely collected and centrally collated.
Status: Immediate – action commenced July 2018, linked to pause in mesh procedures

National Register of Implants used in the treatment of incontinence and prolapse in women.

Recommendation 17:
17. The business case for the establishment of a national register of implants used in the treatment of SUI and POP, with mandatory registration of implants (based on the existing model of the register of orthopaedic implants established by the National Office for Clinical Audit (NOCA)) and with scope for research and audit should be examined by the IOG, the RCSI, and the HSE.
Status: HSE to develop Implementation Plan

Adverse Event Reporting

Recommendation 18:
18. Information collection and adverse event reporting systems must be strengthened to ensure that the long-term safety of these devices is appropriately monitored.
Status: HSE to develop Implementation Plan

Recommendation 19:
19. Existing guidance and governance mechanisms in relation to adverse event reporting should be reviewed by the HSE in conjunction with the HPRA and the SCA to ensure appropriate reporting of device-related adverse outcomes to both the HPRA and the NIMS, with mandatory reporting of serious adverse events.
Status: HSE to develop Implementation Plan

Appendix 1: Summary of International Safety Reviews and Reports

Several reviews of the risks associated with urogynaecological mesh have been published at national and international level by medical device regulators and health system providers. Some of the principal reports and their findings are summarised in this Appendix. Weblinks to the documents are also provided.

1. European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Report (2015)

At European level, the safety of surgical meshes used in urogynaecological surgery was reviewed by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015. The SCENIHR summary finding was that '*clinical outcome following mesh implantation is influenced by material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and the surgeon's experience*'. SCENIHR recommended that '*synthetic sling SUI surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate to severe SUI, when used by an experienced and appropriately trained surgeon. Therefore, the SCENIHR supports continuing synthetic sling use for SUI, but emphasises the importance of appropriately trained surgeons and detailed counselling of patients about the associated risk/benefits*'. The SCENIHR Committee issued recommendations regarding their use including as follows:

- 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,
- 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 existing 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/consultations/public_consultations/scenihr_consultation_27_en.

2. The Dutch Heath Care Inspectorate Report (2013)

In July 2013, following an investigation into patient reports of serious complications after treatment of pelvic organ prolapse with transvaginal mesh, the Dutch Heath Care Inspectorate published a report "Transvaginal Mesh: Serious Complications Demand Cautious Use". The Inspectorate called upon gynaecologists, urologists and surgeons to exercise caution in prescribing and fitting transvaginal mesh. Despite the severity of reported complications, collected data also indicated that many women benefit from surgery with transvaginal mesh. Furthermore, the report noted, very few alternatives to conventional surgery are available without the use of mesh. Therefore, a ban on mesh was considered not to be in the interest of patients.

The report noted that 'the complications experienced by patients can be serious, although in many cases transvaginal mesh is a viable and useful treatment option... It is particularly important that the treating physician informs the patient about possible complications and any alternative treatment options. The Inspectorate advised the professional field to conduct further research to determine the most appropriate clinical response to complications.
https://www.igj.nl/documenten/rapporten/2013/07/02/transvaginal-mesh-serious-complications-demand-cautious-use

3. UK Medicines and Healthcare Products Regulatory Agency (MHRA) Reviews

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) in 2014 published a report entitled 'A summary of the evidence on the benefits and risks of vaginal mesh implants' which concluded that' *for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the individual patient. This conclusion is entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks'.*
https://www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks

In response to concerns about the safety of implanting polypropylene into patients the MHRA also commissioned an evidence review entitled "*In vivo response to polypropylene following implantation in animal models: a review of biocompatibility*" which was published in the International Urogynaecology Journal in 2017. This evidence review found that polypropylene evokes a less inflammatory response compared to other materials which are or can be used in mesh devices in humans. It was also indicated that a lightweight, large pore mesh provides the most satisfactory outcomes. It was noted that while some promising outcomes have been observed with the use of biologically derived and fully reabsorbable meshes, both these types of material currently lack the mechanical strength required for long-lasting repair.
https://www.gov.uk/government/news/interrogating-research-to-protect-public-health

4. Scottish Independent Review of Transvaginal Mesh Implants

In response to patient concerns, an Independent Review (IR) of transvaginal mesh implants was set up by the Cabinet Secretary for Health and Wellbeing in Scotland in 2014. The deliberations of the Independent Review were based on considering published evidence, patient stories and the opinion of clinical experts.

As part of its work, the IR undertook two types of comprehensive systematic evidence reviews. The first was a review of evidence undertaken by those agencies responsible for the safety of medical devices on an international and national basis. The second was a review of published, peer-reviewed Cochrane systematic reviews and health technology assessments undertaken in relation to mesh devices for SUI and POP. In addition, an epidemiological study was conducted using routinely reported Scottish hospital inpatient data. Details of these evidence resources are available at the links below:
https://www.gov.scot/Publications/2015/10/8485/downloads

The IR's Final Report which was published in 2017 sets out concluding findings and recommendations on the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in women. These include recommendations about informed consent, the training and awareness of health professionals, multidisciplinary team working and quality assurance, research, audit and adverse event reporting, and the development of appropriate pathways to meet clinical needs and for the management of those suffering complications.
https://www.gov.scot/Publications/2015/10/8485

https://beta.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/

5. NHS Mesh Oversight Group

In 2014, responding to patient and health professional concerns, NHS England set up a Mesh Working Group, to identify issues causing concern in the treatment of SUI and POP, particularly surrounding the use of mesh devices, and make recommendations to the health system to address them. The Group published an Interim Report in 2015 which highlighted the need for better information for women experiencing SUI and POP, better data and a multi-disciplinary approach to caring for women. A range of recommendations were made under the headings of Clinical Quality, Data and Information and Informed Consent.
https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf

A Mesh Oversight Group was convened to oversee the implementation of these recommendations working alongside the National Institute for Health and Care Excellence (NICE), British Association of Urological Surgeons (BAUS), British Society of Urogynaecology (BSUG), Royal College of Obstetricians and Gynaecologists (RCOG), Medicines and Healthcare Products Regulatory Agency (MHRA), Department of Health (DH) and patient members. The final mesh report published in 2017 summarises the actions that have been taken to fulfil those recommendations. The report also summarises more recent research about vaginal mesh implants and the development of a GP resource and comprehensive patient information leaflet.
https://www.england.nhs.uk/publication/mesh-oversight-group-report/

6. FDA Safety Warnings and Orders

The U.S. Food and Drug Administration (FDA) has taken several actions over recent years to address safety concerns related to surgical mesh for transvaginal POP repair. These include:

- Issued safety communications in 2008 and in 2011 warning doctors and consumers about an increase in adverse event reports related to mesh used for urogynecological procedures;
- Convened an advisory panel in September of 2011 to solicit recommendations on actions to take regarding urogynecologic surgical mesh for transvaginal POP repair;
- Issued orders to manufacturers in January 2012 to conduct postmarket surveillance studies to address specific safety and effectiveness concerns related to surgical mesh used for transvaginal repair of POP; and
- Issued two proposed orders in May 2014 to reclassify the devices from class II to class III and to require manufacturers to submit a PMA application

- The FDA issued two final orders in January 2016 to manufacturers and the public to strengthen the data requirements for surgical mesh to repair pelvic organ prolapse (POP) transvaginally, or through the vagina.

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm262301.htm

7. Australian Therapeutic Goods Administration (TGA) Review 2014

The Australian Therapeutic Goods Administration completed a review of urogynaecological surgical mesh implants in 2014. It found that the use of urogynaecological surgical mesh devices for the surgical treatment of stress urinary incontinence and abdominal pelvic organ prolapse repair was adequately supported by the evidence. However, due to the poor quality of the studies undertaken, the evidence to support the use of these meshes for transvaginal pelvic organ prolapse repair, particularly, posterior repair, was not well established. The TGA review also found that, while adverse events involving these devices were most likely under-reported, the reported complication rate remained low considering many thousands of these mesh devices had been implanted in Australian patients.

The findings from the review highlighted the importance of:

- appropriate patient selection
- surgeon experience
- the need for fully informed patient consent.

The TGA review identified inadequate training/experience for implanting surgeons as a factor in increasing the risk of complications. Certain patients, including those who smoked or were obese, were found to be at higher risk of adverse events and repeated procedures. The most frequently reported adverse events were pain and erosion.
https://www.tga.gov.au/behind-news/review-urogynaecological-surgical-mesh-implants

8. Australian Parliamentary Inquiry

In February 2017, responding to patient concerns, the Australian Senate requested an inquiry to identify how many women in Australia had been adversely affected following transvaginal mesh surgery; to consider the information and support provided to women undergoing transvaginal mesh procedures; to consider the information provided to doctors and surgeons who recommend and undertake transvaginal mesh procedures; and to examine the role of the TGA in approving and monitoring urogynaecological mesh devices for use in Australia. The Inquiry reported in March 2018. It concluded that complications resulting from transvaginal mesh implants constituted ‘a serious public health issue requiring a response at both an individual and at a population level, including counselling, public education, clinical interventions and long-lasting protective mechanisms … this inquiry has highlighted significant shortcomings in Australia's reporting systems for medical devices, with flow-on consequences for the health system's ability to respond to in a timely and effective way to concerns arising from the use of medical devices’. The Inquiry made recommendations relating to adverse event reporting, post-market surveillance, informed consent, clinical pathways for SUI and POP and the management of women with complications.
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report

9. Australian Quality and Safety Commission Mesh Resources

Following a request from state and territory health department representatives, the Australian Quality and Safety Commission has developed resources for consumers, clinicians and health services on the use of transvaginal mesh products for the treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The Commission considered the peer-reviewed evidence; consulted with clinicians; and held consumer forums with women around Australia to ensure that the available evidence and a breadth of views were considered in the development of resources. The Commission convened a Reference Group consisting of consumers, clinical experts nominated by specialist colleges and surgical specialty societies, state and territory health department representatives and the Therapeutic Goods Administration (TGA). Members of the Reference Group have supported the Commission in its development of the following resources, all available at the link below:

- Consumer information resources
- Care pathways for POP and SUI
- Guidance for hospital credentialing of senior medical practitioners to implant and remove mesh for treatment of POP and SUI
- Service model framework for transvaginal mesh implantation, mesh complications and mesh removal services

https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/

10. Health Canada Advisories 2010 and 2014

In 2010, Health Canada issued a Notice to Hospitals (NtH) informing healthcare professionals about complications associated with transvaginal implantation of surgical mesh for the treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). An updated advisory was issued in 2014. It was advised that *'although many women treated with these devices have had good outcomes, Health Canada continues to receive reports of complications, including some serious and life-altering events, associated with the use of these surgical devices.*' Recommendations highlighted the importance of surgical training relevant to specific devices, the need for clinician awareness of complications and appropriate patient information / pre-operative counselling.
http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php

11. New Zealand Parliamentary Inquiry

On 1 June 2016, the Health Committee of the New Zealand House of Representatives released a report in response to a petition by two patients that have experienced complications from surgical mesh. As part of addressing this petition, the Health Committee sought opinion from experts, medical Colleges (including RANZCOG) and Medsafe, New Zealand's Medicines and Medical Devices Safety Authority. The Health Committee's report included seven recommendations in three areas: the investigation of options for a surgical registry, improvement in medical practice and the role of the regulator in pre-market medical device approval. The Government of New Zealand in its response tabled on 24 August 2016 supported all the Committee's recommendations.
http://www.medsafe.govt.nz/devices/surgical-mesh-recommendations-implementation.asp

Appendix 2 HSE Learning Notice Concerning Mesh Devices 05/18

National Women and Infants Health Programme | Every Birth Matters

National Women & Infants Health Programme

Learning Notice: 05/18

Circulation date: 26th June 2018

Learning Notice Concerning Mesh Devices in Uro-Gynaecological Procedures

Actions required By Whom: Hospital Group CEOs, Hospital CEOs and Managers, Clinical Directors, Gynaecology Clinicians in all Directorates and Hospitals.

By When: For **IMMEDIATE ACTION** in Maternity Hospitals and Acute Hospitals with Gynaecological Units/Services. Please ensure that this is brought to the attention of all relevant staff.

Learning: Controversy about the use of mesh devices is not unique to Ireland and has occurred in many jurisdictions. This notice is been issued subsequent to a meeting held on the 14th June between the Minister for Health and patients who have suffered from complications of mesh implantation to correct Stress Urinary Incontinence (SUI). The Chief Medical Officer is currently preparing advice for the Minister on this issue. Bearing this mind, and not wishing to anticipate any conclusions, the following should be noted:

1. Patient Selection

Mesh procedures for stress incontinence should be reserved for patients who have been assessed in an appropriate uro-gynaecological / urological setting and in whom conservative measures have failed. Surgeons must ensure they have appropriate facilities and training plus the ability to either treat the patients who develop complications themselves or an approved, appropriate pathway to refer on to another.

2. Consent and Information

Adequate information must be available to patients pre-operatively. The current NHS information leaflet extends to 16 pages. A national consent form is being prepared, however, prior to its introduction patients should be made aware of the following:

- The mesh is a non-absorbable material. Post-operative complications may necessitate full/partial mesh removal which can be extremely difficult.
- In obtaining consent both the common complications (mesh erosion, procedure failure, temporary bladder emptying difficultly, etc) and the uncommon complications (erosion into bladder, long term pain, etc) should be stated and explained.

3. Complications

All Surgeons inserting mesh for Urodynamic Stress Incontinence (USI) are capable of treating the minor complications. A significant cause of patient dissatisfaction is the difficultly in accessing services should serious complications develop. Such patients have a firmly held conviction, that their needs are not being addressed to their satisfaction in Ireland. A Response Group has convened to address and propose remedies to these issues. Further information will be circulated in due course.

To facilitate information gathering, complications should be noted to the HPRA.

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https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/