National Women & Infants Health Programme

National Clinical Practice Guideline

Investigation and Management of Complications of Early Termination of Pregnancy

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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National Clinical Guideline for Investigation and Management of Complications of Early Termination of Pregnancy

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Short summary:
Evidence-based recommendations for the care of women during and after TOP who experience a complication.
Description:
This national guideline sets out evidence-based standards for the assessment and management of complications of early termination of pregnancy (first 12 weeks of pregnancy), covering clinical evaluation, methods of management by gestation, pain relief, aftercare, safeguarding, and service organisation, with an emphasis on informed consent, equity of access, multidisciplinary support, and alignment with Irish legal and ethical frameworks.

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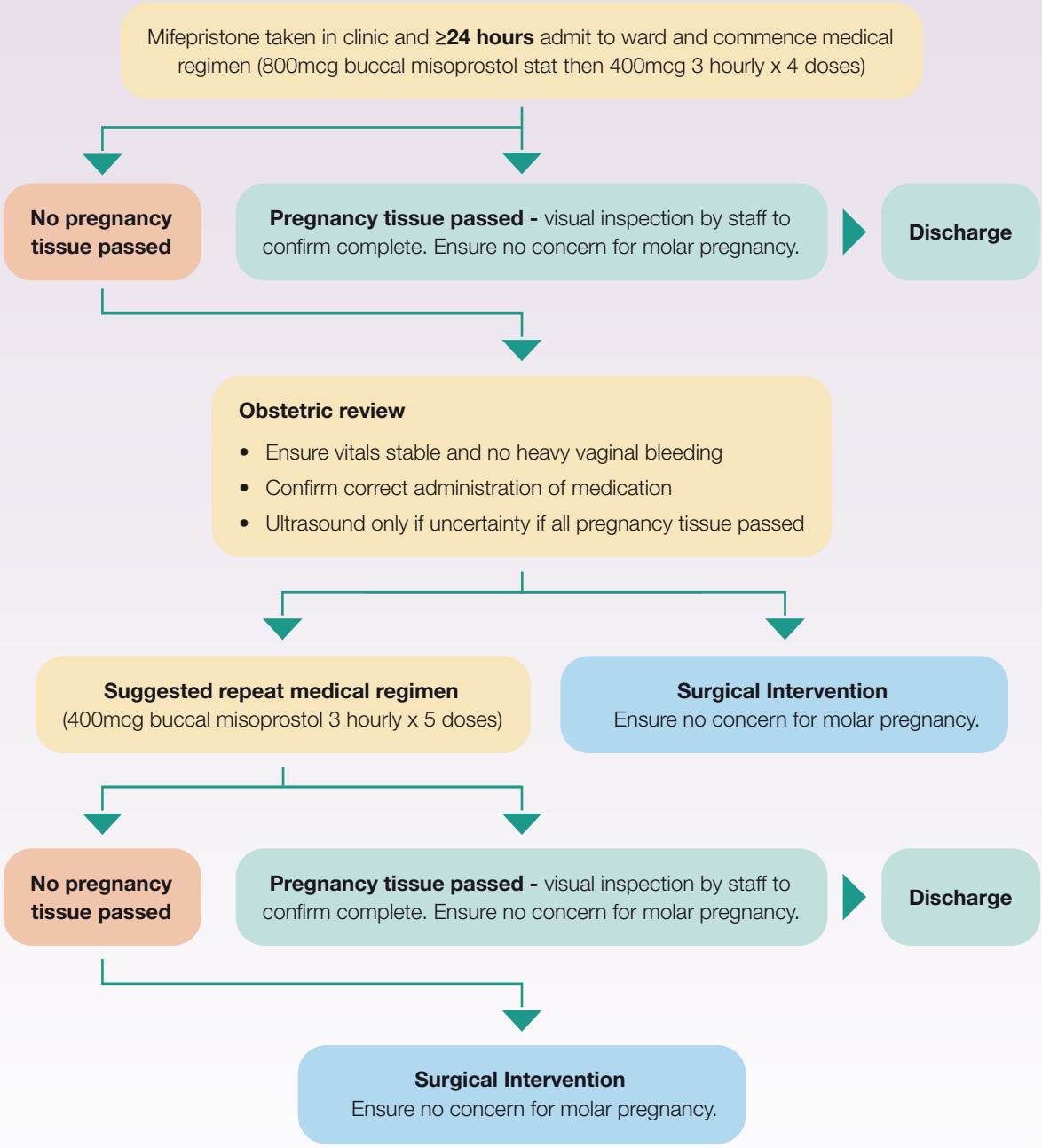
Algorithms

Algorithm I: Management of first trimester medical termination of pregnancy in secondary care



Algorithm II: Management of acute haemorrhage following termination of pregnancy in secondary care

History

- Date of last menstrual period/estimated gestational age?
- When mifepristone/misoprostol were taken?
- Duration of bleeding/how much blood loss?
- Has any pregnancy tissue passed?
- Is there any foul smelling discharge/ abdominal pain?
- Previous uterine surgery?
- Regular medications and any other relevant medical history?

Examination

- Vital signs
- Abdominal examination
- Speculum/bimanual examination

Unstable Patient

- Call for help – Senior Obstetrician/Midwife & Anaesthetist
- Resuscitation;
  - **A**irway
  - **B**reathing
  - **C**irculation
- 2x 14G cannula
- Full blood count (FBC), liver and renal function (U&E, LFT), coagulation profile including fibrinogen level, C-reactive protein (CRP), group & crossmatch (GXM)
- Point of care arterial or venous blood gas
- High flow oxygen
- Intravenous fluids
- Urinary catheter, hourly output monitoring
- Consider blood products; red cells, platelets, fresh frozen plasma, fibrinogen & clotting factors
- Transfer to theatre for evacuation of retained products of conception (ERPC)/manual removal of placenta (MROP)/explorative laparoscopy/laparotomy as indicated from history and examination

Ongoing/incomplete termination

- FBC, U&E, LFT, CRP, GXM
- 1st Trimester – consider ERPC (1st trimester) or MROP (2nd trimester) dependant on clinical scenario
- Consider broad spectrum antibiotics
- Bimanual compression
- Consider Uterotonics;
- Intramuscular/Intravenous oxytocin, intramuscular Syntometrine, intramuscular carboprost
- Consider use of intravenous tranexamic acid, Fibrinogen and clotting factors

Infection

- FBC, U&E, LFT, CRP, GXM
- High vaginal swab (HVS), urine for microscopy and culture +/- blood cultures
- Intravenous broad spectrum antibiotics
- Consider ultrasound to out rule retained pregnancy tissue

Uterine Rupture

- FBC, U&E, LFT, CRP, GXM
- Emergency Laparotomy
- Antibiotics/Blood products

Key Recommendations

1. All healthcare providers, including those not directly involved in providing Termination of Pregnancy (TOP) should be aware that women with complications arising from TOP may present to any healthcare setting and should be treated appropriately and without prejudice. *Best Practice*
2. Women should be counselled that Medical Termination of Pregnancy (MTOP) cannot be reversed, chance of ongoing pregnancy is less than 3% when both mifepristone and misoprostol have been taken and risk of major congenital malformation is approximately 4.2%. *Best Practice*
3. We recommend, if there is little or no bleeding following early MTOP, referral to secondary care services for ultrasound assessment to rule out ongoing or ectopic pregnancy is considered. *Best Practice*
4. We recommend, if any woman in early pregnancy has severe pain or is haemodynamically unstable, urgent assessment in secondary care should be considered to assess for ectopic pregnancy, major haemorrhage or sepsis. *Best Practice*
5. There is no indication for routine ultrasound in women undergoing MTOP in secondary care prior to discharge if appropriate pregnancy tissue corresponding to ultrasound findings has been visualised following expulsion. *Best Practice*
6. If there is uncertainty regarding completion of the early medical termination procedure in secondary care and an ultrasound is performed, the purpose of the ultrasound is to confirm that a gestational sac and its contents are no longer present. *Best Practice*
7. We recommend that, if early MTOP in secondary care is unsuccessful, the woman should be offered further medical or surgical management until termination is complete. *Best Practice*
8. We recommend that, if a woman has ongoing pregnancy symptoms or a positive low sensitivity urine pregnancy test following early MTOP in primary care, they should initially be reviewed by their primary care termination provider. *Grade 1A*
9. We recommend that women should be referred – in a timely fashion – to secondary care termination services if ongoing pregnancy is suspected/confirmed following MTOP. *Best Practice*
10. We strongly recommend that healthcare workers providing MTOP should be familiar with potential complications such as heavy vaginal bleeding, ongoing severe pain and retained pregnancy tissue, and their respective management approaches. *Best Practice*
11. We suggest that ectopic pregnancy be considered in any woman attending with severe, ongoing pain in the setting of minimal vaginal bleeding following MTOP. *Best Practice*
12. Women who experience severe pain, that does not improve despite analgesia, following MTOP in the community, should be advised to contact their primary termination care provider. If out of hours, they should be advised to contact MyOptions.ie which is open 24/7 for medical advice, or the local emergency department, immediately. *Best Practice*
13. We recommend that women should be advised to seek medical assessment if they experience heavy vaginal bleeding that soaks through two or more sanitary pads per hour for two consecutive hours post MTOP in the community. *Best Practice*

14. We suggest that if a woman is clinically well with symptoms suggestive of retained pregnancy tissue they be managed conservatively in the community. *Grade 1B*
15. We recommend referral to secondary care if there is prolonged, ongoing bleeding or a suspicion of infection. *Grade 1C*
16. We recommend that in a haemodynamically unstable woman who has heavy vaginal bleeding, secondary to retained pregnancy tissue, prompt uterine evacuation should be performed. *Grade 1B*
17. We suggest that, if mild genital tract infection is suspected following examination, preliminary investigations can be performed in the primary care setting and oral broad-spectrum antibiotics should be commenced in accordance with local antimicrobial guidelines. *Best Practice*
18. We recommend that, if severe genital tract infection is suspected following examination, resuscitative measures such as commencing intravenous fluids, broad spectrum antibiotics and providing supplementary oxygen should be given without delay. *Best Practice*
19. We strongly recommend that healthcare workers providing Surgical Termination of Pregnancy (STOP) should be familiar with potential complications such as haemorrhage, cervical lacerations and uterine perforation, and their respective management approaches. *Best Practice*
20. Following TOP, all women should be offered contraceptive information and, if desired, given the contraceptive method of their choice, or referral for this service. *Best Practice*
21. Long-acting reversible contraception (LARC) is the preferred method of contraception (for clinicians) and so far as possible, should be commenced immediately at the time of TOP in both primary and secondary care services. *Best Practice*
22. We suggest that women admitted to hospital with complications of TOP should be offered referral to the Medical Social Work (MSW) team and/or for counselling. *Best Practice*
23. The GP TOP provider should be informed when a woman is admitted to hospital with complications of TOP, provided the woman herself consents to this communication. This communication can be via a discharge summary letter or directly by phone to the GP TOP provider. *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 to improve the management of women who experience complications during or after early termination of pregnancy (TOP).

Guidance on the conduct and management of early TOP can be found in; the Irish College of General Practitioners (ICGP) quick reference guide to Clinical Support for Termination of Pregnancy in General Practice [2] and the Institute of Obstetricians and Gynaecologists (IOG) Interim clinical guidance on Termination of Pregnancy under 12 weeks [3].

1.2 Scope

Target users

This Guideline is intended for all healthcare professionals (including doctors, midwives and nurses), particularly those in both primary and secondary care services who are involved in the care of women who have undergone a TOP. The focus of this Guideline is complications relating to early termination of pregnancy (Section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018).

Target population

Women with complications following early TOP.

1.3 Objective

To provide evidence-based recommendations for the care of women during and after TOP who experience a complication.

To promote a standardised approach nationally across all maternity units and primary care centres.

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://assets.gov.ie/11533/2d070cb758a44fcb8b56f28784b10896.pdf

1.4 Guideline development process

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

See Appendix 1 for EAG membership and Appendix 2 for Guideline Programme Process.

This Guideline was written by Dr Sophie Boyd (Cork University Maternity Hospital and University Maternity Hospital Limerick), Dr Sinead Feeney (Galway), Dr Ken Harte (Cork), Dr Ciara McCarthy (Cork), Ms Siobhan Hayes (Cork University Maternity Hospital) and Dr Deirdre Hayes-Ryan (Cork University Maternity Hospital).

1.5 Stakeholder involvement

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

The following additional stakeholders were consulted regarding this Guideline; Cork University Maternity Hospital (CUMH) TOP Midwifery Co-ordinators: Ms Laura Keohane and Ms Sharon Goggin, and Ms Ann-Marie McCarthy, medical social worker, CUMH.

The NWIHP TOP Clinical Advisory Forum also conducted a review of this Guideline during the development phase.

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 woman 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 ensuring informed consent is obtained
- Provide care within 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

This Guideline does not address any issues around the legality of TOP in Ireland.

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] While there has been a trend to remove the word 'woman/women' and use 'gender neutral' language in policy and practice in relation to women's reproductive health and wellbeing, there is no evidence base to inform this change.[6] We also appreciate that there are risks to desexing language when describing female reproduction.[7,8]

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. Finally, all those using maternal and reproductive health care and services should receive individualised, respectful care including use of the gender nouns and pronouns they prefer.[6]

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision.[9] 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.

1.9 Adopting a trauma-informed approach to maternity care

Many women accessing maternity services may have experienced historical or current trauma prior to, or during pregnancy - including emotional, physical, sexual abuse, rape and torture. The perinatal period (pregnancy, birth and the postpartum) can be a time when previous trauma is triggered[10]. Maternity care procedures which may seem routine and 'non-invasive' to healthcare professionals (HCPs), e.g., abdominal palpation or providing breastfeeding support can be triggering for some women with a history of trauma, as can intimate procedures such as vaginal examinations.[11]

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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 Council of Deans of Health. Midwifery Network position paper: use of sexed language. May 2023. https://www.councilofdeans.org.uk/2024/02/midwifery-network-position-paper-use-of-sexed-language/

7 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

8 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

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

10 Horsche A., Garthus-Niegel S., Ayers S, Chandra P., Hartmann K., Caisbuch E., Lalor J (2024). Childbirth-related posttraumatic stress disorder: definition, risk factors, pathophysiology, diagnosis, prevention, and treatment. Am J Obstet Gynecol. 2024 Mar;230(3S): S1116-S1127. doi: 10.1016/j.ajog.2023.09.089

11 Montgomery E. Feeling safe: a metasynthesis of the maternity care needs of women who were sexually abused in childhood. Birth 40:88–95. Birth. 2013 Jun;40(2):88-95. doi: 10.1111/birt.12043

Trauma-informed care (TIC) is a developing approach to healthcare which recognises the importance of psychological safety, and the need to prevent or resist re-traumatisation of individuals.12 It is based on 4 key principles (known as the 4Rs): (1) realisation of trauma; (2) recognition of trauma; (3) responding to trauma and (4) resisting re-traumatisation.13 A trauma-informed approach to maternity care means that all staff in an organisation have an understanding of the impact of trauma on individuals, families and organisations.14 While a universal approach is yet to be agreed, within clinical practice and research, many organisations recognise the need to move towards becoming trauma-informed in the provision of maternity care[14,15]. Such an approach requires commitment, investment and transformation within maternity services.

In simple terms, HCPs should recognise the impact of women's previous or current history of trauma (whether disclosed or not) and adopt a universally sensitive approach to care provision that recognises the impact of trauma on service users and HCPs. Examples of this include ensuring clear communication and consent is sought before any procedures/interventions, ensuring women are provided with dignity and respect at all times.

1.10 Abbreviations and terminology

TOP: Termination of pregnancy refers to any form of termination either medical or surgical termination.

MTOP: Medical Termination of Pregnancy refers to the use of abortifacient medication to end a pregnancy

STOP: Surgical Termination of Pregnancy refers to the use of surgical intervention either through a vacuum aspiration or dilation and evacuation to end a pregnancy.

12 Vogel TM, Coffin E. (2021). Trauma-informed care on labor and delivery. Anesthesiol Clin. 2021 Dec;39(4):779-791. doi: 10.1016/j.anclin.2021.08.007

13 Substance Abuse and Mental health Services Administration. SAMHSA'a Concept of Trauma and Guidance for a Trauma-Informed Approach. HHS Publication No. (SMA) 14-4884. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014

14 Law C, Wolfenden L, Sperlich M, Taylor J. A (2021). Good practice guide to support implementation of trauma-informed care in the perinatal period. The centre for early child development (Blackpool, UK) commissioned by NHS England and NHS Improvement in 2021. https://www.england.nhs.uk/publication/a-good-practice-guide-to-support-implementation-of-trauma-informed-care-in-the-perinatal-period/

15 Ayers, S., Horsch, A., Garthus-Niegel, S., Nieuwenhuijze, M., Bogaerts, A., Hartmann, K., Karlsdottir, S. I., Oosterman, M., Tecirli, G., Turner, J. D., Lalor, J., & COST Action CA18211 (2024). Traumatic birth and childbirth-related post-traumatic stress disorder: International expert consensus recommendations for practice, policy, and research. *Women and birth : journal of the Australian College of Midwives*, 37(2), 362–367. https://doi.org/10.1016/j.wombi.2023.11.006

Chapter 2:
Clinical Practice Guideline

Background

The Health (Regulation of Termination of Pregnancy) Act 2018 was signed into Irish law on 21st December 2018[4]. There are several different circumstances under which TOP can be legally performed (*Table 1*), the most common of which is early termination of pregnancy (Section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018) with 98.6% of TOPs performed in 2021 taking place under this [5].

Section 12 allows TOP to be carried out by medical practitioners up to 12 weeks gestation i.e., 12 weeks + 0 days from first day of last menstrual period, once a minimum of three days has elapsed from the date of certification [4]. Section 11 allows TOP to be carried out in the setting of a fatal fetal anomaly and/or life limiting conditions [4]. Sections 9 and 10 allow TOP to be carried out in the setting of a risk to life or health of the pregnant person [6].

The focus of this Guideline is complications relating to early termination of pregnancy (Section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018). There is currently no national data available relating to complications of termination of early pregnancy available for the Republic of Ireland hence data in this document is guided by international figures.

Recommendations relevant to this Guideline can also be found in:

- Interim Clinical Guidance: Termination of pregnancy under 12 weeks (IOG, 2018)
- Interim Clinical Guidance: Pathway for management of fatal fetal anomalies and/or life-limiting conditions diagnosed during pregnancy: Termination of Pregnancy (IOG, 2020)
- Interim Clinical Guidance: Risk to life or health of a pregnant woman in relation to Termination of Pregnancy (IOG, 2019)
- Quick Reference Guide: Clinical Support for Termination of Pregnancy in General Practice (ICGP, 2021)

Table 1: Sections of the Health (Regulation of Termination of Pregnancy) Act 2018

Section 9	A termination of pregnancy may be carried out in accordance with this section where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that: (a) there is a risk to the life, or of serious harm to the health, of the pregnant woman, (b) the foetus has not reached viability, and (c) it is appropriate to carry out the termination of pregnancy in order to avert the risk referred to in *paragraph (a)*.

Section 10	A termination of pregnancy may be carried out in accordance with this section by a medical practitioner where, having examined the pregnant woman, he or she is of the reasonable opinion formed in good faith that: (a) there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman, and (b) it is immediately necessary to carry out the termination of pregnancy in order to avert that risk.
Section 11	A termination of pregnancy may be carried out in accordance with this section where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that there is present a condition affecting the foetus that is likely to lead to the death of the foetus either before, or within 28 days of, birth.
Section 12	A termination of pregnancy may be carried out in accordance with this section by a medical practitioner where, having examined the pregnant woman, he or she is of the reasonable opinion formed in good faith that the pregnancy concerned has not exceeded 12 weeks of pregnancy.

Medical termination of pregnancy (MTOP) is performed using two abortifacient medications. Mifepristone followed by misoprostol, ideally between 24 to 48 hours later [3,7,8]. Mifepristone is administered orally, while misoprostol is recommended to be administered buccally [3,7,8]. Vaginal misoprostol administration is associated with less gastrointestinal side effects than buccal and is useful for women with severe hyperemesis [7,8]. Misoprostol may be taken orally, but it is less effective than buccal or vaginal routes [7,8]. Mifepristone is a synthetic steroid that works as an abortifacient due to several mechanisms of action; it causes decidual necrosis which aids detachment of the pregnancy, softens, and dilates the cervix and sensitises the uterus to prostaglandins [8]. Misoprostol is a prostaglandin analogue that further softens and dilates the cervix and induces uterine contractions resulting in expulsion of the pregnancy [8]. Dosage and timing of misoprostol is dependent on gestational age and the presence or absence of uterine scarring when being given beyond twelve weeks' gestation [7,8].

MTOP up to nine completed weeks' gestation (9 weeks + 6 days from first day of last menstrual period) can be safely provided in the primary care setting with the last day for administration of mifepristone being the 69th day of pregnancy [7]. MTOP beyond this gestation should be undertaken in a secondary care setting [3].

Surgical termination of pregnancy (STOP) is performed in a secondary care setting. STOP is largely limited to the first trimester in Ireland owing to limited clinician experience with dilatation and evacuation procedures, however this may change in the future. Vacuum aspiration, either via manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA), is the primary method of surgical termination employed at gestations less than 14 weeks' [7,8]. Surgical intervention may also be required as second line treatment following failure of medical termination, retained pregnancy tissue, or retained placenta [7,8].

Complications of TOP may arise in both the primary and secondary care settings. It is important that all healthcare providers are aware that women with complications may present to any healthcare service, including those that are not actively involved in providing termination services. All women should be treated without prejudice by all staff including doctors, midwifery, nursing and ancillary staff. Care cannot be denied particularly in an emergency setting [1,4]. Termination is a safe procedure for which major complications are rare at all gestations [10]. Short and long-term morbidity can be reduced if women presenting with complications are diagnosed early and managed appropriately [7,11,12].

Experiencing a crisis pregnancy can have significant psychosocial effects, and these can be exacerbated by experiencing further complications [13,14]. It is important to recognise the crucial role of allied health professionals who can provide additional support and counselling [15]. Persons undergoing TOP may feel sensitive around the terminology used to describe a pregnancy or termination and consideration should be given to the language used in consultation [16-18].

Recommendations

1. **All healthcare providers, including those not directly involved in providing Termination of Pregnancy (TOP) should be aware that women with complications may present to any healthcare setting and should be treated appropriately and without prejudice.**

Section 1: Change of mind following MTOP

Introduction

With thorough counselling it is very uncommon for a woman to have a change of mind after taking medication for an MTOP [19]. It is important to explain that MTOP is not considered a reversable procedure and that mifepristone and misoprostol are teratogens.

Clinical Question 2.1: **What is the recommended approach to treating a woman who has a change of mind regarding TOP following administration of medication?**

Evidence Statement

Continuation of pregnancy following administration of abortifacient medication is low, occurring at a rate of 0.4% – 2.9% when both mifepristone and misoprostol are administered [20-22]. Data on pregnancy continuation after mifepristone exposure without misoprostol are limited, with one prospective study of 46 women resulting in eight miscarriages, demonstrating a continuation rate of over 80% [23].

There is a potential risk of teratogenesis after taking abortifacient medication, although data is poor and limited to case reports, case control and cohort studies [24]. An observational prospective study of 105 pregnancies demonstrated an overall rate of major congenital malformations of 4.2% in women of whom half had been exposed to mifepristone alone and the other to both mifepristone and misoprostol in the first trimester, only slightly higher than the expected 3% rate in the general population [23].

The proposed mechanism of action for the teratogenicity of misoprostol in the first trimester is that of vascular disruption from uterine contractions causing maldevelopment of the fetus [25]. The risk of teratogenic effects of misoprostol peak when exposure is between 35-56 days from the last menstrual period (LMP) [24]. Over thirty-five different fetal anomalies are described in the literature, including lower limb defects, central nervous system anomalies, upper limb defects and skeletal defects. Specific anomalies include equinovarus, terminal transverse limb defects, arthrogryposis, cranial nerve anomalies and Moebius syndrome [25-27]. In a cohort of 183 women exposed to misoprostol during the first 12 weeks of pregnancy, the major malformation rate was 5.5% with half of the malformations consistent with misoprostol patterns [28]. A 2002 population survey identified that if a woman took misoprostol prior to 13 weeks gestation and subsequently carried a pregnancy to term, the risk of fetal malformation related to misoprostol exposure was less than 10 per 1,000 exposures [24].

Mifepristone is a synthetic steroid that has anti-progesterone and anti-glucocorticoid properties. Progesterone is important in early pregnancy inducing several changes, including promoting uterine relaxation and preparing the endometrium for implantation. Administration of progesterone after commencing MTOP theoretically allows it to compete with mifepristone for binding with progesterone receptors potentially minimising the effect of mifepristone. There is no evidence as to whether progesterone supplementation post mifepristone administration results in a higher number of pregnancies continuing than with expectant management and no evidence on either safety or efficacy when it is used for this purpose [19].

There are no high quality national or international clinical guidelines that recommend the use of progesterone to reverse the effect of mifepristone, and no evidence that it increases the likelihood of continuing pregnancy compared to expectant management alone [29,30]. The Royal College of Obstetricians and Gynaecologists (RCOG), The Faculty of Sexual and Reproductive Healthcare (FSRH), the Royal College of Midwives (RCM), the British Society of Abortion Care Providers (BSACP) as well as the American College of Obstetricians and Gynaecologists (ACOG) do not support prescribing progesterone to stop MTOP [29,31].

Clinical Practice

Women should be counselled regarding the low chance of having an ongoing pregnancy after undergoing MTOP, with rates less than 3% if both mifepristone and misoprostol have been taken. The reason for a change of mind should be explored and the risk of congenital malformation in the event of an ongoing pregnancy should be explained.

An ultrasound for viability should be arranged in the secondary care setting and, if applicable, appropriate referral for pregnancy booking. Progesterone supplementation should not be offered. Exposure to mifepristone alone has not been shown to cause fetal malformations. Exposure to misoprostol is associated with a small increased risk of malformations if the woman has an ongoing pregnancy. Due to an increased incidence of fetal anomalies following exposure to misoprostol, a detailed anomaly scan should be performed in ongoing pregnancies.

Women should be offered further counselling with the medical social work department or relevant perinatal mental health expert regardless of the outcome of the pregnancy.

Recommendations

2. **Women should be counselled that Medical Termination of Pregnancy (MTOP) cannot be reversed, chance of ongoing pregnancy is less than 3% when both mifepristone and misoprostol have been taken and risk of major congenital malformation is approximately 4.2%.**

Section 2: Absence of bleeding following MTOP

Introduction

Following the administration of misoprostol in MTOP peak expulsion of pregnancy tissue occurs 4-6 hours later, however for up to 10% of women it may take up to 24 hours to pass [2]. Causes of absent or scanty bleeding after MTOP in the community can include an incomplete MTOP, ongoing pregnancy, or ectopic pregnancy. Some women may have had an ultrasound performed prior to undergoing MTOP which may have already confirmed a normally sited pregnancy excluding the diagnosis of ectopic pregnancy.

It is also important to note that at very early gestations it may be usual for women to experience light vaginal bleeding. Women undergoing MTOP in secondary care will have had an ultrasound performed, confirming a normally sited pregnancy [3,4]. Causes of absent or scanty bleeding after MTOP in secondary care include ongoing pregnancy or incomplete TOP.

Clinical Question 2.2: **What are the essential considerations when assessing a woman with little or no bleeding following early MTOP in a primary care setting?**

Evidence Statement

The risk of ectopic pregnancy in women undergoing early MTOP is low (0.5-5.9/1.000) compared to women in the general population (11/1,000) [8].

Women known to be at increased risk of ectopic pregnancy include those with a history of previous ectopic pregnancy, previous tubal surgery, assisted reproduction and previous/current salpingitis, or pelvic inflammatory disease. Risk in women with an intra-uterine device in situ is 50% and 33% in women who have undergone tubal ligation [32]. Appropriate safeguards are in place for women at increased risk of ectopic pregnancy with ultrasound prior to commencement of TOP advised [2,3].

Clinical Practice

At the pre-termination consultation, one additional tablet of 400mcg of misoprostol may be provided to the woman to be taken buccally if there is no bleeding within 4 hours of taking the two 400mcg tablets.

If following the additional dose of misoprostol little or no vaginal bleeding occurs, then the woman should be advised to contact their termination provider or if after hours, the MyOptions.ie helpline (Phone 1800 828 010).

If the provider is satisfied that the woman is clinically well and is at an early gestation, serial plasma □hCG sampling may be considered to ensure a satisfactory reduction. If the pregnancy is not ongoing, a 50% reduction in serum □hCG is expected after 48 hours, 70% by day 3 and 90% by day 5 [33]. It is best practice to perform serial □hCG sampling 48 hours apart. Ability to perform serial plasma □hCG levels may be dependent on local resources. If it is not possible to do this in the primary care setting, women may need to be referred into secondary care facilities.

If the □hCG level is not declining as expected, referral to secondary care TOP services for assessment should be made to assess for an ectopic or ongoing pregnancy.

In a woman that has any red flag symptoms i.e., severe ongoing pain or signs of haemodynamic compromise, referral to the nearest Emergency Department is advised for urgent assessment for ectopic pregnancy.

Recommendations

3. **We recommend if there is little or no bleeding following early MTOP, referral to secondary care termination services for ultrasound assessment to out rule ongoing or ectopic pregnancy is considered.**
4. **We recommend if any woman in early pregnancy has severe pain or is haemodynamically unstable urgent assessment in secondary care is considered to assess for ectopic pregnancy, major haemorrhage or sepsis.**

Clinical Question 2.3: **What is the recommended approach when a woman has no bleeding following early MTOP in a secondary care setting?**

Evidence Statement

Under Section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018, a termination may be performed provided at least three days has elapsed from the date of certification and the pregnancy has not exceeded 12 weeks. The Chief Medical Officer of the Department of Health has stipulated that twelve weeks plus 1 day exceeds 12 weeks therefore twelve weeks is 12 weeks + 0 days [4].

Twelve weeks of pregnancy means 84 days since the first day of the woman's last period (12 weeks + 0 Days). For women with uncertain dates, a crown rump length of 63mm is defined as the upper limit for TOP at 12 weeks + 0 days gestation [4].

For women undergoing STOP, 12 weeks is the last date STOP may be performed. For women undergoing medical termination, 12 weeks is the last day that mifepristone may be administered. The Chief Medical Officer of the Department of Health has acknowledged that in some circumstances it may be necessary to extend beyond 12 weeks in order to complete the process of termination [3,4].

The risk of failure of MTOP is increased in the following scenarios: with advancing gestational age; if interval between mifepristone and misoprostol is less than 24 hours or greater than 48 hours; if oral rather than buccal/vaginal administration of misoprostol is used; and if repeat misoprostol dose is omitted [34]. Repeated doses of misoprostol are more likely to be required at higher gestational age and are more effective if taken buccally or vaginally rather than orally [35].

It is best practice to ensure that the termination is complete both due to the potential teratogenicity of misoprostol and risk of morbidity due to haemorrhage or infection with an incomplete termination.

Clinical Practice

Women undergoing MTOP in secondary care have pregnancy tissue examined by appropriately trained clinical staff to ensure completeness of the termination procedure and to out-rule any concern for molar pregnancy that would require necessitate further pathological examination. If pregnancy tissue, appropriate to gestational age and ultrasound measurements, has clearly been seen following expulsion and the woman is clinically well there is no indication for routine ultrasound assessment prior to discharge.

If there is uncertainty regarding completion of MTOP in secondary care and an ultrasound is performed, the purpose of the ultrasound is to confirm that a gestational sac and its contents are no longer present regardless of endometrial thickness measurement.

Should the medical regime process fail, with no passage of pregnancy tissue, then the woman should be reviewed by a senior clinician and further options discussed. It is good practice to ensure the correct dosage and administration of medications occurred as errors in this may explain the lack of success of the treatment.

Prior to initiation of the termination process, a normally sited pregnancy will have been confirmed on ultrasound therefore a repeat ultrasound is not mandatory if there has been no passage of pregnancy tissue. Once the termination process has been initiated it should continue until it is complete.

Provided the woman is haemodynamically stable and without signs of infection, then further options include one immediate further round of medical management or proceeding with surgical intervention.

There are no national or international guidelines or literature to guide dosage or regime for second round medical management in early pregnancy MTOP hence a pragmatic approach has been taken in relation to this. We recommend misoprostol should be administered as follow; 400 micrograms buccally 3 hourly x 5 doses, ceasing sooner if the TOP is complete.

In the event that a second round of medical management is unsuccessful, proceeding to definitive surgical management is recommended. See suggested management of MTOP in the first trimester (Algorithm I).

Recommendations

5. **There is no indication for routine ultrasound in women undergoing MTOP in secondary care prior to discharge if appropriate pregnancy tissue corresponding to ultrasound findings has been visualised following expulsion.**
6. **If there is uncertainty regarding completion of MTOP in secondary care and an ultrasound is performed, the purpose of the ultrasound is to confirm that a gestational sac and its contents are no longer present.**
7. **We recommend that if early MTOP in secondary care is unsuccessful the woman should be offered further medical or surgical management until termination is complete.**

Section 3: Continuing Pregnancy following MTOP

Introduction

Following complete TOP, a swift resolution of pregnancy symptoms such as breast tenderness and nausea occurs, corresponding to the reduction in circulating serum □hCG.

A low sensitivity urine pregnancy test (LSUPT) is provided to women to use 14 days after MTOP in the community to confirm that the termination has been completed [3]. LSUPT detects urinary □hCG levels of greater than 1,000 IU. Failure of pregnancy symptoms to dissipate, failure to pass expected pregnancy tissue or a positive LSUPT 14 days after MTOP may be suggestive of either continuing pregnancy or incomplete MTOP.

Clinical Question 2.4: **How can an ongoing pregnancy be identified in women undergoing early MTOP in a primary care setting?**

Evidence Statement

Continuing pregnancy following early MTOP is low with a meta-analysis of clinical trials yielding estimates of 0.4% at 49 days or less; 0.8% at 50-56 days; 1.8% at 57-63 days and 2.9% at 64-70 days [36,37]. Continued pregnancy is more likely if the medication regime has not been taken correctly or if vomiting has taken place within an hour of administration of mifepristone or within half an hour of administration of buccal misoprostol [38]. Persistence of pregnancy symptoms for more than five to seven days after MTOP or failure to pass expected pregnancy tissue would be suggestive of ongoing pregnancy and women should be advised to contact their provider and referral to secondary care should be considered [3].

Women who undergo MTOP in the community should be offered a follow up appointment two weeks after taking medication for MTOP. This can be either in person or via telephone as there has been shown to be no difference in outcomes with either follow-up method [2,21].

Ensuring medical termination has been completed in women at greater gestational age is of increased importance in Ireland given the legal gestational limit of 12 weeks' (84 days) or a crown rump length (CRL) of ≤63mm [4]. For women undergoing MTOP in the community close to the gestational community limit (close to 69 days from LMP), use of an enhanced follow up protocol should be considered [5,19].

Clinical Practice

The importance of ensuring that the termination has been completed should be emphasised to the woman by the care/TOP provider.

Women undergoing MTOP are provided with a LSUPT and advised to perform this test 14 days post administration of mifepristone. Women who have ongoing pregnancy symptoms or who have a positive LSUPT require a prompt medical review by their care/TOP provider.

Dependent on gestational age, if the provider is satisfied that a substantial bleed has occurred and that the women is clinically well (haemodynamically stable), it may be appropriate to repeat a LSUPT in 48 hours, or to take two serum □hCG readings 48 hours apart to determine if the □hCG levels are declining.

If the LSUPT continues to remain positive or if serum □hCG levels are not declining as expected, then referral to secondary care termination services is appropriate.

For women undergoing MTOP at the limits of gestational age for community medical termination (63-69 days gestation), it may be prudent to identify an ongoing pregnancy earlier in women who were >63 days gestation at the time of taking mifepristone using 48 hourly serial □hCG measurements. If a satisfactory reduction in □hCG levels is not observed, potential continuation of pregnancy will be identified sooner and thus referral to secondary care termination services can be arranged for ultrasound to confirm/out rule ongoing pregnancy.

Recommendations

8. **We recommend that if a woman has ongoing pregnancy symptoms or a positive low sensitivity urine pregnancy test following early MTOP in primary care, they should initially be reviewed by their primary care termination provider.**

Clinical Question 2.5: **What are the further management options for a woman that has an ongoing pregnancy following early MTOP?**

Evidence Statement

Should continuation of pregnancy be confirmed following MTOP and provided the pregnancy has not exceeded the 12-week (84 day) or CRL (≤63mm) legal gestational cut-off, then a repeat termination procedure can be facilitated. Women should be referred to their local secondary care termination provider, and options for medical or surgical treatment should be discussed with the woman. The decision of which method to proceed with should be at the woman's discretion. A full discussion of locally available options, the process and the physical symptoms should take place with the woman to facilitate her to make an informed decision [7,39].

If continuation of pregnancy occurs following MTOP and, due to a delay in recognition, the pregnancy has progressed beyond the 12-week legal gestational cut-off (84 days from LMP or CRL of >63mm), then despite the potential teratogenic effects it is not legal to initiate a repeat termination procedure[2]. In such cases, non-directive counselling should be arranged, and options to avail of TOP in other jurisdictions discussed.

The following are useful resources for both healthcare professionals and women experiencing a crisis pregnancy:

- BPAS – British Pregnancy Advisory Service – https://www.bpas.ie/
- Abortion Support Network – https://www.asn.org.uk/
- Informing Choices Northern Ireland – https://informingchoicesni.org/

Clinical Practice

Should a primary care GP provider suspect ongoing pregnancy post early TOP, referral to secondary care TOP services to confirm/out rule ongoing pregnancy should be arranged in a timely fashion. Provided the legal gestational limit of 12 weeks' (84 days) for termination has not been exceeded, options for medical or surgical repeat termination should be discussed with the woman and the decision of which option to proceed with should be at their discretion and dependant on local resources [4].

If the woman chooses to repeat medical treatment, a complete course of treatment should be given; oral mifepristone followed >24 hours but <48 hours later by buccal misoprostol. Consideration should be given to enhanced follow up to ensure the repeat termination procedure is completed. Retention in secondary care service to confirm passage of pregnancy tissue or scheduled ultrasound follow up in secondary care service, for those suitable for community repeat medical treatment, may be considered.

Recommendations

9. **We recommend that women should be referred in a timely fashion to secondary care termination services if ongoing pregnancy is suspected/confirmed following MTOP.**

Section 4: Pain following MTOP

Introduction

Crampy pain, generally worse than menstrual pain, often starts within 1-4 hours of taking misoprostol and is an expected part of the process [40]. Severe or prolonged pain may be due to ongoing or incomplete termination, ectopic pregnancy, or rarely uterine rupture.

Clinical Question 2.6: **What is the recommended approach when a woman has severe pain following MTOP?**

Evidence Statement

The peak of pain following MTOP commonly occurs at the expulsion of the gestational sac [41]. At advancing gestation, it may be possible to identify when pregnancy tissue has passed following MTOP. In a minority of women, expulsion of pregnancy tissue will occur prior to misoprostol administration [10,41]. It is good practice to take misoprostol as directed, even if pregnancy tissue appears to have passed after mifepristone alone, to reduce the risk of incomplete termination. Pain in the absence of significant bleeding should prompt consideration of an ectopic pregnancy [2].

Uterine rupture is a rare complication of TOP but should be considered in the setting of ongoing pain and bleeding particularly in multiparous women and those at higher gestations due to an increased sensitivity to misoprostol [8,39]. The rate of uterine rupture in women who have a scarred uterus undergoing MTOP between 12 and 24 weeks' is very low at 0.28% [7].

Perception of pain can be exacerbated by fear, anxiety, lack of adequate supports and moral concerns [42].

Clinical Practice

Concern regarding expected levels of pain and bleeding can be mitigated by the provision of clear information and support given in the form of both verbal counselling and written information.

It is best practice to recommend administration of a non-steroidal anti-inflammatory drug (NSAID) (e.g., Ibuprofen 600-800mg orally) in the absence of any medical contraindications, before misoprostol. Use of heat applied to the site of pain can also help [2].

In the community, women who experience severe pain following MTOP, that does not improve despite analgesia and heat, should be advised to contact their primary termination care provider. If out of hours women should contact MyOptions.ie which is open 24/7 for medical advice, or the local emergency department immediately.

In the primary care setting medical review should be undertaken to assess for possible aetiology of pain and the next appropriate step. If the woman has ongoing bleeding, sterile speculum examination can be performed to assess for pregnancy tissue occluding the cervical os which can cause severe pain, as well as syncopal episodes from vagal stimulation.

In the setting of absent or scanty bleeding and pain, the possibility of an ectopic pregnancy should be considered. In a woman who is haemodynamically stable referral to secondary care termination services for ultrasound assessment is recommended. If there are signs of haemodynamic compromise such as tachycardia or hypotension, or if the woman is experiencing severe pain, dizziness or feeling weak, urgent referral to a secondary care emergency department is required.

On admission to secondary care bloods including a full blood count (FBC), urea and electrolytes (U&E) blood group with antibody screen and crossmatch should be sent urgently.

If an ectopic pregnancy is identified, management should be guided by the clinical presentation and examination findings. If the woman has signs of haemodynamic compromise, or evidence of ruptured ectopic on ultrasound, an emergency laparoscopy or laparotomy is indicated.

Recommendations

10. **We strongly recommend that healthcare workers providing MTOP should be familiar with potential complications such as heavy vaginal bleeding, ongoing severe pain and retained pregnancy tissue and their respective management approaches.**
11. **We suggest that ectopic pregnancy be considered in any woman attending with severe, ongoing pain in the setting of minimal vaginal bleeding following MTOP.**
12. **Women who experience severe pain that does not improve despite analgesia following MTOP in the community, should be advised to contact their primary termination care provider. If out of hours they should be advised to contact MyOptions.ie which is open 24/7 for medical advice, or the local emergency department, immediately.**

Section 5: Haemorrhage

Introduction

The most frequent cause of haemorrhage at time of early medical termination is incomplete evacuation of the uterus. Haemorrhage in the second trimester may be due to retained pregnancy tissue, uterine atony or, very rarely, uterine rupture. Haemodynamic instability combined with ongoing vaginal bleeding is a medical emergency and requires escalation in clinical care to prevent morbidity.

Clinical Question 2.7: **What is the recommended approach when a woman has heavy or excessive vaginal bleeding following MTOP?**

Evidence Statement

Bleeding following a MTOP is typically more prolonged than that of a STOP and may be ongoing several weeks following medication administration. Over three quarters of women will describe their bleeding as spotting at 15 days post MTOP [41]. Up to 9% will have ongoing bleeding at 30 days and 1% at 60 days post MTOP [41].

Heavy bleeding requiring blood transfusion following MTOP is rare with a rate of 0.03-0.1% [21,32]. Surgical intervention for excessive bleeding is required in up to 1.4% of MTOP up to 49 days gestation and 2.5% of MTOP up to 63 days gestation [21]. Up to 20 weeks gestation the rate of severe bleeding following MTOP or STOP requiring blood transfusion is 1 in 1000 cases [43].

Unlike post-partum women, haemorrhage in women undergoing medical termination of pregnancy at early gestations is rarely due to uterine atony and therefore the benefit of administration of uterotonic agents in such circumstances is limited. Particularly, the use of oxytocin in the first and early second trimester is not recommended due to low levels of oxytocin receptors in the myometrium [44].

Clinical Practice

Following MTOP in the community, women should be provided with clear information relating to expected pain and bleeding and where and when to seek help if pain or bleeding is beyond expected levels.

If bleeding soaks through two thick full-sized sanitary pads per hour for two consecutive hours, women should seek advice from their TOP provider, contact the MyOptions.ie helpline or go directly to the nearest secondary care emergency department. This is particularly pertinent if bleeding has lightened and then becomes acutely heavy again.

The assessing clinician should be mindful of symptoms such as dizziness or weakness that may indicate symptomatic anaemia. If any of these signs or symptoms are reported by phone, it is good practice to advise the woman to urgently attend the nearest emergency department.

If following assessment in primary care bleeding is not very heavy or is getting progressively lighter, and the woman is clinically well with no signs of haemodynamic compromise, expectant management should be considered.

Women undergoing MTOP in a hospital setting require careful vigilance by staff for complications such as excessive bleeding.

Management of women with acute haemorrhage will depend on the underlying aetiology and the clinical context.

The most common cause of acute haemorrhage in women undergoing MTOP is incomplete evacuation of the uterus. In such cases where there is retained pregnancy tissue or retained placenta and associated bleeding, definitive surgical intervention to evacuate the uterus should not be delayed. Algorithm II describes the suggested management of acute haemorrhage following MTOP in secondary care.

Recommendations

13. **We recommend that women should be advised to seek medical assessment if they experience heavy vaginal bleeding that soaks through two or more sanitary pads per hour for two consecutive hours post MTOP in the community.**

Section 6: Incomplete Termination of Pregnancy

Introduction

Incomplete termination is defined by the presence of an open cervical os and bleeding whereby all pregnancy tissue has not been expelled from the uterus [39]. Symptoms of incomplete termination include ongoing vaginal bleeding and abdominal or pelvic pain [39]. Retained pregnancy tissue can provide an ideal environment for the development of infection which can cause symptoms such as fever or malodourous vaginal discharge [45].

Clinical Question 2.8: **What is the recommended approach to management of incomplete TOP?**

Evidence Statement

Retained pregnancy tissue following TOP is uncommon, with less than five percent of women requiring further management [28]. In a haemodynamically stable woman there is no indication for routine ultrasound post MTOP as it is neither sensitive nor specific for clinically significant [47].

Women who undergo medical termination are more likely to have retained pregnancy tissue than those who undergo surgical management [8,22,39]. In women undergoing a second trimester MTOP, if the placenta has not delivered one hour post-delivery of the fetus, surgical intervention for uterine evacuation should be arranged [19,28]. The risk of having retained pregnancy tissue following STOP is reduced by ensuring adequate provider training and routinely priming the cervix with misoprostol pre-operatively [7,8].

The decision for how to manage retained pregnancy tissue should consider both the woman's clinical status and preference [7]. Options include conservative management, medical management using repeated doses of misoprostol and surgical management with evacuation of retained pregnancy tissue (ERPC). Conservative management of clinically well women with retained pregnancy tissue can be as effective as medical management with misoprostol, it also has the advantage of avoiding medication side effects and intrauterine instrumentation [7,39].

In the absence of signs of infection there is insufficient evidence to support routine antibiotic prophylaxis prior to ERPC for incomplete termination [49].

Clinical Practice

In the primary care setting if a woman has symptoms suggestive of incomplete termination following MTOP, i.e., a positive LSUPT, erratic or increased PV bleeding, they require a medical review.

If, following assessment by the primary care termination provider, there is no concern for ongoing pregnancy, ectopic pregnancy or infection such as endometritis, it may be appropriate to manage the woman conservatively in the community with planned follow up in 10-14 days to ensure complete termination. It is important to inform the woman to re-attend if bleeding becomes heavy or there are signs of infection.

If there is prolonged, ongoing bleeding or suspicion of infection, referral to secondary care for assessment is appropriate.

If following ultrasound assessment in the secondary care setting retained pregnancy tissue is identified, management options include conservative, medical and surgical management.

In a haemodynamically stable woman who has an incomplete MTOP and chooses either conservative or medical management, follow up ultrasound should be arranged in 10-14 days to ensure all tissue has been passed.

For women who opt for medical management of incomplete termination less than 14 weeks gestation, administration of misoprostol should be 400 micrograms sublingually, buccally or vaginally or 600 micrograms orally. In cases of a missed abortion (retained non-viable fetus), mifepristone 200 mg orally should be administered 24-48 hours before misoprostol [43].

In a haemodynamically unstable woman whereby retained pregnancy tissue is causing heavy bleeding and/or systemic infection prompt uterine evacuation should be performed. Routine prophylactic antibiotics should be given as per local guidelines in the absence of infection. If there is a suspicion for infection, a high vaginal swab (HVS) should be taken for culture and sensitivities and broad-spectrum antibiotics should be commenced immediately.

In a woman who has retained pregnancy tissue in situ for a prolonged period i.e., >6-8 weeks from initial MTOP, an alternative surgical approach to ERPC should be considered as tissue can be adherent increasing complication and failure rates. Hysteroscopic resection may be required and should be planned in conjunction with an experienced operator.

Recommendations

14. **We suggest that if a woman is clinically well with symptoms suggestive of retained pregnancy tissue they be managed conservatively in the community.**
15. **We recommend referral to secondary care if there is prolonged, ongoing bleeding or a suspicion of infection.**
16. **We recommend that in a haemodynamically unstable woman who has heavy vaginal bleeding secondary to retained pregnancy tissue prompt uterine evacuation should be performed.**

Section 7: Infection

Introduction

Infection is reported in less than 1% of women following TOP [3,39]. Between 0.1-0.2% of women undergoing early TOP will require intravenous antibiotics for a diagnosis of endometritis [39]. Typical symptoms of infection include fever and chills, pelvic pain, malodorous discharge, and prolonged bleeding [50]. Infection is most often caused by retained pregnancy tissue which can then cause secondary haemorrhage [2,7,8].

Clinical Question 2.9: **What is the recommended approach to management of suspected infection following TOP in the primary care setting?**

Evidence Statement

Routine use of prophylactic antibiotics post MTOP is not recommended [8]. Fever following administration of misoprostol is a common side typically lasting less than 12 hours. While usually mild, it can be as high as 38-40 degrees Celsius. Administration of misoprostol buccally rather than vaginally can further reduce the risk of infection [51]. An incomplete TOP can present with signs of infection as well as protracted bleeding [41,45].

Clinical Practice

Women should be advised to seek assessment if bleeding is not getting lighter, has lightened off and starts getting heavier again, or if it is associated with a foul odour or increasing abdominal or pelvic pain. The woman should be informed of 'red flag' symptoms such as abdominal or pelvic pain, heavy bleeding, or fevers and to seek medical review if any of them arise.

Face to face consultation should be arranged to perform a clinical assessment. A detailed history should be taken to screen for incomplete termination and potential for retained pregnancy tissue if a less than expected volume of pregnancy tissue has passed. Recording of vital signs including temperature, blood pressure, pulse, and respiratory rate as well oxygen saturation is important to assess for signs of sepsis. Consider performing investigations such as Full Blood Count (FBC), C-Reactive Protein (CRP) and an HVS. A Chlamydia and Gonorrhoea screen can be performed by sending a low vaginal/endocervical swab/urine sample as dictated by local protocol.

If the woman is well and mild infection is suspected, oral broad-spectrum antibiotics should be commenced in accordance with local antimicrobial guidelines dependent on the maternity unit or 'antibioticprescribing.ie' for community care (available at; https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/list-of-conditions-and-treatments.html).

If the woman is unwell and has signs of systemic infection, urgent transfer to secondary care should be arranged. If there is any delay in transfer, resuscitative measures including obtaining IV access, administrating IV fluids and broad-spectrum antibiotics should be commenced, and if available supplemental high flow oxygen should be used.

Recommendations

17. **We suggest that if mild genital tract infection is suspected following examination, preliminary investigations can be performed in the primary care setting and oral broad-spectrum antibiotics should be commenced in accordance with local antimicrobial guidelines.**

Clinical Question 2.10: **What is the recommended approach to management of suspected infection in the secondary care setting?**

Evidence Statement

Routine screening for infection in asymptomatic women prior to undergoing TOP is not recommended [3]. Antibiotic prophylaxis for STOP is recommended as it reduces the likelihood of infection by half [8,39,52]. Only a very small number of women with retained pregnancy tissue go on to develop infection [45]. Initial and basic management for women referred into secondary care include recognising the complication and providing resuscitative care [39]. Recognition of sepsis and prompt uterine evacuation in the setting of concomitant retained pregnancy tissue is recommended to minimise mortality [53].

Clinical Practice

If infection of the genital tract is suspected, antibiotic use is indicated. The duration of antimicrobial therapy is usually 7-10 days depending on severity of infection and a broad-spectrum antibiotic may be used whilst awaiting culture and sensitivities. It is good practice to consult local antimicrobial prescribing guidelines before prescribing antibiotics.

Management of women who have a history and examination suggestive of severe systemic infection begins with resuscitative measures and the 'Sepsis 6' bundle [54];

- Blood and urinary cultures, high vaginal swab
- Blood tests including point of care lactate, Full Blood Count (FBC), Urea and electrolytes (U&E) +/- Liver Functions Test (LFT), Coagulation Profile, Fibrinogen, Group and Hold
- Hourly urinary output assessment
- Intravenous fluid administration
- Parenteral antibiotic administration as per local guidelines
- Supplemental oxygen to maintain oxygen saturations ≥94%.

If there is retained pregnancy tissue present, discussion with a senior clinician regarding timing of ERPC is recommended given the increased risk of complications in the setting of infection including heavy bleeding and uterine perforation.

Recommendations

18. **We recommend that if severe genital tract infection is suspected following examination, resuscitative measures such as commencing intravenous fluids, broad spectrum antibiotics and providing supplementary oxygen should be given without delay.**

Section 8: Surgical complications

Introduction

Ideally all surgical terminations under general anaesthetic should be performed using total intravenous anaesthesia (TIVA) with IV propofol and fentanyl. Inhalation agents such as nitrous oxides or isoflurane should be avoided as these agents cause relaxation of the myometrium, which increases the risk of perforation, as well as increasing blood flow and blood loss [7,10,39]. Antibiotic prophylaxis is recommended for all surgical terminations [8]. Single-dose administration of nitroimidazoles (metronidazole), tetracyclines (doxycycline) or penicillins have been shown to be effective when used as prophylactic antibiotics for surgical termination [5].

During vacuum aspiration, the uterus should be emptied using the suction cannula and forceps (if required) only. The procedure should not be routinely completed by sharp curettage as this can increase risk of perforation and adhesions [7]. Providers of STOP need to be experienced with the procedure and familiar with identification and management of potential complications. Women undergoing STOP in secondary care should have pregnancy tissue examined by appropriately trained clinical staff to ensure completeness of the termination procedure and to out-rule any concern for molar pregnancy that would necessitate further pathological examination.

Complications arising from surgical termination are outlined in Appendix 3.

Clinical Question 2.11: **What is the recommended approach to management of haemorrhage in a woman undergoing STOP?**

Evidence Statement

Haemorrhage at the time of surgical termination can result from retained pregnancy tissue, trauma or damage to the cervix, coagulopathy or uterine perforation. Appropriate treatment for haemorrhage depends on its cause and severity and includes re-evacuation of the uterus; administration of uterotonic drugs; blood transfusion; replacement of clotting factors; laparoscopy; exploratory laparotomy [7].

Clinical Practice

If there is increased bleeding from the uterus, direct bimanual compression or intrauterine tamponade will improve tone and reduce bleeding.

A low threshold for re-aspiration should be maintained as retained pregnancy tissue can cause brisk bleeding, and aspiration encourages compression of the placental bed.

In cases of a haematometra, re-aspiration and drainage will also provide resolution.

Clinical Question 2.12: **What is the recommended approach to management of a cervical laceration in a woman undergoing STOP?**

Evidence Statement

Cervical priming is recommended prior to all surgical terminations to reduce the incidence of cervical laceration [10]. Misoprostol 400mcg may be given sublingually one hour prior to the procedure, or buccally/vaginally 2-3 hours prior [10]. An alternative would be mifepristone 200mg orally 24-48 hours prior to the procedure [10]. Poor cervical dilatation may arise due to nulliparity or due to previous cervical surgery. Cervical laceration risk increases with advancing gestation and cervical/uterine anomalies (0.1% to 2%) [3]. Second trimester surgical terminations require additional cervical priming in the form of osmotic dilators [10].

Clinical Practice

Small and superficial laceration related to tenaculum use and application of local anaesthetic is not uncommon during a STOP and will usually resolve spontaneously. Persistent bleeding from the tenaculum site responds well to direct compression by applying pressure or compression with a sponge stick or a ring forceps, or by use of haemostatic agents such as silver nitrate or Ferric subsulfate solution (Monsel's™ solution).

If a laceration is bleeding, or is large (>1 cm), it should be repaired with an absorbable suture. Higher cervical lacerations, especially those suspected to involve a branch of the uterine artery will likely require balloon tamponade (foley or Bakri balloon) to treat the bleeding and rarely may require interventional radiology for embolisation if tamponade is not effective. A senior obstetrician/gynaecologist should be contacted if a high cervical laceration is suspected. If interventional radiology is not available, laparoscopy or laparotomy may be required.

Clinical Question 2.13: **What is the recommended approach to management of uterine perforation in a woman undergoing STOP?**

Evidence Statement

The risk of uterine perforation with surgical termination is approximately 1-4 in 1000 cases. It most commonly occurs at the time of cervical dilation for first trimester STOP and with the use of forceps for evacuation in second trimester surgical termination [7,8]. The risk of perforation increases with uterine anomalies, marked uterine flexion, cervical stenosis, inadequate cervical preparation, difficult or prolonged uterine evacuation and with less experienced providers [55]. In practice, uterine perforation usually goes undetected and resolves without the need for intervention [7].

Clinical Practice

Special management should be considered if any of the following occurs:

- Sudden pain during procedure (if awake)
- Instruments passing without resistance further than expected
- Contact with gritty surface of endometrium is lost
- Fat or bowel brought down with suction or identified on gross examination
- Bleeding more than expected
- Missing fetal parts with an empty uterus following dilation and evacuation (D&E)

- Unstable vital signs following completion of procedure
- Persistent post procedural pain
- Surgical abdomen on examination.

When available and necessary, laparoscopy is the investigative method of choice. If the woman's status or findings during laparoscopy suggest damage to the bowel, blood vessels or other structures, a laparotomy to repair any damage may be needed. Involvement of colorectal, vascular or urological surgeons may be required to ensure appropriate management of these complications.

Recommendations

19. **We strongly recommend that healthcare workers providing STOP should be familiar with potential complications such as haemorrhage, cervical lacerations and uterine perforation and their respective management approaches.**

Section 9: Psychosocial considerations

Introduction

All women experiencing a crisis pregnancy should be made aware of the non-directive counselling and supports available. MyOptions.ie has a full list of local and national unplanned pregnancy counselling agencies that provide unplanned pregnancy and post-termination counselling either face-to-face or over the phone. As with any medical or surgical procedure, complications can arise, and additional psychosocial care may be required.

Clinical Question 2.14: **What are the essential psychosocial considerations in the management of complications of TOP?**

Evidence Statement

It is normal for women to experience a range of emotions during and after a crisis pregnancy that include relief, sadness, guilt, embarrassment, and regret [56]. Most women do not experience any lasting psychological sequelae from undergoing a legal, voluntary TOP [57]. Research has shown that having a TOP alone does not increase a woman's risk for depression, anxiety, or post-traumatic stress disorder [1]. Women who experience a negative emotional reaction immediately following a TOP are more likely to have a poorer mental health outcome [58].

The women most at risk of negative outcomes are those:

- who do not have the psychological support of a partner and/or family
- with pre-existing psychological disorders
- whose religious beliefs or those of their social environment are disapproving of TOP
- who undergo TOP in the second trimester
- who desired pregnancy and underwent TOP for factors such as fatal fetal anomalies [58].

Younger women seeking TOP tend to have greater social and economic disadvantages [59]. The risk factors listed above are often confounding factors for these women and their risk of poorer mental health outcomes are higher [57,59]. It is not uncommon for women to experience recurring emotions about a termination later in life [60]. These are often triggered by life events such as difficulty in future pregnancies or significant milestones such as birthdays. Appropriate support and providing non-judgemental care around the time of termination can help dispel any stigma around TOP and reduce anxiety [13]. Follow up voluntary counselling can influence the emotions they may experience in future [60].

As part of the post termination follow up appropriate discussion around post TOP contraception is important as ovulation can occur as early as 8 days after administration of mifepristone [5,6,29,53].

Clinical Practice

Following TOP, all women should be offered contraceptive information and, if desired, the contraceptive method of their choice or referral for this service. Long-acting reversible contraception (LARC) is preferable and in so far as possible should be commenced immediately at the time of TOP in both primary and secondary care services [62].

In women undergoing STOP an intrauterine device can be inserted at the time of the procedure. In women undergoing MTOP Depo-provera™, Implanon™, and oral contraceptive agents can all be commenced at the time of administration of medication without effecting efficacy [53].

Women admitted to hospital with complications of TOP should be offered referral to the medical social work (MSW) team. Voluntary counselling sessions pre and post TOP should be available to women and their partners.

Consideration for referral to specialist mental health services should be given to women who have a history of mental health disorders.

If any concerns arise in relation to child protection and/or safeguarding, clinicians should be cognisant of the Children First Act (2015).[16]

The GP TOP provider should be informed when a woman is admitted to hospital with complications of TOP, provided the woman herself consents. This communication can be via a discharge summary letter or directly by phone to the GP TOP provider by the secondary care team. This feedback will facilitate GP TOP providers in ongoing education as well as recording and evaluating efficacy and safety data.

Recommendations

20. **Following TOP, all women should be offered contraceptive information and, if desired, the contraceptive method of their choice or referral for this service.**
21. **Long-acting reversible contraception (LARC) is the preferred method of contraception (for clinicians) and so far as possible should be commenced immediately at the time of TOP in both primary and secondary care services.**
22. **We suggest that women admitted to hospital with complications of TOP should be offered referral to the Medical Social Work (MSW) team and/or for counselling.**
23. **The GP TOP provider should be informed when a woman is admitted to hospital with complications of TOP, provided the woman herself consents. This communication can be via a discharge summary letter or directly by phone to the GP TOP provider.**

16 https://www.irishstatutebook.ie/eli/2015/act/36/enacted/en/html

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, PUBMED and Cochrane Library were searched using terms related to complications of TOP including 'termination of pregnancy', 'abortion', 'medical termination' and 'surgical termination'. Searches were limited to humans and English language articles published in the last 33 years. Guidelines from other national and international professional bodies on TOP and the associated complications were also reviewed.

3.2 Appraisal of evidence

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

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

A number of evidence-based recommendations for the management of complications of TOP were agreed upon. They have been developed 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 4) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for Guideline Developers' 2019.[17]

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.

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

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two.

The literature review process was conducted by all the Guideline writing group outlined in chapter one between December 2021 and February 2022. Dr Sinead Feeney, Dr Ken Harte and Dr Ciara McCarthy performed a literature search for all clinical questions specifically applicable to the primary care setting. Dr Sophie Boyd and Dr Deidre Hayes Ryan performed a similar literature review for all questions specifically applicable to secondary care setting. All submissions were reviewed by the principal Guideline writer, Dr Sophie Boyd. The Guideline was then drafted by Dr Sophie Boyd and Dr Deidre Hayes Ryan and approved by the writing group.

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 [63]. While we acknowledge that for this particular Guideline an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[18] (Appendix 5).

3.6 Future research

An important outcome of the Guideline development process is in highlighting gaps in the evidence base. TOP has only been legally permissible in the Republic of Ireland since 1st January 2019 [4]. The legislation is planned for review in 2022 [4] and following this there may be changes. With each change comes the need for further research and education.

Within Ireland there is limited published data on TOP beyond the basic statistics published in annual Department of Health reports [6]. One tertiary unit published a year in review of termination services which highlighted already varying practice in accordance with best practice and in management of complications of TOP [61].

To further improve patient guidance and best practice guidelines national data on adverse outcomes of TOP need to be collected and audited regularly. By identifying areas that require improvement and tailoring education and training to address them ensures safer service provision in the future.

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/

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[19] for developing Policies, Procedures, Protocols and Guidelines (2023) 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.

19 Health Service Executive (2023). How to develop HSE National Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://assets.hse.ie/media/documents/How_to_Develop_HSE_National_Policies_Procedures_Protocols_and_Guidelines_gQBQ4os.pdf

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.[20]

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 maternity units are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including Guideline committees will also be instrumental in the circulation of new and updated guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline and supporting documents available to all employees through standard networks. Electronic versions available on the https://www2.healthservice.hse.ie/organisation/national-pppgs/ 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.

In the case of this Guideline, we will disseminate it to the Institute of Obstetricians and Gynaecologists (IOG), Irish College of General Practitioners (ICGP), Nursing and Midwifery Board of Ireland (NMBI) and ask that it be made easily accessible to their members.

20 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

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, dissemination by the HSE Acute Hospitals Directorate to all acute hospitals, maternity units and primary care services ensures it is rolled out nationwide. Additionally, direct distribution to members of the Institute of Obstetricians and Gynaecologists (IOG) and to other interested parties and professional bodies will be facilitated by access to the Guideline on both HSE and RCPI websites.

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

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

6.2 Education plans required to implement the Guideline

Knowledge amongst staff has been shown to be poor in relation to termination services [64] and it is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required to provide a safe service.

Training of healthcare workers who work in acute presentation settings such as out of hours primary care centres and emergency departments to be aware of the management of a woman with a complication from a TOP is essential. The use of training and simulation days to prepare staff is important to foster good diagnostic and clinical skills.

Education around termination and the complications of TOP should be encompassed in the standard teaching syllabus for medical, midwifery and nursing students.

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. This Guideline has been developed with the aim of being applicable to all healthcare workers. As women may present to any healthcare facility seeking medical attention this Guideline has been written to provide guidance to healthcare workers regardless of their familiarity with TOP and its complications.

Potential external barriers include:

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

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

There is no role for conscientious objection in the emergency management of complications of TOP [1]. The treatment required must be provided to a person undergoing a TOP as matter of priority [1].

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.

In the case of this Guideline education around TOP and the associated complications is required. Given that termination is only currently available in certain primary and secondary care centres, healthcare workers may not have the same experience and knowledge base and thus local and national training is required.

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 change, as necessary. Audit should also be undertaken to provide evidence of continuous quality improvement initiatives. Audit of community care data is equally as important as secondary care data. Implementation of a centralised national electronic database to facilitate contemporaneous collection and analysis of anonymised community and secondary care data should be considered a priority.

Auditable standards for this Guideline include:

1. Number of women referred from primary care to secondary care TOP service pre TOP and indication for same *(e.g.; beyond gestational age for community TOP, medical co-morbidities, request for surgical TOP procedure)*
2. Number of women post MTOP in the community managed in primary care for complications *(e.g.; mild infection, retained pregnancy tissue)*
3. Number of women attending out of hours as an emergency to secondary care following MTOP in the community, timing and indication for same *(e.g.; pain, bleeding, generally unwell)*
4. Number of women referred from primary care to secondary care TOP service post MTOP, timing and indication for same *(e.g.; suspected ongoing pregnancy, suspected ectopic, retained pregnancy tissue, infection)*
5. Numbers of confirmed ongoing pregnancies following MTOP in the community and gestational age at time of confirmation
6. Number of confirmed ectopic pregnancies following MTOP in the community
7. Complication rate following MTOP in secondary care (as listed in Appendix 3).
8. Complication rate following STOP in secondary care (as listed in Appendix 3).

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.[21]

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

21 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.[22]

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.

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 because 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.

8.3 Review of the Guideline

This Guideline was reviewed by the authors in December 2025, no edits were deemed necessary at this time.

The Guideline was also updated to the most recent template; this includes the updating of 1.8 and the inclusion of 1.9 in chapter one.

22 Health Service Executive (2023). How to develop HSE National Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://assets.hse.ie/media/documents/How_to_Develop_HSE_National_Policies_Procedures_Protocols_and_Guidelines_gQBQ4os.pdf

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Supporting Evidence

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

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

Glossary

CAG Clinical Advisory Group

CRL Crown rump length

CRP C-reactive protein

D&E Dilatation and evacuation

EAG Expert Advisory Group

ERPC Evacuation of retained pregnancy tissue

EVA Electric vacuum aspiration

FBC Full blood count

G&H Group and hold

GPT Guideline Programme Team

GXM Group and crossmatch

HSE Health Service Executive

HVS High vaginal swab

IOG Institute of Obstetricians & Gynaecologists

IU International units

IV Intravenous

LARC Long-acting reversible contraception

LFT Liver function tests

LMP Last menstrual period

LSUPT Low sensitivity urine pregnancy test

MSW Medical social work

MTOP Medical termination of pregnancy

MVA Manual vacuum aspiration

NSAID Non-steroidal anti-inflammatory drug

NWHIP National Woman & Infants Health Programme

PPPG Policy, Procedures, Protocols & Guidelines

ßhCG Beta human chorionic gonadotropin

STOP Surgical termination of pregnancy

TIVA Total intravenous anaesthesia

TOP Termination of pregnancy

U&E Urea & electrolytes

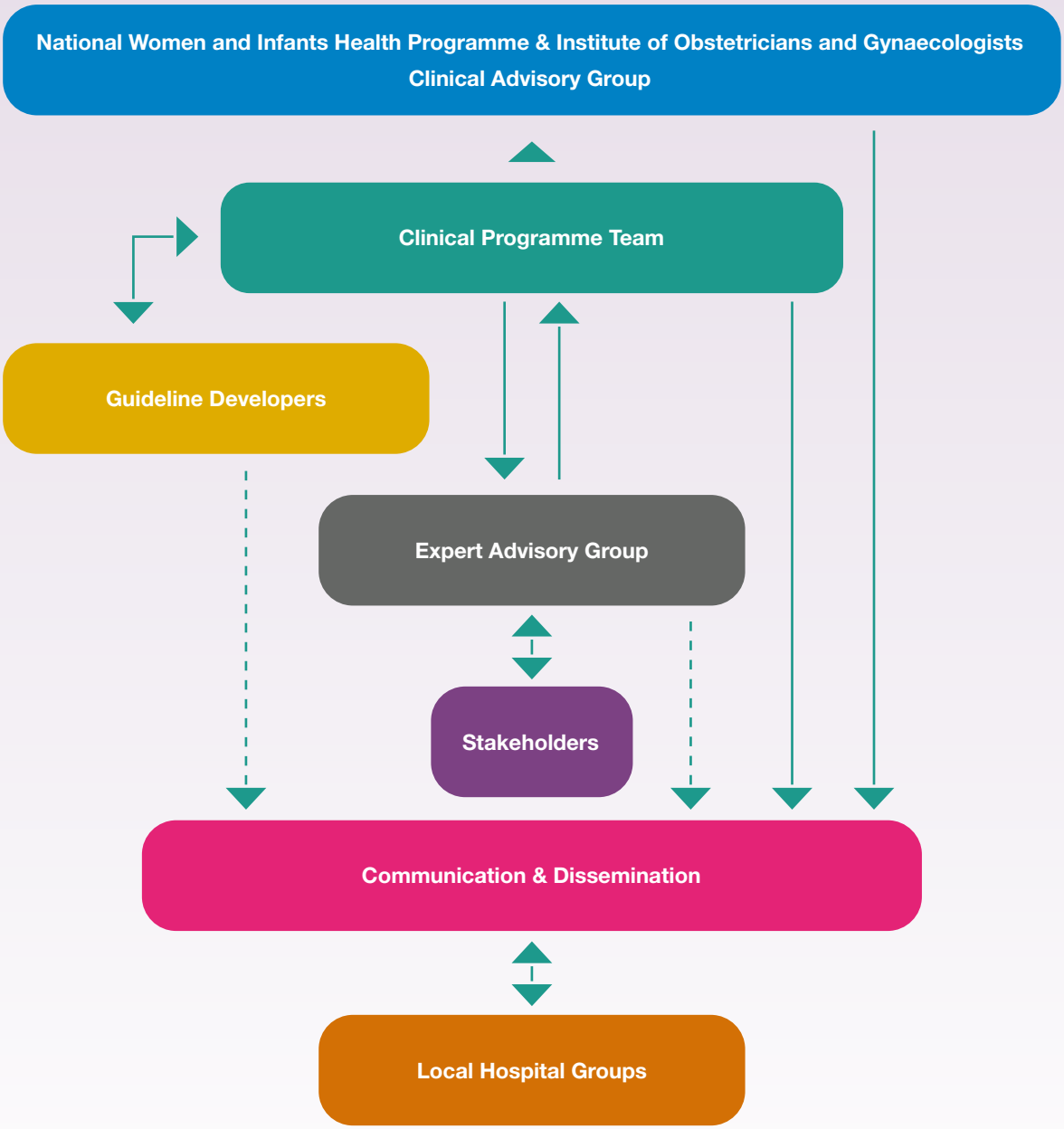
Appendix 1:
Expert Advisory Group members 2021-

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

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

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **Risks of Complications of Termination of Pregnancy**[39]

Risks of complications of termination of pregnancy	Medical	Surgical
Continuing Pregnancy	1-2 in 100	1 in 1000
Severe bleeding requiring transfusion	< 20 weeks: < 1 in 1000 > 20 weeks: 4 in 1000	< 20 weeks: < 1 in 1000 > 20 weeks: 4 in 1000
Infection	<1 in 100	<1 in 100
Further intervention to complete the procedure	< 14 weeks: 70 in 1000 > 14 weeks: 13 in 100	< 14 weeks: 35 in 1000 > 14 weeks: 3 in 100
Cervical Injury	–	1 in 100
Uterine Perforation	–	1-4 in 1000
Uterine Rupture	< 1 in 1000*	–

* Without previous caesarean delivery 4 in 10,000, with previous caesarean delivery 2.8 in 1000

Appendix 4: AGREE II Checklist[23]

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	

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

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

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

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

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarised box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalise on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

Appendix 5: **Grades of Recommendation**[24]

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….

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

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

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

Appendix 6: **NWIHP/IOG CAG members (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.