National
Women & Infants
Health Programme

National Clinical Practice Guideline

Diagnosis and Management of Pelvic Organ Prolapse

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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The National Women and Infants Health Programme (NWIHP) and the Institute of Obstetricians and Gynaecologists (IOG) Clinical Advisory Group (CAG) 2022

Version Number: Version 1.0

Publication Date: December 2022

Date for Revision: December 2025

Electronic Location:

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

https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/

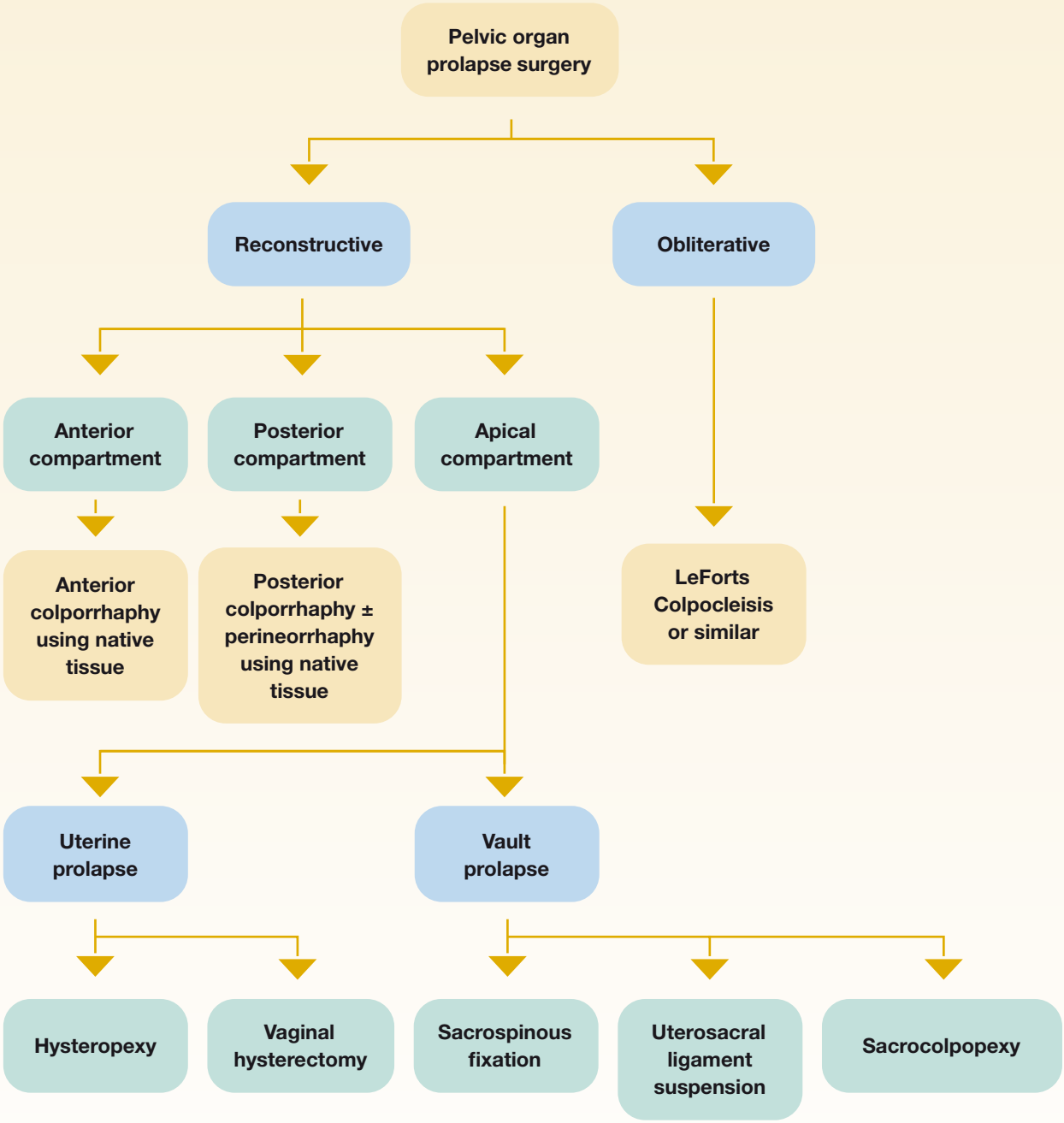
Version control

Version	Date Approved	Section numbers changed	Author

Cite this document as:
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

Table of Contents

Algorithm


Pelvic organ prolapse surgery
Reconstructive
Obliterative
Anterior compartment
Posterior compartment
Apical compartment
Anterior colporrhaphy using native tissue
Posterior colporrhaphy ± perineorrhaphy using native tissue
LeForts Colpocleisis or similar
Uterine prolapse
Vault prolapse
Hysteropexy
Vaginal hysterectomy
Sacrospinous fixation
Uterosacral ligament suspension
Sacrocolpopexy

Key Recommendations

1. We recommend that a complete medical, surgical, obstetric, and gynaecologic history should be taken from all women referred with pelvic organ prolapse. *Best practice*
2. We recommend that treatment is indicated only if prolapse is causing bothersome bulge and pressure symptoms, sexual dysfunction, lower urinary tract dysfunction, or defecatory dysfunction. *Best practice*
3. We recommend that lower urinary tract function should be assessed. This includes an evaluation for urinary incontinence and type (stress or urge) and the adequacy of bladder emptying. *Best practice*
4. We recommend that assessment of bowel function should be undertaken to determine if there is a history of straining with bowel movements, laxative use, faecal incontinence, and incomplete rectal emptying. *Best practice*
5. We recommend that symptoms of sexual dysfunction such as dyspareunia, lack of sensation, and anorgasmia should be assessed. *Best practice*
6. We recommend that a physical examination should include an abdominal examination in addition to the pelvic examination to rule out pelvic masses. *Best practice*
7. We recommend that a detailed examination of the pelvic organ prolapse should be performed digitally, or with a split speculum. *Best practice*
8. We recommend that pelvic organ prolapse should be assessed as the woman performs the Valsalva manoeuvre, repetitive coughing, or both. *Best practice*
9. We recommend that the presence and degree of prolapse should be recorded using a standardised quantification system, such as the POP-Q (Pelvic Organ Prolapse Quantification) or Baden-Walker system. *Best practice*
10. We recommend that if the findings during supine physical examination do not match the woman's reported symptoms, repeating the pelvic examination in the standing position may reveal the greatest descent of pelvic organ prolapse. *Best practice*
11. We recommend that pelvic floor muscle activity should be assessed according to a standardised format, such as the modified Oxford grading system. Hypertonicity should be noted if observed by objective assessment. *Best practice*
12. We recommend that the vaginal tissues should be assessed for atrophy. *Best practice*
13. We suggest that pelvic floor ultrasound (translabial, endovaginal, or introital) is not required in the diagnosis and assessment of pelvic organ prolapse without mesh complications. *Grade 2C*
14. We recommend that observation of symptoms alone by the woman herself for as long as she is happy with this approach is a reasonable option for women who do not wish to undergo treatment for pelvic organ prolapse. *Best practice*

15. We recommend that all women with pelvic organ prolapse should be counselled regarding lifestyle modifications. *Best practice*
16. We suggest that a referral to a specialist pelvic floor physiotherapist should be considered in all women with pelvic organ prolapse. *Best practice*
17. We suggest that a 16-week course of supervised pelvic floor muscle therapy should be considered in all women with Stage 1 or 2 POP. *Grade 2C*
18. We suggest local oestrogen should be considered for women with hypo-oestrogenic symptoms or evidence of vaginal atrophy who do not have contraindications to vaginal oestrogen. *Grade 2C*
19. We suggest that women should be offered a vaginal pessary as an alternative to surgery. *Grade 2C*
20. We recommend a pessary should be considered for a woman with symptomatic pelvic organ prolapse who wishes to become pregnant in the future. *Best practice*
21. We suggest that women in who a ring pessary has failed should be offered a Gellhorn pessary or alternative. *Grade 2C*
22. We recommend women who are offered a Gellhorn or shelf pessary, or similar, should be advised regarding the contraindication to sexual intercourse. *Best practice*
23. We suggest, if possible, women should be taught to change their pessaries independently. If a woman is unable to remove and replace her pessary, regular follow-up (such as every 3-6 months) is necessary. *Grade 2C*
24. We suggest an annual follow-up is recommended for women who are able to change their pessaries independently. *Grade 2C*
25. We suggest that treatment for pessary-related erosion should consist of removing the pessary for 2-4 weeks, local oestrogen therapy, and antimicrobials, if necessary. *Grade 2C*
26. We recommend that caregivers to patients with dementia should be made aware of the regular pessary changes needed to avoid complications. *Best practice*
27. We recommend that any decisions regarding pessary use in women with diminished mental capacity should be made in line with the HSE National Consent Policy. *Best practice*
28. We recommend that surgical management should be individualised for each woman. *Best practice*
29. We recommend that women who wish to have a procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible. *Best practice*
30. We recommend that obliterative surgery is an appropriate option for women who are older, medically unfit for other surgeries, and are sexually inactive. *Best practice*
31. We recommend that the permanent, irreversible nature of obliterative procedures should be discussed with the woman. *Best practice*
32. We recommend that women who wish to have an obliterative procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible. *Best practice*
33. We recommend that surgical management should be individualised for each woman. *Best practice*
34. We strongly recommend an anterior colporrhaphy is recommended for the treatment of isolated anterior compartment prolapse (cystocele). *Grade 1A*
35. Posterior colporrhaphy ± perineorrhaphy is strongly recommended for the treatment of posterior compartment prolapse. *Grade 1A*

36. We recommend those women with combined rectal mucosal prolapse and vaginal prolapse would benefit from colorectal and gynaecologist collaboration. *Best practice*
37. For women with a uterus, we recommend a discussion should be had to determine whether the woman wishes to have her uterus removed or retained. *Best practice*
38. We recommend women undergoing a vaginal hysterectomy should have an apical suspension performed at the same time. *Grade 1B*
39. We recommend that those women wishing to preserve their uterus should be offered a vaginal sacrospinous hysteropexy. *Best practice*
40. We strongly recommend that women with vault prolapse should be offered a sacrocolpopexy or either a vaginal sacrospinous fixation (SSF) or uterosacral ligament suspension (ULS). *Grade 1A*
41. We recommend that women wishing to undergo a sacrocolpopexy should be made aware of the risk of mesh erosion with this procedure. *Best practice*
42. We strongly recommend that women should be informed that functional and anatomical outcomes are similar between SSF and USL. *Grade 1A*
43. We recommend vaginal based native tissue repairs such as SSF or USL may be more appropriate in women with co-morbidities such as obesity or pelvic radiotherapy, or previous pelvic surgery. *Best practice*
44. We recommend that symptoms of SUI should be discussed during the initial consultation. *Best practice*
45. We recommend that concomitant continence procedures should be discussed with women with overt symptoms of SUI. *Best practice*
46. If SUI is elicited once the prolapse is reduced, we strongly recommend concomitant continence procedures should be discussed with the woman. *Grade 1A*
47. We strongly recommend that women should be counselled that a concomitant continence procedure has a higher risk of adverse events, such as bleeding, urinary tract infection, and bladder injury compared to not performing the procedure. *Grade 1A*
48. We recommend that a staged approach be discussed with all women with POP who have concomitant SUI. *Best practice*
49. If SUI is not elicited once the prolapse is reduced, we suggest the woman should be counselled that they have a low risk of developing de novo SUI. *Grade 2B*
50. We recommend women should be offered an in-person return appointment with the operating surgeon within six months of their surgery. *Best practice*
51. We recommend a vaginal examination should be performed by the surgeon at the postoperative clinic visit. *Best practice*
52. We recommend that women with recurrent symptoms and/or complications such as voiding dysfunction or mesh erosion should have access to further referral to another urogynaecologist or urologist. *Best practice*

Chapter 1: **Initiation**

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

1.1 Purpose

The purpose of this Guideline was to develop and provide a comprehensive evidence-based guidance for the management of pelvic organ prolapse.

1.2 Scope

Target Users

The Guideline is a resource or all clinicians working in General Practice, Urogynaecology, Urology, and Colorectal Surgery with an interest in the pelvic floor.

Target Population

This Guideline is targeted at women with pelvic organ prolapse, regardless of age.

1.3 Objective

To provide evidence-based recommendations for the care of women with pelvic organ prolapse as well as promoting a standardised approach nationally across all gynaecology units.

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 writing group for this Guideline included:

- Prof. Declan Keane, Consultant Obstetrician and Gynaecologist, National Maternity Hospital, Holles Street, Dublin 2
- Dr Gerard Agnew, Consultant Obstetrician and Gynaecologist, National Maternity Hospital, Holles Street, Dublin 2
- Dr Bobby O'Leary, Urogynaecology Research Fellow, National Maternity Hospital, Holles Street, Dublin 2

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 National Women and Infants Health Programme UroGynae Working Group were consulted in regard to this Guideline. Members include:

Nurse/Midwifery: Ms Linda Kelly, Advanced Midwifery Practitioner, National Maternity Hospital, Dublin.

Physiotherapy: Ms Shalini Wiseman, Physiotherapist, Cork University Maternity Hospital

Urology: Mr James Forde, Consultant Urologist, Beaumont Hospital

Urogynaecology: Members of the Continence Foundation of Ireland including

- Prof Barry O'Reilly, Consultant Obstetrician & Gynaecologist, Cork University Maternity Hospital
- Ms Orfhlaith O'Sullivan, Consultant Obstetrician & Gynaecologist, Cork University Maternity Hospital
- Prof Declan Keane, Consultant Obstetrician & Gynaecologist, National Maternity Hospital
- Dr Gerry Agnew, Consultant Obstetrician & Gynaecologist, National Maternity Hospital
- Dr Suzanne O'Sullivan, Consultant Obstetrician & Gynaecologist, Cork University Maternity Hospital

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]

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

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 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.

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

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

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

1.8 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

Many women with Pelvic organ prolapse (POP) are asymptomatic, however, for some, it may cause vaginal pressure, voiding dysfunction, defaecatory dysfunction, sexual dysfunction, all of which potentially reduce a woman's quality of life. Women have a lifetime risk of 12-13% of undergoing surgery for the treatment of POP[1], with 1-in-5 of those undergoing a repeat procedure[2].

It is expected that by 2050, up to 50% of women will experience from some degree of POP[3]. Given that 12-13% of these women will require a surgical procedure, the burden of POP on our health service – both financially and clinically – will be large. As of 2001, the cost of POP surgery in the United States was estimated as $1012 million[4], and in 2009, the cost in England was estimated as €81,030,907 [5]. These figures are only likely to increase in line with the prevalence of POP.

Pelvic organ prolapse (POP) is defined as the descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff).[6-9] Pelvic organ prolapse requires further investigation if it is causing prolapse symptoms (i.e. pressure with or without a bulge) or sexual dysfunction, or if it is disrupting normal lower urinary tract or bowel function.[6,7]

POP can have a significant impact on a woman's perception of her body image and can disrupt their intimate, work, and social interactions[10]. Rates of depression are higher in women undergoing surgery for POP than in healthy controls and these women describe an overall lower quality of life.[10,11]

Recommendations relevant to this Guideline can also be found in:

- National Clinical Practice Guideline: Assessment and Management of Stress Urinary Incontinence in women. (2022) [9]
- National Clinical Practice Guideline: Diagnosis and Management of Mesh Complications (2022) [10]

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

10 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

Introduction

POP is a common condition and multiple international management guidelines exist. The evidence base for each of these overlaps, and generally speaking the recommendations are similar across the English-speaking world. Each of the guidelines assessed for use in this Guideline are from large internationally recognised organisations, representing contemporary evidence-based practice across the world. These guidelines are from the National Institute for Clinical Evidence (NICE), United Kingdom Continence Society (UKCS), and International Continence Society (ICS) in the United Kingdom, the American College of Obstetricians and Gynaecologists (ACOG), the Australian Commission on Safety and Quality in Healthcare, and the Society of Obstetricians and Gynaecologists of Canada (SOGC). The quality of the evidence behind these varies dependent on availability in the literature, and this is noted throughout the Guideline where recommendations are graded accordingly.

Clinical Question 2.1: **How should women with suspected pelvic organ prolapse be initially investigated?**

Evidence Statement

All women with pelvic organ prolapse should be initially assessed by taking a history. This history should include an assessment of 1) lower urinary tract dysfunction, 2) bowel dysfunction, and 3) sexual dysfunction.[7] In addition to a comprehensive history, physical examination is a key component in the assessment of pelvic organ prolapse[6-9].

History

The American College of Obstetricians and Gynaecologists (ACOG), International Continence Society (ICS), National Institute for Clinical Excellence (NICE), and Australian guidelines all recommend that a complete medical, surgical, obstetric, and gynaecologic history should be taken from all women referred with POP.[6-9] In addition, the nature of vaginal bulge symptoms and the degree of bother associated with the bulge should be recorded.[6,7] Key information to elicit from the woman includes whether the protrusion is limiting physical activities or sexual function or becoming progressively worse or bothersome.[6-8]

Many women with POP on physical examination do not report symptoms of POP.[6,7] Treatment is indicated only if prolapse is causing bothersome bulge and pressure symptoms, sexual dysfunction, lower urinary tract dysfunction, or defecatory dysfunction[7-9,12,13].

The ACOG, ICS, and NICE guidelines make specific mention that lower urinary tract function should be assessed. This includes an evaluation for urinary incontinence and type (stress or urge) and the adequacy of bladder emptying.[6-8] In particular, international guidelines have highlighted the importance of voiding dysfunction, and if voiding becomes more difficult when the effects of gravity are more pronounced, such as after long periods of standing.[7,8] The ACOG, NICE, and ICS recommend evaluating whether a woman needs to splint (i.e., the need to push on or support the bulging tissue) to initiate or complete voiding.[6-8]

International guidelines are in agreement that an assessment of bowel function should be undertaken to determine if there is a history of straining with bowel movements, laxative use, faecal incontinence, and incomplete rectal emptying.[6-8] The symptom of splinting (manually supporting the perineum or vagina, typically using a pad or fingers) often is correlated with the presence of a posterior compartment defect (e.g., rectocele).[6] The ICS recommend that each woman should be assessed for symptoms of dyspareunia, coital incontinence (of urine or stool), and sexual dysfunction that is related to the prolapse.[7]

Physical examination

Some symptoms of POP overlap with that of large pelvic masses, and so the ACOG, ICS, NICE, and Australian guidelines suggest that while these masses are uncommon, all women should have a physical examination that includes an abdominal examination to rule out pelvic masses.[6-9,13] Assessment of each individual compartment is important and this can be achieved with the use of a split speculum, such as a Sims speculum. Alternatively, this examination can be performed digitally. POP may not be obvious at rest and an assessment may need to be carried out as the woman performs the Valsalva manoeuvre, repetitive coughing, or both.[6] Despite this, findings may not correlate with a woman's symptoms, and repeating the pelvic examination in the standing position may reveal the greatest descent of POP.[8]

Quantification

NICE guidelines recommend an objective quantification of POP, using a standardised quantification system, such as the POP-Q (Pelvic Organ Prolapse Quantification) or Baden-Walker system.[8] Additionally, the ACOG, ICS, and NICE guidelines recommend that pelvic floor muscle activity be assessed according to a standardised format, such as the modified Oxford grading system and that hypertonicity should be noted if observed by objective assessment.[6-8]

Atrophy

POP and vaginal atrophy are more common in postmenopausal women and the ACOG, ICS, and NICE guidelines recommend assessing vaginal tissues for atrophy.[6-8]

Ultrasonography

Pelvic floor ultrasound (translabial, endovaginal, or introital) is not required in the diagnosis and assessment of pelvic organ prolapse without mesh complications.[6,8] In general, no additional testing beyond a systematic history and physical examination is required in women with POP prior to treatment.[6]

Urine testing and urodynamics

The presence of urinary urgency or other lower urinary tract symptoms warrants at minimum a urinalysis, with culture and microscopy performed if indicated. Referral to urodynamics may be considered if there is bothersome incontinence with prolapse to the level of the hymen or greater, previous surgery, or voiding dysfunction.[6]

Clinical Practice

History

A detailed history which assesses lower urinary tract dysfunction, bowel dysfunction, and sexual dysfunction is necessary in the initial assessment of any woman with POP. This should include an evaluation for urinary incontinence and the adequacy of bladder emptying.

Physical examination

- All women with POP should have an abdominal examination in addition to the pelvic examination to rule out pelvic masses.
- POP can be assessed using a split speculum or digitally. POP should be assessed as the woman performs the Valsalva manoeuvre, repetitive coughing, or both.
- The presence and degree of POP should be recorded using a standardised quantification system, such as the POP-Q (Pelvic Organ Prolapse Quantification) system.
- If the findings during supine physical examination do not match the woman's reported symptoms, repeating the pelvic examination in the standing position may reveal the greatest descent of POP.
- Pelvic floor muscle activity should be assessed according to a standardised format, such as the modified Oxford grading system.

- The vaginal tissues should be assessed for atrophy.
- Pelvic floor ultrasound is not required in the diagnosis and assessment of pelvic organ prolapse without mesh complications.
- The presence of urinary urgency or other lower urinary tract symptoms warrants at a urinalysis, with culture and microscopy performed if indicated.
- Referral to urodynamics may be considered if there is bothersome incontinence with prolapse to the level of the hymen or greater, previous surgery, or voiding dysfunction.

Recommendations

1. We recommend that complete medical, surgical, obstetric, and gynaecologic history should be taken from all women referred with pelvic organ prolapse.
2. We recommend that treatment is indicated only if prolapse is causing bothersome bulge and pressure symptoms, sexual dysfunction, lower urinary tract dysfunction, or defaecatory dysfunction.
3. We recommend that lower urinary tract function should be assessed. This includes an evaluation for urinary incontinence and type (stress or urge) and the adequacy of bladder emptying.
4. We recommend that assessment of bowel function should be undertaken to determine if there is a history of straining with bowel movements, laxative use, faecal incontinence, and incomplete rectal emptying.
5. We recommend that symptoms of sexual dysfunction should be assessed.
6. We recommend that a physical examination should include an abdominal examination in addition to the pelvic examination to rule out pelvic masses.
7. We recommend that a detailed examination of the pelvic organ prolapse should be performed digitally, or with a split speculum.
8. We recommend that pelvic organ prolapse should be assessed as the woman performs the Valsalva manoeuvre, repetitive coughing, or both.
9. We recommend that the presence and degree of prolapse should be recorded using a standardised quantification system, such as the POP-Q (Pelvic Organ Prolapse Quantification) or Baden-Walker system.
10. We recommend that if the findings during supine physical examination do not match the woman's reported symptoms, repeating the pelvic examination in the standing position may reveal the greatest descent of pelvic organ prolapse.
11. We recommend that pelvic floor muscle activity should be assessed according to a standardised format, such as the modified Oxford grading system. Hypertonicity should be noted if observed by objective assessment.
12. We recommend that the vaginal tissues should be assessed for atrophy.
13. We suggest that Pelvic floor ultrasound (translabial, endovaginal, or introital) is not required in the diagnosis and assessment of pelvic organ prolapse without mesh complications.

Clinical Question 2.2: **What conservative management options are available for women with pelvic organ prolapse?**

Evidence Statement

Treatment of pelvic organ prolapse is entirely dependent on the woman's wishes, with a 'wait and see' approach being a perfectly reasonable option for a woman if that is her wish.[9]

Observation

Observation is a reasonable option for cases of mild prolapse in which the woman's quality of life is not affected by the prolapse, the woman does not wish for further treatment, or in a woman with multiple medical comorbidities.[6,8,9,13]

Lifestyle changes

Lifestyle changes such as weight reduction (if appropriate)[8], avoiding chronic strain (constipation, heavy lifting and chronic cough)[7], correct position for voiding and defecation, and smoking cessation should be advised to all women with POP.

Pelvic floor muscle training

Supervised pelvic floor muscle therapy with nurse/midwife continence advisors and/or physiotherapists with a special interest in the pelvic floor may be beneficial in women with POP.[6-9] Pelvic muscle training may improve symptoms or slow the progression of POP[6], though are less likely to be effective in more advanced prolapse.[7] Consider a programme of supervised PFMT for at least 16 weeks as first plan for women with symptomatic POP-Q stage 1 and 2 POP.[8] Depending on availability, these programmes can include biofeedback, pelvic floor muscle release, and educational strategies. If programme beneficial consider advising the woman to continue PFMT training.[8]

Severe POP is rare in pregnancy[14], though up to 40% of pregnant women report some degree of prolapse symptoms.[15] Supervised PFMT may be beneficial in pregnancy[16], though the evidence is weaker than in the non-pregnant population. Similarly, POP symptoms are relatively common in the postnatal period and supervised PFMT may improve symptoms of prolapse at up to one-year after delivery, though the evidence is poor[17,18]

Local oestrogen therapy

There is little evidence that local oestrogen therapy either improves or treats POP[6,7], though local oestrogen therapy may reduce irritation in a woman with evidence of vaginal atrophy[6,8] or in those with hypoestrogenic symptoms without contraindications to vaginal oestrogen therapy.[7]

Clinical Practice

- In cases of mild prolapse in which the woman's quality of life is not affected, the woman does not wish for further treatment, or in a woman with multiple medical comorbidities, observation alone may be appropriate.
- Where necessary lifestyle changes should be advised to all women with POP.
- Supervised PFMT with a specialist physio should be considered in all women with POP.
- Local oestrogen therapy should be considered for any woman with evidence of vaginal atrophy or in those with hypoestrogenic symptoms.

Recommendations

14. We recommend that observation alone is a reasonable option for women who do not wish to undergo treatment for pelvic organ prolapse.
15. We recommend that all women with pelvic organ prolapse should be counselled regarding lifestyle modifications.
16. We suggest that a referral to a specialist pelvic floor physiotherapist should be considered in all women with pelvic organ prolapse.
17. We suggest that a 16-week course of supervised pelvic floor muscle therapy should be considered in all women with Stage 1 or 2 POP.
18. We suggest local oestrogen should be considered for women with hypo-oestrogenic symptoms or evidence of vaginal atrophy without contraindications for vaginal oestrogen.

Clinical Question 2.3: **How should pessaries be utilised in the management of women with pelvic organ prolapse?**

Evidence Statement

Patient selection

The ICS, ACOG, Australian Commission on Safety and Quality in Healthcare, and NICE guidelines recommend that women be offered a vaginal pessary as an alternative to surgery.[6-9]

The United Kingdom Continence Society (UKCS) Guideline on vaginal pessaries specifically suggests that a pessary should be considered for a woman with symptomatic POP who wishes to become pregnant in the future.[19]

Most guidelines have similar suggestions, recommending that alternative therapies to pessaries in the following circumstances:[6,8,19]

- Inability to comply with regular follow-up
- Previous radiotherapy affecting the vaginal tissues
- Insufficient vaginal length or width
- Vaginal atrophy which has not responded to local oestrogen therapy

Counselling

Over 90% of women can be fitted successfully with a pessary. Studies have shown that an unsuccessful first fitting of a vaginal pessary is likely[19], and that several fittings before an appropriate size is found may be required.[20]

Typically, ring pessaries are used first, though multiple types of pessary exist, and the UKCS Guideline suggests that women may require a trial of different types.[8,19,20] Similarly, women in whom the insertion of a ring pessary has failed should be offered a Gellhorn pessary or alternative.[19] To date, no study has proven the benefit of one pessary over others.[19]

Use of a Gellhorn or shelf pessary, or similar, is a contraindication to penetrative sexual intercourse.[19] International studies have shown that pessaries are less successful in more advanced prolapse.[6,19] Although complications can occur, pessary use is a low-risk intervention that can be offered to all women who are considering treatment of POP.[6,8,9,19]

Changing pessaries

Independent change of pessaries by women themselves is safe, and both the ACOG and UKCS guidelines recommend that women independently change their pessaries, if clinically appropriate.[6,19] Annual follow-up is recommended for women who are able to change their pessaries independently.[6] If a woman is unable to remove and replace her pessary, regular follow-up (such as every 3-6 months) is recommended by the ACOG, NICE, and UKCS.[6,8,19]

Complications

Severe pessary-associated complications are uncommon, though milder adverse events such as bleeding or vaginal erosions can occur in up to 12% of women.[19] Pessaries exert pressure on the vaginal wall and may result in local devascularisation or erosion in 2-9% of women.[6]

Treatment of complications

There is little evidence base for the ideal treatment of pessary-related erosions, though the ACOG and UKCS guidelines both suggest removal of the pessary for 2-4 weeks, local oestrogen therapy, and antimicrobials, if necessary. Local oestrogen is not mandatory and resolution may occur without local oestrogen therapy.[6,19]

If problems persist despite treatment, pessaries may need to be changed more frequently or a different pessary may be required.

It is recommended by the ACOG and NICE that caregivers to women with dementia be made aware of the regular pessary changes needed to avoid complications.[6,8] A woman with dementia may require someone to support and enable them to participate in decision making around management of their POP and any decisions should be made in line with the HSE National Consent Policy[21].

Use of pessaries in pregnancy

While severe POP is rare in pregnancy[14], up to 40% of women describe some degree of prolapse symptoms in the antenatal period[15]. Pessaries are a reasonable option for treatment of symptomatic POP in pregnancy due to their low side effect profile. There is little evidence to guide the use of pessaries in pregnant women and much of what is published is at the case report level[14]. Ring pessaries are a reasonable first line option in pregnant women[14,19], with use of space-occupying pessaries reserved for cases where a ring pessary has failed[14].

If self-management is not feasible, the pessary should be regularly changed by a healthcare professional. There is no evidence to support a particular timeframe for the interval between pessary changes, thus this interval and the decision to remove the pessary prior to delivery should be individualised based on each particular case.

Clinical Practice

- Women should be offered a vaginal pessary as an alternative to surgery.
- A pessary should be considered for a woman with symptomatic POP who wishes to become pregnant in the future.
- Women should be informed that they may require several fittings before an appropriate size pessary is found.
- Women in whom a ring pessary has failed should be offered a Gellhorn pessary or alternative.
- Women who are offered a Gellhorn or shelf pessary, or similar, should be advised regarding the contraindication to sexual intercourse.
- If possible, women should be taught to change their pessaries independently.
- Annual follow-up is recommended for women who are able to change their pessaries independently.
- If a woman is unable to remove and replace her pessary, regular follow-up (such as every 3-6 months) is necessary.
- Treatment for pessary-related erosion should consist of removing the pessary for 2-4 weeks, local oestrogen therapy, and antimicrobials, if necessary.
- If problems persist despite treatment:
    - Pessaries may need to be changed more frequently
    - A different pessary may be required
- Caregivers to women with dementia should be made aware of the regular pessary changes needed to avoid complications.
- Although complications can occur, women should be reassured that pessary use is a low-risk intervention that can be offered to all women who are considering treatment of POP.
- Alternative therapies to pessaries should be considered in the following circumstances:
    - Inability to comply with regular follow-up
    - Previous radiotherapy affecting the vaginal tissues
    - Inadequate vaginal length or width
    - Vaginal atrophy which has not responded to local oestrogen therapy
- Pessaries can be used in pregnancy to treat symptomatic POP.
- Ring pessaries are a reasonable first-line option in pregnancy, with space-occupying pessaries for use as a second line.
- The timing of pessary changes and removal should be individualised in pregnancy.

Recommendations

19. We suggest that women should be offered a vaginal pessary as an alternative to surgery.
20. We recommend a pessary should be considered for a woman with symptomatic POP who wishes to become pregnant in the future. (Best practice)
21. We suggest that women in who a ring pessary has failed should be offered a Gellhorn pessary or alternative.
22. We recommend women who are offered a Gellhorn or shelf pessary, or similar, should be advised regarding the contraindication to sexual intercourse.
23. We suggest, if possible, women should be taught to change their pessaries independently. If a woman is unable to remove and replace her pessary, regular follow-up (such as every 3-6 months) is necessary.
24. We suggest an annual follow-up is recommended for women who are able to change their pessaries independently.
25. We suggest that treatment for pessary-related erosion should consist of removing the pessary for 2-4 weeks, local oestrogen therapy, and antimicrobials, if necessary.
26. We recommend that caregivers to women with diminished mental capacity should be made aware of the regular pessary changes needed to avoid complications.
27. We recommend that any decisions regarding pessary use in women with diminished mental capacity should be made in line with the HSE National Consent Policy.

Clinical Question 2.4: **What surgical management options are available for women with pelvic organ prolapse?**

Evidence Statement

The ACOG, NICE, and Australian surgical guidelines all agree that some women will opt for surgery without a trial of pessary, and that this approach is reasonable.[6,8,13] Surgery for pelvic organ prolapse can be categorised as obliterative or reconstructive.

Counselling

The NICE guidelines specify the importance of pre-operative counselling: specifically regarding the risk of recurrent prolapse, potential need for further operative procedures or pessaries after their initial surgical procedure.[8]

Choice of procedure

The ACOG, NICE, and Australian guidelines suggest an individualised approach to surgery for each woman. This approach will depend on the degree of prolapse, which compartments are affected, and the woman's own personal wishes for surgery.[6,8,13]

Consent

Women who engage with the healthcare service for management of POP have a fundamental ethical and legal right to decide what happens to their own bodies and so it is essential that valid consent is obtained for any intervention. Consent for any surgical intervention for the treatment of POP should be obtained in line with the HSE National Consent Policy[21].

Clinical Practice

- Surgical management should be individualised for each woman. The choice of procedure will depend on the degree of prolapse and which compartments are affected.
- The surgical options offered to each woman will depend on the urogynaecology surgeon's own ability to perform each procedure, and so not all procedures will be offered by all urogynaecology surgeons.
- Women who wish to have a procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible.

Recommendations

28. **We recommend that surgical management should be individualised for each woman.**
29. **We recommend that women who wish to have a procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible.**

Clinical Question 2.5: **What obliterative surgical options are available for the management of pelvic organ prolapse?**

Evidence Statement

The ACOG, NICE, and Australian surgical guidelines all agree that some women will opt for surgery without a trial of pessary, and that this approach is reasonable.[6,8,13]

Counselling

The NICE guidelines specify the importance of pre-operative counselling: specifically regarding the risk of recurrent prolapse, potential need for further operative procedures or pessaries after their initial surgical procedure.[8] Given that obliterative procedures such as these are permanent and irreversible, the ICS, NICE, and Australian guidelines make specific recommendations that women should be adequately counselled about their nature prior to surgery.[7,8,13]

Available surgeries

Multiple obliterative surgical procedures exist for the treatment of POP, and no one procedure has been shown to be superior to others[6,7,13,22]. LeFort's Colpocleisis appears frequently in the literature and is an appropriate option for women who are older, medically unfit for other surgeries, and sexually inactive[6-8,13]. While randomised controlled trials are lacking, colpocleisis is associated with high patient satisfaction in appropriately selected patients.[6,8,13,22]

Clinical Practice

- Obliterative surgery is an appropriate option for women who are older, medically unfit for other surgeries, and sexually inactive.
- Obliterative procedures such as these are permanent and irreversible.
- Women should be adequately counselled prior to embarking on these procedures.
- Women who wish to have an obliterative procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible.

Recommendations

30. **We recommend that obliterative surgery is an appropriate option for women who are older, medically unfit for other surgeries, and are sexually inactive.**
31. **We recommend that the permanent, irreversible nature of these procedures should be discussed with the woman.**
32. **We recommend that women who wish to have an obliterative procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible.**

Clinical Question 2.6: **What reconstructive surgical options are available for women with pelvic organ prolapse?**

Evidence Statement

The ACOG, NICE, and Australian surgical guidelines all agree that some women will opt for surgery without a trial of pessary, and that this approach is reasonable.[6,8,13]

Counselling

The NICE guidelines specify the importance of pre-operative counselling: specifically regarding the risk of recurrent prolapse and the potential need for further operative procedures or pessaries after their initial surgical procedure.[8]

Anterior compartment prolapse

Anterior colporrhaphy is an effective treatment for most anterior vaginal wall prolapse[6] and is recommended for the repair of anterior compartment prolapse.[6-8] Vaginally placed mesh is associated with improved anatomical and subjective outcomes when compared to native tissue repair, though has longer operating times, greater blood loss and higher rate of cystotomy, de-novo stress urinary incontinence.[23]

Posterior compartment prolapse

There is no evidence showing that superiority of mesh surgery over non-mesh surgery for posterior compartment prolapse.[6,8,24] Similarly, mesh can be associated with an increased risk of complications.[6,8] Posterior colporrhaphy without mesh insertion ± perineorrhaphy is thus recommended for the treatment of posterior compartment prolapse.[6,8,13] While evidence is limited, those women with combined rectal mucosal prolapse and vaginal prolapse may benefit from colorectal and gynaecologist collaboration.[7]

Apical compartment prolapse

The choice of procedure for repair of apical compartment prolapse is dependent on the presence of the uterus (vault vs. uterine prolapse).[8,13]

Uterine prolapse

The NICE guidelines recommend that in women with uterine prolapse, that a discussion regarding uterine sparing surgery or removal of her uterus should be had.[8]

If her uterus is to be removed, the options include vaginal hysterectomy with apical suspension or abdominal procedures including sacrocolpopexy with hysterectomy or supra-cervical hysterectomy with sacral cervicopexy. Vaginal hysterectomy with apical suspension has a lower reoperation rate for prolapse than abdominal sacrohysteropexy[7,8,13]

For women undergoing vaginal hysterectomy for treatment of POP, suspension of the vaginal apex to either the uterosacral or sacrospinous ligaments reduces the risk of recurrent POP.[6,8,13] While multiple different procedures exist, the McCall Culdoplasty is most commonly described in the literature[6,8,13]

Vaginal hysteropexy is equally effective as vaginal hysterectomy with apical suspension and is associated with reduced blood loss and operating time, though reoperation rates are higher with vaginal hysteropexy. [7,8,13] Abdominally placed mesh for sacrohysteropexy has a higher reoperation rate for prolapse than sacrocolpopexy with concomitant hysterectomy, however, there is no direct comparison between abdominal – or minimal access – sacrohysteropexy and sacrospinous hysteropexy[13,22] Women who wish to preserve their uterus should be offered a vaginal sacrospinous hysteropexy.[8,13]

While data is not complete, generally speaking, abdominal sacrocolpopexy (ASC) should be reserved for recurrent vault prolapse and post-hysterectomy prolapse.[7]

Vault prolapse

Procedures for the treatment of vault prolapse can be divided into abdominal (sacrocolpopexy) and vaginal based approaches (uterosacral ligament suspension and sacrospinous fixation).

The sacrocolpopexy has been shown to be superior both functionally and anatomically than other approaches to treat vault prolapse.[6,7,13,22] The ICS, NICE, and SOGC guidelines recommend discussion regarding the risk of mesh erosion prior to sacrocolpopexy.[7,8,22] Minimally-invasive sacrocolpopexy – either laparoscopic or robotic – is associated with less blood loss and shorter hospitalisation, though has longer operative times compared to the open route.[6,13,22] There is not clear evidence to suggest the laparoscopic route over robotic-assistance.[6] The NICE and SOGC guidelines recommend that the choice of approach (open, laparoscopic, or robotic) be guided by the surgeon in consultation with the woman.[8,22]

All of the international guidelines agree that for women with vault prolapse, sacrocolpopexy or either a vaginal sacrospinous fixation or uterosacral ligament suspension are three surgical options.[6-8,22,24] Functional and anatomical outcomes are similar between SSF and USL.[7,13,22]

Randomised controlled trials evaluating procedures for the treatment of apical compartment prolapse – generally laparoscopic or robotic sacrocolpopexy using mesh – were generally carried out in recent years, whereas comparative evidence for non-mesh treatment of prolapse was limited and tended to rely on older studies.

Vaginal based native tissue repairs such as SSF or USL may be more appropriate than an abdominal or laparoscopic approach in some women with comorbidities or previous surgery, though this is not evidence-based and should be decided between the surgeon and woman.

Examples of such conditions that should raise the consideration of a vaginal approach are:

a. Obesity

b. Medically unfit for abdominal procedures

c. Prior radiation to the pelvis

d. Prior pelvic surgery

Clinical Practice

- Surgical management should be individualised for each woman, depending on the degree of prolapse, which compartments are affected, and the woman's own personal wishes for surgery.
- Anterior colporrhaphy is recommended for the treatment of isolated anterior compartment prolapse.
- Posterior colporrhaphy ± perineorrhaphy is recommended for the treatment of posterior compartment prolapse.
- Those women with combined rectal mucosal prolapse and vaginal prolapse would benefit from colorectal and gynaecologist collaboration.
- For women with a uterus, a discussion should be had to determine whether the woman wishes to have her uterus removed or retained.
- For women with a uterus, they should be offered a vaginal hysterectomy with apical suspension or a vaginal hysteropexy.
- Women with vault prolapse who wish to have surgery should be offered a sacrocolpopexy or either a vaginal sacrospinous fixation or uterosacral ligament suspension.
- Women wishing to undergo a sacrocolpopexy should be made aware of the risk of mesh erosion with this procedure.
- The choice of three different approaches for sacrocolpopexy (open, laparoscopic, and robotic) should be guided by their surgeon in consultation with the woman.
- Vaginal based native tissue repairs such as SSF or USL may be more appropriate in some women, i.e. those who are:
    - Obese
    - Medically unfit for abdominal procedures
    - Prior radiation to the pelvis
    - Prior pelvic surgery
- The surgical options offered to each woman will depend on the surgeon's own ability to perform each procedure, referral to another surgeon may be necessary if the initial surgeon does not have the expertise required.

Recommendations

33. We recommend that surgical management should be individualised for each woman.
34. We strongly recommend an anterior colporrhaphy is recommended for the treatment of isolated anterior compartment prolapse (cystocele).
35. Posterior colporrhaphy ± perineorrhaphy is strongly recommended for the treatment of posterior compartment prolapse.
36. We recommend those women with combined rectal mucosal prolapse and vaginal prolapse would benefit from colorectal and gynaecologist collaboration.
37. For women with a uterus, we recommend a discussion should be had to determine whether the woman wishes to have her uterus removed or retained.
38. We recommend women undergoing a vaginal hysterectomy should have an apical suspension performed at the same time.
39. We recommend that those women wishing to preserve their uterus should be offered a vaginal sacrospinous hysteropexy.
40. We strongly recommend that women with vault prolapse should be offered a sacrocolpopexy or either a vaginal sacrospinous fixation or uterosacral ligament suspension.
41. We recommend that women wishing to undergo a sacrocolpopexy should be made aware of the risk of mesh erosion with this procedure.
42. We strongly recommend that women should be informed that outcomes are similar between SSF and USL.
43. We recommend vaginal based native tissue repairs such as SSF or USL may be more appropriate in women with co-morbidities or previous pelvic surgery.

Clinical Question 2.7: **How should women with concomitant urinary incontinence be managed?**

Evidence Statement

Approximately 50% of women with POP to the level of the vaginal hymen will have some degree of stress urinary incontinence (SUI).[6,25]

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. Additionally, cost implications for concomitant treatment of stress urinary incontinence were not reported.

Initial visit

The ACOG, ICS, and NICE guidelines all recommend discussing symptoms of SUI during a woman's initial visit for management of POP and to consider concomitant continence procedures in women with overt symptoms of SUI.[6-8]

Physical examination

Advanced POP may mask urinary incontinence and it is best practice to examine women who have a negative cough stress test following reduction of the prolapse, either digitally or with a speculum. International studies have shown that if SUI is elicited when the prolapse is reduced (occult SUI), there is a higher risk of *de novo* stress incontinence after repair of prolapse compared to those without occult SUI.[6-8,13] Similarly, women without occult SUI are unlikely to develop *de novo* SUI after prolapse surgery.[6,13]

Surgical risks

Continence procedures performed at the same time as prolapse surgery have a higher risk (15% vs 10%) of adverse events (bleeding, urinary tract infection, and bladder injury) and urinary retention (6% vs 1%) compared to prolapse surgery alone.[6,8,13,25] Most studies do not report longer-term issues such as overactive bladder, voiding dysfunction, or need for reoperation.[25]

Performing continence surgery in a staged approach (i.e. a prolapse repair followed by a continence procedure at a later date) could potentially reduce these surgical risks, however, there is minimal evidence to support this method[13,25] and as such, any decision should be made following consultation between the woman and the operating surgeon.

Clinical Practice

- Symptoms of SUI should be discussed during the initial consultation.
- Concomitant continence procedures or delayed or interval procedures should be discussed with women with overt symptoms of SUI.
- A woman with a negative cough stress test should be examined again with the prolapse reduced, either via speculum or digitally.
- If SUI is elicited once the prolapse is reduced, concomitant continence procedures should be discussed with the woman.
- If SUI is not elicited once the prolapse is reduced, the woman should be counselled that they have a low risk of developing de novo SUI.
- Women should be counselled that a concomitant continence procedure has a higher risk of adverse events compared to not performing the procedure.
- Women should be counselled that the risks associated with concomitant procedures may be less with a staged approach, but the evidence to support this is lacking.
- Any continence procedure should be performed in accordance with HSE guidelines on stress urinary incontinence.
- The surgical options offered to each woman will depend on the surgeon's own ability to perform each procedure, and so not all procedures will be offered by all surgeons.
- Women who wish to have a procedure that is not performed by their surgeon should be referred to another surgeon who has expertise in this area, if possible.

Recommendations

44. We recommend that symptoms of SUI should be discussed during the initial consultation.
45. We recommend that concomitant continence procedures should be discussed with women with overt symptoms of SUI.
46. If SUI is elicited once the prolapse is reduced, we strongly recommend concomitant continence procedures should be discussed with the woman.
47. We strongly recommend that women should be counselled that a concomitant continence procedure has a higher risk of adverse events, such as bleeding, urinary tract infection, and bladder injury compared to not performing the procedure.
48. We recommend that a staged approach be discussed with all women with POP who have concomitant SUI.
49. If SUI is not elicited once the prolapse is reduced, we suggest the woman should be counselled that they have a low risk of developing de novo SUI.

Clinical Question 2.8: **How should women undergoing surgery for pelvic organ prolapse be followed-up?**

Evidence Statement

Initial postoperative visit

There is no evidence suggesting an ideal length of time for follow-up after surgery for POP, though the NICE guidelines recommend offering an appointment with the operating urogynaecology surgeon within six months of surgery[8] and that this visit should include a vaginal examination by the operating surgeon, if possible.[6]

Postoperative follow up with a specialist physiotherapist should be ordered where successful outcomes were achieved pre-operatively[8]

Onward referral

The NICE and Australian guidelines suggest that women who have had surgery for POP who develop recurrent symptoms or further complications should have access to further referral to another urogynaecology surgeon or urologist, as appropriate.[8,9]

Clinical Practice

- The operating surgeon should offer women a review within 6 months after surgery for pelvic organ prolapse. This review should include a vaginal examination by the operating surgeon.
- Providers should ensure that women who have had surgery for pelvic organ prolapse have access to further referral to another urogynaecology surgeon or urologist if they have recurrent symptoms or suspected complications.

Recommendations

50. We recommend women should be offered an in-person return appointment with the operating surgeon within six months of their surgery.
51. We recommend a vaginal examination should be performed by the surgeon at the postoperative clinic visit.
52. We recommend that women with recurrent symptoms and/or complications should have access to further referral to another urogynaecologist or urologist.

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 "Pelvic Organ Prolapse". 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 No: 123, Society of Obstetricians and Gynaecologists of Canada (SOGC) Guideline No: 413, 6th International Consultation on Incontinence Guideline 2018, American College of Obstetricians and Gynaecologists Practice Bulletin No: 214, United Kingdom Continence Society Guideline for best practice in the use of vaginal pessaries for pelvic organ prolapse, Australian Committee On Safety And Quality In Healthcare Guideline, and relevant Cochrane reviews were also used to inform this Guideline.

The primary outcome data (cure and improvement) was cross checked 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 management of pelvic organ prolapse 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: a manual for guideline developers', 2019[11].

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

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

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two. One reviewer (BO'L) carried out the review of the relevant literature. DK and GA were responsible for review of the final documents selected. Quality of the evidence was assessed by the three developers (DK, GA, and BO'L).

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.[18]

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[12]. (Appendix 4)

3.6 Future research

The current evidence base 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 pelvic organ prolapse.

Further research into adverse events is required, especially those which impact on a woman's quality of life. Pelvic organ prolapse is a common condition, one with a high rate of surgical intervention and so training of surgeons and their ongoing surgical throughput may also need assessment. This would provide women with the necessary, broad range of evidence to help them understand the benefits and harms associated with their choice of surgery. Similarly, further research should include some assessment of the effect of POP on women's mental health as well as qualitative and quantitative assessments of quality of life.

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

12 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. https://pubmed.ncbi.nlm.nih.gov/23978245/

The assessment of long term safety and performance of any procedure will require a multicentre, long-term approach (e.g. ideally five years or longer) and so may be impractical. A potential solution is a national database or registry – anonymised or otherwise – for reporting and recording of complications. Hopefully such an approach would help to generate uniform and comprehensive data on surgery for pelvic organ prolapse.

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

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[13] 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 (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See appendix 6 for list of CAG members.

13 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[14].

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

Senior management within the gynaecology units 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 websites (https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/) and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each Guideline and where relevant a downloadable version of the recommended algorithm will be available.

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

Chapter 6: **Implementation**

6.1 Implementation plan

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

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

In the case of this guideline the following have been put in place to help facilitate its implementation

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

6.2 Education plans required to implement the Guideline

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

This Guideline education plan suggests that each local clinical setting will identify the educational needs that are necessary to implement this Guideline in practice. The level of education may vary from in-service, continuing professional development to stand alone modules or postgraduate education programmes.

This Guideline education plan suggests group education such as GP information evenings and in-house study days on the guidance available and the appropriate care pathway.

6.3 Barriers and facilitators

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

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment). The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

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

In the case of this Guideline, as it is for use in both primary and secondary care settings, there are some barriers that will impact on the full implementation of the Guideline. It is recommended that each local clinical setting to which this Guideline applies should determine what resources are necessary for its implementation. The implementation of the Guideline can be facilitated by ensuring that all clinicians understand and appreciate that the Guideline contributes to the quality and safety of patient care.

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

6.4 Resources necessary to implement recommendations

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

All stakeholders involved in the care of women with pelvic organ prolapse have a responsibility for the implementation of this Guideline.

6.5 Roles and responsibilities

Senior managers

- Assign personnel with responsibility, accountability and autonomy to implement the Guideline
- Ensure local policies and procedures are in place to support its implementation
- Facilitate education to all relevant clinical staff to ensure they have the knowledge and skills to implement the Guideline
- Monitor the implementation of this Guideline
- Ensure audit processes are in place

Heads of department

- Ensure all relevant staff members are aware of this Guideline
- Ensure staff are supported to undertake education programmes and related training as appropriate

Clinical staff

- All clinical staff should comply with this Guideline and related policies, procedures and protocols. Clinical staff should adhere to their professional scope of practice guidelines and maintain competency
- In using this Guideline clinicians must be aware of the role of appropriate delegation

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 patient 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 pelvic organ prolapse.

Implementation of the Guideline must be audited in order to ensure that the Guideline positively impacts care. Suggested audit standards include:

- Number of women assessed for POP with a standardised quantification system, such as the POP-Q (Pelvic Organ Prolapse Quantification) system
- Number of women prescribed vaginal oestrogen
- Number of women referred to physiotherapy
- Outcomes of those who has successfully completed a physiotherapy programme
- Number of women offered a pessary
- Number of fittings required in women offered a pessary
- Number of women managing their pessary independently
- Number of women using a pessary treated for vaginal erosions
- Length of time between pessary changes
- Number of women offered a post-operative in-person return appointment
- Post-operative outcomes:
    - Degree of prolapse at postoperative visit (POP-Q or similar)
    - Quality of life score (validated scale used eg. EQ-5D, SF-36, ICIQ)

- Adverse outcomes:
  - Damage to surrounding structures including perforations intraoperatively
  - Post-operative catheterisation for >10 days within 3 months
  - Chronic pain or discomfort at 12 months
  - Dyspareunia/impact on sexual function at 6 and 12 months
  - 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[15].

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

15 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.[16]

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

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

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

8.2 Method for amending the Guideline

As new evidence become available it is inevitable that Guideline recommendations will fall behind current evidence based 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.

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

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Supporting Evidence

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

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

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

Glossary
(for the Purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

ACOG American College of Obstetricians and Gynaecologists

CAG Clinical Advisory Group

EAG Expert Advisory Group

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

NICE The National Institute for Health and Care Excellence

NCEC National Clinical Effectiveness Committee

NWIHP National Women and Infants Health Programme

PPPG Policy, Procedures, Protocols and Guidelines

RCPI Royal College of Physicians of Ireland

SSF Sacrospinous fixation

ULS Uterosacral ligament suspension

UKCS United Kingdom Continence Society

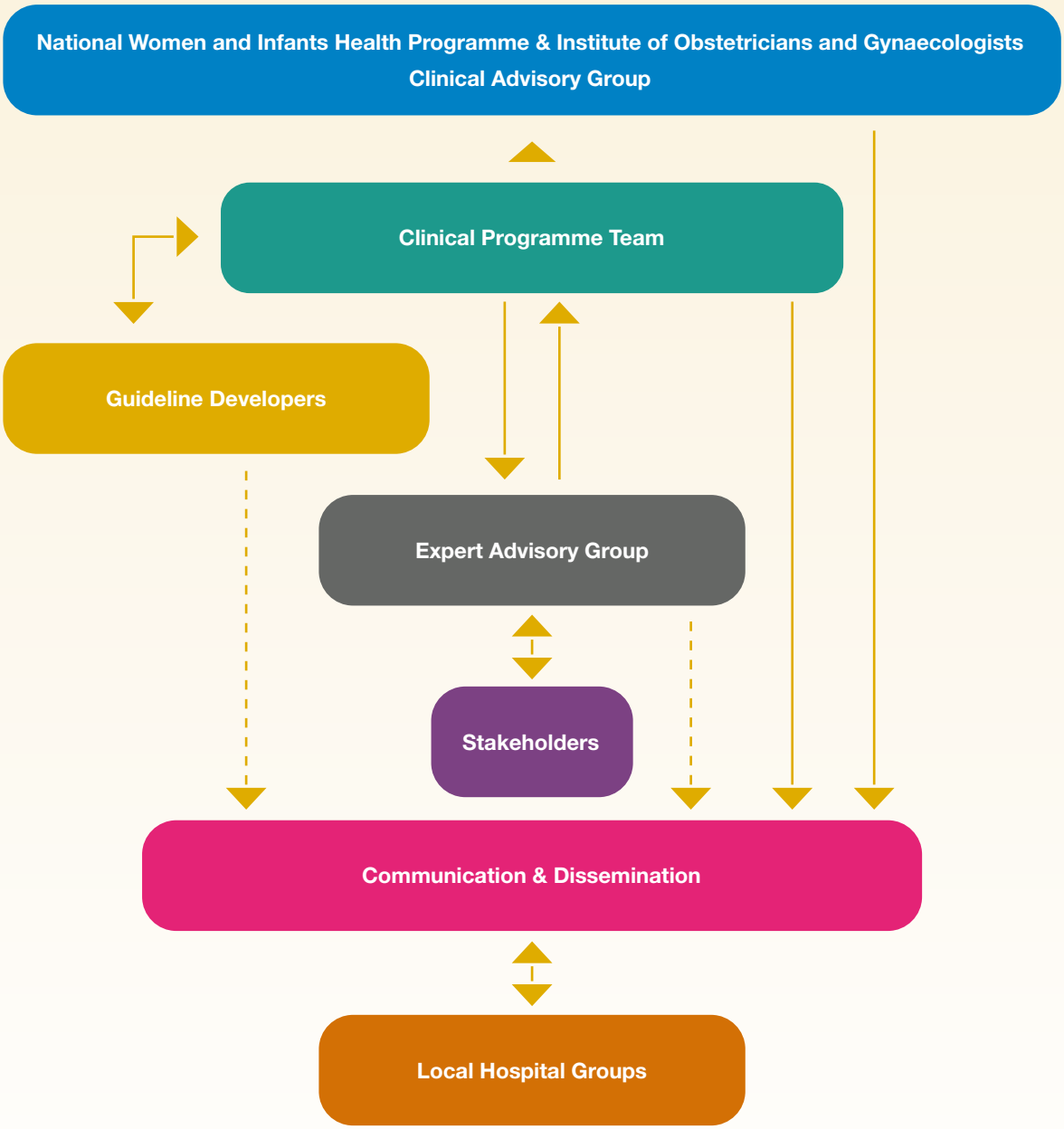
Appendix 1: **Expert Advisory Group Members 2021-**

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

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

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **AGREE II checklist**[17]

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	

17 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 summarized 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 capitalize 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	

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

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

Appendix 4: **Grades of Recommendation**[18]

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…

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

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 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.