National
Women & Infants
Health Programme

National Clinical Practice Guideline

Diagnosis and Management of Mesh Complications

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

Guideline Development Group

Ms Orfhlaith O'Sullivan (Consultant Obstetrician and Gynaecologist)

Professor Barry O'Reilly (Consultant Obstetrician and Gynaecologist)

Dr Michael Carey (Urogynaecology Clinical Fellow)

Guideline Programme Team

Professor Keelin O'Donoghue (Clinical Lead)

Ms Nicolai Murphy (Programme Manager)

Approved by

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Algorithm

Diagnostic and referral pathway for transvaginal mesh complications

History

Mesh not inserted recently, or a history of mesh is not documented

Recent mesh insertion e.g., <6 weeks since transvaginal mesh procedure performed

Woman experiencing significant pain in the pelvis / vagina / lower back / thigh, bleeding from the vagina / bladder / bowel, infection, extrusion through the vagina, urinary tract symptoms such as retention, urinary infection and incontinence

Does the woman report any of the following since their operation?

- Pain in the pelvis / lower back / thigh
- Awareness of the mesh during intercourse or pain during intercourse for the patient or their partner
- A prickling or pain in the vagina
- Vaginal bleeding
- Mesh palpable in the vagina
- Recurrent urinary or vaginal infection
- Other urinary tract symptoms such as incontinence, voiding difficulties, retention

If no symptoms to date:

- Reassurance only required

If YES:

- Describe and document all symptoms reported by the woman
- Record impact of symptoms on quality of life, relationships, social and occupational function
- Take a comprehensive gynaecological and obstetric history and consider all potential causes of the woman's symptoms (continence, prolapse, sexual function, abnormal cervical cytology)
- Take a comprehensive mesh operative history:
  - Initial procedure, any subsequent procedures, when and where procedures were performed
  - Treatments received for mesh complications (medications, physical therapies, any other treatments)
- Mental health history
- Where possible, obtain a copy of the woman's operation records to confirm what transvaginal mesh procedures were performed

Continued overleaf

Clinical Assessment

- Clinical health assessment
- Abdominal, pelvic and vaginal examination
  - Signs of mesh complications on examination may include tenderness on palpation, visible mesh in the vagina, vaginal adhesions and/or scarring
  - Comprehensive investigation for causes of the woman's symptoms as indicated clinically

Management

If mesh complications are suspected, offer the woman referral to a relevant specialist or to a multidisciplinary clinical service that specialises in the treatment of women with transvaginal mesh complications. Women with uncomplicated mesh erosion or exposure may opt for treatment by a gynaecology, urology or urogynaecology service.

Key Recommendations

1. We recommend standardised terminology be used at all times. *Best Practice*
2. We recommend that all symptoms reported by each woman, including immediate and delayed post-operative symptoms be described and documented. *Best Practice*
3. We recommend the impact of symptoms on quality of life, relationships, social and occupational function be recorded. *Best Practice*
4. We recommend a comprehensive gynaecological and obstetric history be taken and all potential causes of the woman's symptoms are considered. *Best Practice*
5. We recommend a comprehensive mesh operative history is taken. *Best Practice*
6. We recommend where possible a copy of the woman's clinical and operative records be obtained. *Best Practice*
7. We recommend a physical examination be performed and should include an abdominal, pelvic and vaginal examination. *Best Practice*
8. We recommend that comprehensive investigation for causes of the woman's symptoms should be performed as indicated clinically. *Best Practice*
9. We recommend that it is incumbent on the clinical team to develop as complete a diagnostic understanding as possible before embarking on surgical treatment. *Best Practice*
10. We recommend that the treatment options for mesh complications depend on the woman's individual circumstances, the findings of the comprehensive assessment and the woman's personal preferences. *Best Practice*
11. We suggest that physiotherapy is provided pre and post operatively as it has been shown to be effective in women with myofascial pain and pelvic floor dysfunction. *Grade 2B*
12. We recommend that women presenting with chronic pain should receive multidisciplinary biopsychosocial care including care from a pain management specialist. *Best Practice*
13. We recommend that prior to considering surgery the woman's case should be discussed as part of a multidisciplinary team meeting. *Best Practice*
14. We recommend that surgery to remove the vaginal mesh should be avoided if the position of the mesh or the scar tissue around the mesh, makes it unsafe to remove. *Best Practice*
15. We suggest that mesh exposure without pain can be treated in a less invasive way. *Grade 2B*
16. We suggest that an isolated vaginal exposure can be treated with localised excision or depending on size localised oestrogen therapy. *Grade 2B*
17. We recommend that surgical management of mesh complications should be carried out in a mesh centre by an appropriately credentialed medical practitioner as part of a multidisciplinary team with access to specialists in Urogynaecology, Urology and Colorectal Surgery and Physiotherapists. *Best Practice*

18. We recommend that staff within the service where the surgical management is planned should have experience in mesh removal. *Best Practice*
19. We recommend that the woman should be counselled that mesh removal surgery may exacerbate pain and may result in worsening incontinence or prolapse. This should be clearly documented. *Best Practice*

Chapter 1: **Initiation**

The National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) define clinical guidelines as systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.[1]

1.1 Purpose

The purpose of this Guideline was to develop and provide a comprehensive evidence-based guide for all healthcare professionals in the management of vaginal mesh complications. The Guideline provides guidance for the diagnosis and management of mesh complications which occur following the insertion of mesh for the management of incontinence and prolapse in women.

It is intended to provide guidance relating to identification of potential complications and to provide a platform for shared decision making with the woman. Voiding dysfunction after mid urethral slings (MUS) and recurrence of stress urinary incontinence and prolapse following mesh procedures are not considered true mesh complications as they reflect functional outcomes and will not be addressed in this Guideline.

1.2 Scope

Target Users

The Guideline is a resource for all healthcare professionals working in Gynaecology and Urology services nationally including all allied healthcare professionals who may be involved in providing care to women who experience complications following treatment with transvaginal mesh. These include Continence Nurses, Dietitians, General Practitioners (GP), Occupational Therapists, Pain Specialists, Physiotherapists, Psychiatrists, Psychologists, Social Workers, Surgeons (including Urogynecologists, Urologists, Gynaecologists, Plastic and Reconstructive Surgeons, Orthopaedic Surgeons and Colorectal Surgeons).

Target Population

This Guideline is a resource for women with pelvic floor disorders.

1.3 Objective

To provide evidence-based recommendations for the care of women with mesh complications as well as promoting a standardised approach nationally across all Gynaecology Departments in the diagnosis and management of such complications.

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1 National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) (2015) National quality assurance criteria for clinical guidelines. Version 2. Dublin: NCEC and HIQA. https://www.hiqa.ie/sites/default/files/2017-01/National-Quality-Assurance-Criteria.pdf

1.4 Guideline development process

The Guideline Developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. Their role was to critically review the Guideline prior to submission to the National Women and Infants Health Programme (NWIHP) for final approval.

See appendix 1 for EAG group membership and appendix 2 for Guideline Programme Process.

This Guideline was developed by:

Dr Michael Carey, Urogynaecology Clinical Fellow, Cork University Maternity Hospital, Wilton, Cork

Ms Orfhlaith O'Sullivan, Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital, Wilton, Cork

Professor Barry O'Reilly, Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital, Wilton, Cork

1.5 Stakeholder involvement

Stakeholders are people who have a common interest in improving health services. This includes persons that are responsible for delivering and those who receive services related to the clinical Guideline.

The following additional stakeholders were consulted in regard to this Guideline.

Physiotherapy:

Physiotherapists working with both mesh centres and independent practitioners with expertise in pelvic floor disorders were consulted.

Urology:

Members of the Irish Society of Urology, including the chair of the female urology group.

- Ms Helen Hegarty, Consultant Urologist, Chair of the female urology group (RCSI)
- Mr James Forde, Consultant Urologist, Beaumont Hospital.
- Mr Ciaran Brady, Consultant Urologist, Mercy University Hospital.

Urogynaecology:

Members of the continence foundation of Ireland including:

- Prof Barry O'Reilly, Consultant Obstetrician & Gynaecologist, Cork University Maternity Hospital
- Prof Declan Keane, Consultant Obstetrician & Gynaecologist, National Maternity Hospital
- Prof Chris Fitzpatrick, Consultant Obstetrician & Gynaecologist, Coombe Womens and Infants University Hospital, Dublin (retired 2021)
- Dr Susmita Sarma, Consultant Obstetrician & Gynaecologist, University Hospital Galway
- Dr Gerry Agnew, Consultant Obstetrician & Gynaecologist, National Maternity Hospital
- Dr Suzanne O'Sullivan, Consultant Obstetrician & Gynaecologist, Cork University Maternity Hospital
- Dr Paul Hughes, Consultant Obstetrician & Gynaecologist, University Hospital Kerry
- Dr Breffni Anglim O'Regan, Consultant Obstetrician & Gynaecology, Coombe Womens and Infants University hospital, Dublin
- Dr Aoife O'Neill, Consultant Obstetrician & Gynaecologist, Coombe Women and Infants University hospital, Dublin
- Dr Fadi Salameh, Consultant Obstetrician & Gynaecologist, Rotunda Hospital, Dublin

Psychiatry:

Dr James Kinahan, Consultant Liaison Psychiatrist, Cork University Hospital, Cork

Pain management specialist:

Dr Kirk Levins, Consultant Anaesthetist, Pain Specialist, St. Vincent's University Hospital and National Maternity Hospital, Dublin.

Urogynaecology Nurses:

Ms Ann Humphreys, Advanced Midwifery Practitioner in Urogynaecology, Cork University Maternity Hospital.

In addition, nurses and midwives working within the urogynaecology services nationally were consulted.

1.6 Disclosure of interests

Guideline developers and reviewers bring a range of experiences and perspectives to the work of the national Guideline Programme. It is likely that both Guideline developers and stakeholders/reviewers will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. These can include employment and other sources of income, speaking engagements, publications and research, and membership of professional or voluntary organisations. The involvement of individuals with relevant content expertise is essential for enhancing the value of Guideline recommendations, but these individuals may also have interests that can lead to conflicts of interest, as may peer reviewers, patient representatives and researchers.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the Clinical Practice Guideline in question[2]. Declaring an interest does not mean there is a conflict of interest.

It is important that interests are openly declared so they can be appropriately managed. Conflicts of interest can bias recommendations and ultimately be harmful to patients and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines.[3]

The Guidelines International Network (GIN), a global network of Guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles.[4]

For this national clinical practice guidelines, all Guideline developers are asked to complete a conflict of interest declaration form. The response to declared interests will be managed by the Guideline programme team, in accordance with GIN principles. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

2 NICE (2019) Policy on declaring and managing interests for NICE advisory committees. https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

3 Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. CMAJ. 2021, 193(2):E49-E54. DOI: 10.1503/cmaj.200651 https://www.cmaj.ca/content/193/2/E49

4 Holger J. Schünemann, Lubna A. Al-Ansary, Frode Forland, *et al.*; for the Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163:548-553. doi:10.7326/M14-1885 https://www.acpjournals.org/doi/10.7326/m14-1885

1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice, using a multidisciplinary approach. Information in this Guideline is current at the time of publication.

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the patient and the diagnostic and treatment options available.

Clinical material offered in this Guideline does not replace or remove clinical judgment or the professional care and duty necessary for each woman.

Clinical care carried out in accordance with this Guideline should be provided within the context of locally available resources and expertise.

This Guideline is only applicable to tertiary mesh centres as MESH centres were set up to specifically deal with MESH complications. Guidance should be sought from NWHIP regarding non mesh centres managing MESH complications. The referral pathway to the tertiary level care is detailed in the algorithm.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate, and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advising women of their choices and ensure informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements

1.8 Use of language

Within this guidance we use the terms ‘woman’ and ‘women’s health’. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[5]. We also appreciate that there are risks to desexing language when describing female reproduction[6][7]. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services.

5 Moseson H, Zazanis N, Goldberg E, *et al*. The Imperative for Transgender and Gender Nonbinary Inclusion. Obstet Gynecol. 2020;135(5):1059-1068. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/

6 Brotto LA, Galea LAM. Gender inclusivity in women’s health research. BJOG: An International Journal of Obstetrics & Gynaecology. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231

7 Gribble KD, Bewley S, Bartick MC, *et al*. Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. *Frontiers in Global Women’s Health*. 2022;3. Accessed June 9, 2022. https://www.frontiersin.org/article/10.3389/fgwh.2022.818856

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision [8]. With this in mind, the use of birth is preferable to the term delivery in all circumstances and is used consistently where possible throughout the guidelines. It is acknowledged that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) and in some contexts, substituting with the term delivery is considered appropriate and this term may be used instead.

8 https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/

Chapter 2:
Clinical Practice Guideline

In urogynaecology, urology and gynaecology mesh has been used as a surgical management option for Stress Urinary Incontinence (SUI) and pelvic organ prolapse (POP) including both vaginal and abdominal surgeries.

Recommendations relevant to this Guideline can also be found in the:

- National Clinical Practice Guideline: Assessment and Management of Stress Urinary Incontinence in women (2022)[9]
- National Clinical Practice Guideline: Diagnosis and Management of Pelvic Organ Prolapse (2022)[10]

Background

The use of native tissue has historically provided a method of treating SUI and POP. Studies have highlighted that there is an increased failure rate with the use of native tissue, especially when operating on women with severe SUI or POP or women who have had a previous failed native tissue repairs[1]. In recent decades, this frustration with surgical failures has prompted the development of materials and techniques using synthetic mesh[2].

The use of mesh to treat women with SUI and recurrent POP has been invaluable since its development, in particular cases of SUI and POP repair where there is simply no native tissue left to approximate without compromising future vaginal function [1, 3]. As with all operations and surgical interventions, complications do occur. The 2011 Update to the Food and Drug Administration's Public Health Notification 2011 regarding use of transvaginal mesh stated that these complications are not rare and can be difficult to treat.

https://www.fda.gov/files/medical devices/published/Urogynecologic-Surgical-Mesh--Update-on-the-Safety-and-Effectiveness-of-Transvaginal-Placement-for-Pelvic-Organ-Prolapse-(July-2011).pdf

Evolution of Mesh

Surgical mesh material was initially designed and used for hernia repair [4]. The clinical need for prosthetic materials to replace the defective abdominal wall fascia was recognised in the seventeenth century [5]. The first prosthetic material used in hernia repair in 1902 was made of silver [6], followed by tantalum in 1940 [7]. Tantalum wire mesh became quite popular at that time owing to its inertness and antimicrobial properties [8]. However, metals are inherently unsuitable for soft-tissue repairs such as hernia repairs, as they are stiff and can fragment [9]. After the plastics revolution in the early twentieth century, materials made of nylon (polyamide) and Dacron (polyester, also known as polyethylene terephthalate) started to be used [10].

9 Craven, S., Salameh, F., O' Sullivan, S. National Clinical Practice Guideline: Assessment and Management of Stress Urinary Incontinence in women. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022

10 O'Leary B, Agnew G, Keane D. National Clinical Practice Guideline: Diagnosis and Management of Pelvic Organ Prolapse. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022

It was, however, only after Usher, a hernia surgeon, optimised both the material and textile properties of plastic mesh (Marlex) that acceptance became widespread [4]. He used a high-density polyethylene and a new manufacturing method to extrude it as a monofilament [4]. In 1962, an improved version of Marlex mesh made of polypropylene (PPL) was introduced. PPL had improved material and textile properties and increased heat resistance compared with polyethylene, enabling effective sterilisation without compromising the material properties.

The initial PPL design remained largely unchanged over the following 50 years, but modifications to the textile properties of the mesh were continuously made to improve clinical outcomes. A relationship between the physical properties of the material (such as pore size and fibre diameter) and material-related complications was a well-defined phenomenon by 1997 and was formalised in the Amid classification of surgical meshes [11]. This classification grouped the most frequently used materials in hernia surgery into 4 types.

- **Type 1:** Knitted monofilament type with large pores and good elasticity – hence they are easier to work with. They allow macrophages, fibroblasts (which are >75 µm) and bacteria (1–2 µm) to enter. Thus, infection and adhesions are a problem, but infections can be treated without removal of mesh.
- **Type 2:** Knitted multifilament mesh with small interstices (>75 µm) and reduced elasticity. They prevent adhesions but infections are difficult to treat as antibiotics and white blood cells cannot penetrate, thus necessitating removal of the mesh.
- **Type 3:** Nonknitted, nonwoven multifilament type with large pores, small interstices and restricted elasticity. They allow bacteria to infiltrate but not macrophages; infection can be a problem. Type II and III meshes result in a greater foreign body reaction than Type I.
- **Type 4:** Coated biomaterial that contains pores of <1 µm. Often used for adhesion prevention in abdominal surgery; not used in gynaecological surgery.

Lightweight meshes reduced inflammation, foreign body reaction, fibrosis [12,13] chronic pain and abdominal stiffness in clinical studies [14]. Also, lightweight meshes with large pores had increased flexibility compared with heavyweight meshes and were similarly elastic to the abdominal wall [15]. As a result, the initial heavy weight meshes with small pores (<10µm, such as Marlex) were replaced with lightweight meshes with large pores[16].

Widespread use of the surgical mesh in the pelvic floor started after 1995 when Ulmsten and Petros first described intravaginal slingoplasty [17]. In these operations, a mesh sling made of PPL was applied with its own introducer as a day-case procedure, forming the basis for the modern mid-urethral tape procedure. The first intravaginal synthetic sling material to receive clearance from the FDA in 1996 was ProteGen, which is a polyester mesh coated in bovine collagen [18]. This product was recalled three years after FDA clearance owing to severe complications such as extrusion, infection and pain [19]. Despite this experience, ProteGen was used as a predicate device and the tension-free vaginal tape (TVT) from Ethicon made of PPL was approved by the FDA in 1999 [20], which then opened the way forward for other vaginal mesh products [18].

The first prosthetic materials used in pelvic floor reconstruction were reproductions of hernia mesh, such as Gynae care. Initially, only anterior and posterior compartment repairs were augmented with mesh. Mesh was placed between the vaginal epithelium and underlying endopelvic connective tissue. Mesh was then developed to augment apical suspensions with attachment to pelvic supportive connective tissue structures, including the sacrospinous-coccygeus ligament complex, arcus tendineus fascia pelvis (ATFP), iliococcygeus fascia, and obturator membrane [21].

Early transvaginal mesh kits used metal trocars to guide placement of mesh. These mesh kits were fixated and used a transcutaneous insertion technique either para-rectally or trans-obturator or both with the inherent complication of infection, sinus formation and tethering. These kits used a standardised piece of mesh and a consistent approach reducing the likelihood of excessive tension on the mesh arms. The first kits that targeted apical vaginal compartment repair included the Gynecare Prolift (Ethicon, Inc, Somerville, NJ), the Perigee (American Medical Systems, Minnetonka, MN) and the Apogee (American Medical Systems, Minnetonka, MN), and the Avaulta (BARD, Covington, GA).

- **The Prolift system** was available as a four-armed anterior implant, a two-armed posterior implant, or a six-armed combined implant. This system used a metal trocar with a flexible mesh retrieval device that was passed through the obturator foramen and through the sacrospinous ligament bilaterally to correct apical vaginal wall defects.
- **The Perigee system** was designed to treat anterior and apical vaginal compartment defects. This system used four trans obturator side-specific trocars that were passed through the ATFP just proximal to the level of the ischial spine and to the level of the bladder neck.
- **The Apogee system** was designed to treat posterior and apical vaginal compartment defects. This system used two side-specific trocars that passed through the ATFP to the level of the ischial spines via the ischiorectal fossa.
- **The Avaulta anterior system** was designed to treat anterior and apical vaginal compartment defects. This system had compartment specific trocars with a flexible InSnare retrieval device that was passed anteriorly through the obturator foramen to place the proximal mesh arms near the ischial spine and the distal arms at the level of the bladder neck. There were two additional distal posterior arms that attached bilaterally to the junction of the bulbocavernosus and transverse perineal muscles. The mesh was available with or without an acellular collagen barrier.

The subsequent second-generation mesh kits use either a pulley stitch or self-fixating tips to attach mesh to the sacrospinous ligament and ATFP. These newer kits include the Pinnacle (Boston Scientific, Marlborough, MA), the Elevate (American Medical Systems, Minnetonka, MN), the Uphold system (Boston Scientific, Marlborough, MA) and Coloplast Restorelle Direct Fix (Coloplast, Minneapolis, MN). The Prosima (Ethicon, Inc, Somerville, NJ) system was a single-incision, fixation-less system that was held into place by a pessary-like vaginal support device for three weeks postoperatively.

- **The Pinnacle system** was designed to treat anterior and apical prolapse. The Capio needle driver device secured four mesh arms through the sacrospinous ligament and the ATFP bilaterally.
- **The Elevate system** was designed to treat apical and either anterior or posterior prolapse. The mesh was placed with self-fixating tips through the sacrospinous ligaments (and the obturator foramen for the anterior system) bilaterally.
- **The anterior Prosima** was the first fixation-less vaginal mesh system. The mesh was laid in place with an inserter such that the arms extended just anterior and superior to the ischial spines and lay across the ATFP. A pessary-like vaginal support device was sewn into place at the time of surgery and stayed in place for 3 to 4 weeks to allow tissue ingrowth into the graft.
- **The Uphold system** was designed to treat apical prolapse with or without the uterus in situ. The Capio needle driver secured two mesh arms through the sacrospinous ligament and the mesh was secured to the vaginal vault or cervix and under the bladder.
- **The Coloplast Restorelle Direct Fix** was designed to treat apical and either anterior or posterior compartment prolapse. This ultralightweight mesh was secured by two mesh arms to the sacrospinous ligament with the Digitex suture delivery device. Additional mesh arms were secured to the obturator internus fixation point for distal anterior fixation or to the ATFP for distal posterior fixation.

3rd generation mesh has been used more recently and are simply a mesh overlay as part of a standard vaginal repair. Unlike the previous mesh kits there are no associated anchor or fixing tips.

Section 1: Mesh complications – how they present

Introduction

Surgical complications associated with mesh insertion/implantation for SUI and POP include erosion of the mesh into the vagina, perforation of urinary tract or rectum/bowel either at the time of surgery or later, infection or abscess formation directly related to the mesh insertion and haematoma formation [23-28]. Voiding dysfunction and recurrence of SUI or prolapse are functional outcomes of the surgery and there not considered as mesh complications [22]. Other recognised complications of mesh surgery include pain and sexual dysfunction [29,30].

Women experiencing mesh complications should be given the opportunity to voice their concerns and engage in shared discussion. They should be reviewed by a multi-disciplinary team with expertise in mesh complications. Depending on the presenting symptoms and the physical examination findings, women may require additional investigations. Women may require multiple investigations and procedures to address their symptoms and for some of these women, relief may be incomplete. We should ensure that clinically appropriate investigations are performed and avoid unnecessary, superfluous or potentially harmful investigations. Women should be involved in clear open discussion regarding potential benefits and risks of these investigations and her consent gained. We should strive to provide optimal investigations and treatment at the initial diagnosis of a mesh-related complication.

With regard to mesh insertion/implantation and subsequent complications the use of universally recognised and accepted terminology and classification systems is vital to ensure standardisation of management and treatment options (appendix 3). It is recommended that the terminology laid out by IUGA-ICS committee for use in diagnosis, management and outcomes assessment of mesh related complications be adopted by healthcare professionals managing mesh complications [31].

It is also beneficial to adopt a categorisation system for surgical procedures for the treatment of mesh complications, the AUGS-IUGA classification is widely accepted and used by specialists worldwide (appendix 3). Having a clear categorisation and classification system will allow for improved communication amongst healthcare professionals, both national and internationally in relation to management and treatment plans for these women [22].

Clinical Question 2.1: **What are the essential steps when first reviewing a woman who presents with mesh complications?**

Evidence Statement

The evidence to support this recommendation is largely derived from statements by professional bodies, journal publications as well as from research exploring clinicians' knowledge and decision-making in the area of diagnosis and management of mesh complications. To inform the development of this Guideline, existing policies and recently published international documents on the management of mesh complications were also reviewed.

The AUGS-IUGA joint position statement on the management of mesh related complications clearly outlines the expected approach to management of mesh complications be taken by specialists in female pelvic medicine and reconstructive surgery Within the Irish healthcare setting these specialists are called urogynaecologists or urologists (specialising in female urology) and will have undergone specific training in these fields [22].

Identifying and gaining all pertinent information relating to the index surgery, [32, 33] is imperative irrespective of whether the procedure is still carried out and whether the specialist has experience with the specific procedure [22]. Physical examination is vital to help identify the location of the pain and its relationship to the implanted mesh.

Furthermore, if the pain is not reproducible on examination or unrelated to the mesh caution is recommended regarding attributing the pain to the mesh implant and another explanation for the pain should be sought [18]. Where available validated quality of life questionnaires and pain scores should be used to appraise the impact of the symptoms on the woman's life and also as a tool to objectively assess the impact of treatments and therapies on the pain symptoms.

Clinical Practice

When seeing women with a known or suspected mesh complication, ensure that the setting is appropriate, and all medical notes are available including all operation notes and previous consultations with healthcare professionals relating to the mesh implantation and suspected complication (refer to algorithm1). Where previous investigations have been conducted the results should be available. Adequate time should be set aside to conduct the consultation.

Out-patient care

During the initial consultation a detailed history must be taken [34, 35]. It should include information pertaining to the original mesh surgery, current symptoms, investigations undergone for these symptoms and any subsequent surgeries.

Symptoms assessment

Describe and document all symptoms reported by the woman. Time of the onset of symptoms should be documented clearly. Symptoms experienced by the woman can vary in their intensity from mild to severely debilitating. Women with a vaginal exposure may be asymptomatic and exposure can be identified at examination for non-mesh related symptoms [36].

These symptoms include:

- Pain: in the pelvis/vagina/lower back/thigh
- Bleeding from the vagina/bladder/bowel
- Infection
- Extrusion or exposure of the mesh through the vagina
- Urinary tract symptoms such as retention, urinary tract infection and incontinence
- Awareness of the mesh during intercourse or pain during intercourse for the woman (dyspareunia) or their partner (hyspareunia)
- A 'prickling' feeling or pain in the vagina
- Mesh palpable in the vagina
- Vaginal infection/discharge

A detailed record of the reported impact of symptoms on the woman's mental health, quality of life, relationships, social and occupational function should be documented.

Detailed History Taking

Take a comprehensive gynaecological and obstetric history and consider all potential causes for the woman's symptoms (continence, prolapse, sexual function, abnormal cervical cytology).

Take a comprehensive mesh operative history including the following questions:

- What was the index procedure?
- What was the indication for the index procedure?
- Were there any intraoperative and post-operative complications of mesh insertion?
- What type of mesh was used?
- Were there any subsequent procedures performed?
- When, where and by whom were the procedures performed?
- What was the timing of onset of symptoms relative to index procedure?

Details regarding previous treatments or management for mesh complications (analgesics, local oestrogen therapy, physical therapies, steroid injections, previous mesh excision and any other treatments) should be sought and documented.

Where possible, obtain a copy of the woman's operation records to confirm what transvaginal mesh procedures were performed and the type of mesh inserted.

It should be noted that physiological changes of aging i.e., vaginal atrophy, can influence lower urinary tract symptoms including urinary tract infection, vaginal dysfunction and pain in the absence of a mesh exposure In these circumstances, women may be best managed with local oestrogen therapy without the need for mesh excision [37,38,39].

A detailed background medical and mental health history should be taken and documented including treatments used. Make a note of comorbidities i.e., diabetes mellitus, smoker, raised body mass index, immunosuppression, steroid use, prior pelvic radiation and previous vaginal surgery.

Validated quality of life questionnaires and pain scores should be completed by women to assess the impact of the presenting symptoms and assess the impact of therapeutic treatments [40].

Recommendations

1. **We recommend standardised terminology be used at all times.**
2. **We recommend that all symptoms reported by each woman, including immediate and delayed post-operative symptoms be described and documented.**
3. **We recommend the impact of symptoms on quality of life, relationships, social and occupational function be recorded.**
4. **We recommend a comprehensive gynaecological and obstetric history be taken and all potential causes of the woman's symptoms are considered.**
5. **We recommend a comprehensive mesh operative history is taken.**
6. **We recommend where possible a copy of the woman's clinical and operative records be obtained.**

Clinical Question 2.2: **What are the recommended clinical assessments in a woman that presents with mesh complications?**

Evidence Statement

The evidence to support this recommendation is largely derived from journals as well as from research exploring clinicians' knowledge and decision-making in the area of diagnosis and management of mesh complications.

To inform the development of this Guideline, existing policies and recently published international documents on the management of mesh complications were also reviewed.

Clinical assessment of the mesh complication allows for a better understanding of the issues and also devising an appropriate management plan.

The AUGS-IUGA recommend a pelvic examination for all women. For those unable to tolerate the examination awake consideration should be given to performing an examination under anaesthetic [22]. A neurological examination of the pelvis can help to differentiate between local effects and those resulting from nerve entrapment.

Furthermore, cystoscopy, vaginoscopy and digital rectal examination should also be considered depending on the clinical findings. Imaging such as endoluminal or transperineal ultrasound or magnetic resonance imaging are beneficial in diagnostics and planning surgical management [22]. The NICE guidance on mesh complications highlights the benefits of neurophysiology when nerve damage is suspected. Unfortunately, it can exacerbate pain symptoms and can be difficult to perform [32]. This guidance document also suggests that laparoscopy may be beneficial but cautioned regarding the risks of such a procedure.

Clinical Practice

All women who have had a mesh procedure, whether they have symptoms or not require a clinical assessment. This is irrespective of when the mesh has been inserted. If a woman believes they have had mesh inserted despite a lack of supporting evidence a physical assessment is also required. In this cohort of women, it is important to obtain all medical and operative notes.

A physical examination should include abdominal, pelvic and vaginal examinations. Signs of mesh complications on examination may include tenderness on palpation, visible mesh in the vagina, vaginal adhesions and/or scarring [33]. If there is a vaginal mesh exposure (from a MUS, transvaginal mesh (TVM) or sacrocolpopexy (SCP) mesh) the size and location of mesh exposure should be documented.

A thorough pelvic examination should be performed to determine the source of pain, if this is the presenting complaint. Examination of the pelvic floor should be carried out to assess for myofascial pain [30].

Examination depending on mesh type:

- **Retropubic or transobturator MUS**

  In women with a retropubic or transobturator MUS, examination should include vaginal, retropubic and groin palpation (depending on the type of MUS) to elicit if there is pain associated with a certain portion of the MUS.

- **Sacrocolpopexy mesh**

  In women with pain associated with SCP mesh, the vaginal portion of the mesh should be palpated to elicit if there is localised pain.

- **Transvaginal mesh**

  In women with TVM mesh pain, the pain is more likely to be elicited at the attaching arms rather than in the central vagina. Both vaginal and pelvic floor examination at the level of attachment points (sacrospinous ligament, obturator foramen, arcus tendineus fascia pelvis, iliococcygeus fascia, bladder neck and ischiorectal fossa) should be carried out [30].

Comprehensive investigation for causes of the woman's symptoms should be performed as indicated clinically. This may involve questionnaires to carefully assess pelvic function and continence, pain, occupational and sexual function, quality of life and mental health.

Biopsychosocial assessment will be required for women's symptoms which are new, disabling, persistent and are not adequately explained by the mesh procedure. The biopsychosocial assessment should be conducted by mental health professionals, psychiatry and psychology, working as part of the specialist multidisciplinary team

Additional tests may be performed such as:

- Urodynamics
- Examination under general anaesthetic
- Cystoscopy
- Specialised Imaging including ultrasound and/or magnetic resonance imaging

It is incumbent on the clinical team to develop as complete a diagnostic understanding before embarking on surgical treatment. The provider should have an appropriate index of suspicion to engage the relevant consultative assistance (e.g., colorectal, urology or neurosurgery) ahead of time. It is worth considering that, during surgical treatment of vaginal mesh exposures, unexpected mesh exposures in the bladder or bowel are encountered in 3% of cases [41]. The decision about which additional diagnostic tests to perform will be made by the clinical team in discussion with the woman and will directed by the individual clinical circumstances.

All clinicians should adhere to the IUGA-ICS classification of complications Guideline in appendix 3 [31,42].

Recommendations

7. We recommend a physical examination be performed and should include an abdominal, pelvic and vaginal examination.
8. We recommend that comprehensive investigation for causes of the woman's symptoms should be performed as indicated clinically.
9. We recommend that it is incumbent on the clinical team to develop as complete a diagnostic understanding as possible before embarking on surgical treatment.

Section 2: Treatment of mesh complications

Introduction

The treatment options for mesh complications depend on the woman's individual circumstances, the findings of the comprehensive assessment and the woman's personal preferences. If the woman does not report symptoms of mesh complications reassurance alone is appropriate. The different treatment options for mesh complications include physiotherapy and other physical therapies, pain management, medications, surgery and/or a combination of these.

If the mesh insertion is recent, e.g. ≤ 6 weeks since mesh surgery performed, urgent referral to the treating specialist for management +/- referral to mesh centre is required. If the mesh insertion is not recent, or a history of mesh is not documented and if mesh complications are suspected, the woman should be referred to a specialised mesh centre.

These centres have relevant specialists and a multidisciplinary clinical service that have been developed to treat women with mesh complications. Prior to undertaking surgery to manage mesh complications the woman's case should be discussed at a multidisciplinary team meeting. The risks of the planned procedure should be clearly documented and explained to the woman. These include worsening of her symptoms, new onset pain, injury to surrounding organs, urinary, bowel or sexual dysfunction [13]. Where it is not feasible to remove the mesh completely, partial removal should be considered and may be as effective and associated with reduced incidence of complications [32].

Clinical Question 2.3: **What are the recommended treatment options for mesh complications?**

Evidence Statement

The evidence to support this recommendation is largely derived from journals as well as from research exploring clinicians' knowledge and decision-making in the area of diagnosis and management of mesh complications. To inform the development of this Guideline, existing policies and recently published international documents on the management of mesh complications were also reviewed [22,31,34-36,40,43,44].

The AUGS-IUGA joint position statement on the management of mesh complications outlines the management options available for differing types of complications [18]. With regard to mesh exposure important factors that influence decision making include the site, size and symptoms associated with the exposure. Treatment options vary from observation to complete excision. With specific regard to pain, where a myofascial or fibromuscular component is identified on examination physiotherapy is recommended. A prolonged course of physical therapy is not advised if there is little response and other treatments should be considered [45]. The use of analgesic and steroid injections can offer both diagnostic and therapeutic benefits [46]. The role of mesh excision for pain is dependent on the index surgery, the site of pain and response to local management options.

Studies have shown surgical excision of mesh from the groin/thigh post transobturator MUS insertion can be associated with increased pain and incapacitation [47]. Where mesh exposure and the symptom of pain coexist, pain should be the driving consideration when making a decision on mesh removal. Mesh exposure associated with vaginal mesh for prolapse (TVM) or SCP mesh is unlikely to resolve spontaneously. While trimming can be beneficial, repeated trimmings is not recommended. Where infection is a contributing factor mesh removal is recommended.

Clinical Practice

When dealing with mesh complications, several different management strategies may be required as individual therapies or in combination.

Physiotherapy and other physical therapies

Physiotherapy has been shown to be effective in women with myofascial pain and pelvic floor dysfunction[48]. This may involve several treatments by health professionals with expertise in the anatomy of the female pelvis. These include massage techniques, bladder retraining, movement therapies, electrical stimulation, dry needling and exercise to relieve chronic pain. Occupational therapies such as aids and equipment to help with activities of daily living may also be offered.

Pain management

Women presenting with chronic pain should receive multidisciplinary biopsychosocial care. The biological aspect of care should include a referral to a pelvic pain specialist.

Initial assessment by a pelvic pain specialist should involve examination of both the pelvis and spine. The aetiology of chronic pain after mesh surgery is varied and can be categorised as musculoskeletal, visceral or neurological.

Trauma to the muscular tissue can occur with traction, local hematoma, and secondary fibrosis causing restriction and pain in movement. Clinical presentation of mesh related pain of muscular origin includes isolated spasm, pain with position change, or activity-related fatigue relieved by rest. Pain is typically intermittent and activity related. Pelvic organ muscle involvement may present as dyspareunia or dysfunction of urination or defecation. Pain of muscular origin may be amenable to targeted treatment with botulinum toxin.

Visceral pain may be caused by trocar placement or mesh penetration and typically presents as a dull and constant pain that may be exacerbated by usage of the related organ (vagina, bladder and bowel). Pelvic organ prolapse (recurrent or new) may also cause pain or obstruction after mesh placement.

Neuropathic pain may present as a result of nerve injury at the time of surgery or as a result of nerve entrapment. Typically, this presents with pain that is often described as burning, shooting or stabbing and is usually constant. Treatment may involve the use of medication, pulsed radiofrequency lesioning or spinal cord/sacral nerve root stimulation.

Spinal pathology can cause referred pelvic pain. A common pathology that can present with pelvic pain is sacroiliac joint dysfunction, which should be ruled out during the initial consultation.

Medications

Medication can be used to treat pain, incontinence and mood and sleep disorders. Medication used for pain management should be prescribed in accordance with the WHO analgesic ladder. Medications for pain include common analgesics (such as paracetamol and NSAIDs), antidepressants, anticonvulsants, NMDA receptor antagonists and muscle relaxants. Opioids (for example, codeine, oxycodone and morphine) are not indicated for the treatment of chronic pain. In those women that are opioid dependent, it is the responsibility of the initial prescriber to formulate a plan for weaning.

Medication-based therapies to treat continence and problems with urinating include different types of muscle relaxants. A suitable medication plan can be made with discussion with specialised urologist or urogynaecologist and the woman.

Mental health

Any mental health disorder identified should be addressed in parallel with assessment and treatment of the mesh complication, e.g., adjustment disorder, anxiety disorder, mood disorder. All mental disorder should receive appropriate treatment through existing pathways in the community e.g., primary care mental health services.

Persistent physical symptoms should be managed through biopsychosocial stepped care within the specialist multidisciplinary team.

Surgical Management

Surgical procedures for the treatment of mesh complications may include, mesh revision, partial vaginal mesh excision, complete vaginal mesh excision, extravaginal mesh excision or total mesh excision (appendix 4) [22]. The decision regarding the extent of the surgery is dependent on the woman' symptoms, examination findings, co morbidities and the potential for further complications or exacerbation of symptoms.

Surgical management of mesh complications should be carried out by an appropriately credentialed medical practitioner (urogynaecologist/urologist specialising in female urology) as part of a multidisciplinary team with access to other specialists in urogynaecology, urology and colorectal, plastic and reconstructive surgery and orthopaedic surgery.

Asymptomatic mesh exposure:

In women presenting with asymptomatic MUS mesh exposure that is less than 1cm, observation is advised, in accordance with the National Institute of Health and Care Excellence Document [49]. In women with asymptomatic TVM or SCP vaginal mesh exposure surgical removal is unlikely to be required. Local vaginal oestrogen may reduce the size of the exposed mesh area if the woman is post-menopausal [50, 51].

Symptomatic mesh exposure:

In women with exposed MUS mesh who are symptomatic (bleeding, discharge or dyspareunia), partial vaginal excision can be performed [52 53]. The optimal amount of vaginal mesh to be excised is difficult to determine, and one must weigh up the risk of mesh exposure recurrence versus stress urinary incontinence recurrence [54, 55]. In women with exposed TVM or SCP mesh who are symptomatic (bleeding, discharge or dyspareunia) surgical revision should be considered if there is no response following 3 months of local oestrogen therapy [49].

In women with a retropubic MUS with pain elicited along a portion of the mesh who have not improved with conservative measures, either vaginal or retropubic mesh removal may be beneficial, depending on where the pain is reproduced. Women with a transobturator MUS who are experiencing groin pain will usually improve with removal of the vaginal portion of the mesh through release of tension [56,57]. Groin dissection to remove the mesh should be considered in women not responding to removal of the vaginal portion, or where pain is elicited on palpation of the groin [46]. It must be noted however that there can be significant morbidity associated with removal of the groin portion.

In women with pain associated with SCP mesh that do not respond to conservative measures, total mesh removal should be considered so that the woman is not exposed to repeated procedures. In women with pain associated with TVM, either partial or complete vaginal excision should be performed to release the tension on the attaching arms [58]. Where examination suggests a nerve impingement, both neurological and radiological investigations should be carried out prior to mesh removal [59].

Surgery to remove vaginal mesh may not resolve the womans symptoms. The decision to surgically remove vaginal mesh should not be embarked upon without due diligence. Surgery to remove the vaginal mesh should be avoided if the position of the mesh, or the scar tissue around the mesh makes it unsafe to remove. The woman and their treating doctor should develop a plan for pre- and post-operative care, including long term management of existing and new symptoms. The woman should be counselled that mesh removal surgery may exacerbate pain and may result in worsening incontinence or prolapse.

Prior to surgery, individual cases should be discussed at an MDT meeting. The woman's symptoms, examination and investigation findings and previous treatments should be discussed, and a treatment plan agreed and documented based on the clinical evidence. Following discussion at the MDT meeting the healthcare professional will discuss the proposed plan and if surgery is intended get informed consent. If the woman does not accept the proposed plan a second opinion should be sought within another mesh removal centre.

The service where the surgical management is planned should have experience in mesh removal. Women who have undergone either partial or complete mesh removal should have their initial follow up at the hospital where the mesh was removed. If their symptoms have completely resolved, they may be referred back to their general practitioner. However, where symptoms persist referral to appropriate specialities should be undertaken promptly.

Recommendations

10. We recommend that the treatment options for mesh complications depend on the woman's individual circumstances, the findings of the comprehensive assessment and the woman's personal preferences.
11. We suggest that physiotherapy is provided pre and post operatively as it has been shown to be effective in women with myofascial pain and pelvic floor dysfunction.
12. We recommend that women presenting with chronic pain should receive multidisciplinary biopsychosocial care including care from a pain management specialist.
13. We recommend that prior to considering surgery the woman's case should be discussed as part of a multidisciplinary team meeting.
14. We recommend that surgery to remove the vaginal mesh should be avoided if the position of the mesh or the scar tissue around the mesh, makes it unsafe to remove.
15. We suggest that mesh exposure without pain can be treated in a less invasive way.
16. We suggest that an isolated vaginal exposure can be treated with localised excision or depending on size localised oestrogen therapy.
17. We recommend that surgical management of mesh complications should be carried out within a mesh centre by an appropriately credentialed medical practitioner as part of a multidisciplinary team with access to specialists in urogynaecology, urology and colorectal surgery and physiotherapists.
18. We recommend that staff within the service where the surgical management is planned should have experience in mesh removal.
19. We recommend that the woman should be counselled that mesh removal surgery may exacerbate pain and may result in worsening incontinence or prolapse. This should be clearly documented.

Chapter 3: Development Of Clinical Practice Guideline

3.1 Literature search strategy

A comprehensive literature review was undertaken which included national and international publications.

A search was conducted of current international guidelines in UK, USA, Canada and New Zealand/ Australia. In addition, a review of literature through the Cochrane library was carried out. The search terms used were mesh, mesh complications, mesh exposure, vaginal mesh complications, pain, voiding dysfunction, bowel dysfunction, dyspareunia and infection.

We included peer reviewed literature, excluded papers not in English and abstract only format. We searched without limitations until the end of March 2022.

3.2 Appraisal of evidence

Following a comprehensive literature review the quality, validity and relevance of the evidence gathered were critically appraised by the Guideline developers under the following headings:

- Study design
- Relevance of primary and secondary outcomes
- Consistency of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

A number of evidence-based recommendations for the diagnosis and management of mesh complications were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (appendix 5) as recommended by the Department of Health in the How to Develop a National Clinical Guideline manual, 2019.[11]

The purpose of AGREE II is to provide a framework to:

1. Assess the quality of guidelines.
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines

11 Department of Health (2019). How to develop a National Clinical Guideline. Available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two. An initial review of the literature was conducted by Dr Michael Carey and a final review of the documents selected was performed by Ms Orfhlaith O'Sullivan and Professor Barry O'Reilly.

Literature included statement papers developed by professional bodies in Urogynaecology and Urology. Much of the literature is based on clinical observations and best practice developed over time. There are no randomised control trials available on the management of mesh complications such as pain. Individual case studies were not included for the purposes of developing this Guideline. It was agreed that the evidence available was applicable to an Irish setting.

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations [60].[12]

While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[13] (Appendix 6)

3.6 Future research

An important outcome of the Guideline Development Process is in highlighting gaps in the evidence base. Management of mesh complications is individualised and relatively uncommon, leading to difficulty in performing randomised controlled trials in the area.

However, areas where further research is beneficial include:

- Success rates from partial and full excision of mesh in resolution of symptoms
- The impact of partial mesh removal on specific symptoms: pain, functional outcomes including recurrent/de novo SUI, POP recurrence, sexual function and quality of life measures
- The impact of total mesh removal on specific symptoms: pain, functional outcomes including recurrent/de novo SUI, POP recurrence, sexual function and quality of life measures
- Impact of menopause on the development of mesh complications
- The effect of local topical oestrogens in treating mesh exposure in premenopausal women

Collection of Irish data relative to the incidence of mesh use for SUI and POP and the incidence of associated complications would be beneficial for the counselling/consenting women for these procedures.

12 Guyatt, Gordon, *et al*. "GRADE Guidelines: 1. Introduction – GRADE Evidence Profiles and Summary of Findings Tables." *Journal of Clinical Epidemiology*, vol. 64, no. 4, 2011, pp. 383-94, https://doi.org/10.1016/j.jclinepi.2010.04.026.

13 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

This Guideline was written by the Guideline Developers under the direction of the Guideline Programme Team. An Expert Advisory Group was formed to review the Guideline prior to submission for final approval with the National Women and Infants Health Programme Clinical Advisory Group (CAG) (appendix 7). The roles and responsibilities of the members of each group and their process were clearly outlined and agreed.

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework[14] for developing Policies, Procedures, Protocols and Guidelines (2016) (appendix 8) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists and advocates (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG.

14 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/

Chapter 5: Communication and Dissemination

A communication and dissemination plan for this Guideline has been developed by the GPT and endorsed by NWIHP.

Effective ongoing clear communication is essential in explaining why the Guideline is necessary and securing continued buy-in. It provides an opportunity to instil motivation within staff, helps overcome resistance to change and gives an opportunity for feedback.[15] (DOH 2018)

The Clinical Guideline will be circulated and disseminated through the Guideline Programme Team as well as through the professional networks who participated in developing and reviewing the document.

Senior management within the Gynaecology/Maternity units are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including Guideline committees will also be instrumental in the circulation of new and updated Guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline available to all employees through standards networks as well as storing it in the online PPPG repository. Electronic versions available on the NWIHP (https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/) and RCPI websites (https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/) and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each Guideline and where relevant a downloadable version of the recommended algorithm will be available.

15 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: https://health.gov.ie/national-patient-safety-office/ncec/

Chapter 6: **Implementation**

6.1 Implementation plan

Implementation was considered at the beginning, and throughout the Guideline development process. The local multidisciplinary clinical team, senior executive and clinical management in each maternity and gynaecology unit are ultimately responsible for the appropriate structured adoption and implementation of the guidelines within their area of responsibility. They must ensure that all relevant personnel under their supervision have read and understood the Guideline and monitor both its effectiveness and adoption.

Within each site, local multidisciplinary teams are responsible for the clinical implementation of Guideline recommendations and ensuring that their local clinical practices and processes reflect and are aligned with the Guideline recommendations.

In the case of this Guideline, we would recommend it is distributed to all members of the Institute of Obstetricians and Gynaecologist and to all HSE hospitals. Furthermore, it should also be distributed to all members of the Royal College of Surgeons in Ireland and the members of the College of Anaesthetists. The Irish physiotherapy groups should also be made aware of the Guideline.

The following have been put in place to help facilitate the implementation of this Guideline.

- Quick Summary Document (QSD) for clinical staff (includes key recommendations, auditable standards, algorithms and recommended reading)
- Clinical Guideline mobile application
- Plain language summary

6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required.

This Guideline education plan includes group education on the guidance available and the appropriate care pathway.

6.3 Barriers and facilitators

To ensure successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users. (DOH 2018, 2019)

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment).

The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

- Structural factors (e.g., budget or service redesign)
- Organisational factors (e.g., lack of facilities or equipment)
- Individual factors (e.g., knowledge, skills, training)
- Women's perceptions

In the case of this Guideline, it will be necessary to examine possible barriers and consider implementation strategies to address them. By example, this may include discussion with relevant management groups with regards budgetary impact or providing training to the relevant staff.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement of each hospital. Hospitals should review existing service provision against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline.

Chapter 7: Audit and Evaluation

7.1 Introduction to audit

It is important that both implementation of the Guideline and its influence on outcomes are audited to ensure that this Guideline positively impacts on the care of the woman. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with the job of conducting the audit should be identified on receipt of the most recent version of the Guideline.

7.2 Auditable standards

Audit using the key recommendations as indicators should be undertaken to identify where improvements are required and to enable changes as necessary. Audit should also be undertaken to provide evidence of continuous quality initiatives.

Each unit should implement a systemic process of gathering information pertaining to the subject matter of this Guideline. A record should be kept of all complications associated with the insertion of mesh.

Auditable standards for this Guideline include:

1. Assessing the number of women referred to the mesh centres
2. Have women with mesh complication been assessed as part of a MDT
3. What are the overall rates of mesh complications in the Irish setting
4. What percentage of women are undergoing surgery
5. The types of surgery that women are undergoing

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved (HIQA. 2012).[16]

Implementation of this Guideline will be audited periodically at national level, with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital clinical management to support implementation.

16 Health Information Quality Authority (2012). National Standards for Safer Better Healthcare [Internet]. Available from: https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

Chapter 8: Revision Plan

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly.[17]

The Guideline Development Group will be asked to review the literature and recent evidence to determine if changes are to be made to the existing Guideline. If the Guideline Development Group are unavailable, the GPT along with the NWIHP senior management team will select a suitable expert to replace them.

If there are no amendments required to the Guideline following the revision date, the detail on the revision tracking box must still be updated which will be a new version number and date.

The recommendations set out in this Guideline remain valid until a review has been completed.

8.2 Method for amending the Guideline

As new evidence become available it is inevitable that Guideline recommendations will fall behind current evidence based practice. It is essential that clinical guidelines are reviewed and updated with new evidence as it becomes available.

In order to request a review of this Guideline one of the following criteria must be met:

a) 3 years since the Guideline was published

b) 3 years since last review was conducted

c) Update required as a result of new evidence

Correspondence requesting a review of the Guideline should be submitted to the National Women and Infants Health Programme. Any such requests should be dealt with in a timely manner.

17 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

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Supporting evidence

GRADE: http://www.gradeworkinggroup.org/

AGREE: http://www.agreetrust.org/agree-ii/

HSE: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Glossary
(for the purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

ATFP Arcus Tendineus Fascia Pelvis

CAG Clinical Advisory Group

EAG Expert Advisory Group

FDA Food and Drug Administration

GP General Practitioner

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

MUS Mid Urethral Slings

NCEC National Clinical Effectiveness Committee

NICE The National Institute for Health and Care Excellence

NWIHP National Women and Infants Health Programme

POP Pelvis Organ Prolapse

PPL Polypropylene

PPPG Policy, Procedures, Protocols and Guidelines

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

SUI Stress Urinary Incontinence

TVT Tension-free Vaginal Tape

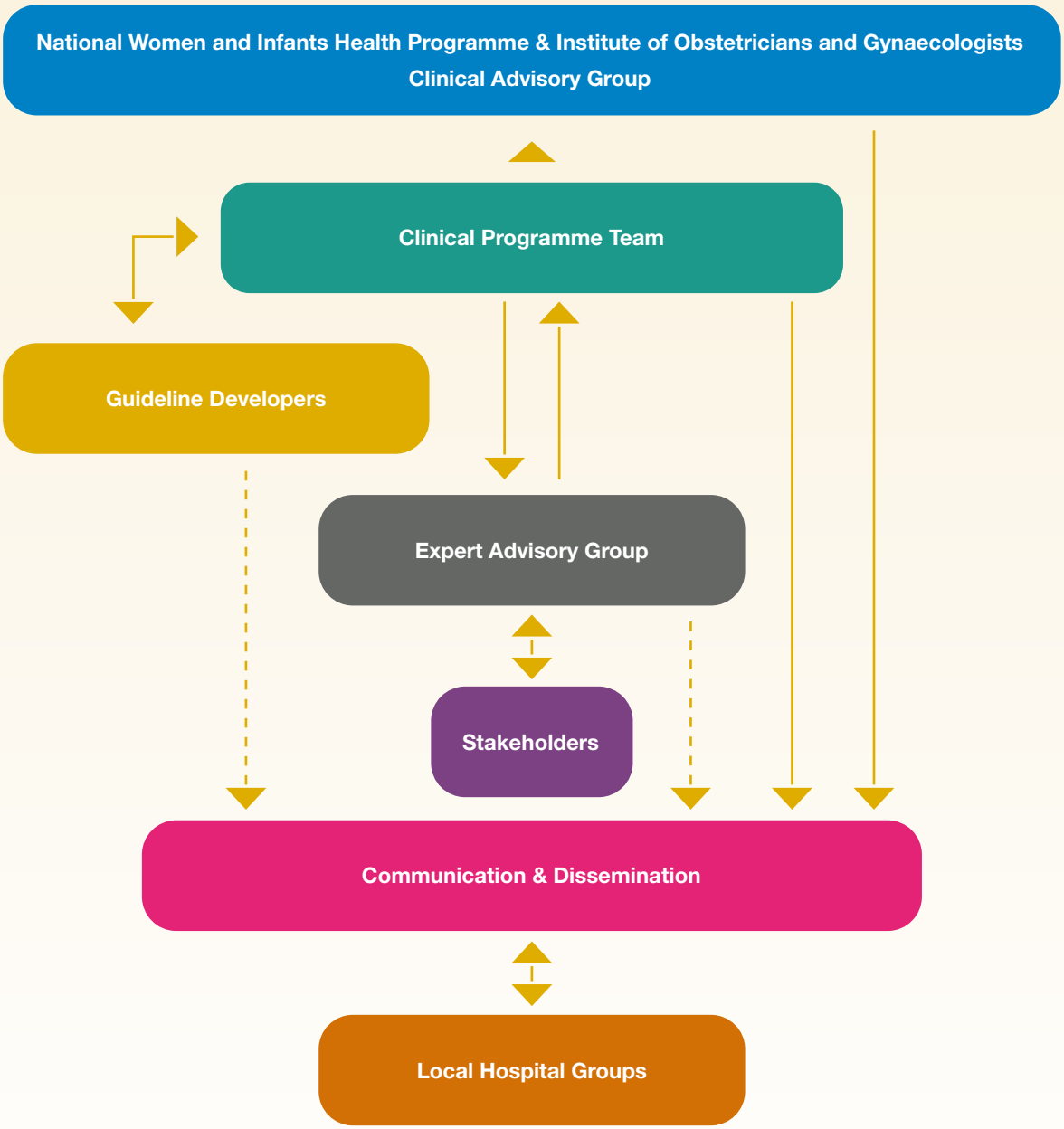
Appendix 1:
Expert Advisory Group Members 2021-

Name	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Hospital, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Prof Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Hospital Galway
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Hospital
Prof John Murphy	Consultant Neonatologist and Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology	National Women and Infants Health Programme
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director
Prof Valerie Smith	Professor of Midwifery	School of Nursing and Midwifery, Trinity College Dublin
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women & Infants University Hospital
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Womens Health Lead	Irish College of General Practitioners
Mr Fergal O' Shaughnessy *And* Dr Brian Cleary *(Shared nomination)*	Senior Pharmacist, Honorary Lecturer *And* Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Niamh Connolly-Coyne *And* Ms Mandy Daly *(Shared nomination)*	Board of Directors	Irish Neonatal Health Alliance
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Hospital
Ms Fiona Dunlevy *And* Ms Sinéad Curran *(Shared nomination)*	Dietician Manager	Coombe Women & Infants University Hospital National Maternity Hospital
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3:
Terminology for the diagnosis, management and outcomes assessment of mesh related complications[18]

A classification by category (C), time (T), and site (S) of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in female pelvic floor surgery

CATEGORY

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal**: no epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	**1A**: Abnormal prosthesis or graft finding on clinical examination	**1B**: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	**1C**: Infection (suspected or actual)	**1D** = Abscess
2	**Vaginal**: smaller ≤ 1cm exposure	**2A**: Asymptomatic	**2B**: Symptomatic	**2C**: Infection	**2D** = Abscess
3	**Vaginal**: larger >1cm exposure, or any extrusion	**3A**: Asymptomatic 1-3A*a* if no prosthesis or graft related pain	**3B**: Symptomatic 1-3B (*b-e*) if prosthesis or graft related pain	**3C**: Infection 1-3C /1-3D (*b-e*) if prosthesis or graft related pain	**3D** = Abscess
4	**Urinary Tract**: compromise or perforation Including prosthesis (graft) perforation, fistula and calculus	**4A**: Small intraoperative defect e.g. bladder perforation	**4B**: Other lower urinary tract complication or urinary retention	**4C**: Ureteric or upper urinary tract complication	
5	**Rectal or Bowel**: compromise or perforation including prosthesis (graft) perforation and fistula	**5A**: Small intraoperative defect (rectal or bowel)	**5B**: Rectal injury or compromise	**5C**: Small or Large bowel injury or compromise	**5D** = Abscess
6	**Skin and / or musculoskeletal**: complications including discharge pain lump or sinus tract formation	**6A**: Asymptomatic, abnormal finding on clinical examination	**6B**: Symptomatic e.g. discharge, pain or lump	**6C**: Infection e.g. sinus tract formation	**6D** = Abscess
7	**Patient**: compromise including hematoma or systemic compromise	**7A**: Bleeding complication including haematoma	**7B**: Major degree of resuscitation or intensive care*	**7C**: Mortality * *(additional complication - no site applicable - **S 0**)	

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours | **T2**: 48 hours to 2 months | **T3**: 2 months to 12 months | **T4**: over 12 months

SITE

S1: Vaginal: area of suture line | **S2**: Vaginal: away from from area of suture line | **S3**: Trocar passage Exception: Intra-abdominal (**S5**) | **S4**: other skin or musculoskeletal site | **S5**: Intra-abdominal

N.B.
1. Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.
2. The highest final category for any single complication should be used if there is a change over time. (patient 888)
3. Urinary tract infections and functional issues (apart from 4B) have not been included.

IUGA ICS

CODE ☐☐☐- T ☐- S ☐

18 Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, Dwyer PL, Fatton B, Kocjancic E, Lee J, Maher C, Petri E, Rizk DE, Sand PK, Schaer GN, Webb RJ.

An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery.

Int Urogynecol J. 2011 Jan;22(1):3-15. doi: 10.1007/s00192-010-1324-9. PMID: 21140130
https://pubmed.ncbi.nlm.nih.gov/21140130/

Terminology involved in classification

TERMS USED	DEFINITION
PROSTHESIS	A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure
A: Mesh	A (prosthetic) network fabric or structure
B: Implant	A surgically inserted or embedded prosthesis
C: Tape (Sling)	A flat strip of synthetic material
GRAFT	Any tissue or organ for transplantation. This term will refer to biological materials inserted
A: Autologous Grafts	From the woman's own tissues e.g. dura mater, rectus sheath or fascia lata
B: Allografts	From post-mortem tissue banks
C: Xenografts	From other species e.g. modified porcine dermis, porcine small intestine, bovine pericardium
COMPLICATION	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery
CONTRACTION	Shrinkage or reduction in size
PROMINENCE	Parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial separation)
SEPARATION	Physically disconnected (e.g. vaginal epithelium)
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible e.g. vaginal mesh visualized through separated vaginal epithelium
EXTRUSION	Passage gradually out of a body structure or tissue
COMPROMISE	Bring into danger
PERFORATION	Abnormal opening into a hollow organ or viscus
DEHISCENCE	A bursting open or gaping along natural or sutured line

An example of a *non-procedure specific* table of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in female pelvic floor surgery using the category (C), Time (T) and Site (S) system. The CTS Classification Code is placed adjacent to a description of the complication. One might expect these tables to be often procedure-specific

Patient Number	Description of complications	Code	Code
000	Retropubic haematoma following a tape procedure (first 24 hours)	7A /T1/ S3	
111	Persistent thigh pain six weeks after an obturator tape	6B /T2/ S4	
222	Bowel obstruction and 2cm vaginal vault exposure with bleeding 6 months after a mesh sacrocolpopexy	5C /T3/ S5	3B /T3/ S1
333	Mesh fibre exposure (lateral vaginal) in a woman at a 6 week postop review whose partner is describing discomfort with intercourse	1B /T2/ S2	
444	A midline vaginal exposure of mesh (< 1cm) with redness, dyspareunia, discharge 15 months after an anterior colporrhaphy using mesh.	2C*c*/T4/S1	
555	Lateral vaginal extrusion with malodorous discharge and a midline rectovaginal fistula 8 months after a posterior vaginal tape	3C /T3/ S2	5B /T3/ S1
666	Intraoperative obturator vessel injury during a transobturator tape procedure requiring major resuscitation	7B /T1/ S3	
777	Persistent intravesical tape / calculus formation / haematuria 2 years after a retropubic tape procedure	4B /T4/ S3	
888	Pelvic abscess presenting 8 days after a mesh sacrocolpopexy complicated by an intraoperative bowel defect (final category). Initial code was 5A/T1/S5	5D /T2/S5	
999	Tender prominent mesh contraction noted 9 months after an anterior mesh repair (no symptoms, husband unwell)	1B*b*/T3/S1	
XXX	Persistent postvoid residual of 150mls with recurrent UTI requiring posterior division of suburethral tape 4 months after insertion	4B /T3/S1	

Appendix 4: **AUGS/IUGA Joint position statement on the management of mesh related complications for the FPMRS specialist**

Surgical procedures for the treatment of Mesh complications[19]

Surgical Procedures for the Treatment of Mesh Complications
Mesh revision Either no mesh is removed (eg, dissecting and primarily closing vaginal epithelium), or small edge of mesh is removed such that the structural integrity of the implant is left intact.
Partial vaginal mesh excision A segment/component of the mesh is removed or transected, such that the structural integrity of the implant is altered
Complete vaginal mesh excision This involves removal of segments or components of mesh beyond, or not in contact with, the vagina. Note the following: • Because of the wide variation of devices and approaches, this category should include additional description of which mesh segments were removed • This term should be used in addition to any relevant vaginal mesh excision if performed
Total mesh excision The surgical goal is the removal of 100% of the implant (extirpation)

19 Joint Position Statement on the Management of Mesh-Related Complications for the FPMRS Specialist. Female Pelvic Med Reconstr Surg. 2020 04;26(4):219-32. PubMed PMID: 32118617. eng. https://pubmed.ncbi.nlm.nih.gov/32118617/

Appendix 5: AGREE II Reporting Checklist[20]

AGREE Reporting Checklist 2016

This checklist is intended to guide the reporting of Clinical Practice Guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/ rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	

20 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field (www. agreetrust.org)

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	
DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/ risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalize on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

From: Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at http://www.agreetrust.org.

Appendix 6: **Grades of Recommendation**[21]

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We strongly recommend… We recommend that …should be performed/ administered… We recommend that … is indicated/ beneficial/ effective….

21 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We recommend… We recommend that … should be performed/ administered… We recommend that … is (usually) indicated/ beneficial/ effective…
1 C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality	We recommend… We recommend that … should be performed/ administered… We recommend that … Is (maybe) indicated/ beneficial/ effective…
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values	We suggest… We suggest that … may/might be reasonable…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances	We suggest… We suggest that … may/might be reasonable…
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable.	We suggest… is an option We suggest that … may/might be reasonable.
Best practice	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			We recommend… We recommend that … should be performed/ administered… We recommend that … Is usually) indicated/ beneficial/effective

Appendix 7:
NWIHP/IOG CAG Membership 2022

Dr Cliona Murphy (Chair). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Angela Dunne. Director of Midwifery, National Women and Infants Health Programme.

Kilian McGrane. Director, National Women and Infants Health Programme.

Dr Peter McKenna. Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof John Murphy. Clinical Lead Neonatology, National Women and Infants Health Programme.

Prof Maeve Eogan. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Dr Aoife Mullaly. Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof Keelin O'Donoghue. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Prof Nóirín Russell. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Prof Richard Greene. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof John Morrison. Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Dr Suzanne O'Sullivan. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof Fergal Malone. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof John Higgins. Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Dr Mendinaro Imcha. Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof Shane Higgins. Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Prof Mike O'Connell. Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Brian Cleary. Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

Appendix 8: **Policies, Procedures, Protocols and Guidelines Checklist**

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing clinical PPPG	
Stage 1 initiation	**Checklist**
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	☐
Synergies/co-operations are maximised across departments/organisations (Hospitals/ Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	☐
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	☐
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	☐
The views and preferences of the target population have been sought and taken into consideration (as required).	☐
The overall objective(s) of the PPPGs are specifically described.	☐
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	☐
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	☐
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	☐
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	☐
There is service user/lay representation on PPPG Development Group (as required).	☐
Information and support is available for staff on the development of evidence-based clinical practice guidance.	☐

Stage 2 development	**Checklist**
The clinical question(s) covered by the PPPG are specifically described.	☐
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	☐
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	☐
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	☐
There is an explicit link between the PPPG and the supporting evidence.	☐
PPPG guidance/recommendations are specific and unambiguous.	☐
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Budget impact is documented (resources required).	☐
Education and training is provided for staff on the development and implementation of evidence- based clinical practice guidance (as appropriate).	☐
Three additional standards are applicable for a small number of more complex PPPGS:	☐
Cost effectiveness analysis is documented.	☐
A systematic literature review has been undertaken.	☐
Health Technology Assessment (HTA) has been undertaken.	☐
Stage 3 governance and approval	**Checklist**
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	☐
The PPPG has been reviewed by independent experts prior to publication (as required).	☐
Copyright and permissions are sought and documented.	☐
Stage 4 communication and dissemination	**Checklist**
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	☐
Plan and procedure for dissemination of the PPPG is described.	☐
The PPPG is easily accessible by all users e.g. PPPG repository.	☐

Stage 5 implementation	**Checklist**
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	☐
Education and training is provided for staff on the development and implementation of evidence- based PPPG (as required).	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Stage 6 monitoring, audit, evaluation	**Checklist**
Process for monitoring and continuous improvement is documented.	☐
Audit criteria and audit process/plan are specified.	☐
Process for evaluation of implementation and (clinical) effectiveness is specified.	☐
Stage 7 revision/update	**Checklist**
Documented process for revisions/updating and review, including timeframe is provided.	☐
Documented process for version control is provided.	☐

To view in full refer to website: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/