National
Women & Infants
Health Programme

National Clinical Practice Guideline

Assessment and Management of Stress Urinary Incontinence in Women

INSTITUTE OF
OBSTETRICIANS &
GYNAECOLOGISTS

ROYAL COLLEGE OF
PHYSICIANS OF IRELAND

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Algorithms/Summary Tables:

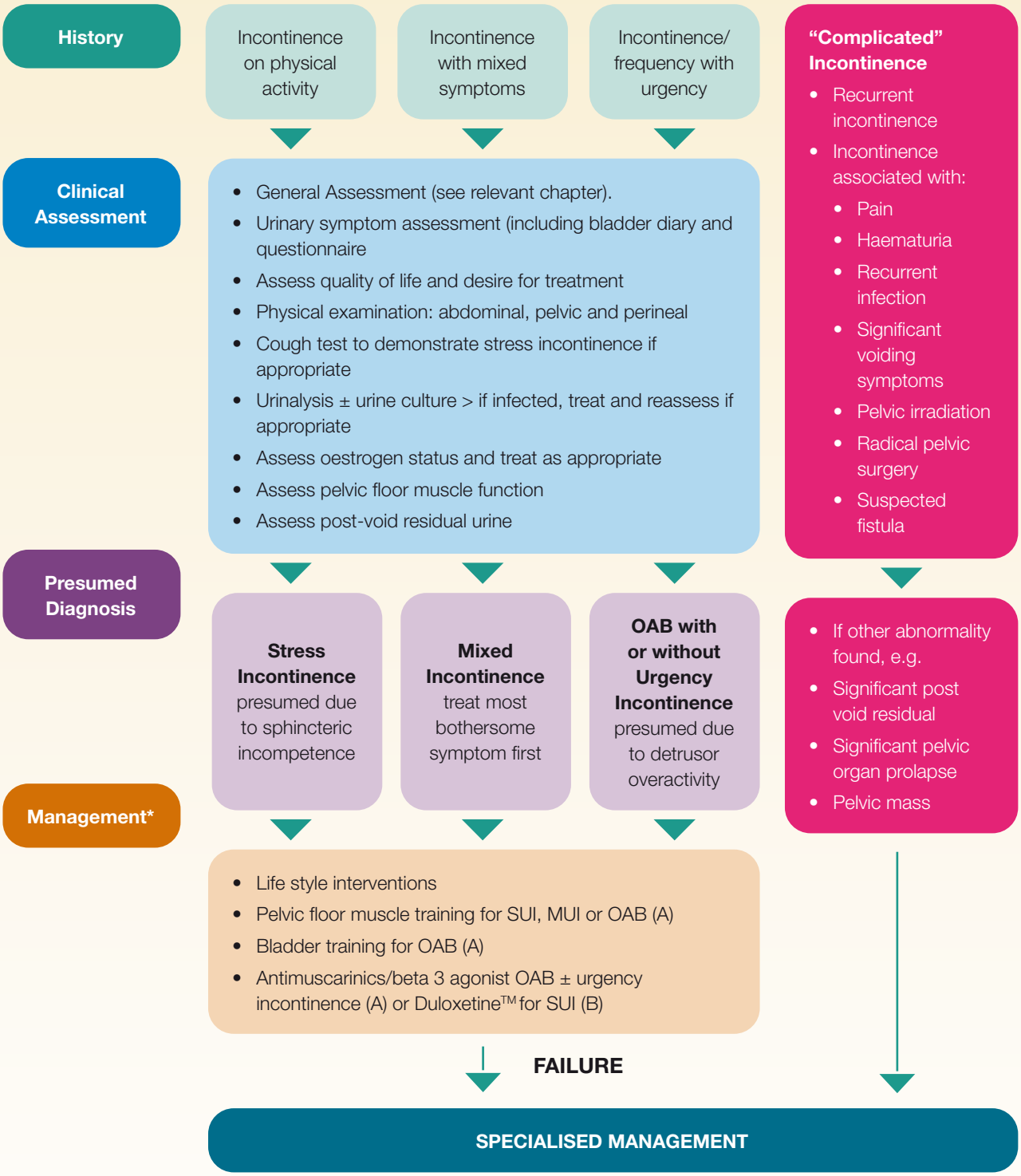
Table 1: Distinguishing Incontinence Aetiology by History

Question	SI	UI
Description of incontinence episodes	Loss with cough, sneeze or activity	Sudden urgency with inability to reach toilet
Precipitating factors	Cough, physical exercise, strain	Full bladder, sensory triggers (e.g. Running water)
Urinary frequency	Normal	Often increased
Nocturia	<1	Variable
Volume of urine loss	Small amounts, pad sufficient	Large amounts, soaked clothing, runs down legs

SI: Stress Incontinence; UI: urgency incontinence

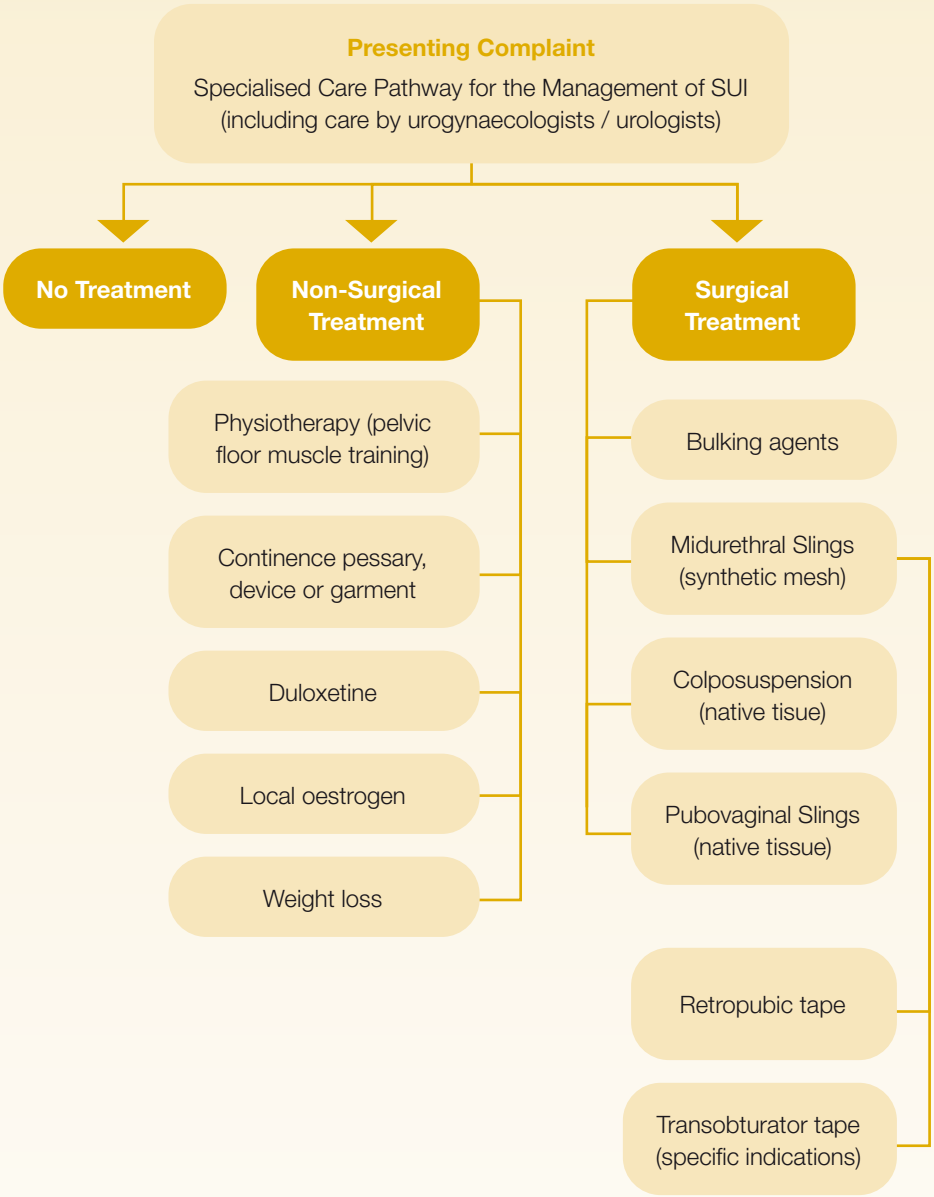
Adapted from: *Farrell, S.A., et al. The Evaluation of Stress Incontinence Prior to Primary Surgery* [1].

Algorithm 1: Initial Management of Female Urinary Incontinence



Adapted from: *ICI 2016 initial management algorithm of female UI*[2]

Algorithm 2: Specialised Care Pathway for the Management of Stress Urinary Incontinence in Women



Key Recommendations

1. We strongly recommend taking a detailed history (to include obstetric and gynaecological history), and a clinical examination be undertaken in women presenting with suspected SUI. *Grade 1A*
2. A clinical assessment involving pelvic and vaginal examination should be undertaken in patients presenting with suspected Stress Urinary Incontinence. *Grade 1A*
3. We recommend that basic investigations to include urine dipstick/microscopy should be carried out in the first instance. Additional investigations, primarily urodynamics, should be followed up as indicated. *Grade 1C*
4. Urodynamic testing is an invasive and time-consuming investigation and there is a small risk of UTI following testing. We would therefore not recommend urodynamics be carried out before initiating conservative treatment. *Grade 1C*
5. We recommend urodynamic testing be performed prior to all surgical procedures for stress urinary incontinence. *Grade 1B*
6. We recommend that urodynamic testing is carried if the type of urinary incontinence is unclear, if there is mixed incontinence, if there is a voiding disorder or if there is a previous continence procedure. *Grade 1B*
7. Referral for additional investigations may be indicated, and we recommend that those treating women with SUI should be aware of these indications. *Grade 1C*
8. We recommend that all women should be offered non-surgical therapy as first line treatment of SUI. Lifestyle modification (fluid restriction, smoking cessation), weight loss, continence pessaries, pharmacological agents (duloxetine) and local vaginal oestrogen therapy are conservative options for SUI. Pelvic floor muscle training with a specialist physiotherapist for a minimum of three months, can be delivered in the primary care setting prior to referral to specialist. *Grade 1C*
9. We recommend that neither cystoscopy nor imaging are indicated as part of the evaluation of SUI, unless there is concern about urinary tract anomalies *Grade 1C*
10. We recommend that women should be fully informed regarding treatment options available to them, including the potential risks and benefits to enable them to decide which course of treatment they wish to proceed with. *Best Practice*
11. In women with SUI, or stress-predominant mixed urinary incontinence, who are considering surgery, we recommend that physicians should offer the following treatment options: no further treatment, pelvic floor physiotherapy, non-surgical options (e.g., continence pessary) or surgical treatment. *Grade 1B*
12. We recommend that women undergoing surgery for SUI should be fully informed on all surgical options available to them and counselled on associated benefits and potential risks of each surgery. For women undergoing surgery with a Mid-Urethral Sling (MUS), when the choice of surgery involves a Mid-Urethral Sling (MUS), the HSE's Mid Urethral Sling Mesh Procedure for the Surgical Treatment of Stress Urinary Incontinence information and Consent should be used. *Best Practice*

13. We recommend that details of all surgical procedures using a mesh, bulking agent or other implant for the treatment of SUI are registered with the HPRA and recorded on the National Register of Pelvic Floor Implants. Reporting of complications via HPRA is linked to the register. *Best Practice*
14. We recommend that surgery for SUI should only be undertaken by appropriately trained surgeons who undertake such operations regularly, and who work within a Multidisciplinary Team (MDT) where all women undergoing surgery are discussed and treatment pathways are agreed by the MDT. *Best Practice*
15. We suggest that mesh implants should only be considered after all the options for conservative and non-mesh surgery have been discussed. We suggest that single Incision Slings and TVT-O should not be used. We suggest retropubic slings should be used for uncomplicated SUI and Trans-Obturator Tapes should only be considered in women with a high risk of bowel or other injury using the retropubic route. *Grade 2A*

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 guidance for the assessment and care of women with Stress Urinary Incontinence (SUI) who are aged 18 and over. It provides advice for specialists in urogynaecology and urology, and general practitioners around the provision of safe, evidence-based care to women diagnosed with SUI. These guidelines are intended for healthcare professionals working in HSE services, and they are designed to guide clinical judgement but not replace it.

1.2 Scope

Target Users

The Guideline is a resource for all healthcare staff caring for women with SUI. This includes specialists in the field of Obstetrics and Gynaecology, General Practitioners, Nursing and Midwifery Staff, as well as Health and Social Care Professionals involved in the care of women with SUI.

Target Population

The Guideline is a resource for all women undergoing assessment and management of SUI.

1.3 Objective

To provide evidence-based recommendations for the care of women with SUI, as well as promoting a standardised approach nationally across all maternity units and general hospitals where gynaecological services are in place.

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.

The principal Guideline developers were Dr Suzanne O'Sullivan, Dr Simon Craven and Dr Fadi Salameh.

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

1.5 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

- Aoife Cullen, Women's Health Physiotherapist, National Maternity Hospital
- Sarah Mullins, Women's Health Physiotherapist, National Maternity Hospital

ANP urology/urogynaecology

- Ann Humphreys, Urodynamics and Urogynaecology Nurse Specialist, Cork University Maternity Hospital
- Linda Kelly, Advanced Midwife Practitioner Urogynaecology/Urodynamics, National Maternity Hospital

Continence Foundation of Ireland/Royal College of Physicians of Ireland

- Prof Declan Keane, Consultant Obstetrician/Urogynaecologist, National Maternity Hospital
- Dr Susmita Sarma, Consultant Obstetrician/Urogynaecologist, University Hospital Galway
- Dr Gerry Agnew, Consultant Obstetrician/Urogynaecologist, National Maternity Hospital
- Ms Orfhlaith O'Sullivan, Consultant Obstetrician/Urogynaecologist, Cork University Maternity Hospital
- Prof Barry O'Reilly, Consultant Obstetrician/Urogynaecologist, Cork University Maternity Hospital
- Dr Paul Hughes, Consultant Obstetrician/Gynaecologist, University Hospital Kerry
- Dr Mark Skehan, Consultant Obstetrician/Gynaecologist, University Maternity Hospital Limerick
- Dr Hilary Ikele, Consultant Obstetrician/Gynaecologist, Mayo University Hospital
- Dr Breffini Anglim, Consultant Obstetrician/Urogynaecologist, Coombe Women and Infants University Hospital, Dublin

Irish Society of Urology (ISU)

- Ms Helen Hegarty, Consultant Urologist, Chair ISU
- Mr James Forde, Consultant Urologist, Beaumont Hospital
- Ms Lisa Smyth, Consultant Urologist, Tallaght University Hospital
- Mr Ciaran Brady, Consultant Urologist, Cork University Hospital

RCSI

- Ms Helen Hegarty, Consultant Urologist

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 Guideline, 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.

1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice, using a multidisciplinary (MDT) 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 specific woman.

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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

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

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.

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.

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

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

Chapter 2: **Clinical Practice Guideline**

Background

Stress urinary incontinence (SUI) is the involuntary leakage of urine which occurs with increases in intra-abdominal pressure (e.g. with sneezing, coughing, laughing) in the absence of a bladder contraction. SUI is the most common type of incontinence in younger women, with the highest incidence in women ages 45 to 49 years [3,4]. SUI has a significant negative impact on quality of life (QOL)[1]. SUI also has a large economic impact on health systems necessitating the implementation of cost-effective management plans [5]. Treatment can be non-surgical and surgical [4]. There are many options for the treatment of SUI and this Guideline aims to outline the currently available management techniques.

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

- National Clinical Practice Guideline: Diagnosis and Management of Mesh complications (2022)[9]
- National Clinical Practice Guideline: Diagnosis and Management of Pelvic Organ Prolapse (2022)[10]
- National Clinical Guideline on assessment, promotion and management of continence in adults (2019)[11]

Clinical Question 2.1: **What are the necessary steps involved in the assessment of a woman presenting with suspected Stress Urinary Incontinence?**

Evidence Statement

The minimum evaluation in assessing women with symptoms of SUI includes the following: 1) history, 2) physical examination and 3) demonstration of stress incontinence [6]

9 Carey M., O'Reilly, B., O'Sullivan, O., National Clinical Practice Guideline: Diagnosis and Management of Mesh complications. 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

11 https://www.hse.ie/eng/services/list/2/primarycare/community-funded-schemes/continence/healthcare-professionals/guideline-assessment-promotion-and-management-of-continence-in-adults-2019.pdf

History

The purpose of history taking is to determine the type of urinary incontinence (UI) that is bothersome to women. Urinary incontinence is commonly classified as stress, urge, or mixed. The history should include questions about the type of incontinence; precipitating events, frequency of occurrence, severity, pad use, and effect of symptoms on activities of daily living [3,6]. Questions should be asked to assess symptoms related to bladder storage and emptying functions. Storage symptoms include frequency, nocturia, urgency, and incontinence [6]. Emptying or voiding symptoms include hesitancy, slow stream, intermittent flow, straining to void, feeling of incomplete emptying, need to immediately re-void, postmicturition leakage, position-dependent micturition and dysuria [6]. Women with uncomplicated SUI will have classic symptoms of leakage on effort or physical exertion [1,6]. In contrast, inability to reach the toilet that is associated with urgency indicates the presence of urge urinary incontinence. A bladder diary which records fluid intake and measured voids as well as incontinence episodes may be used in order to gain clarity on a woman's symptoms [3].

Physical Examination

The primary purpose of the physical examination is to exclude confounding or contributing factors to the incontinence or its management [1].

Physical examination should include a functional assessment observing the mental status and mobility as well as body mass index of the patient[7]. Patients with poor mobility and mild cognitive impairment are 30% more likely to have urinary incontinence [8]. In addition, epidemiological studies showed that obesity is a strong independent risk factor for prevalent and incident urinary incontinence [9]. There was a clear dose-response effect of weight on urinary incontinence with each 5-unit increase in body mass index associated with up to 70% increase in the urinary incontinence risk.

An abdominal and pelvic examination should be performed to rule out a pelvic mass and to check for chronic urinary retention with overflow incontinence [1,3]. A vaginal examination should be performed to assess for pelvic organ prolapse (POP). An assessment of pelvic floor muscle tone, contraction and urethral mobility may also be performed by trained specialists [1,3,6].

Clinical Practice

- A detailed history is necessary in the initial assessment of urinary incontinence and should include a detailed obstetric and gynaecological history (Table 1). Characterisation of the type of urinary incontinence with a focus on the degree of bother, severity, timing of incontinence and presence of urgency symptoms (mixed symptoms) should be performed. Consider other disease processes that can present as urinary incontinence but require further evaluation and different management pathways.
- A bladder diary which records fluid intake and measured voids as well as incontinence episodes may be used in order to gain clarity on a woman's symptoms.
- Clinical examination should include general status including mental status, obesity and mobility. An abdominal and pelvic examination should be performed to rule out a pelvic mass and to assess for chronic urinary retention with overflow incontinence.
- A vaginal examination should be performed to assess for pelvic organ prolapse (POP), and an assessment of pelvic floor muscle tone and contraction may also be performed by trained specialists.

Recommendations

1. **We strongly recommend taking a detailed clinical history (to include obstetric, gynaecological, medical and surgical history) should be undertaken in women presenting with suspected SUI.**
2. **A clinical assessment involving pelvic and vaginal examination should be undertaken in patients presenting with suspected Stress Urinary Incontinence.**

Clinical Question 2.2: **What investigations should be undertaken in women presenting with suspected Stress Urinary Incontinence?**

The investigations required for women presenting with suspected SUI are outlined below. A series of basic investigations should be carried out and followed up by additional investigations if indicated.

Evidence Statement

Urine testing

Urinary tract infection (UTI) can mimic various causes of urinary incontinence, including detrusor overactivity (instability) and urodynamic stress incontinence [10]. A midstream urine specimen should be tested both by urinalysis and microscopy to detect the presence of blood, glucose, protein, leucocytes and nitrites. If microscopy shows the presence of red blood cells in the urine, referral for specialist investigations is required. Aseptic, transurethral urine samples provide a less contaminated specimen for culture. However, on urinalysis, catheter specimens may be falsely positive for blood. In symptomatic women, urinalysis has a significant false negative rate and should be accompanied by urine culture and sensitivity[11]. An appropriate course of antibiotic treatment should be prescribed pending culture results. If a woman does not have symptoms of UTI and her urine tests negative for either leucocytes or nitrites, a urine sample for culture and microscopy is not necessary as she is unlikely to have UTI.

Assessment of residual urine

Measure post-void residual volume by bladder scan (ultrasound) or catheterisation in women with symptoms suggestive of voiding dysfunction or chronic urinary retention. Where possible, a bladder scan should be used in preference to catheterisation on the grounds of acceptability to women. Women who are found to have a palpable bladder on bimanual or abdominal examination after voiding should be referred to a specialist [12]. During the clinical assessment, seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigations (e.g. Urodynamics, where history is suggestive of urge incontinence/mixed urinary incontinence/surgery required).

Urodynamic Studies (UDS)

Urodynamic investigation attempts to measure bladder function, urethral function and voiding function. This pressure-flow study with or without the use of fluoroscopy (video urodynamics), remains the gold standard for the evaluation of lower urinary tract function [13]. The study involves insertion of a catheter into the bladder and a second catheter to measure abdominal pressures into the rectum or vagina. The catheter in the bladder serves as a filling catheter and is also used for real-time pressure monitoring. An abdominal pressure tracing is helpful to distinguish intravesical pressure variations (due to intra-abdominal transmission) from contractions of the detrusor itself [14].

Key filling-phase metrics obtained with urodynamic testing include bladder capacity, bladder sensation, bladder wall compliance and presence of involuntary detrusor contractions.

- Bladder capacity is measured by emptying the bladder fully by way of catheter and refilling with warm sterile water. Capacity is determined when the woman communicates to the provider that she is no longer able to tolerate further filling of the bladder.
- Bladder sensation is measured by asking women to report standardised verbal sensory thresholds of "first sensation of filling," "first desire to void," and "strong desire to void."[15]
- Bladder compliance is defined as the change in volume divided by the change in pressure during filling (i.e., before a detrusor contraction)
- Involuntary detrusor contraction: during the filling phase this is abnormal and is used to make the urodynamic diagnosis of detrusor overactivity. It is important to distinguish detrusor overactivity, which is a urodynamic diagnosis, from the term OAB, which is a purely clinical term (based on symptoms). Detrusor overactivity may be noted with the symptom of urgency, with or without leakage, in association with a detrusor pressure rise. The woman can cough and perform the Valsalva manoeuvre to detect stress incontinence in the absence of a detrusor contraction.

The voiding phase of urodynamics provides information about bladder contractility, urinary flow rate, urethral sphincter activity, and characterisation of possible bladder outlet obstruction [16]

Urodynamic testing is an invasive and time-consuming investigation and there is a small risk of UTI following testing. It is therefore not indicated before initiating conservative treatment [16].

Urodynamics may be helpful in the following circumstances [13]:

- Diagnosis is unclear and more invasive treatments are planned
- Conservative therapy has failed
- Prior incontinence surgery has failed
- A woman has expressed voiding complaints, especially after stress incontinence surgery
- Pelvic organ prolapse is present beyond the hymen
- A woman has a complicated medical history (e.g., neurologic disease, diabetes mellitus) or there is concern for upper urinary tract disease

Clinical Practice

Basic investigations

- Undertake a urine dipstick test in all women presenting with urinary incontinence to detect the presence of blood, glucose, protein, leucocytes and nitrites in the urine.
- If a woman has lower urinary tract symptoms or if their urine tests positive for both leucocytes and nitrites, a midstream urine specimen should be sent for microscopy, culture and analysis of antibiotic sensitivities. Prescribe an appropriate course of antibiotic treatment pending culture results. If microscopy shows the presence of red blood cells in the urine, referral for specialist investigations is required.
- If a woman does not have symptoms of UTI and her urine tests negative for either leucocytes or nitrites, a urine sample for culture and microscopy is not necessary as she is unlikely to have UTI.
- Residual urine can be measured by ultrasound or by catheterisation in the absence of access to ultrasound, if voiding dysfunction or chronic urinary retention is suspected.

- During the clinical assessment, seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigations (e.g. UDS, where history is suggestive of urge incontinence/mixed urinary incontinence/surgery required)

Additional investigations – Urodynamics (UDS)

- UDS are a series of tests that can aid in clarifying bladder dysfunction and therefore improve symptom management. These tests include:
  - Cystometry, leak point pressure measurement and pressure flow study.
  - Electromyography.
  - Pressure flow study.
  - Uroflometry.
  - Postvoid residual measurement.
  - Video urodynamic tests.
- Uroflometry involves measuring urine flow with a full bladder and assessing residual urine volumes post voiding.
- Filling cystometry involves a fine tube through the urethra which allows fluid to flow into the bladder while measuring and recording pressure inside the bladder. Another pressure transducer tube is placed either into the rectum or vagina and intra-abdominal pressure is measured and subtracted from the intravesical pressure to calculate the detrusor pressure. This allows increases in bladder pressure due to detrusor contractions to be measured and separated from intra-abdominal pressure rises. During the filling phase women are asked to cough or perform a Valsalva manoeuvre in order to assess for SUI and to rule out stress provoked detrusor overactivity as a cause for incontinence.
- This is an invasive and time-consuming investigation and there is a small risk of UTI as a result of performing the procedure. It is therefore not routinely indicated before initiating conservative treatment.
- Urodynamics should be performed before surgery for SUI.
- Urodynamics are indicated if there is mixed incontinence, a voiding disorder, a previous continence procedure or if the type of urinary incontinence is unclear.

Recommendations

3. **We recommend that basic investigations to include urine dipstick/microscopy should be carried out in the first instance as appropriate. Additional investigations, primarily urodynamics, should be followed up if indicated.**
4. **Urodynamic testing is an invasive and time-consuming investigation and there is a small risk of UTI following testing. We do not recommend urodynamics be carried out before initiating conservative treatment.**
5. **We recommend urodynamic testing should be performed on all women prior to any surgical procedures for stress urinary incontinence.**
6. **We recommend that urodynamic testing is carried out if the type of urinary incontinence is unclear, if there is mixed incontinence, if there is a voiding disorder or if there is a previous continence procedure.**

Clinical Question 2.3: **When should a woman be referred for specialist investigations?**

Evidence Statement

This section lists the instances where it is recommended that those presenting with SUI be referred for further specialist investigation. (See Algorithm 1 – complicated incontinence)

Prior to embarking on the management of suspected SUI it is important to exclude – through history and physical examination – which women require onward referral to specialist services. It is well documented in the literature that use or timing of medications may worsen incontinence (i.e., diuretics), and comorbid conditions may contribute to incontinence (obesity, constipation, sleep apnoea, tobacco use, dementia, and depression) [3].

There are however signs or symptoms suggestive of serious underlying pathology (listed below), such as cancer or serious neurologic disease, that need to be out ruled and their presence should prompt immediate referral to an incontinence specialist [3,17].

- dominant symptom of bladder or urethral pain
- palpable bladder or pelvic mass on bimanual or abdominal examination after voiding
- lifelong history of incontinence (present since childhood)
- associated anal incontinence
- suspected neurological disease
- voiding difficulty
- previous continence surgery
- previous pelvic cancer or
- a suspected fistula

Clinical Practice

In women with urinary incontinence, indications for consideration for referral to a specialist service include:

- dominant symptom of bladder or urethral pain
- palpable bladder or pelvic mass on bimanual or abdominal examination after voiding
- lifelong history of incontinence (present since childhood)
- associated anal incontinence
- suspected neurological disease
- voiding difficulty
- previous continence surgery
- previous pelvic cancer or
- a suspected fistula

Recommendations

7. **Referral for additional investigations may be indicated, and we recommend that those treating women with SUI should be aware of these indications.**

Clinical Question 2.4: **How is Stress Urinary Incontinence managed conservatively?**

Evidence Statement

Surgical treatments are widely used for SUI, however many women prefer a self-managed conservative option to avoid long-term recurrence or possible complications of surgical interventions[18]. Moreover, some women are not eligible for surgery or prefer to defer it (e.g. women who plan to conceive [18]). If a woman has uncomplicated SUI or SUI is the predominant symptom in mixed urinary incontinence, conservative therapy is recommended [6]

Lifestyle modification, pelvic floor muscle training, continence pessaries, pharmacological agents (duloxetine) and local vaginal oestrogen therapy are conservative options for SUI.

Absorbent containment products are not recommended in the primary treatment of UI [3]. These should only be offered as a coping strategy pending definitive treatment, as an adjunct to ongoing therapy or for long-term management of UI only after all other treatment options have been explored. If deemed necessary, advice on containment products, pads or support garments should be given in line with the HSE National Clinical Guideline on continence care[19]

Lifestyle

Excessive fluid intake can exacerbate urinary incontinence (UI), whereas restriction of fluids may result in an increase in urine concentration that may irritate the bladder mucosa and promote urgency, frequency and urinary tract infections [20]. The daily volume of fluid intake should be approximately 1500 ml or 30 ml/kg body weight per 24 h [21].

Research has shown that smoking is strongly associated with UI [22] and urgency [23] in women. This association is likely from the increases in intra-abdominal pressure caused by chronic coughing in smokers [22] or from increased detrusor activity, which has been shown to be induced by nicotine [24]. Women who smoke should receive education concerning the relationship between smoking and UI and should be provided with strategies for stopping. The HSE provides a range of free services open to anyone who wants to quit smoking (https://www2.hse.ie/quit-smoking/)

Behavioural and weight-related risk factors:

Having a body mass index > 30 kg/m^2 is an independent risk factor for UI in women [25]. Obesity has been hypothesised to promote UI by increasing intra-abdominal pressure leading to chronic stress on the pelvic floor that leads to overt structural damage resulting in UI [26]. Surgical weight loss has been shown to reduce UI in women who are morbidly obese [27,28]. Even moderate weight loss has been shown to improve UI symptoms in overweight women [29,30]. Aside from mechanical mechanisms, neuroendocrine processes could be the link between adiposity and UI. Adipose tissue produces leptin which can increase autonomic nervous activity especially noradrenergic sympathetic nerves[31]. Sympathetic overactivity in animal models (e.g. spontaneously hypertensive rat) or humans with increased sympathetic activity

exhibit urinary frequency, OAB and UI[32]. Therefore, significant adipose tissue could increase circulating leptin and produce UI as a result of changes in autonomic nervous activity. Thus, weight loss should be considered as a first-line option for the treatment of UI in overweight women.

Pelvic Floor Muscle Training (PFMT)

Urethral closure is maintained by an adequate support provided by the endopelvic fascia and the tonic contraction of the levator ani muscles. When properly carried out, PFMT restores the ability to contract these muscles in a timed and coordinated way and thus improves or restores continence [33]. A systematic review of 12 trials (involving 672 women) showed better continence-specific quality of life, fewer incontinence episodes per day and less leakage on pad test in women who practiced PFMT compared to controls [34]. A specialist physiotherapist and a motivated woman are needed to obtain good results with PFMT. PFMT could be taught in individual or in group sessions. A Cochrane review which compared several PFMT approaches for SUI found that regular supervision (weekly) for three months combined with group sessions contribute to the success of PFMT; with up to 90% of women reported improvement [35]. NICE recommend 8 contractions, 3 times a day for 3 months[3]. Electrical stimulation and/or biofeedback should be considered for women who cannot actively contract pelvic floor muscles to aid motivation and adherence to therapy [3].

Continence Pessary

Vaginal pessaries are one of the oldest medical devices and have been used for centuries as a conservative treatment of POP [36] and, more recently, for SUI [37]. Incontinence pessaries are silicone or rubber devices that are placed vaginally. They are designed to support the urethra and bladder wall, increase urethral length, and provide gentle compression of the urethra against the pubic bone. This structural arrangement reduces and often prevents leakage when intra-abdominal pressure increases and can prevent SUI [38,39]. From this position, an incontinence pessary supports the urethrovesical junction in the same way a vaginal sling implanted surgically would [40].

Vaginal continence pessaries are effective at managing SUI, with success rates of 55-62% [41,42], if they are fit properly and managed by frequent removals and four to six monthly follow up. They can be considered among first line of conservative treatment of SUI associated with exercise and increased intra-abdominal pressure. Satisfaction rate with pessary use is high [43], and, if any, only minor complications occur, with vaginal discharge being the most common complaint [44].

Medication (Duloxetine)

Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor. Serotonin and norepinephrine promote urine storage by relaxing the bladder and increasing sphincter resistance [45]. Three large multicentre, double-blind, placebo-controlled trials investigated the efficacy of duloxetine to treat SUI. More than 1635 women in five different continents were included in these trials. The trials demonstrated that duloxetine can decrease the frequency of incontinence episodes by up to 50% compared to placebo. However, the high rate of treatment discontinuation (up to 22%) due to adverse effects was consistent in all three trials; nausea was the most common adverse effect [45]. Duloxetine was approved by the European Medicines Agency (EMA) to treat SUI in 2004. Duloxetine (Yentreve ®) is available for the management of moderate to severe SUI, the recommended dose is 40mg twice daily.

Local vaginal oestrogen therapy

In women who have gone through the menopause, low oestrogen levels may contribute to urinary incontinence. A 2021 Cochrane review found 34 trials including more than 19,000 women of whom over 9000 received local oestrogen. The review found a significant improvement in SUI in women who received local (vaginal) oestrogen compared to placebo [46].

Management after failed conservative therapy

In those women who fail first line conservative management, onward referral to specialist care is advised for consideration of surgical therapy [3]. Cystoscopy and imaging of the lower urinary tract (ultrasound/MRI) are not necessarily indicated in the evaluation of women considering surgical therapy for SUI who are otherwise healthy and have a normal urinalysis [3]. Undertaking these investigations are at the direction of the lead care provider. Further evaluation (cystoscopy/imaging) should be reserved for women in whom bladder pathology is suspected based on history or concerning findings on physical exam or urinalysis [47]. In particular, cystoscopy is recommended in [48]:

- All women with macroscopic haematuria
- Women with asymptomatic microscopic haematuria older than 40 years
- Women with symptomatic microscopic haematuria in the absence of urinary tract infection

The recommended definition of microscopic haematuria is three or more red blood cells per high-power microscopic field from two of three properly collected urinalysis specimens [48].

A cystoscopy should also be performed in women in whom there is a concern for structural lower urinary tract abnormalities [47].

Clinical Practice

Initial (conservative) Management

- At the initial clinical assessment, categorise the woman's urinary incontinence as SUI, mixed urinary incontinence or urgency urinary incontinence/overactive bladder. Direct treatment based on this diagnosis. In mixed urinary incontinence, direct treatment towards the predominant symptom.
- If the woman has uncomplicated SUI, or SUI is the predominant symptom in primary mixed urinary incontinence, conservative therapy is recommended. Lifestyle interventions including cessation of smoking and reduction of excessive fluid intake should be advised. Weight loss should be recommended if the woman has a body mass index of 30 kg/m2 or more.
- A referral for PFMT under the supervision of a specialist physiotherapist is recommended as a first line treatment. Eight contractions, three times per day for three months is the minimum recommended duration of treatment.
- A personalised home exercise programme should be devised based on the objective assessment completed by the specialist physiotherapist.
- Continence pessaries are effective at managing SUI if they are fit properly and managed by frequent removals and four to six monthly follow up.
- SSRI (duloxetine) may be considered as a conservative option for SUI.
- Local vaginal oestrogen therapy (unless otherwise contraindicated) may be offered to women with vaginal atrophy and SUI.
- Initial assessment, history and clinical examination as well as basic investigations and instigation of lifestyle measures, and referral for specialist physiotherapy should be commenced in the primary care setting.

Management after failed conservative therapy

- If first line conservative therapy fails, referral for specialist care is recommended.
- Routine cystoscopy or imaging are not necessarily indicated in the assessment of women with uncomplicated SUI

Recommendations

8. We recommend that all women should be offered non-surgical therapy as first line treatment of SUI. Lifestyle modification (fluid restriction, smoking cessation), weight loss, continence pessaries, pharmacological agents (duloxetine) and local vaginal oestrogen therapy are conservative options for SUI. Completion of a course of pelvic floor muscle training with a specialist physiotherapist, is recommended prior to surgery for all women with SUI and can be delivered in the primary care setting prior to referral to specialist.
9. We recommend that neither cystoscopy nor imaging are indicated as part of the primary evaluation of SUI, unless there is concern about urinary tract anomalies.

Clinical Question 2.5: **How is stress urinary incontinence managed surgically?**

Where conservative management of SUI is suboptimal or unsuccessful, surgical management can be considered.

Evidence Statement:

There are more than 200 procedures for SUI described in literature. NICE recommends four types of procedures for SUI [3]:

1. Retropubic mid-urethral sling with synthetic mesh,
2. Colposuspension (open or laparoscopic),
3. Autologous fascial sling and
4. Urethral bulking agents

These procedures are discussed below. Anterior colporrhaphy, needle suspension, paravaginal defect repair, porcine dermis slings and Marshall-Marchetti-Krantz procedures should not be performed to treat SUI [49].

Mid-urethral sling with synthetic mesh

When the mid-urethral sling (MUS) was introduced in the late 1990s, transvaginal midurethral mesh tapes were rapidly adopted because they were thought to be less invasive and have lower associated morbidity; this despite the lack of long-term data. Safety concerns have since been raised about midurethral mesh tapes for SUI. Various national reports have been published, including the Independent Medicines and Medical Devices Safety (IMMDS) Review Report [50], the Use of Uro-Gynaecological Mesh in Surgical Procedures in Ireland [51] and the Scottish Independent Review and the Australian Transvaginal Mesh Report [52]. There are reported serious complications such as erosion and shrinkage which are not rare [53]. To this end, a period of high vigilance restriction is in place regarding use of vaginal mesh in Ireland.

Although currently suspended, it is expected that going forward, in order to reduce mesh related complications, a low weight, macroporous, inert, monofilament mesh with elasticity between 20 and 35% should be used [54]. All tapes for synthetic MUS should therefore be made of a type 1 mesh.

Retropubic tapes

a) Bottom-up approach:

This was the original tension free vaginal tape (TVT) procedure described by Ulmsten in 1996. More than 100,000 TVT procedures have been performed worldwide. The tape is a synthetic, polypropylene, monofilamentous mesh with a pore size of 75-150 mm (type 1 mesh) inserted via a small suburethral incision, blindly guided into the retropubic space using two trocars, and exits through two small skin incisions above the pubic rami. The tape is left tension free underneath the urethra. The main complication is bladder injury, however, in most cases it has no long-term effects if recognised at the time and the trocar repositioned [55]. It is advisable to perform a cystoscopy to exclude bladder perforation. A Cochrane Systemic Review of retropubic slings reported a subjective cure rate of 85% and an objective cure rate of 92% at 12 months [56]. Complications included infection, bleeding, pain, bladder perforation (4.7%), tape erosion (0.7%), voiding dysfunction (2.2%) and de novo urgency symptoms (10.3%). Bowel injury rates are reported as 0.04% [56]. This is a rare but potentially fatal complication of retropubic tapes.

b) Top-down approach:

Retropubic tapes can also be introduced via a Top-down approach [57], however this technique is no longer recommended by NICE [3]. This is supported by the Cochrane review on retropubic slings which evaluated both approaches and found the bottom up approach to be superior. They reported a lower cure rate at 12 months for Top down when compared to bottom up approach (subjective cure rate of 77% (RR 1.10, 95% CI 1.01-1.20), and objective cure rate of 87% (RR 1.06, 95% CI 1.01 to 1.11)), as well as significantly higher rates of bladder perforation 8.5% (RR 0.55, 95% CI 0.31-0.98), tape erosion 3.5% (RR 0.27, 95% CI 0.08-0.95), and voiding dysfunction (RR 0.40, 95% CI 0.18-0.90) [56]. In light of this evidence, a top-down approach is not recommended.

Transobturator tapes

A transobturator approach may be considered where there is a specific clinical contraindication to a retropubic approach (for example, previous pelvic procedures or radiotherapy). Transobturator approach was introduced by DeLorme in 2001 with a view to decreasing the risk associated with the passage of trocars in the retropubic space, especially the risk of bladder or bowel injury. This was an outside-in procedure (TOT). Subsequently an inside-out procedure (TVT-O) was introduced by de Leval. There is a lower incidence of bladder and bowel injury with the transobturator approach, however, the incidence of vaginal perforations or erosions and groin pain are reported to be higher than the retropubic approach [56].

Retropubic vs Transobturator approach

Debate persists about the efficacy of transobturator (TOT) versus retropubic (TVT) MUS. The AUA, EAU and International Consultation of Incontinence (ICI) do not prefer TVT over TOT approach and have stated that they have equivalent outcomes with insufficient evidence to draw conclusions about the long-term efficacy of TVT versus TOT[58]. Furthermore, a systematic review and meta-analysis comparing TOT and TVT MUS found no difference in subjective cure rate at 2-12 months (OR 0.85; 95% CI 0.60-1.21)[59].

However, several studies have reported different long-term efficacies of TVT as compared to TOT. Kenton *et al.* showed that the cure rate was 7.9% greater in the TVT group than in the TOT group 5 years after surgery[60]. One meta-analysis reported that TVT had a better cure rate than TOT in a general cohort of women with SUI during a follow-up of at least 1 year[61]. A critical issue, however, is that such differences in cure rates are minimal and marginally clinically relevant[62]. The AUA acknowledges the lack of data, but has stated that preliminary data appear to favour the durability of TVT. Although the EAU found that while TVT and TOT had equivalent patient-reported outcomes after 5 years, TVT had higher objective and subjective cure rates after 8 years [60].

Groin pain is a specific complication of the transobturator approach, and estimated rates vary from 9% to 12% [56]. Other complications include infection, bleeding, pain, tape erosion (1.3-6%), voiding dysfunction (4%), and de novo urgency symptoms (7%)[56]. However, the greatest problem with obturator tapes is the difficulty of complete removal, which is hampered by their placement deep in the obturator foramen, requiring dissection of the groin [63]. In the largest series of vaginal mesh removals for all indications, the commonest type of mesh removed was the obturator tape for incontinence and the removal of these meshes also had the highest complication rates [63].

In the 2019 NICE guideline on the management of UI [3], the advice is more directive: 'do not offer a transobturator approach unless there are specific clinical circumstances (for example, multiple previous abdominal procedures) in which the retropubic approach should be avoided'. These recommendations were made in light of the above risks associated with TOT along with a systemic review that showed that TOT was worse than TVT in terms of subjective outcomes 1 year after surgery [64].

Colposuspension (open or laparoscopic)

Open

The Burch colposuspension was first described in 1961 [65]. It involves suturing the retropubic paravesical tissues to the ileopectineal ligament of the pelvic sidewall and is usually performed through a low Pfannenstiel incision. Colposuspension has the longest follow-up data of all operations for SUI.

A Cochrane review of open colposuspension [66] evaluated 53 trials involving 5244 women. Overall cure rates ranged from 85% to 90% within the first 12 months, falling to 70% at five years. Complications include wound infection (7%), UTI (32%), bleeding, pain, bladder injury (2%), deep vein thrombosis (2%), de novo detrusor overactivity (13%), voiding difficulties, incisional hernia (2%) and injury to abdominal structures [56,67]. The rate of developing post-operative pelvic organ prolapse in the longer-term is significantly higher at 9%, compared to 0.5% for the TVT (RR 8.18; 95% CI 1.96-34.19)[66]. It has been reported in up to 25% of women.

Other colposuspension procedures such as the Marshall-Marchetti-Kranz and the paravaginal defect repair are no longer recommended in the surgical treatment of SUI [3,49]

Open colposuspension versus synthetic midurethral tapes

A Cochrane meta-analysis of five trials comparing the TVT and open colposuspension found no difference in subjective cure at 12 months (RR 0.88; 95% CI 0.67-1.16). Two trials performed follow-up at 2 years, again these did not show any significant difference between the TVT and open colposuspension groups (RR 1.11, 95% CI 0.91-1.34), neither did follow-up of the same cohort at 5 years (RR 0.91, 95% CI 0.74-1.12) (9, 17, 18). Further meta-analysis for objective cure also found no difference within 1 year (RR 1.21; 95% CI 0.84-1.75), 1-5 years (RR 1.12; 95% CI 0.82-1.54) and more than 5 years (RR 0.70; 95% CI 0.30-1.64) [68,69]

Laparoscopic colposuspension

The laparoscopic procedure also inserts sutures from the retropubic paravesical tissues into the ileopectineal ligaments. It allows the option to perform the procedure by the transperitoneal or extraperitoneal route, using mesh, staples or a variety of sutures and to vary the site of the anchor. The laparoscopic procedure requires the surgeon to have advanced laparoscopic suturing skills. Hence, NICE guidelines state that laparoscopic colposuspension should be undertaken only by an experienced laparoscopic surgeon, working in a multidisciplinary team, with expertise in the assessment and treatment of urinary incontinence. Depending on the skill and experience of the surgeon, operating time for the laparoscopic approach is typically longer than for the open procedure. However, duration of hospital stay is shorter, with less perioperative complications (12%), and postoperative pain [70]. As with open colposuspension, other complications include de novo detrusor overactivity (11%), voiding difficulties (9%), and new or recurrent POP (11%).

Laparoscopic colposuspension versus synthetic MUS

A Cochrane review compared laparoscopic colposuspension to the TVT [70]. There was no significant difference in subjective cure rates (RR 0.91, 95% CI 0.80-1.02) at 18 months or at long-term follow-up of 4-8 years (RR 1.18, 95% CI 0.36-3.81).

Further analysis showed there to be no difference in perioperative complications, de novo detrusor overactivity or voiding dysfunction. The procedural costs appeared to be similar, but laparoscopy had a longer operating time, duration of hospital stay, and recovery time.

Laparoscopic colposuspension versus open colposuspension

To date, the majority of randomised trials comparing laparoscopic colposuspension with MUS procedures and open colposuspension have been underpowered. Subsequent metanalysis of subjective cure found there to be no significant difference between laparoscopic and open colposuspension at 12 months (RR 0.97; 95% CI 0.79-1.18). At 1-5 years there was a trend towards favouring open colposuspension, but this was not statistically significant (RR 0.88; 95% CI 0.75-1.03) [70].

One longitudinal cohort study has reported on the 10 year outcomes of laparoscopic versus open colposuspension and found no difference in subjective cure rates at six months (laparoscopic 71%, open 67%, $p = 0.669$), two years (laparoscopic 58%, open 50%, $p = 0.364$), and 10 years (laparoscopic 48%, open 32%, $p = 0.307$) [71].

Urethral bulking agents

The injection of bulking agents into the urethral submucosa is designed to create artificial urethral cushions that can improve urethral coaptation and hence restore continence[72]. Typically, the fluid is injected directly into the submucosa of the proximal or mid-urethra. The procedure can be performed under local or general anaesthesia. The ideal agent for injection should be long lasting, hypoallergenic, non-migratory and should cause the least inflammatory response[72]. The agent can be made of silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer [73]. Bulking with collagen is no longer available. Bulking agents are effective and safe first-line treatment option for women with SUI providing durable outcomes at 7 years[74]. Repeat injections have been shown to be safe in those in whom efficacy deteriorates over time[75,76].

Objective cure ranges from 48% to 59%. Complications are usually transient and include dysuria 90%, haematuria 58%, frequency 74%, acute retention 11% and UTI 6% [3]. Abscess formation has been reported. Despite its minimally invasive and “low-risk” nature, urethral bulking agents are not without complications. Generally, the incidence of complications is lower for bulking agents when compared with more invasive surgical treatment alternatives of female SUI. The majority of complications are mild, transient and do not warrant additional invasive treatment[77]. Furthermore, prior urethral bulking does not seem to negatively influence outcomes if future anti-incontinence surgery is needed [77,78].

Bulking agents versus sling/colposuspension

The cure rate from bulking agents is inferior to synthetic MUS procedures [3]. Bulking agents are usually selected by women who have other co-morbidities or who wish to have a less invasive treatment with the understanding that the chance of cure is lower than with MUS or colposuspension. There is a role for bulking agents in women who have had a MUS and have a well-supported urethra. Studies have demonstrated good outcomes and low complication rates [79]. It is therefore logical to employ a bulking agent in this situation [76].

Autologous fascial slings (AFS)

Currently, the only biological material recommended by NICE for use in SUI surgery is AFS [3]. While the rectus fascial sling has been traditionally used in the UK, some centres in the USA now use tensor fascia lata. This is especially useful in women with elevated body mass index and complicated histories of abdominal surgery. Some authors have found tensor fascia lata to be less challenging, with reduced perioperative and long-term complications, without compromising functional outcomes [80].

Aldridge Sling

Use of the first autologous sling was described by Aldridge in 1942 [81]. This is performed through a combined abdominal and vaginal approach. A suburethral incision is made and a plane dissected from either side along the retropubic space to the pubic crest. If the tissue comes from the rectus sheath, a curved clamp is passed along the now dissected retropubic space, the sheath grasped abdominally and pulled down underneath the urethra. The rectus sheath sling from either side is then sutured together underneath the urethra and the incisions closed.

'Sling on a string'

Newer AFS techniques were developed to address concerns about surgical morbidity, operative time and cosmetic results of slings [82]. The 'sling on a string' (SOAS) is one example. These techniques are tension free and placed at the mid urethra. They have much lower morbidity and rates of urinary retention [83]. The SOAS technique harvests a shorter length of the sling (8-10 cm), thus requiring a smaller skin incision with less fascial dissection and morbidity. The sling is suspended from the rectus fascia like a hammock [83]. The suture used to anchor the SOAS to the rectus fascia varies between surgeons; some prefer to use absorbable sutures, while others prefer nonabsorbable sutures[84].

An RCT comparing sling techniques found the SOAS technique to be as effective as the traditional longer sling, with better short-term sequelae. SOAS was quicker, less painful and associated with fewer hospital readmission [83].

Continence rates vary from 87-92% for autologous slings [3]. Reported complications include sling failure, haemorrhage, infection (6%), persistent thigh pain (11%), POP (1%), voiding dysfunction (4-7%), UTI (27%), and lower extremity neuropathy[3].

Autologous slings versus synthetic MUS

Autologous slings are equal to synthetic slings in terms of efficacy in the short term (RR 0.97, 95% CI 0.78-1.20), and medium to long-term (RR 1.23, 95% CI 0.91-1.66). However minimally invasive synthetic slings have a shorter operating time, fewer perioperative complications apart from bladder perforation, less voiding dysfunction and de novo detrusor overactivity [85].

Conclusion

SUI is a common condition affecting one in ten women over the age of 60 years. A wide range of surgical procedures have been described for the treatment of SUI, including MUS procedures with fascia or mesh, laparoscopic and open suspension of the bladder neck and bulking agents. The choice of operation is dependent on surgical skill and training, resources and an individual woman's preference. Historically, new surgical procedures for the treatment of SUI have been quickly adopted into clinical practice, often without a robust evidence base. Given the emerging mesh complications of recent years, caution is advised when considering changing practice outside of a research context without long-term follow up data.

Clinical Practice

If conservative, non-surgical management for SUI does not provide the desired outcome, and the woman wishes to consider a surgical procedure, a clear, unbiased and informed approach is necessary. The option of doing nothing should also be offered and documented within an informed consent approach.

There is public concern about the use of mesh procedures. For all of the procedures recommended in this section, including non-mesh procedures, there is evidence of benefit but limited evidence on the long-term adverse effects. For mesh procedures in particular, the true prevalence of long-term complications is unknown.

If a woman is considering a surgical procedure for SUI, she should be counselled about all surgical options available (see Appendix 8). Discussion of these options with the woman should be carried out by the incontinence specialist responsible for carrying out the surgical procedure. Details of the discussion should be documented in the woman's notes and should include:

- A procedure description and summary of the benefits and risks of all appropriate surgical treatment options for SUI whether or not they are available locally
- A full discussion about the uncertainties around the long-term success rates and potential adverse effects for all procedures, particularly those involving the implantation of mesh materials
- An explanation of the differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions, return to normal activities and expected recovery period is required
- Consider any social or psychological factors that may affect the woman's decision and consider risk factors she may have that will impact her bladder function in the long-term including smoking, obesity, menopausal status and the presence of overactive bladder symptoms.

Informed Consent

Fully informed consent is necessary before proceeding with any surgical intervention for SUI. This involves a detailed discussion on the procedure, and any surgical alternatives including doing nothing. Documentation of having undergone or having been offered conservative therapy is recommended.

For any procedure involving the use of a MUS, the National "Mid Urethral Sling Mesh Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women. Patient Information Booklet and Consent Pack" should be used. These are currently under development and due to be published in 2023.

This information booklet includes a detailed description of the procedure and the intended benefits, as well as advice on pre-surgical preparation. Alternative surgical procedures are described. A detailed list of possible surgical complications is presented beside a description of the rate of incidence of such complications.

Following discussion with the incontinence specialist responsible for the surgical procedure, the consent is initially obtained in clinic by the assessing doctor to indicate that a woman wishes to proceed with this operation and is happy with the information and explanation provided. This form documents that alternative options have been discussed and that further conservative therapy is declined. The booklet is then given to the woman to take home so she has access to information at all times. When the woman is admitted for surgery consent will once again be sought, confirming that she still wishes to proceed with surgery and that all her questions have been answered to her satisfaction. This pack also carries a form that confirms the woman's consent to her details being recorded and sent to the Irish National Register of Pelvic Floor Implants site https://www.hpra.ie/homepage/medical-devices/special-topics/vaginal-mesh-implants.

It may also be useful to record and explore the expected outcome of treatment from the woman's perspective in order to inform discussion around expectations and what can or cannot be expected as a result of surgical intervention.

NICE recommends three types of procedures for SUI: retropubic MUS procedures, colposuspension and autologous fascial sling [4]. Consider urethral bulking agents to manage SUI if alternative surgical procedures are not suitable for and/or acceptable to the woman [4].

Surgical Options for the Treatment of SUI

- Urethral bulking agents
- Midurethral slings (MUS)
- Colposuspension (open or laparoscopic/robotic)
- Autologous fascia pubovaginal slings

Urethral bulking agents

- Consider urethral bulking agents to manage SUI if alternative surgical procedures are not suitable for or acceptable to the woman.
- Explain that these are permanent injectable materials, that repeat injections may be required and that they may not resolve incontinence.
- There is limited evidence on long term effectiveness and adverse events. However, to date, evidence that prior urethral bulking negatively influences outcomes if future anti-incontinence surgery is needed does not exist.
- The woman should be counselled about the type of injection material that is used and the potential problems that may occur.
- Providers must ensure that data on surgical procedures for SUI that involve the use of an implant or of an injectable material, are recorded in a national registry – https://www.hpra.ie/homepage/medical-devices/special-topics/vaginal-mesh-implants.
- If the woman's chosen procedure for SUI is not available from the consulting surgeon, refer her to an alternative surgeon.

Synthetic mid-urethral sling procedures

- When offering a retropubic MUS, advise the woman that it is a permanent implant and complete removal might not be possible. For any procedure involving the use of a MUS, the National "Mid Urethral Sling Mesh Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women. Patient Information Booklet and Consent Pack" is recommended. These are currently under development and due to be published in 2023.

- If a retropubic MUS is inserted, record the details of the surgical implant used, including its name, manufacturer, date of insertion, and the surgeon's name and contact details. The procedure should be notified to the HPRA and National Register of Pelvic Floor Implants at https://www.hpra.ie/homepage/medical-devices/special-topics/vaginal-mesh-implants.
- A type 1 macroporous coloured polypropylene mesh is recommended.
- A transobturator approach may be considered where there is a specific clinical contraindication to a retropubic approach (for example, previous pelvic procedures or radiotherapy) and the woman must be advised of the increased risk of groin pain, and that removal may be extremely complicated or may not be possible.
- 'Top-down' retropubic MUS, TVT-O slings, and single-incision sub-urethral short mesh slings should not be used, and anterior colporrhaphy, needle suspension, paravaginal defect repair, porcine dermis slings and Marshall-Marchetti-Krantz procedures should not be performed to treat SUI.

Autologous fascia pubovaginal slings

- This involves the placing of autologous fascia lata or rectus fascia at the level of the midurethra.
- Success rates vary between 87% and 92% at 3-15 year follow up [86 87]
- For women who choose this approach after full counselling around all options, or for other indications, this is an acceptable option for the management of SUI, taking into consideration the increased morbidity of harvesting the fascia[88 89].
- There is no role for use of other substitutes such as porcine dermis or cadaveric fascia due to their inferior results.

Colposuspension

- This type of surgery can be considered in women undergoing concomitant open or minimally invasive abdominal-pelvic surgery. This can also be considered in women who want to avoid morbidity related to harvesting of fascia or who want to avoid the use of mesh.
- Data suggests that the colposuspension may be inferior to fascial sling in most efficacy related outcomes.

Follow-up after surgery

- All women should be offered a follow-up appointment with their incontinence specialist who carried out the procedure within 3 months of the procedure.
- Details of the surgical recovery and symptom resolution should be recorded. A vaginal examination describing any tender areas, suture or mesh exposure should be documented.

Collecting data on surgery and surgical complications

- Ask women having surgery for SUI that involves mesh or injectable products, or who have experienced complications related to such surgery, for their consent to enter their data in a national register. Offer each woman a copy of her data.
- Providers must ensure that hospital and consultant identifiers data are recorded in a National Registry of Surgery for Urinary Incontinence that involves mesh or any other implant at https://www.hpra.ie/homepage/medical-devices/special-topics/vaginal-mesh-implants.

Organisation of specialist services

- All surgeons or departments that perform any surgery for SUI should record all procedures in an electronic database. Details of the date, consultant, and type of procedure should be recorded. Any mesh or injectable material, including the product identifier, manufacturer and identification codes must be recorded.
- Details and dates of investigations or procedures relating to surgical complications or adverse events should be recorded.
- All procedures involving the use of mesh or an injectable agent should be reported to the National Register of Pelvic Floor Implants using the notification form (see https://www.hpra.ie/ homepage/ medical-devices/special-topics/vaginal-mesh-implants) after a woman has given written informed consent for these details to be recorded and saved on the Register.
- Any complication arising from these procedures must be notified to the HPRA (see Appendix 7) and to the National Register of Pelvic Floor Implants. This register will ensure that follow-up data are collected on adverse events, and both suspected and confirmed mesh-related complications. This register should report annually and be quality assured.

Local Multi-Disciplinary Teams

Local multidisciplinary teams (MDTs) for women with primary SUI should:

- review the proposed treatment for all women considering MUS or mesh implant procedures for primary SUI
- review the proposed management for women with primary SUI if input from a wider range of healthcare professionals is needed
- work within an established clinical network that has access to a regional MD

Local MDTs for women with primary SUI should include:

- At least 2 consultants with experience in managing urinary incontinence in women
- A urogynaecology, urology or continence specialist nurse
- A pelvic floor specialist physiotherapist
- Expert advice from a colorectal surgeon, urologist, urogynaecologist, pain specialist and psychologist or psychiatrist can be sought from the MDT as required
- Members of the local MDT should attend all MDT meetings that involve discussion of women under their care.

Recommendations

10. We recommend that women seeking help with SUI should be fully informed regarding treatment options available to them, including the potential risks and benefits to enable them to decide which course of treatment they wish to proceed with.
11. Women with SUI or stress-predominant mixed urinary incontinence who are considering surgery should be offered the option of no further treatment, continuing with pelvic floor physiotherapy, non-surgical options (e.g., continence pessary) and surgical treatment.
12. We recommend that women undergoing surgery for SUI should be fully informed on all surgical options available to them and counselled on associated benefits and potential risks of each surgery. When the choice of surgery involves a Mid-Urethral Sling (MUS), the HSE's Mid Urethral Sling Mesh Procedure for the Surgical Treatment of Stress Urinary Incontinence information and Consent should be used.
13. We recommend that details of all surgical procedures using a mesh, bulking agent or other implant for the treatment of SUI are registered with the HPRA and recorded on the National Register of Pelvic Floor Implants. Reporting of complications via HPRA is linked to the register.
14. We recommend that surgery for SUI should only be undertaken by appropriately trained surgeons who undertake such operations regularly, and who work within a Multidisciplinary Team (MDT) where all women undergoing surgery are discussed and treatment pathways agreed by the MDT.
15. We suggest that mesh implants should only be considered after all options for conservative and non-mesh surgery have been discussed. We suggest that Incision Slings and TVT-O should not be used. We suggest retropubic slings should be used for uncomplicated SUI and Trans-Obturator Tapes should only be considered in women with a high risk of bowel or other injury using the retropubic route.

Chapter 3: Development of Clinical Practice Guideline

3.1 Literature search strategy

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

Medline, EMBASE and the Cochrane Database of Systematic Reviews were searched using terms relating to "stress urinary incontinence". Searches were limited to humans and restricted to the titles of English language articles published between 1961-2022. Reference lists from key papers were searched by hand. Relevant meta-analyses, systematic reviews, intervention and observational studies were reviewed.

International guidelines were reviewed including the National Institute for Health and Care Excellence (NICE) Guideline 2019, European Association of Urology (EAU) Guideline 2018, and the American Urological Association (AUA) Guideline 2017. The 6th International Consultation on Incontinence (ICI) 2017, was also used to inform this Guideline.

NICE Guideline 2019, EAU Guideline 2018, the AUA Guideline 2017, along with Cochrane reviews provided outcome data from individual randomised controlled trials, study characteristics, and findings of risk of bias assessment. We cross checked the primary outcome data (cure and improvement) against primary trial reports, whereas all other data, including adverse events, were extracted verbatim from the relevant Guideline and Cochrane reviews.

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 assessment and management of SUI 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 3) as recommended by the Department of Health in the How to Develop a National Clinical Guideline manual, 2019.[12]

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

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two. Two reviewers (FS and SC) carried out the review of the relevant literature. Both were responsible for review of the final documents selected. Quality of the evidence was assessed using the GRADE approach for network meta-analysis by one reviewer (SO'S).

We initially planned to analyse data according to relevant subgroups (i.e., urodynamic or symptom based diagnosis of SUI, previous anti-incontinence surgery, co-existing vaginal prolapse, and concomitant prolapse surgery). This was not feasible however, because most trials did not provide information on these characteristics.

Specifically, when analysing the literature for surgical management of SUI in women; the quality of evidence was moderate for transobturator MUS versus retropubic MUS or transobturator MUS versus single incision slings, which were assessed by most of the included studies. The other comparisons had a limited number of studies and quality of evidence was judged to be low, or very low.

Randomised controlled trials evaluating mesh procedures were generally carried out in recent years, whereas comparative evidence for previous mainstream procedures was limited and tended to rely on older studies. Indeed, our searches identified no new trials for open or laparoscopic colposuspension compared with traditional slings or MUS. Compared with recent trials on the use of mesh procedures for SUI, older publications referring to traditional procedures tended to be of poorer reporting quality, which could have contributed to lower the evidence level for traditional procedures.

Data for the assessment of complications were sparse for all surgical procedures, particularly over the long term. There was considerable uncertainty around the estimates of effect, reflecting that in most cases the sample size was small, the event rate was low, and the study period was relatively short.

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

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.[13] 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.[14] (Appendix 4)

3.6 Future research

An important observation of the Guideline Development Process is identifying gaps in the evidence base. The current evidence base on SUI is fractured, focusing on pairwise comparisons with a lack of comparative data for all interventions, making it difficult to judge which intervention is most effective overall. Evidence from randomised controlled trials is insufficient to establish long term effectiveness and safety of surgical interventions for SUI.

Further research is needed that details adverse events that might not be common but could have an important adverse impact on women's quality of life. MUS procedures are among the most effective surgical interventions for SUI, further research must identify which complications arise from the device itself (including type of mesh material used), insertion technique, or whole procedure. This would provide women with the necessary, broad range of evidence to help them understand the benefits and harms associated with the device and guide their choice of surgery.

The assessment of long term safety and performance of mesh and non-mesh procedures would ideally require a large multicentre trial with an extended follow-up period (i.e., a minimum of five years and possibly longer). A more realistic, less expensive, option would be to promote awareness of later complications associated with mesh among health professionals, as well as more precise reporting and recording of complications in national databases and registries to generate uniform and comprehensive data on surgery for SUI.

Another challenge in current clinical practice is the lack of standardised data collection and the absence of a core outcome set for evaluation of surgery for SUI. This affects primary research and limits aggregation of data from primary studies for evidence synthesis. It is incumbent on stakeholders, incontinence related organisations, and researchers to develop core outcome sets and adverse events profile associated with surgery for SUI that are relevant to women, which will aid high quality, multicentre research.

13 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.

14 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. 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[15] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 5) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists and advocates (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. See Appendix 6 for list of CAG members.

15 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.[16]

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 each hospital group and service are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including Guideline committees are also 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 (https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/) websites 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.

16 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. Each hospital group executive and clinical management team, working with the local multidisciplinary clinical team, and reporting to the HSE, is ultimately responsible for the appropriate structured adoption and implementation of this Guideline.

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 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

Management of women with SUI will be within a multidisciplinary framework going forward, and the MDT will be responsible locally for implementation of, and adherence to this Guideline.

6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment both locally and nationally. Training of surgeons and their ongoing surgical competency and outcomes may need assessment.

In the case of this Guideline, NWIHP and the IOG will facilitate the organisation of a surgical retraining course for those who will be performing SUI surgery. Education around the management of SUI will also be organised for higher specialist trainees.

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)
- Patient perceptions

It is 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.

Geographical location within the island of Ireland and population density are highlighted as issues in relation to equity of access. Increasing evidence from reports in the literature show that optimal outcomes are often achieved by multidisciplinary teams in centres of excellence. With increasing medical sub-specialisation and the training needs of NCHDs, it is becoming increasingly difficult to provide the full range of services in smaller hospitals. The issue of centres of excellence can generate a perception of inequality in terms of service availability. While tele-medicine holds the potential to improve access to consultation, in person diagnosis and treatment for SUI is usually required and telemedicine is unlikely to provide an appropriate alternative in the foreseeable future. As well as access to transport and telemedicine, it is also important to consider providing conservative treatment and diagnostics in smaller centres e.g. the initial diagnostic work up/treatment, with follow-up/referral for subsequent treatments in the larger tertiary centres.

In the case of this Guideline, only units with the appropriate facilities and expertise to provide all levels of conservative and surgical intervention as part of an MDT as described here, will be able to implement this Guideline fully and provide surgical care to women with SUI.

NWIHP and the DOH support the implementation of this Guideline, and the Institute of Obstetricians and Gynaecologists, Royal College of Surgeons of Ireland and the Continence Foundation of Ireland support and endorse this Guideline.

6.4 Resources necessary to implement recommendations

Urinary incontinence is a potentially debilitating social problem, with significant cost implications to the individuals and the healthcare service. The estimated annual cost to the healthcare system in the UK exceeds GBP 700 million (1999/2000 GBP) while in the USA, approximately, USD 13.12 billion (1995 USD) of the total direct costs of urinary incontinence is spent on SUI alone [90-92]. In the UK an estimated more than GBP 178 million (1999/2000 GBP) is borne by women on an individual basis annually [90,93]. This constitutes a significant individual financial burden.

In Ireland there is no statutory requirement to provide products for incontinence, so each healthcare group has developed their own policy and guidelines. As a result, there is a wide variation of access to the provision of incontinence and containment products resulting in cost pressures and disproportionate distractions from best clinical practice.

NWIHP have funded extra support staff including administration staff, specialist nurses, physiotherapists, pain specialists, urogynaecologists and urologists, as part of a large project dealing with women who have had complications as a result of mesh procedures for prolapse and SUI, and the formation of two centres of excellence who will provide care for such women.

The implementation of this Guideline should be undertaken and overseen in keeping with best clinical practice and quality improvement in each hospital group. 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 women's care. 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 improvement initiatives.

Each unit should implement a systematic process of gathering information and tracking over time to achieve the objectives and recommendations of this Guideline. Outcomes of audits should be benchmarked against other units providing care to women with SUI. Implementation of the Guideline must be audited in order to ensure that the Guideline positively impacts care.

Auditable standards for this Guideline include:

1. Number of women referred to physiotherapy
2. Number of women who have successfully completed a physiotherapy programme
3. Number of women who have had a urodynamic study assessment prior to surgical intervention
4. Use of urodynamic studies in those who are not considering or being considered for surgical management
5. Completion of national consent form at time of booking and repeat consent before surgery
6. Number of women that have consented for their data to be used in National Pelvic Floor Implant Register
7. Full completion of data in National Pelvic Floor Implant Register
8. MDT discussion for all women who undergo mid-urethral sling surgery

In addition to these auditable standards the following Post-operative outcomes and adverse outcomes should be monitored and recorded:

Post-operative outcomes

a. Urinary incontinence score at 3 and 12 months (validated scale used)

b. Urinary incontinence quality of life score at 3 and 12 months (validated scale used)

c. Quality of life score (validated scale used e.g. EQ-5D, SF-36)

Adverse outcomes:

a. Damage to surrounding structures including perforations intraoperatively

b. Erosions/exposure at 12 months

c. Post-operative catheterisation for >10 days within 3 months

d. Chronic pain or discomfort at 12 months

e. Dyspareunia/impact on sexual function at 6 and 12 months

f. Overactive Bladder symptoms (new onset) within 12 months

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.[17]

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

17 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.[18]

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 becomes available it is inevitable that guideline recommendations will fall behind current evidence based clinical 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.

18 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)

AFS Autologous fascial sling

AGREE Appraisal of Guidelines for Research and Evaluation

AUA American Urological Association

BMI Body mass index

CAG Clinical Advisory Group

CFI Continence Foundation Ireland

DVT Deep vein thrombosis

EAG Expert Advisory Group

EAU European Association of Urology

GPT Guideline Programme Team

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

ISU Irish Society of Urology

IUGA International urogynacological association

MDT Multidisciplinary team

MRI Magnetic resonance imaging

MUI Mixed urinary incontinence

NCEC National Clinical Effectiveness Committee

NCEC National Clinical Effectiveness Committee

NCHD Non-consultant hospital doctor

NICE The National Institute for Health and Care Excellence

NICE National Instituite for Health and Care Excellence

NWIHP National Women and Infants Health Programme

OAB Overactive bladder

PFMT Pelvic floor muscle training

POP Pelvic organ prolapse

PPPG Policy, Procedures, Protocols and Guidelines

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

RCSI Royal College of Surgeons of Ireland

RCT Randomised controlled trial

SOAS Sling on a string

SUI Stress urinary Incontinence

TOT Transobturator tape (outside-in approach)

TVT Tension free vaginal tape

TVT-O Transobturator tape (inside-out approach)

UDS Urodynamic studies

UI Urinary incontinence

US Ultrasound

UTI Urinary tract infection

UUI Urge urinary incontinence

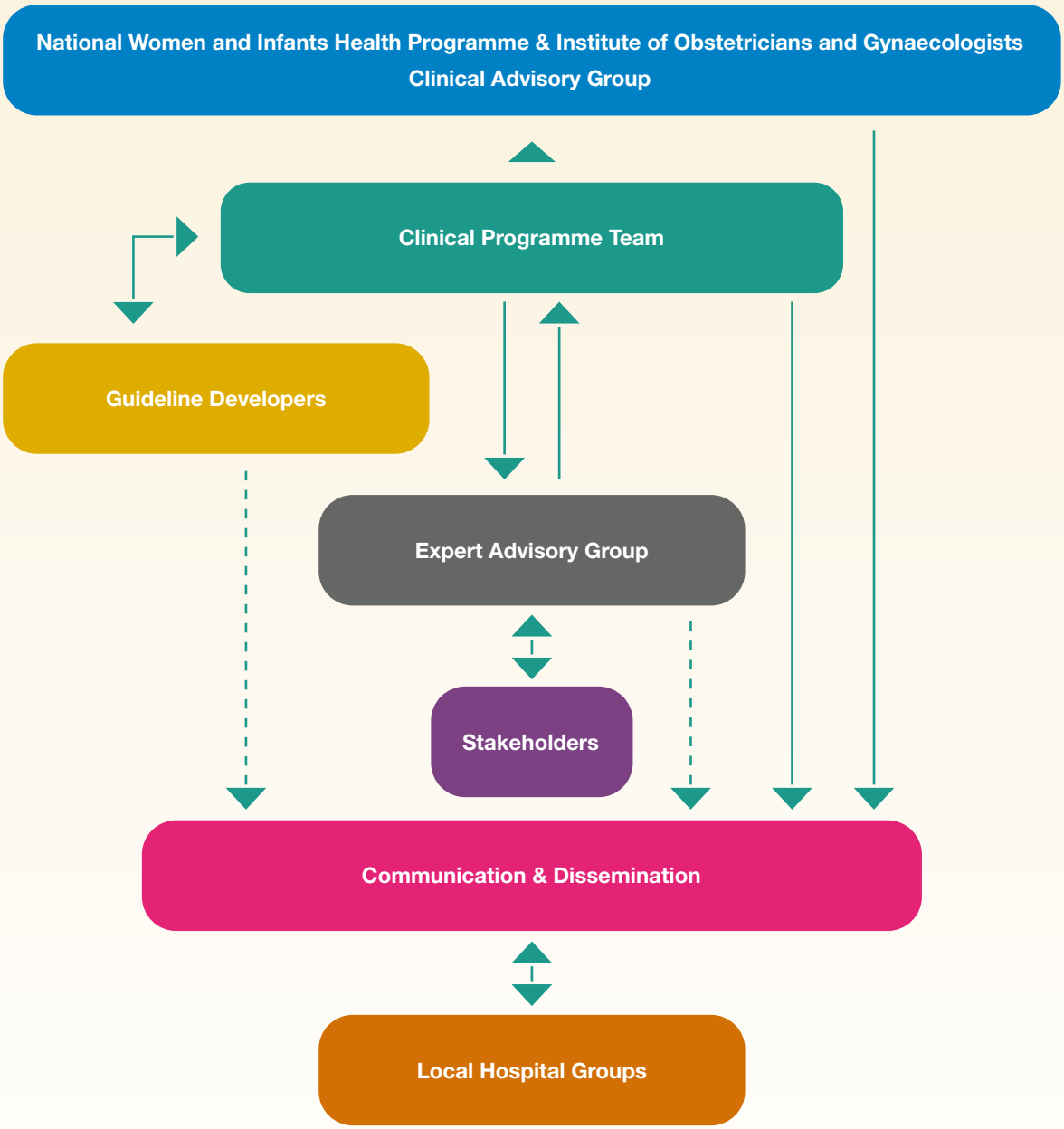
Appendix 1:
Expert Advisory Group Members 2021-

Attendee	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 Women's 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: **AGREE II checklist**[19]

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	

19 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	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarised box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
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 capitalise on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
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	
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	

Appendix 4: **Grades of Recommendation**[20]

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….
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…

20 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

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
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…
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…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
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 5: **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/

Appendix 6: **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 7: Reporting of Vaginal Mesh Implant Adverse Incidents – A Guide

Guide for Healthcare Professionals

Reporting of Vaginal Mesh Implant Adverse Incidents

The Health Products Regulatory Authority (HPRA) is the competent authority for medical devices in Ireland and maintains a medical devices vigilance system to protect the health and safety of patients, users and others. This is achieved by the evaluation of vigilance reports received from manufacturers, Healthcare Professionals and members of the public, providing information to users on the safe use of medical devices and where appropriate, evaluating an action for the market place e.g. device recall or device modification.

The following is a guide for Healthcare Professionals including consultants and general practitioners, as well as national mesh administrators to encourage the reporting of adverse incidents associated with vaginal mesh implants (for treatment of stress urinary incontinence and pelvic organ prolapse) to the HPRA.

What to report?

Specifically, in relation to vaginal mesh implants (for treatment of stress urinary incontinence and pelvic organ prolapse) the types of complications that should be reported and have been reported world-wide include (non-exhaustive list);

- Abscess/swelling/Seroma
- Acute and/or chronic pain
- Adhesion formation/Granulation tissue formation
- Allergic reaction/'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- Atypical vaginal discharge
- Bleeding including haemorrhage, or haematoma
- Constipation/defecation dysfunction
- Dyspareunia and/or pain to partner during intercourse from exposed mesh
- Excessive contraction or shrinkage of the tissue surrounding the mesh
- Haematuria
- Infection/sepsis
- Mesh contraction, shrinkage or migration
- Mesh erosion, exposure, or extrusion through the vaginal epithelium
- Nerve or vascular injury
- Neuro-muscular problems in the pelvic area

- Recurrence of prolapse/Repeat surgery for other complications
- Significant reduction in quality of life/emotional problems
- Recurrent urinary tract infections
- Vaginal scarring
- Visceral injury (e.g. Bladder, urethra and bowel perforation)
- Voiding dysfunction, incontinence, urge incontinence, recurrence of incontinence,
- urinary frequency, urinary retention, lower urinary tract obstruction
- Any other complications considered related to a vaginal mesh implant affecting patient or partner When reporting adverse incidents associated with vaginal mesh implants to the HPRA, if possible, please indicate whether the mesh was used to treat stress urinary incontinence or pelvic organ prolapse. Please also include information on the timelines involved between surgery and onset of complications and any other information that you believe would be useful

This guide is aimed specifically at Healthcare Professionals, however, members of the public are also encouraged to report adverse incidents associated with vaginal mesh implants. Receipt of adverse incident reports from Healthcare Professionals, members of the public assist the HPRA in effectively monitoring potential issues with medical devices.

Appendix 8: Treatment Options for Surgical Management of Stress Urinary Incontinence in Women[21]

Stress Urinary Incontinence (SUI) Surgical Care Pathway

Mid-urethral sling (MUS) (synthetic mesh)	GoR*
The most extensively researched option for SUI establishing efficacy and safety profile	A
As effective or more effective than colposuspension or pubovaginal sling with less perioperative and post-operative morbidity	B
Recommended surgical treatment for female SUI	C
Retropubic versus transobturator mid-urethral sling (MUS)	**GoR***
Short-term success rates are similar for retropubic and transobturator mid urethral slings	A
Transobturator MUS are quicker to perform, are associated with less blood loss, lower rates of bladder perforation and less post-operative voiding dysfunction. Most of these differences are small and the complications are manageable	A
In the medium term (>5 years) the reoperation rate for recurrent SUI is higher in the transobturator MUS group. The incidence of vaginal perforations, erosions and groin pain are also higher than with the retropubic approach.	B
Retropubic passage of the MUS is considered as the preferred approach, with transobturator reserved for those with specific contraindications for a retropubic approach	C
Pubovaginal (fascial) sling	**GoR***
Similar success rates compared to MUS with longer operating time and higher voiding dysfunction; fascial sling has lower rates of chronic pelvic pain, no risk of erosion or extrusion and higher rates of post-operative morbidity.	B
Lower rate of bladder perforation during surgery compared to MUS.	B
Fascial sling has higher patient satisfaction and treatment success compared to colposuspension.	B
Longer operating time, post-operative hospital stay (2-3 days) and recovery period than MUS.	B
Consider in women wishing to avoid mesh-related complications	-

21 **Adapted from:** *UroGynaecological Society of Australasia (UGSA) Surgical treatment of SUI pathway (2016).*

Colposuspension	GoR*
Inferior outcomes to pubovaginal slings for primary surgery and associated with less voiding dysfunction	B
Outcomes similar to synthetic MUS, however longer operating time and recovery, slower return to activities of daily living and higher risk of prolapse in the medium term.	B
When a laparoscopic approach is performed, the same technique as for open colposuspension is used and success rates are similar with less morbidity than with an open approach.	B
Lower rates of success, with higher re-treatment rates, when compared to pubovaginal slings for primary repair.	B
Consider in women wishing to avoid mesh-related complications	-
Bulking Agent	**GoR***
May be a useful option for recurrent SUI with a well-supported urethra.	B
Greater symptomatic improvement was observed with surgical treatments, although the advantage needs to be balanced against risk of intervention.	C
Consider in women wishing to avoid mesh-related complications	-
Mini-slings	
The Australian Therapeutic Goods-Administration (TGA) states that there is lack of adequate scientific evidence for it to be satisfied that the benefit to patients associated with the use of a single incision mini-sling for the treatment of SUI outweighs the risk. These products have been removed from the Australian Register of Therapeutic Goods (ARTG)	

* GoR – The Grade of Recommendation (GoR) has been derived from the 6th International Consultation on Incontinence[2]**.** The recommendations for grading follow the Oxford Centre for Evidence-Based Medicine (see Appendix 9 for explanation of Oxford system Levels of Evidence and Grades of Recommendation)

Appendix 9: Explanation of Modified Oxford system Levels of Evidence and Grades of Recommendation[22]

Oxford Centre for Evidence-Based Medicine Levels of Evidence and Grades of Recommendation

Levels of Evidence

- **Level 1 evidence** (incorporates Oxford 1a, 1b) usually involves meta-anaylsis of trials (RCTs) or a good quality randomised controlled trial, or 'all or none' studies in which no treatment is not an option, for example in vesicovaginal fistula.
- **Level 2 evidence** (incorporates Oxford 2a, 2b and 2c) includes "low" quality RCT (e.g. < 80% follow up) or metaanalysis (with homogeneity) of good quality prospective 'cohort studies'. These may include a single group when individuals who develop the condition are compared with others from within the original cohort group. There can be parallel cohorts, where those with the condition in the first group are compared with those in the second group.
- **Level 3 evidence** (incorporates Oxford 3a, 3b and 4) includes: good quality retrospective 'case-control studies' where a group of patients who have a condition are matched appropriately (e.g. for age, sex etc) with control individuals who do not have the condition. Good quality 'case series' where a complete group of patients all, with the same condition/disease/therapeutic intervention, are described, without a comparison control group.
- **Level 4 evidence** (incorporates Oxford 4) includes expert opinion were the opinion is based not on evidence but on 'first principles' (e.g. physiological or anatomical) or bench research.

Grades of Recommendation

- **Grade A** recommendation usually depends on consistent level 1 evidence and often means that the recommendation is effectively mandatory and placed within a clinical care pathway. However, there will be occasions where excellent evidence (level 1) does not lead to a Grade A recommendation, for example, if the therapy is prohibitively expensive, dangerous or unethical. Grade A recommendation can follow from Level 2 evidence. However, a Grade A recommendation needs a greater body of evidence if based on anything except Level 1 evidence.
- **Grade B** recommendation usually depends on consistent level 2 and or 3 studies, or 'majority evidence' from RCT's.
- **Grade C** recommendation usually depends on level 4 studies or 'majority evidence' from level 2/3 studies.
- **Grade D** "No recommendation possible" would be used where the evidence is inadequate or conflicting and when expert opinion is delivered without a formal analytical process.

22 Adapted from International Consultation on Incontinence 6th Edition 2017[2].