HSE

National Women & Infants Health Programme

National Clinical Practice Guideline

First Trimester Miscarriage

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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Algorithms

Algorithm 1: Triage and assessment of first trimester early pregnancy pain and bleeding

Initial Midwifery Triage

- Confirm gestation (date of last menstrual period)
- Positive urine pregnancy test
- Clinical assessment (vital signs)

Clinical Features/Red Flags

- Systolic blood pressure ≤ 100mmHg
- Pulse rate ≥ 99 bpm
- IMEWS triggers
- Pain
  - Right/left iliac fossa pain
  - Shoulder tip pain
- Dizziness, pre-syncope, syncope or maternal collapse
- Altered level of consciousness
- Malodorous vaginal discharge
- Any other clinical concern

If Yes to Any ▶

If no to all ▼

Blood Loss/Red Flag

Excessive bleeding (i.e. changing a pad soaked with blood clots every 15 minutes or 4 soaked pads over one hour)

If Yes to Any ▶

If no to all ▼

High Risk of Ectopic Pregnancy

- Smoking
- Pelvic inflammatory disease
- Previous ectopic pregnancy
- Assisted reproduction
- Intrauterine contraceptive device (IUCD)
- Previous tubal surgery or pathology
- Endometriosis

If Yes to Any ▶

If no to all ▼

Escalation

Inform Senior Staff

(Medical and Midwifery)

- Transfer to resuscitation area
- Intravenous access
- Bloods
- Full blood count
- Group and save +/- Cross match
- IV Fluids
- Analgesia
- Clarify allergies

Triage as non-urgent and requiring medical review

Await medical review in emergency room OR

Consider if direct referral to the early pregnancy unit is appropriate with safety netting

Consider timing as per relevant clinical risk factors.

Provide relevant information leaflet and emergency contact information

Algorithm 2: Assessment and management of first trimester bleeding

History

- Date of last menstrual period
- Duration and quantity of bleeding
- Has any pregnancy tissue passed?
- Is there abdominal pain and/or foul discharge?
- Is there any associated symptom
  - e.g. shoulder tip pain, pain out of proportion to bleeding, syncope?
- Regular medication and/or relevant medical history
- Previous uterine or abdominal surgery?
- Examination
- Vital signs
- Abdominal examination
- Speculum/bimanual pelvic examination

Haemodynamically compromised woman

- Call for help – Senior Obstetrician/Midwife/ Anaesthetist
- Resuscitation
  - Airway
  - Breathing
  - Circulation
- 2x 14G cannulas
- Full blood count, urea and electrolytes, coagulation profile fibrinogen, group and save and cross-match
- Point of care arterial and/or venous sample
- High flow oxygen
- Intravenous fluids
- Urinary catheter, monitor output hourly
- Consider blood products: red cells, platelets, fibrinogen, fresh frozen plasma and clotting factors

Confirm pregnancy location

- Consider previous ultrasound scan findings
- Consider performing immediate transabdominal/transvaginal ultrasound scan or if the woman is clinically stable refer to the early pregnancy unit for ultrasound scan

Ectopic pregnancy

- Refer to National Clinical Practice Guideline Diagnosis and Management of Ectopic Pregnancy

Intrauterine pregnancy visualised

Pregnancy of unknown location

- Refer to National Clinical Practice Guideline Diagnosis and Management of Ectopic Pregnancy

Intrauterine pregnancy

- Gestational sac with fetal heartbeat present or absent
- Differential diagnosis
  - Viable pregnancy
  - Pregnancy of uncertain viability
  - Missed miscarriage
  - Incomplete miscarriage

Individualise care according to clinical findings

Ongoing/incomplete miscarriage presenting with moderate to severe haemorrhage

- Full blood count (FBC), coagulation profile and fibrinogen, group and cross-match
- High vaginal swab (HVS), urine for microscopy and culture if infection suspected
- Intravenous access
- Consider surgical evacuation for retained pregnancy tissue
- Consider broad spectrum antibiotics if infection suspected
- Consider use of intravenous tranexamic acid, fibrinogen and clotting factors

Complete miscarriage

- No intrauterine gestational sac visualised
- Previous departmental ultrasound scan confirming intrauterine pregnancy
- If miscarriage is considered complete and the woman remains clinically well with a stable haemoglobin, no further follow-up (i.e. high sensitivity urinary pregnancy test or ultrasound) is indicated.

In the absence of a previous ultrasound scan confirming an intrauterine pregnancy, women with ultrasound scan features suggestive of complete miscarriage should be managed as pregnancy of unknown location

Adapted from: Queensland Clinical Guide. Early pregnancy loss. Flowchart: F22.29-2-V5-R27 http://www.health.qld.gov.au/qcg

Algorithm 3: Management of first trimester miscarriage

Miscarriage diagnosis is confirmed

Discuss management options relevant to woman's preferences and clinical indications

The Miscarriage information booklet should be provided

Conservative

Indications

- Woman's preference
- Clinically stable

Contraindications

- Haemodynamic instability
- Infection
- Suspected gestational trophoblastic disease
- Medical conditions increasing risk of haemorrhage

Complications

- Feeling faint (1-2/100)
- Heavy bleeding (1/100)
- Haemorrhage requiring blood transfusion (1/1000)
- Retained pregnancy tissue requiring further treatment (3-10/100)
- Infection (1-3/100)

Management

- Evaluate history and examination to assess suitability for conservative management
- Offer conservative management for 2 weeks.
- Women should be advised to contact their local early pregnancy unit in the following instances:
  - Passage of pregnancy tissue followed by lightening or resolution of bleeding (i.e. complete miscarriage)
  - Prolonged heavy/abnormal vaginal bleeding
- To confirm if miscarriage is complete:
  - Ultrasound should be completed 2 weeks after cessation of bleeding
  - If a woman declines ultrasound follow-up and is clinically well, a high sensitivity urinary pregnancy test should be completed 3 weeks after cessation of bleeding. If this test is positive, women should contact their local early pregnancy unit
- Persistent heavy and/or abnormal vaginal bleeding warrants immediate ultrasound follow-up

Medical

Indications

- Woman's preference
- Clinically stable
- Cytogenetic sampling as inpatient management

Contraindications

- Haemodynamic instability
- Infection
- Suspected gestational trophoblastic disease
- Medical conditions increasing risk of haemorrhage

Complications

- Feeling faint (1-2/100)
- Heavy bleeding (1/100)
- Haemorrhage requiring blood transfusion (1/1000)
- Retained pregnancy tissue requiring further treatment (7/100)
- Infection (1-3/100)
- Misoprostol side-effects (≥ 1/10 diarrhoea, ≥ 1/100 – < 1/10 nausea and vomiting, ≥ 1/1000 – < 1/100 fever)

Management

- Evaluate history and examination to assess suitability for inpatient or outpatient medical management
- Dispense mifepristone followed by misoprostol 24 to 48 (ideally 36) hours later
- If vaginal bleeding has not started 48 hours after taking misoprostol, women should contact their local early pregnancy unit. A second dose of misoprostol may need to be administered
- Follow-up (high sensitivity urine pregnancy test or ultrasound) after inpatient management is not indicated if miscarriage is confirmed complete by a healthcare professional (i.e. fetal tissue and /or pregnancy tissue are present in obtained pregnancy tissue)
- Outpatient follow-up is recommended 3 weeks after completing medical management by either high sensitivity urinary pregnancy test or ultrasound

Surgical

Indications

- Woman's preference
- Previously unsuccessful conservative or medical management
- Cytogenetic sampling

Absolute indications

- Haemodynamic instability
- Persistent excessive bleeding
- Septic miscarriage
- Suspected gestational trophoblastic disease

Complications

- Feeling faint (1-2/100 only if awake during surgery)
- Heavy bleeding (1/100)
- Haemorrhage requiring blood transfusion (1/1000)
- Retained pregnancy tissue requiring further treatment (1-3/100)
- Infection (1-3/100)
- Uterine perforation (1-4/1000)
- Cervical trauma (1/100)
- Ashermans Syndrome (1/100)
- Anaesthesia risks (<1/1000)

Management

- Evaluate history and examination to assess suitability for surgical management
- Dispense misoprostol or mifepristone for cervical priming
- Consider ultrasound during surgical evacuation
- No follow-up indicated unless retained pregnancy tissue or gestational trophoblastic disease is suspected (i.e. with high sensitivity urinary pregnancy test or ultrasound)

Adapted from: Queensland Clinical Guide. Early pregnancy loss. Flowchart: F22.29-1-V5-R27 http://www.health.qld.gov.au/qcg

Key Recommendations

Assessment of Miscarriage

1. Women (with a positive urinary pregnancy test) who present with heavy bleeding, soaking 4 or more pads over 1 hour, and/or severe pain require urgent medical assessment in secondary care. (Best Practice)
2. Women who are considered clinically stable after appropriate medical assessment are suitable for outpatient follow-up in the early pregnancy unit and should be advised to re-attend secondary care if new and/or red flag symptoms (excessive bleeding, severe lower abdominal pain, new onset unilateral pain, shoulder tip pain, presyncope and malodourous vaginal discharge) develop. (Best Practice)
3. If a woman who is less than 6 weeks gestation presents with bleeding but no pain and has no risk factors for ectopic pregnancy (i.e. previous ectopic pregnancy), these women should be advised to repeat a high sensitivity urine pregnancy test (HSUPT) after 2 weeks. A positive test result, persistent bleeding and/or development of pain warrants referral to the local early pregnancy unit or out-of-hours emergency services if indicated. (Best Practice)
4. Ultrasound performed by appropriately qualified clinicians, who have completed accredited ultrasound training, is the primary modality to diagnose miscarriage. (Best Practice)
5. Transvaginal ultrasound is the recommended imaging modality for diagnosing miscarriage in women who are less than 8 weeks gestation. (Grade 1C)
6. When an intrauterine pregnancy is visualised on ultrasound, serum β-hCG has no role in predicting early pregnancy viability and should not be utilised to diagnose miscarriage. (Grade 1C)
7. If a pregnancy location is not visualised on ultrasound in a woman who reports heavy vaginal bleeding and/or pain, serial serum β-hCG should be measured and further guidance should be sought from the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy. (Best Practice)
8. A systematic approach should be utilised when performing both transvaginal and transabdominal ultrasound scans, including visualisation of relevant anatomical structures in the sagittal and transverse planes in addition to the adnexa. (Best Practice)

Diagnosis of Miscarriage

9. An ultrasound diagnosis of missed miscarriage is confirmed when no cardiac activity is identified in a fetal pole with a crown-rump length ≥7 mm on transvaginal ultrasound or >8 mm on transabdominal ultrasound. If a fetal pole and/or yolk sac is not visualised, a mean gestational sac diameter measuring ≥25 mm on both transvaginal and transabdominal ultrasound is diagnostic of a missed miscarriage. (Grade 1B)
10. If on transvaginal ultrasound, the mean gestational sac diameter is <25 mm with no yolk sac or fetal pole or if the fetal pole is measuring <7 mm with no cardiac activity identified within 30 seconds, then a diagnosis of pregnancy of uncertain viability may be made. A repeat ultrasound assessment is recommended after 7 to 10 days to clarify the diagnosis. (Grade 1B)

11. The presence of intrauterine retained pregnancy tissue with or without increased endometrial thickness (i.e. ≥15 mm) and no visualisation of an adnexal mass on ultrasound is diagnostic of an incomplete miscarriage. (Grade 1B)
12. The widest endometrial thickness diameter measuring <15 mm with prior ultrasonographic evidence of an intrauterine gestational sac or retained pregnancy tissue before bleeding onset is diagnostic of a complete miscarriage. (Grade 1C)
13. In the absence of a previous ultrasound scan confirming an intrauterine pregnancy, women with ultrasound features suggestive of complete miscarriage should be managed as a pregnancy of unknown location. Clinicians should refer to the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy for further management recommendations. (Best Practice)

Management of Miscarriage

14. Conservative or medical management in the absence of excessive bleeding, infection, and haemodynamic instability are appropriate management options for miscarriage. (Best Practice)
15. For medical management of missed miscarriage, we recommend pre-treatment with mifepristone 24 to 48 hours before misoprostol administration. (Grade 1A)
16. Misoprostol should be administered buccally, rather than orally, to improve treatment efficacy for medical management of miscarriage. (Grade 1B)
17. If vaginal bleeding has not started 48 hours after taking misoprostol, women should be advised to contact their local early pregnancy unit. A second dose of misoprostol may need to be administered. (Best Practice)
18. For inpatient medical management, further doses of misoprostol may be considered if no bleeding is observed 3 to 4 hours after taking 800mcg of misoprostol. A total of 4 further doses of 400mcg of misoprostol may be administered buccally every 3 to 4 hours until pregnancy tissue passes. (Grade 1B)
19. Surgical management for miscarriage should be performed using either manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA) and this management option should be offered to women exceeding 9 weeks gestation on ultrasound or those with a gestational sac diameter measuring > 30 mm. (Grade 2B)
20. A follow-up ultrasound scan is recommended 2 weeks after cessation of bleeding in women who undergo conservative management. Women who experience persistently heavy/abnormal vaginal bleeding during this 2-week period warrant immediate medical review and ultrasound assessment. (Best Practice)
21. For women who undergo medical management, a HSUPT or ultrasound completed 3 weeks after initiating medical management is recommended. (Best Practice)
22. If a woman opts to complete a HSUPT and this test is positive, or prolonged bleeding with a negative HSUPT is reported, women should be advised to contact their local early pregnancy unit for individualised care. (Best Practice)
23. In the management of incomplete miscarriage, conservative, medical and surgery are appropriate management options. (Grade 1B)
24. We recommend 800mcg of misoprostol, to be administered buccally for medical management of incomplete miscarriage. (Grade 1B)
25. Ultrasound should be offered 2 weeks after cessation of bleeding in women who opt for conservative management for incomplete miscarriage. (Best Practice)

26. To ensure miscarriage is complete, follow-up with either a HSUPT or ultrasound 3 weeks after initiating medical management for incomplete miscarriage is recommended. (Best Practice)
27. Delayed or protracted vaginal bleeding as a result of incomplete miscarriage or inevitable miscarriage warrants urgent medical assessment in secondary care. (Best Practice)
28. Women who experience delayed or protracted bleeding and present with signs of haemodynamic instability should be resuscitated and assessed by senior clinicians before planning definitive management. (Best Practice)
29. All non-sensitised women who are rhesus negative should receive anti-D immunoglobulin prophylaxis if having surgical management for first trimester miscarriage. (Grade 2C)

Histopathological Examination

30. Histopathological Examination is usually performed where pregnancy tissue is available to exclude gestational trophoblastic disease. (Best Practice)
31. Women should be informed of the procedures and hospital policies that relate to management of pregnancy tissue, including options around burial of fetal tissue and/or return of pregnancy tissue. Specifically, women should be informed that often small quantities of pregnancy tissue are obtained, and it may not be possible to identify fetal tissue. (Best Practice)
32. For women who experience miscarriage in the community and present to secondary care with the pregnancy tissue, each maternity unit/hospital should have an established care pathway for pregnancy tissue, including discussion of histological examination and management of fetal tissue. Relevant healthcare professionals should be aware of these procedures. (Best Practice)
33. There is a need to review practice nationally in relation to the management of early pregnancy tissue, including its ultimate disposal, with a view to providing guidance on best practice. (Best Practice)

Complications of Miscarriage

34. Infection and retained pregnancy tissue are intermediate complications of delayed or unsuccessful management of miscarriage, while chronic endometritis often presents later. Intrauterine adhesions are a rare complication from excessive and/or repetitive uterine curettage. (Grade 2C)

Bereavement and Supportive Care

35. Healthcare professionals should be aware of the psychological sequalae associated with miscarriage which can affect women/couples and may contribute to long-term mental health morbidity if the necessary supports are not provided. Signposting to appropriate supports including psychological counselling, bereavement services and informal supportive resources may be indicated. (Best Practice)
36. Standards described in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death relating to sensitive communication, compassionate care, dignity and respect should be followed when caring for women/couples who have experienced miscarriage. (Best Practice)

Follow-up and Future Pregnancy Planning

37. Follow-up care after miscarriage should be tailored to each individual woman specifically relating to bereavement and psychological needs and communication of histopathological results. Written information outlining appropriate supports and follow-up plans should be provided to women/couples. (Best Practice)

38. Future pregnancy and family planning after miscarriage are important components of care. Women should be counselled appropriately in relation to future pregnancy planning and/or contraceptive options. (Best Practice)

39. For women who experience recurrent miscarriage, guidance should be sought from the National Clinical Practice Guideline: Recurrent Miscarriage for definitions, relevant investigations and management options for these women. (Best Practice)

Organisation and Provision of Services

40. All women who experience early pregnancy complications should be referred to a dedicated early pregnancy clinic for centralisation and coordination of care. (Best Practice)

41. Each early pregnancy unit should be accessible with sufficient staffing and facilities to provide appropriate clinical assessment, management and support for women/couples who experience miscarriage. (Best Practice)

Education

42. Healthcare professionals who care for women with early pregnancy complications should be supported through training and have access to education to fulfil their roles and responsibilities. (Best Practice)

43. A formal policy on staff support for those working in early pregnancy loss should be available and should outline a range of supports as described in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death. Support options including supervision, individual debriefing, peer group support and services of a professional counsellor such as the HSE Employee Assistance Programme to mitigate burnout and fatigue. (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 comprehensive evidence-based guidance for the assessment and management of miscarriage in the first trimester (the first 12 weeks) of pregnancy.

1.2 Scope

Target Users

The Guideline is a resource for all clinicians (doctors, advanced midwifery practitioners,[2] midwives, nurses and allied healthcare professionals) working in primary, secondary and tertiary care. The Guideline may also be a resource for women/couples who experience miscarriage as well as advocacy/support and research groups. To increase accessibility to this information, a plain language summary will also be available.

The scope of this Guideline is limited to assessment and management of first trimester miscarriage only and does not address investigation and treatment of recurrent miscarriage. Guidance for recurrent miscarriage is available in the National Clinical Practice Guideline: Recurrent Miscarriage.[1]

Target Population

Women and/or couples presenting with first trimester miscarriage.

1.3 Objective

To provide evidence-based recommendations for the care of women with suspected and confirmed miscarriage as well as promoting a standardised approach nationally across all maternity units/hospitals considering organisation of care, standardised management options in addition to supportive care and counselling.

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

2 Nursing and Midwifery Board of Ireland (NMBI) (2018) Advanced Practice (Midwifery) Standards and Requirements. Dublin.

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.

The following were involved in the development and writing of this Guideline:

- Dr Clare Crowley (Specialist Registrar, Cork University Maternity Hospital)
- Ms Louise Dooley (Clinical Midwife Specialist, Cork University Maternity Hospital)
- Ms Niamh Spillane (Clinical Midwife Manager 3, Cork University Maternity Hospital)
- Ms Lynsey Manning (Midwife in EPU, Limerick University Maternity Hospital)
- Dr Ciara McCarthy (General Practitioner and ICGP Women's Health Lead, Cork)
- Dr Deirdre Hayes Ryan (Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital)
- Professor Keelin O'Donoghue (Consultant Obstetrician and Maternal-Fetal Medicine Subspecialist, 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 Expert Advisory Group has representatives from Obstetrics, Midwifery, Neonatology as well as Pharmacy.

Representatives from the Miscarriage Association of Ireland reviewed the Guideline and the Guideline Development Group are grateful for their input.

Dr Sorcha Ní Loingsigh, Consultant Haematologist and Clinical Lead Advisor in Transfusion, Irish Blood Transfusion Service and Dr Eoghan Molloy, Consultant Haematologist, Cork University Hospital consulted the Transfusion SIG of the Irish Haematology Society for guidance in recommendations around Anti-D Immunoglobulin.

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

- Dr Yvonne O'Brien, Consultant Obstetrician and Gynaecologist, Galway University Hospital Portiuncula University Hospital
- Ms Helen Byrnes, Clinical Midwife Specialist in Bereavement and Loss, University of Galway

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.[3] 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 women 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.[4]

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.[5]

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.

Professor Keelin O'Donoghue is Clinical Lead for Guideline Development in Maternity and Gynaecology at the National Women and Infants Health Programme (NWIHP), HSE (2021-) and leads implementation for the HSE's National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (2017-). In the last five years, she has received research funding for projects related to pregnancy loss, perinatal death and maternal-fetal medicine from Science Foundation Ireland, the Health Research Board, the Irish Research Council, the Department of Children and Youth Affairs, the Irish Hospice Foundation, the MPS Foundation and Féileacáin. Prof. O'Donoghue served/serves on the following Committees/Groups (in non-remunerated roles): Institute of Obstetricians and Gynaecologists (IOG) Speciality Training Committee (2014-); IOG Executive Council (2018-2022); Royal Irish Academy Life and Health Sciences Multidisciplinary Committee (2022-); Department of Health National Screening Advisory Committee (2019-2023); Termination of Pregnancy (Review Recommendations National Implementation Group (2023-); Perinatal Mortality National Clinical Audit Governance Committee (2014-); Clinical Advisory Group, NWIHP (2017-); International Stillbirth Alliance Advocacy Working Group (2022-).

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3 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

4 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

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

1.7 Disclaimer

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

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the 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 ensure informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements.

1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[6]. 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.[7] We also appreciate that there are risks to desexing language when describing female reproduction[8] [9].

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.[7]

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6 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/

7 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/

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

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

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision[10]. 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[11] . 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[12].

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[13]. 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[14]. 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[15]. 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 care15, [16]. 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.

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Chapter 2: Clinical Practice Guideline

Background

Miscarriage is defined as unintended pregnancy loss before the fetus reaches viability.[2] The term includes all spontaneous pregnancy losses from conception until 24 weeks gestation.[2] Early pregnancy loss or miscarriage usually occurs in the first trimester, and is estimated to complicate 15% of pregnancies, equating to 23 million miscarriages globally per annum.[3]

Definitions

The definitions for early pregnancy loss or early miscarriage vary across countries and professional organisations. The definition and diagnosis of early miscarriage is largely determined by ultrasonographic diagnostic criteria. The previous National Clinical Practice Guideline for Management of Early Pregnancy Miscarriage restricted gestation within 12 weeks,[4] while the accompanying National Clinical Practice Guideline Ultrasound Diagnosis of Early Pregnancy Miscarriage limited gestation within the first 13 weeks of pregnancy.[5] The American College of Obstetricians and Gynaecologists (ACOG) and the National Institute for Health and Care Excellence (NICE) in the UK define early miscarriage as a loss within 13 weeks gestation.[6,7] A recent Cochrane review evaluating the safety and efficacy of different miscarriage management options for early miscarriage, based their recommendations on pregnancies less than or equal to 14 weeks.[8]

Considering the relevant resources and current management practices across the Republic of Ireland, in this Guideline, early miscarriage will be defined up until and including 12+6 weeks gestation. A pregnancy within this definition includes those confirmed with urinary or serum β-hCG as well as those diagnosed by ultrasonography. Miscarriage after both spontaneous conception and artificial reproductive technologies (ARTs) are included in this definition of early miscarriage.

This Guideline provides recommendations for first trimester miscarriage only, since second trimester miscarriage largely has a different aetiology and requires different management.[9] Both pregnancy of unknown location (PUL) and ectopic pregnancies are excluded from this guideline, and appropriate guidance is available in the National Clinical Practice Guidelines: The Diagnosis and Management of Ectopic Pregnancy.[10] Molar pregnancies are also excluded, and relevant guidance is presented in the National Clinical Guideline Diagnosis, Staging and Treatment of Patients with Gestational Trophoblastic Disease.[11] Finally, this Guideline is not a substitute to guide management of early termination of pregnancy (TOP). Appropriate guidance and recommendations to manage early TOP and its complications are available in the Interim Clinical Guidance Termination of Pregnancy under 12 weeks and the National Clinical Practice Guideline: Investigation and Management of Complications of Early Termination of Pregnancy.[12,13]

Terminology

The terms miscarriage and early pregnancy loss are used interchangeably, and there is no consensus on terminology in the literature.[6] In 1985, Beard *et al.* advocated for the term miscarriage to replace abortion, considering the perceived distress the term abortion caused women.[14] The endorsement of this change in terminology, combined with shifts in legal, social, technological, and professional developments, prompted medical practitioners to implement this change in language in clinical practice.[15] Since patient centred care has evolved, use of sensitive and medically accurate terminology to describe early pregnancy loss forms an essential component of holistic care.

Consequently, it is now generally accepted that the term "abortion" and "pregnancy failure" should not be used to describe spontaneous miscarriage. The terms "anembryonic pregnancy", "blighted ovum" and "products of conception" should also be avoided.

The European Society of Human Reproduction and Embryology (ESHRE) special interest group for early pregnancy loss have published recommendations for appropriate terminology relating to first trimester miscarriage to ensure clarity and standardisation.[16]

Considering these recommendations, we propose and will use the following terminology to describe first trimester pregnancy loss:

Early pregnancy loss	spontaneous loss of pregnancy (i.e. biochemical pregnancy loss, miscarriage, ectopic pregnancy) before 12+6 weeks of gestational age
Biochemical pregnancy loss	spontaneous pregnancy loss based on previously positive urinary or decreasing serum β-hCG that then becomes negative, without ultrasound evaluation
Viable intrauterine pregnancy (VIUP)	intrauterine sited gestational sac containing a fetal pole with cardiac activity visualised on ultrasound
Pregnancy of unknown location (PUL)	temporary classification to describe a pregnancy that cannot be visualised inside or outside the uterus on transvaginal ultrasound in the context of elevated β-hCG
Pregnancy of uncertain viability (PUV)	intrauterine pregnancy with a mean gestational sac diameter <25 mm with no yolk sac or fetal pole, or fetal pole measuring <7 mm with no cardiac activity observed within 30 seconds on transvaginal ultrasound
Threatened miscarriage	history of vaginal bleeding, in the presence of an intrauterine pregnancy visualised on ultrasound, before fetal viability is ascertained
First trimester miscarriage	a non-viable intrauterine pregnancy with either an empty gestational sac or a gestational sac containing a fetal pole without cardiac activity within 12+6 weeks gestation
Inevitable miscarriage	history of vaginal bleeding in the presence of an open cervical os with an intrauterine pregnancy visualised on ultrasound

Missed miscarriage	Intrauterine sited gestational sac containing a fetal pole with no cardiac activity where the crown-rump length measures ≥7 mm on transvaginal ultrasound or >8 mm on transabdominal ultrasound. If a fetal pole is not visualised, a mean gestational sac diameter ≥25 mm with no yolk sac and/or fetal pole on both transvaginal and transabdominal ultrasound is also diagnostic of a missed miscarriage
Incomplete miscarriage	Retained intrauterine pregnancy tissue with or without increased endometrial thickness (i.e. ≥15 mm) and no visualisation of an adnexal mass on ultrasound
Complete miscarriage	an empty uterine cavity with no intrauterine or extrauterine pregnancy visualised on transvaginal ultrasound, where the widest endometrial thickness diameter measures <15 mm with prior ultrasonographic evidence of an intrauterine gestational sac or retained pregnancy tissue before onset of bleeding

Risk factors

The most common aetiology for miscarriage is fetal chromosomal abnormalities accounting for approximately 60% of pregnancy losses.[17] There is a strong association between advancing maternal age and risk of trisomy, particularly trisomy 16, which rises linearly from 20 to 40 years of age.[17] Several maternal medical conditions including antiphospholipid syndrome, systemic lupus erythematosus, diabetes mellitus and hyperthyroidism are also associated with miscarriage.[3] Factors such as smoking and alcohol consumption may increase risk of miscarriage.[18, 19] Discussion of risk factors for miscarriage and recurrent miscarriage are beyond the scope of this guideline, and are addressed in detail in the National Clinical Practice Guideline: Recurrent Miscarriage.[1]

Significance of miscarriage

Miscarriage has both physical and psychological consequences that not only impact women's health but also present implications for future pregnancy planning. The risk of miscarriage increases by approximately 10% with every additional miscarriage and in women diagnosed with three or more miscarriages this risk rises to 42%.[3] Miscarriage is also associated with future obstetric complications including, preterm birth, intrauterine fetal growth restriction, antepartum haemorrhage, placental abruption, and stillbirth.[3,20] Recurrent miscarriage is a predictor for chronic health conditions including cardiovascular disease and venous thromboembolism.[3]

Anxiety, depression, and post-traumatic stress are often complications of miscarriage for women, and to some degree their partners.[21,22] Further psychological consequences include intense grief and sadness for couples.[23] Women with a history of mental health problems or previous miscarriage may be at a higher risk of psychological morbidity.[24] In women who have experienced at least one pregnancy loss, symptoms of anxiety, depression and perceived stress are often more pronounced in subsequent pregnancies.[25,26]

Quality of care received and interactions with healthcare professionals at the time of miscarriage impact women's/couple's emotional and psychological wellbeing and can have lasting implications for women/couples. Studies examining the needs and care experiences of women and/or partners who were diagnosed with miscarriage identified more information, acknowledgement of miscarriage as a valid loss, psychological support and privacy in the hospital environment as key standards of care.[27,28]

The financial and psychosocial implications of miscarriage for women/couples are recognised and contribute to absenteeism from the workplace, decreased work productivity and fear of discrimination preventing miscarriage disclosure.[29,30] The grief and distress caused by pregnancy loss has prompted some countries to legislate for bereavement/compassionate/pregnancy loss leave acknowledging the profound significance of this event.[31,32] In Ireland, the PLACES Project – Pregnancy Loss in Workplaces: Informing policymakers on support mechanisms explored the lived experiences of women (and their partners) who have had a pregnancy loss before 24 weeks gestation. Considering these experiences the report sets out recommendations for supportive, protected and compassionate care in the workplace for those who have a pregnancy loss.[32]

Miscarriage Care in Ireland

There is a lack of standardised reporting and recording of miscarriage in Ireland as acknowledged by both the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death and the National Maternity Bereavement Experience Survey.[33,34] Previous National Clinical Practice for Management of Early Pregnancy Miscarriage stated that 20% of clinical pregnancies were complicated by miscarriage equating to 14,000 miscarriages per annum in Ireland.[4,35] Since birth rates have declined and definitions of miscarriage vary internationally, it is likely that this statistic under-estimates current miscarriage rates.[3] Additionally, information describing the incidence rates of hospitalisation for management of miscarriage and/or associated complications is limited. One study utilising retrospective data obtained through the Hospital In-Patient Enquiry database found that the rate of hospitalisation for miscarriage has declined over time.[36] However, this study did not include women who are managed in the community as well as those who do not present to healthcare services further underestimating overall miscarriage figures.

Recommendations relevant to this Guideline can also be found in:

- National Clinical Practice Guideline: Recurrent Miscarriage[1]
- National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy[10]
- National Clinical Practice Guideline – Diagnosis, Staging and Treatment of Patients with Gestational Trophoblastic Disease[11]
- Interim Clinical Guidance Termination of Pregnancy under 12 weeks[12]
- National Clinical Practice Guideline: Investigation and Management of Complications of Early Termination of Pregnancy[13]

Section 1: Assessment

Introduction

The clinical presentation of first trimester miscarriage varies. Women present to various care settings including primary care, maternity units/hospitals or co-located emergency departments in general hospitals. Irrespective of the care setting, national guidance recommends that the Irish Maternity Early Warning Score (IMEWS) is utilised to triage and assess all women with a confirmed clinical pregnancy.[37,38] Evidence to support clinicians in triaging and assessing women who present with first trimester vaginal bleeding and/or pain is derived from retrospective and prospective observational studies in addition to the NICE Guideline Ectopic pregnancy and miscarriage: diagnosis and initial management.[7,39-42] After appropriate clinical assessment, NICE guidelines advocate that women should be referred to a dedicated early pregnancy unit (EPU), alternatively known as an early pregnancy clinic/assessment unit (EPC/EPAU), and if clinically indicated women should attend this service within 24 hours.[7]

Clinical Question 2.1: What are the initial steps to assess a woman with signs and symptoms of early pregnancy loss?

Evidence Statement

Vaginal bleeding in the first trimester is a common early pregnancy complication, with a reported prevalence ranging between 7% and 24%.[43-46] Given the prevalence of this complication, women often present to primary care, maternity units/hospitals or emergency departments in general hospitals for clinical assessment to seek reassurance.[47,48] Emergency nurses do not regularly assess and care for women who present with first trimester vaginal bleeding and/or pain.[49] Limited evidence suggests there is uncertainty relating to triage, assessment and care of these women.[49,50] To ensure appropriate triage and assessment of these women, implementation of IMEWS is recommended across all hospital care settings to facilitate early recognition of signs of deterioration.[38] Consideration of IMEWS triggers, coupled with effective communication and accessible care pathways for women with a confirmed clinical pregnancy who present to emergency services is key to optimise care.[51,52]

The quantity of bleeding appears to correlate with the risk of miscarriage. Heavy bleeding confers to a high risk of miscarriage in comparison to lighter vaginal bleeding, while symptoms of nausea and vomiting are associated with a positive prognosis.[53] To estimate blood loss, speculum examination is a reliable indicator of reported bleeding quantity.[39] Although clinical history and examination are key, particularly in haemodynamically compromised women, both have limited diagnostic value. A Danish prospective study found clinical diagnosis of miscarriage based on clinical symptoms and findings were inaccurate in more than 50% of cases compared to ultrasound.[40] Sterile speculum examination aided diagnosis and clinical management in only 4.2% and 1.3% of women respectively who were subsequently diagnosed with a miscarriage.[41]

Serum β-hCG is often measured on initial presentation. However a single measurement of serum β-hCG is non-diagnostic, and cannot be used to differentiate between viable and non-viable pregnancies.[54] Considering serum β-hCG has no role in determining pregnancy viability, ultrasound has become the standard of care to diagnose miscarriage.[55] Ultrasound performed by suitably qualified clinicians in emergency departments demonstrate a specificity and sensitivity of 98% and 90% respectively in detecting a intrauterine pregnancy.[42] Women who present with pain and/or bleeding in early pregnancy should initially be triaged and assessed by clinicians in either primary or secondary care with appropriate referral to an EPU for further assessment to formalise diagnosis.

Clinical Practice

Primary Care

In the primary care setting if a woman presents with vaginal bleeding and/or pain, in the context of a positive high sensitivity urinary pregnancy test (HSUPT), a medical review is warranted. Firstly, a thorough history including onset and quantity of vaginal bleeding, pain characteristics and any associated symptoms should be documented. In the absence of ultrasonographic confirmation of an intrauterine pregnancy, date of last menstrual period (LMP) should be recorded to estimate current gestation.

The woman's past obstetric history particularly recurrent miscarriage, previous ectopic pregnancy and consideration of relevant risk factors for ectopic pregnancy recurrence is important for risk stratification. For women who present with suspected or confirmed ectopic pregnancy, clinicians should refer to the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy for further guidance.[10] If however, a woman who is less than 6 weeks gestation presents with bleeding but no pain and has no risk factors for ectopic pregnancy (i.e. previous ectopic pregnancy), these women should be advised to repeat a HSUPT after 2 weeks. If this test is negative, miscarriage is considered complete.

Abdominal examination may elicit guarding where ectopic pregnancy is suspected. If a woman presents with excessive bleeding with or without signs of haemodynamic compromise, emergency transfer to secondary care is warranted.

Sterile speculum examinations are not routinely performed in the primary care setting. However, in a woman presenting with heavy bleeding in the first trimester, particularly if haemodynamic compromise is also present, then consideration should be given to sterile speculum examination and removal of pregnancy tissue/blood clots from the cervical os while awaiting emergency transfer to secondary care.

If following assessment by the primary care provider, the woman is deemed haemodynamically stable, and risk of ectopic pregnancy is low, timely referral to the local EPU for assessment within 24 to 48 hours is appropriate. However, if urgent assessment is warranted, women should be reviewed in EPU within 24 hours of referral or in out-of-hours emergency care services if clinically indicated.

It is important to inform the woman to present to secondary care if the following symptoms develop:

- Excessive bleeding (i.e. changing a pad soaked with blood clots every 15 minutes over 1 hour or 4 soaked pads over 1 hour)
- Severe lower abdominal pain
- New onset unilateral pain
- Shoulder tip pain
- Presyncope out of proportion to quantity of bleeding

Emergency Department in General Hospital

Women of reproductive age who experience vaginal bleeding/pain, outside working hours, often present to main hospital emergency departments, which are usually co-located with maternity units/hospitals. Urinary hCG should be performed as an initial investigation. IMEWS should be utilised to triage and assess women, with a confirmed clinical pregnancy. To guide triage nurses and emergency medical teams each emergency department should have a clear standard operating procedure (SOP) to refer these women to the emergency/assessment room in the maternity unit/hospital for appropriate care and follow-up.

Emergency/Assessment Room in Maternity unit/hospital

In the emergency/assessment room the triaging midwife should implement IMEWS to identify women at risk of clinical deterioration and prioritise medical review accordingly. Quantity of vaginal bleeding, severity of pain and signs of hypovolaemic shock should also be considered (see Algorithm 1 and Appendix 3). Severe pain not responsive to simple analgesia and changing a pad soaked with blood clots more than once over 1 hour requires immediate clinical assessment.

In this clinical situation, prompt assessment and resuscitation are essential. Core components of resuscitation preclude to:

- Airway
- Breathing:
    - Respiratory rate with consideration of supplemental oxygen if indicated.
- Circulation:
    - Intravenous (IV) access, bloods including full blood count, renal and liver function, coagulation profile, group, and crossmatch and IV fluid resuscitation.
- Examination:
    - Abdominal examination to assess for pain and signs of acute abdomen. If ectopic pregnancy is suspected, bimanual examination may elicit cervical excitation or adnexal tenderness.
    - Sterile speculum examination is indicated to quantify the volume of bleeding or identify localised causes of vaginal bleeding (i.e. polyp or cervical ectropion). In instances where miscarriage is formally diagnosed or a woman is undergoing conservative/medical management, pregnancy tissue extruding from the cervical os may be removed to reduce bleeding.

If moderate to heavy vaginal bleeding persists, review by a senior clinician to determine whether emergency surgical evacuation or admission to secondary care for observation and formal ultrasound assessment is appropriate. Excessive bleeding with signs of haemodynamic compromise, such as tachycardia and hypotension, warrant immediate surgical evacuation.

Routine serum β-hCG should not be performed as an initial investigation on women who present with suspected miscarriage, threatened miscarriage and pregnancy of uncertain viability (PUV). Awaiting the result of serum β-hCG should not delay medical assessment and should not determine the decision to perform an ultrasound. If indicated, clinicians who have undergone formal training in ultrasound may perform bedside ultrasound scans to assess for the presence or absence of an intrauterine gestational sac.

In instances where ectopic pregnancy and pregnancy of unknown location (PUL) are diagnosed on ultrasound, serum β-hCG should be performed and the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy should be reviewed for further guidance.[10]

Both clinical and ultrasonographic findings should be considered to plan appropriate follow-up: either inpatient or outpatient management with EPU follow-up. For women who are deemed clinically stable and suitable for outpatient follow-up in EPU, it is important to inform these women to re-attend their local maternity unit/hospital if bleeding becomes heavier (i.e. changing a pad soaked with blood clots every 15 minutes over 1 hour or 4 soaked pads over 1 hour), new onset pain develops or pain is not relieved with paracetamol.

Recommendations

1. Women (with a positive urinary pregnancy test) who present with heavy bleeding, soaking 4 or more pads over 1 hour, and/or severe pain require urgent medical assessment in secondary care.
2. Women who are considered clinically stable after appropriate medical assessment are suitable for outpatient follow-up in the early pregnancy unit and should be advised to re-attend secondary care if new and/or red flag symptoms (excessive bleeding, severe lower abdominal pain, new onset unilateral pain, shoulder tip pain, presyncope and malodourous vaginal discharge) develop.
3. If a woman who is less than 6 weeks gestation presents with bleeding but no pain and has no risk factors for ectopic pregnancy (i.e. previous ectopic pregnancy), these women should be advised to repeat a high sensitivity urine pregnancy test (HSUPT) after 2 weeks. A positive test result, persistent bleeding and/or development of pain warrants referral to the local early pregnancy unit or out-of-hours emergency services if indicated.

Clinical Question 2.2: What is the recommended approach to assess and follow-up women who present with bleeding and/or pain?

Evidence Statement

Considering the prevalence of vaginal bleeding and/or pain in early pregnancy, it is essential women with these symptoms are assessed and managed according to clinical acuity to ensure timely diagnosis and appropriate follow-up. Findings from the Irish Maternity Indicator System National Report stated that 43% of all women who delivered in 2022 attended EPU on at least one occasion.[56] Of those who attended EPU, a national prospective cohort study found 46.1% of women presented with threatened miscarriage and 47.4% of women sought a reassurance ultrasound scan.[57] Current evidence shows that women who present with first trimester bleeding and/or pain have a higher risk of miscarriage.[58,59] Given these symptoms are often distressing for women/couples, qualitative evidence indicates that provision and continuity of care provided by EPU services is valued.[60]

EPU is a dedicated service, staffed with healthcare professionals who have specialist knowledge and experience of early pregnancy complications. Ultrasonography and, if clinically indicated, measurement of serum β-hCG is available in an EPU.

Serum β-hCG is not appropriate to diagnose missed miscarriage and is not clinically useful to determine pregnancy viability in women who present with PUV.[54] Suboptimal doubling times of serial serum β-hCG levels are associated with early pregnancy loss yet reassuring serial β-hCG levels are observed in 8% of miscarriages.[61] If complete miscarriage is suspected after heavy vaginal bleeding, and no intrauterine pregnancy was previously visualised on ultrasound, serial serum β-hCG is clinically indicated to differentiate this from a PUL.[62] To diagnose complete miscarriage, declining serial serum β-hCG values demonstrate a sensitivity of 93 to 97% indicating the utility of β-hCG surveillance in this clinical situation.[63,64] Serum β-hCG surveillance should not be routinely used to guide miscarriage diagnosis and management where a viable intrauterine pregnancy is visualised on ultrasound.

Ultrasound is the standard to diagnosis miscarriage.[55] Whether to utilise transabdominal or transvaginal ultrasound is dependent on several clinical factors – transabdominal ultrasound may be more useful to visualise intrauterine pregnancies in women who have a multi-fibroid uterus, while transvaginal ultrasound provides higher resolution to visualise intrauterine gestational sacs and ectopic pregnancies in women who are less than 8 weeks gestation.[7,65,66]

Transvaginal ultrasound may be considered an invasive examination however, evidence indicates it is an acceptable procedure for most women.[67,68] The diagnostic superiority of transvaginal ultrasound appears to trump women's concerns about the actual procedure itself. Definitive diagnosis not only avoids unnecessary over-investigation but also potentially alleviates women's anxiety.[69]

However, ultrasound performed at very early gestations may not identify an intrauterine pregnancy or viable fetus.[69] Initial ultrasound scans performed in early pregnancy are non-diagnostic in 8 to 31% of examinations, necessitating repeat scans.[70] Reproducibility of ultrasound scans performed at 6 to 7 weeks gestation are accurate. At this early gestation, intra- and inter-observer differences in crown-rump length (CRL) measurements are minimal.[71] Since ultrasound scans performed before 6 weeks gestation are often non-diagnostic, ultrasound scans should be deferred until a later gestation, unless there is a clear clinical indication to perform it earlier [69].

Clinical Practice

Women who are clinically stable with light vaginal bleeding and/or loss of pregnancy symptoms should be referred directly to EPU from their primary care provider for further evaluation, while women with red flag signs and symptoms (excessive bleeding, severe or sudden onset of lower abdominal pain, presyncope, pyrexia or malodourous vaginal discharge) should be assessed and managed urgently. Primary care providers should have access to their local EPU or refer women directly to out-of-hours emergency care in the maternity unit/hospital if clinically indicated.

For women who present and are admitted to secondary care, each maternity unit/hospital should have specific pathways to refer women for assessment. Each EPU should triage and organise appointments in accordance with gestational age and clinical indication.

Table 1: Suggested triage pathways in early pregnancy assessment

Triage	Gestational age	Clinical indication
Urgent (i.e. immediately or within 24 hours of referral)	No limit on gestational age	• Vaginal bleeding and pain in current pregnancy • Pain in current pregnancy • Suspected ectopic pregnancy • Intrauterine contraceptive device insitu • Prolonged/abnormal bleeding post-surgical or medical management for miscarriage or retained pregnancy tissue
As soon as possible	At 6 weeks gestation or earlier if clinically indicated	• Vaginal bleeding with no pain in current pregnancy • Previous ectopic pregnancy but clinically well in current pregnancy • Previous gestational trophoblastic disease or suspected gestational trophoblastic disease in current pregnancy • Uterine surgery within the previous 6-12 months, i.e. myomectomy, caesarean section
Routine	8 weeks gestation	• Assess pregnancy viability in women with recurrent first trimester miscarriage • A pre-existing medical condition known to increase miscarriage risk (e.g. insulin-dependent diabetes)

Women's partners should be allowed to accompany them to EPU if they wish them to do so. At the beginning of the consultation, a brief history of presenting symptoms, date of LMP and cycle regularity/ number of embryos transferred (if relevant), date of first positive UPT and obstetric history will be documented. If there is bleeding, the quantity and whether pregnancy tissue has passed should also be clarified. Further clinical examination should be considered if necessary.

Serum β-hCG does not predict pregnancy viability and should not be routinely measured in women who present with PUV or to confirm miscarriage diagnosis. In instances where complete miscarriage cannot be differentiated from a PUL in a woman who reports heavy vaginal bleeding and/or pain, serial serum β-hCG surveillance should be commenced and clinicians should refer to the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy for guidance. [10]

Ultrasound will be offered to further evaluate early pregnancy complications. The procedure and clinical rationale for ultrasound should be explained to women. Both transabdominal and transvaginal ultrasound are utilised, however for gestations less than 8 weeks transvaginal ultrasound is the modality of choice to diagnose miscarriage. For some women, transabdominal ultrasound will suffice, and women should be advised to attend EPU with a full bladder to optimise assessment. The woman's wishes should be respected if she declines a transvaginal ultrasound, and this should be recorded on the ultrasound report.

If an ultrasound is performed at too early a gestation (less than 6 weeks) in asymptomatic women, it may generate more anxiety than it alleviates if findings are equivocal. In such circumstances, women should be informed that subsequent ultrasound assessments will be required to confirm a viable intrauterine pregnancy.

Women who present to EPU should be provided with necessary information as outlined in the Miscarriage Information Booklet developed by the Pregnancy Loss Research Group and the National Women and Infants Health Programme (NWIHP).[17]

Recommendations

4. **Ultrasound performed by appropriately qualified clinicians, who have completed accredited ultrasound training, is the primary modality to diagnose miscarriage.**
5. **Transvaginal ultrasound is recommended imaging modality for diagnosing miscarriage in women who are less than 8 weeks gestation.**
6. **When an intrauterine pregnancy is visualised on ultrasound, serum β-hCG has no role in predicting early pregnancy viability and should not be utilised to diagnose miscarriage.**
7. **If a pregnancy location is not visualised on ultrasound in a woman who reports heavy vaginal bleeding and/or pain, serial serum β-hCG should be measured and further guidance should be sought from the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy.**

17 https://www.ucc.ie/en/pregnancyloss/

Section 2: Diagnosis

Introduction

The use of high-resolution ultrasonography, particularly transvaginal, is considered the standard to diagnose intrauterine pregnancies and to monitor subsequent development. Knowledge of the typical ultrasound appearances of normal early pregnancy development and a good understanding of its pitfalls is essential for accurate diagnosis of miscarriage.

Clinical Question 2.3: How is a viable intrauterine pregnancy differentiated from a miscarriage on ultrasound?

Evidence Statement

High quality ultrasonography performed by appropriately trained healthcare professionals is essential to diagnosis miscarriage. Ultrasound is operator dependent, requiring specialist knowledge and skills, and therefore should only be carried out where there is a clear clinical indication.[72] Performed by appropriately trained healthcare professionals, low inter-observer variability and high reliability is demonstrated.[73]

Embryological landmarks namely the intrauterine gestational sac, yolk sac, embryo/fetal pole and cardiac activity are necessary prerequisites to evaluate early pregnancy viability.[74,75] Knowledge of the typical ultrasonographic appearance and chronology of early pregnancy development is not only essential to diagnose early pregnancy complications, but also to avoid diagnostic pitfalls.

The gestational sac is the first structure to appear and can be visualised on transvaginal ultrasound from 4+4 weeks gestation.[76] In viable intrauterine pregnancies, from 5 to 6 weeks gestation, the mean sac diameter grows at approximately 1 mm/day.[76] However, there is an overlap in gestational sac growth rates between viable and non-viable intrauterine pregnancies.[77] A smaller than predicted gestational sac, both alone and combined with other parameters, may indicate a poor pregnancy outcome.[75] Various study methodologies and inconsistent inclusion criteria restricts the generalisation of these findings. Consequently, the predictive value of smaller gestational sacs in isolation is unreliable and should be interpreted with accompanying presenting variables.[75]

The yolk sac is the first structure identified in the gestational sac, confirming an intrauterine pregnancy.[74,75] The yolk sac is first visualised by transvaginal ultrasound at 5 weeks gestation.[78] Typically, the yolk sac increases linearly in size from 6 to 10 weeks gestation and subsequently decreases in size.[78] The presence of a large yolk sac is associated with a poor prognosis.[78,79] Although the aetiology of a large yolk sac is unknown, it is estimated 18 to 66% of yolk sac diameters measuring 5 to 6 mm are associated with abnormal karyotypes.[80,81] This finding indicates that variations in yolk sac size and abnormal sonographic features are likely the consequence of poor embryonic development rather than being the primary cause of miscarriage.[75,78]

In the first trimester, crown-rump length (CRL) measurement of the fetal pole is the most accurate metric to determine gestational age.[74,75] In the advent of improved ultrasonographic resolution, the traditional Robinson and Hadson CRL curve to estimate gestation, has been replaced with a newly defined CRL curvature confirming gestations from 5+5 weeks gestation.[71] At 6 weeks gestation, intra- and inter-observer differences in CRL measurements are negligible which is unlikely to result in a difference of more than two days when dating a pregnancy.[71] Furthermore, CRL growth rate of 0.2 mm/day is associated with 100% specificity for miscarriage.[77] Although suboptimal CRL growth rates appear to correlate with

miscarriage risk, this combined with abnormalities in gestational sac and yolk sac development is a strong predictor for subsequent miscarriage.[77,79]

Cardiac activity is usually evident at the sixth week of gestation when the fetal pole measures 1 to 2 mm.[74] Caution should be exercised when assessing for the presence or absence of cardiac activity since exposure to unnecessary waveforms at early gestations may be harmful.[82] To limit this exposure, M-mode should be utilised to assess cardiac activity.[72] From 6 to 8 weeks gestation, there is a rapid increased in heart rate from 110 to 159 bpm.[83] Slowing cardiac activity is associated with subsequent miscarriage.[83] However, a single observation of an abnormally slow heart rate is not diagnostic of miscarriage, but a continuous decline of embryonic cardiac activity is inevitably associated with early pregnancy loss.[75]

Ultrasound is ultimately operator dependent, and this dependence combined with improved image quality can translate into increased risk for iatrogenic error.[69,84] Uncertainty around LMP dates, contraception failure and BMI ≥30 kg/m^2 can limit ultrasound findings.[55,72] Qualitative evidence indicates that women with an elevated BMI often experience weight stigmatisation in their interactions and communications with healthcare providers.[85] Effective and skilful communication with these women is key, considering the distress that is often accompanied with an early pregnancy loss.

Absence of embryonic structures within a gestational sac, irrespective of gestational sac growth rate, is associated with a poor prognosis and a repeat ultrasound scan is necessary to confirm diagnosis.[75,77] In this instance, a repeat ultrasound scan should be performed 7 to 10 days after the initial ultrasound scan to avoid inadvertent diagnosis.[86,87]

Clinical Practice

A systematic approach should be followed when performing both transabdominal and transvaginal ultrasound. All anatomical structures to be examined should be visualised in both the sagittal and transverse planes.

Anatomical structures to visualise during early pregnancy ultrasound

Uterus	• Shape, size, outline and echotexture • Position, e.g. anteverted, retroverted, retroflexed • Uterine structural deviations (i.e. fibroids, congenital uterine anomalies)
Endometrial cavity	• Appearance of the endometrium and endometrial thickness measurement (if empty) • Presence or absence of gestation sac or intracavitary fluid collection • Location of sac within the endometrial cavity (if present), i.e. non-mobile and located eccentrically from the endometrium in comparison to intracavity fluid which is mobile and located centrally within the endometrial cavity. A gestational sac located in the anterior lower cavity should be differentiated from caesarean scar ectopic at a later gestation (i.e. absence of sliding sign)

Gestational sac (if present)	• Shape, size, outline and echotexture • Number of gestation sacs present • Presence of regular trophoblastic rim, or irregular, absent trophoblastic rim around the sac (i.e. intracavity fluid) • Sac contents, i.e. yolk sac or fetal pole • Measure mean gestational sac diameter (if no fetal pole is present) • Assess around the sac for presence or absence of subchorionic haematoma
Fetal pole (if present)	• Number of embryos present • Measure CRL – magnify image and take several measurements to calculate average measurement • Assess for presence or absence of cardiac activity
Ovaries	• Shape, size, outline and echotexture of ovaries • Presence of corpus luteum or corpus luteal cyst • Check for ovarian masses. If present, measure in three planes
Adnexa	• Check for adnexal masses (i.e. ectopic or heterotopic pregnancy). If present, measure in three planes
Pouch of Douglas	• Assess for presence or absence of free fluid

* Adapted from the Society of Radiology and British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice (2023) [72]

Image quality and identification of pertinent sonographic markers may be limited by the presence of uterine fibroids, polyps, and ovarian cysts. Elevated BMI may also restrict findings. In these instances, such limitations should be documented in the accompanying ultrasound report and women/couples should be informed of these limitations. All relevant images, both normal and abnormal, should be archived in a retrievable format for subsequent review and interpretation. All imaging studies should be accompanied by a report and stored electronically.

A standardised reporting protocol should be followed and this includes:

- Presence or absence of intrauterine gestational sac(s)
- Number of sacs and mean sac diameter
- Presence of haematoma
- Yolk sac
- Fetal pole
- CRL with expected gestation
- Fetal cardiac activity absent or present
- Extrauterine observation including ovaries, adnexal mass/fluid in the Pouch of Douglas
- Technical factors including elevated BMI and presence of intrauterine pathology affecting resolution and image quality
- Type of ultrasound: transabdominal and/or transvaginal ultrasound

(see Appendix 4 for the recommended early pregnancy ultrasound scan template)

Necessary images and reports should be uploaded on to an auditable electronic hospital system to provide audit data.

After the ultrasound is complete, a clear explanation of findings and/or limitations should be discussed and explained to women/couples using appropriate language and terminology. If diagnosis is not confirmed or there are uncertainties, a repeat ultrasound should be organised 7 to 10 days after the initial ultrasound scan to assess growth of the gestational sac or fetal pole and to determine whether fetal cardiac activity develops. Repeating the ultrasound scan before this time interval is non-diagnostic, and this should be explained to women/couples.

A second ultrasound is indicated in the following clinical circumstances:

- The first ultrasound was completed at too early a gestation and ultrasound findings were non-diagnostic.
- The first ultrasound was performed informally during emergency out-of-hours (i.e. bedside ultrasound scan)
- Interim diagnosis after the first ultrasound (i.e. PUV)
- The woman requests a second ultrasound.

Considering both ultrasound and clinical findings, an appropriate plan for follow-up should be formulated.

Recommendations

8. **A systematic approach should be utilised when performing both transvaginal and transabdominal ultrasound scans, including visualisation of relevant anatomical structures in the sagittal and transverse planes in addition to the adnexa.**

Clinical Question 2.4: What are the necessary ultrasonographic criteria required to diagnose miscarriage?

Evidence Statement

Advances in diagnostic approaches over time has resulted in specific care pathways for women with early pregnancy complications. For years, ultrasonographic criteria to diagnose miscarriage varied across several international guidelines.[88,89] This guidance was often based on low quality methodological evidence such as expert committee reports or opinion and small retrospective observational studies.[88,90,91]. The current ultrasonographic criteria to diagnosis miscarriage has evolved largely from recommendations from the national miscarriage misdiagnosis review in 2010.[92] To avoid miscarriage misdiagnosis, it is essential to consider these review recommendations and to adhere to defined sonographic criteria with adequate safety margins.

Missed Miscarriage

Missed miscarriage is often diagnosed on transvaginal ultrasound before the onset of symptoms. Before implementation of stringent diagnostic ultrasonographic criteria, a systematic review found much variation in ultrasound criteria and substantial diagnostic inaccuracy as demonstrated by low sensitivity and specificity parameters.[93] Most of the included studies were of low quality utilising various methodologies contributing to significant heterogeneity.[93] Sonographic uncertainties can be further compounded by

intra and inter-observer variation when measuring CRL and particularly mean gestational sac diameter. For experienced operators measuring a mean gestational sac diameter inter-observer limit of agreement can vary up to 20%.[73] In practice, this variation meant that if the mean gestational sac diameter measured 20 mm, another operator may measure the same gestational sac as 16 to 24 mm.[73] Considering this variation in gestational sac measurements, safe cut-off values to diagnose miscarriage needed to be significantly higher to avoid a false positive missed miscarriage diagnosis.

In response to diagnostic errors and inter-observer variation, two prospective multicentre studies aimed to re-define mean gestational sac measurements and CRL thresholds to confirm miscarriage diagnosis.[77,94] The false positive rate of miscarriage diagnosis declined with increasing mean gestational sac and CRL measurements. There were no cases misdiagnosed when a mean gestational sac was ≥21 mm and a fetal pole with a CRL measuring ≥5.3 mm were defined as diagnostic thresholds.[94] Considering these findings, these diagnostic criteria were recommended by previous National Clinical Practice Guideline: Ultrasound Diagnosis of Early Pregnancy Miscarriage in addition to international guidelines by NICE and ACOG to minimise the risk of false positive miscarriage diagnosis.[5-7] To assess the validity of diagnostic thresholds recommended by these guidelines, a prospective multicentre study found that a mean gestational sac measuring ≥25 mm and CRL ≥7 mm used to diagnose missed miscarriage were associated with 100% specificity, which was substantiated with narrow confidence intervals.[87]

Incomplete Miscarriage

The diagnosis of incomplete miscarriage on ultrasound can be challenging and standardised diagnostic criteria are lacking. Endometrial thickness (ET) – measured as anterior to posterior diameter of the uterine cavity – on transvaginal ultrasound usually confirms diagnosis.[55] A recent systematic review found a wide range of cut-off values to diagnose incomplete miscarriage, however a threshold of ≥15 mm was utilised in over 50% of included studies.[95] Methodological heterogeneity, inconsistent cut-off parameters and variation in follow-up timings restrict the generalisation of study findings. Moreover, the specificity, sensitivity, and reproducibility of agreed ultrasonographic diagnostic criteria for incomplete miscarriage is uncertain, contributing to further diagnostic uncertainty. To counteract the limitations of ET measurements, subjective assessment of the morphological appearance of the tissue within the uterine cavity, coupled with doppler vascularity assessment has been proposed.[96] However, no good quality prospective studies have determined the accuracy of these diagnostic criteria. Considering the inaccuracy of ultrasonographic criteria to diagnose incomplete miscarriage, the best approach is to apply widely utilised criteria described in available studies and previous National Clinical Practice Guideline: Management of Early Pregnancy Miscarriage: presence of intrauterine retained pregnancy tissue with or without ET measurement ≥15 mm at 2 weeks or more after primary treatment.[4,95]

Complete Miscarriage

A complete miscarriage is diagnosed when a previously visualised intrauterine pregnancy is no longer present after a history of vaginal bleeding.[55] In the absence of a previous transvaginal ultrasound confirming an intrauterine pregnancy, women with ultrasound features suggestive of complete miscarriage should be managed as PULs.[7,84] Although there is a paucity of high-quality evidence, considering both clinical and ultrasonographic findings, to guide optimal management of complete miscarriage, one study found nine (5.6%) women who presented after spontaneous vaginal bleeding and accompanying ultrasound findings suggestive of complete miscarriage were subsequently diagnosed with an ectopic pregnancy.[62] These women did not have a ultrasound confirming a previous intrauterine pregnancy before bleeding onset. Considering these findings and the absence of robust evidence to guide management, women who present with spontaneous vaginal bleeding without confirmed ultrasonographic evidence of an intrauterine pregnancy should be managed as PULs. To confirm a complete miscarriage, ultrasonography confirming an intrauterine pregnancy before commencement of bleeding is key.

Clinical Practice

The following criteria should be observed when confirming a diagnosis of miscarriage on ultrasound. If there is any uncertainty a second opinion should be sought and/or repeat ultrasound performed.

Missed miscarriage	
Clinical presentation	• Asymptomatic • Light spotting or light vaginal bleeding • Loss of pregnancy symptoms
Diagnostic criteria	Transvaginal ultrasound • Fetal pole with a CRL ≥7 mm with no cardiac activity • Mean gestational sac diameter ≥25 mm with no yolk sac and/or fetal pole Transabdominal ultrasound • Fetal pole with a CRL >8 mm with no cardiac activity • Mean gestational sac diameter ≥25 mm and no yolk sac and/or fetal pole * If on transvaginal ultrasound, the mean gestational sac diameter is <25 mm with no yolk sac or embryo, or if the fetal pole is <7 mm with no cardiac activity identified within 30 seconds, then a diagnosis of PUV may be made. A repeat ultrasound examination should be performed after 7 to 10 days to confirm the diagnosis.

Incomplete miscarriage	
Clinical presentation	• History of spontaneous heavy vaginal bleeding • Persistent vaginal bleeding after conservative, medical or surgical management
Diagnostic criteria	Transvaginal ultrasound • Presence of definitive separate intrauterine retained pregnancy tissue with or without ET diameter ≥15 mm and no visualisation of adnexal mass(s)

Complete miscarriage	
Clinical presentation	• History of spontaneous heavy bleeding that has become light and/or stopped
Diagnostic criteria	Transvaginal ultrasound • The widest ET diameter measures <15 mm and there was previous ultrasonographic evidence of an intrauterine gestational sac or retained pregnancy tissue * In the absence of a previous ultrasound confirming an intrauterine pregnancy, women with ultrasound features suggestive of complete miscarriage should be managed as PULs

It is not essential for a second sonographer to confirm miscarriage, provided that the first sonographer is appropriately qualified and has complied with the above diagnostic criteria.

Ultrasound findings and images should be uploaded to the hospital ultrasound reporting system in a standardised format. Once diagnosis is confirmed, this should be communicated to women/couples in an appropriate manner. Sympathies should be offered to women/couples and the pregnancy loss acknowledged. The Miscarriage Booklet developed by the Pregnancy Loss Research Group and NWIHP should be provided.[18] A copy of relevant ultrasound scan images may also be offered to women/couples. Time should be facilitated to answer questions and to listen carefully to the woman's views. Some women may require further time to accept the final diagnosis, and, in this instance, a further ultrasound scan may be considered. When the woman understands and has had time to accept the diagnosis, appropriate follow-up to guide further management is required.

Recommendations

9. **An ultrasound diagnosis of missed miscarriage is confirmed when no cardiac activity is identified in a fetal pole with a crown-rump length ≥7 mm on transvaginal ultrasound or >8 mm on transabdominal ultrasound. If a fetal pole and/or yolk sac is not visualised, a mean gestational sac diameter measuring ≥25 mm on both transvaginal and transabdominal ultrasound is diagnostic of a missed miscarriage.**
10. **If on transvaginal ultrasound, the mean gestational sac diameter is <25 mm with no yolk sac or fetal pole or if the fetal pole is measuring <7 mm with no cardiac activity identified within 30 seconds, then a diagnosis of pregnancy of uncertain viability may be made. A repeat ultrasound assessment is recommended after 7 to 10 days to clarify the diagnosis.**
11. **The presence of intrauterine retained pregnancy tissue with or without increased endometrial thickness (i.e. ≥15 mm) and no visualisation of an adnexal mass on ultrasound is diagnostic of an incomplete miscarriage.**
12. **The widest endometrial thickness diameter measuring <15 mm with prior ultrasonographic evidence of an intrauterine gestational sac or retained pregnancy tissue before bleeding onset is diagnostic of a complete miscarriage.**
13. **In the absence of a previous ultrasound scan confirming an intrauterine pregnancy, women with ultrasound features suggestive of complete miscarriage should be managed as a pregnancy of unknown location. Clinicians should refer to the National Clinical Practice Guideline: The Diagnosis and Management of Ectopic Pregnancy for further management recommendations.**

18 https://www.ucc.ie/en/pregnancyloss/

Section 3: Management of Miscarriage

Introduction

Management options for miscarriage consist of conservative, medical, and surgical interventions. For women who opt for conservative and medical management, appropriate follow-up for these women is essential. Possible outcomes after each management option are either complete or incomplete miscarriage.

Clinical Question 2.5: What are the management options for miscarriage?

Evidence Statement

Conservative Management

Conservative management involves no medical or surgical intervention and is appropriate for women who present with spontaneous miscarriage in the first trimester. Evidence indicates up to 70% of women opt for conservative management, often with the intention of pursuing a natural treatment approach.[96] Several studies found conservative management was successful in 29 to 76% of women diagnosed with missed miscarriage.[97-99] A recent Cochrane meta-analysis concured with these findings, indicating that medical (RR 1.42, 95% CI 1.22 to 1.66) and surgical (RR 2.12, 95% CI 1.41 to 3.20) management are more likely to result in complete miscarriage in comparison to conservative management in women diagnosed with missed miscarriage.[8] Although relative effects from this meta-analysis did not show significant differences for serious complications including blood transfusion and intensive care admission, conservative management was associated with unplanned or emergency surgery.[8] Considering the current evidence as well as women's preferences, conservative management is appropriate in the absence of infection and excessive bleeding.

Medical Management

Medical management is the preferred option for many women [100] as it allows for planned, expedited expulsion of non-viable pregnancy tissue, while avoiding the risks of surgery. Misoprostol, a prostaglandin analogue, is the mainstay of management for miscarriage. However, misoprostol alone is not effective to manage missed miscarriage, with 15 to 40% of women requiring additional doses, ultimately prolonging treatment.[101,102] For women diagnosed with missed miscarriage, pre-treatment with mifepristone, a competitive progesterone-receptor antagonist, is useful to prime the myometrium and cervix before prostaglandin exposure.[100,103]

To manage missed miscarriage, both national and international evidence demonstrated that 200mg of oral mifepristone combined with 800mcg of misoprostol compared to 800mcg of misoprostol alone resulted in higher gestational sac expulsion rates and reduced emergency surgical evacuation.[100,103-105] In one large randomised controlled trial including 300 women diagnosed with a missed miscarriage under 13 weeks gestation, this regimen resulted in an increased rate of complete expulsion in 83% of women compared to 67% women in the misoprostol alone group [100]. Uterine aspiration was required in 8.8% of women who had mifepristone pre-treatment in comparison to 25% of women who had misoprostol only.[100] There was no difference in incidence of serious adverse events between both groups [100]. For outcomes including pain and bleeding intensity, women who received both mifepristone and misoprostol reported earlier onset of heavy bleeding with higher pain scores for a shorter duration in comparison to women who took misoprostol alone.[106] Considering the efficacy and efficiency of

this regime, updated NICE and ACOG guidelines recommends clinicians to offer mifepristone prior to misoprostol administration.[6,7]

The time interval between mifepristone and misoprostol administration is an important prerequisite to determine treatment success. The administration time between mifepristone and misoprostol often ranges from 24 to 48 hours, with a time interval of 36 hours being most efficacious.[107,108] Mifepristone must be administered in the presence of a doctor, and this factor must be considered when timing subsequent misoprostol administration to ensure appropriate timing interval between medications.

Misoprostol can be administered orally, buccally, sublingually, and vaginally in both the inpatient and outpatient setting. Most trials evaluated the effect of vaginal misoprostol,[100,103] however vaginal administration is less acceptable for many women due to pain and inconvenience associated with self-administration.[109,110] Buccal administration results in uterine activity and a side-effect profile that are similar to the vaginal route.[111,112] Thus, buccal administration is recommended.

Current evidence indicates medical management is safe for women who have had a previous caesarean section.[113,114] Compared to women without uterine surgery, complete miscarriage rates, duration of pain and bleeding are comparable.[113] Reassuringly complication rates did not differ, and no cases of uterine ruptures occurred.[113,114] Considering this evidence, recommended medical regimens are appropriate for women who have had a previous caesarean section, without additional precautions.

The National Interim Clinical Guidance for Termination of pregnancy under 12 weeks states repeated doses of misoprostol may be required in women who are 9 to 12 weeks gestation undergoing medical termination of pregnancy (MTOP) in hospital.[12] For medical management of missed miscarriage, a large prospective cohort study found women exceeding 9 weeks gestation may require further doses of misoprostol to ensure pregnancy tissue expulsion.[115] To facilitate this regime, inpatient medical management should be offered to women who are diagnosed with a missed miscarriage at later gestations.

In essence, medical management is acceptable to women, with 89.4% of women describing their overall experience as either “good” or “neutral”.[100] Inpatient medical management should be offered to women who present at later gestations, however, women who are haemodynamically stable (normotensive with a normal pulse rate and no IMEWS triggers) and have no signs of infection, outpatient management is recommended. Most women prefer this option with 73 to 93% of women choosing this method of management. [116,117] Evidence indicates when women are appropriately counselled in EPU, risk of emergency evacuation and infection is as low as 1.9% and 1-3% respectively.[116-118] With appropriate patient selection, outpatient management is considered safe, efficient, and acceptable.[116-118]

Surgical Management

Surgical uterine evacuation methods consist of aspiration methods such as electrical vacuum aspiration (EVA) or manual vacuum aspiration (MVA), both of which can be performed under general or spinal anaesthesia in the operating theatre or with local anaesthesia in the outpatient setting. Historically, surgical evacuation was completed with sharp curettage, however since the advent of vacuum aspiration in the 1970s, WHO advocated for aspiration methods to replace sharp curettage given the lower risk of endometrial damage.[119,120]

A recent Cochrane meta-analysis deemed vacuum aspiration with cervical priming as superior to medical and expectant management particularly for women diagnosed with missed miscarriage.[8] Women often choose this option for its short treatment duration requiring no follow-up.[121] Vacuum aspiration is the definitive treatment for previously unsuccessful treatment, haemodynamic instability, and infected retained pregnancy tissue. Limited retrospective evidence shows that a gestational sac

diameter measuring more than 30 mm on ultrasound may be an independent predictive factor for unsuccessful medical management, potentially necessitating surgical intervention.[122] Several cohort studies found pregnancies exceeding 9 weeks gestation on ultrasound were more likely to require surgical management for unsuccessful medical treatment.[115,123] Although the success rate of vacuum aspiration approaches 95%, the procedure is associated with rare, but serious surgical complications.[124] The most common complications include incomplete uterine evacuation, uterine perforation, haemorrhage, cervical trauma and post-procedure infection.[102,118]

To reduce the risk of uterine and cervical trauma, cervical priming with misoprostol or mifepristone has been proposed.[125] Mifepristone is particularly useful to prime the cervix and is generally well tolerated with minimal side-effects, however administration must be witnessed by a doctor 12 to 24 hours pre-operatively and this may be challenging to plan.[126,127] For pragmatic purposes, misoprostol is usually the medication of choice. In both the operative and outpatient setting, cervical priming before manual vacuum aspiration decreases the need for manual cervical dilation and shortens surgical time but does not reduce cervical dilation difficulty and excessive bleeding risk.[125] Given cervical and uterine injuries are relatively rare, it is therefore difficult to quantify whether cervical priming significantly reduces the risk of these complications.[125]

MVA in the outpatient setting is becoming more common and is associated with reduced costs and service efficiency.[128] A systematic review comparing MVA to EVA found no difference in success rates (relative risk 1.00; 95% CI 0.99-1.02) and patient satisfaction (relative risk 1.02; 95% CI 0.87-1.20).[129] Compared to blunt curettage, both MVA and EVA are associated with decreased blood loss, pain, perforation risk and reduced operating time.[130] Although outpatient MVA is convenient and acceptable for many women, operator skillset, appropriate facilities with access to emergency care and adequate analgesia during and after the procedure are essential factors to optimise care and safety.[131]

Given the significant distress associated with miscarriage, some women may not be able to tolerate MVA under local anaesthesia and elect for general anaesthesia.[131] Since acceptability is the biggest predictor of patient satisfaction, consideration of women's preferences is essential to optimise care.[132,133]

Clinical Practice

Each management option should be discussed with the woman/couple after miscarriage is diagnosed on ultrasound. The rationale, benefits, risks, complications, and side effects of medications should be addressed and discussed accordingly.

Conservative Management

Conservative management for 2 weeks is an appropriate option for women with confirmed miscarriage who are clinically stable with no signs of infection or excessive vaginal bleeding. Women should be counselled on what to expect including bleeding patterns, quantity of blood loss and signs of infection. For women with a missed miscarriage, women should be informed that complete resolution may take several weeks, and that the overall efficacy is lower compared to other management options. Follow-up should take place at 2 weeks after the initial assessment, however medical review should be expedited if clinically indicated or if the woman wishes to change management pathway.

Abdominal pain and cramps are often a symptom of miscarriage, and women should be advised to take over the counter pain relief if indicated. If bleeding is not self-limiting, i.e. changing a pad soaked with blood clots every 15 minutes over 1 hour, women should attend their local EPU or out-of-hours emergency care in the maternity unit/hospital for immediate clinical assessment.

If pregnancy tissue is passed at home, women should be advised that it can be difficult to differentiate between pregnancy tissue and blood clots. If pregnancy tissue is collected, women may bring this to their local maternity unit/hospital for examination. Maternity units/hospitals should have local guidelines for how this is managed in the emergency room/EPU.

To ensure safe and efficient management, provision of the necessary written information about what to expect throughout the process, including advice on analgesia, as well as local EPU and maternity unit/hospital contact phone numbers and when to present to secondary care is important.

Medical Management

Medical management is an effective and acceptable method to offer women who have a missed miscarriage in the absence of infection, excessive bleeding, and pyrexia. Medical management can be completed in the outpatient or inpatient setting.

Inpatient management may be indicated in the following circumstances:

- Large gestational sac (e.g. mean gestational sac diameter >50 mm)
- Increased bleeding risk
- Woman's preference
- Live >1 hour from the hospital and/or no transportation
- Limited English
- Limited social support

After appropriate counselling, 200mg of oral mifepristone is taken in the presence of a doctor. Mifepristone is usually well tolerated however the most common side-effect is nausea. If vomiting occurs within 1 hour of consuming mifepristone women should be advised to contact their local EPU and a repeat dose of mifepristone may be considered.

Women who choose outpatient management should be advised to take misoprostol in an appropriate location with planned social supports (i.e. at home or suitable destination with support person present and organised childcare). Some EPUs/maternity units provide women with pre-made packs of prescribed misoprostol and an accompanying information leaflet. 800mcg of buccal misoprostol should be self-administered no earlier than 24 hours and no later than 48 hours (ideally 36 hours) after mifepristone. Analgesia such as ibuprofen can be consumed 30 minutes before administering misoprostol. It is important to advise women when taking misoprostol to allow tablets to dissolve in their cheek over 30 minutes to increase likelihood of success. Food and fluids should not be consumed during this period. If vomiting occurs during this 30-minute period, then a further dose of misoprostol needs to be taken with consideration of an anti-emetic medication. Vomiting after this 30-minute period is not an indication for a further dose of misoprostol as most of the medication residue has absorbed.

Bleeding usually ensues after 1 hour, often peaking at 4 to 6 hours after taking misoprostol. Until pregnancy tissue passes, bleeding is typically heavy with blood clots and associated abdominal cramps. If pregnancy tissue is collected, women may bring this tissue to their local maternity unit/hospital, however women should be advised it may not be possible to differentiate pregnancy tissue from blood clots. Thereafter, this bleeding and pain usually subsides to period-like bleeding for a duration of 7 to 10 days. If, however, bleeding has not started 48 hours after taking misoprostol, women should be advised to contact their local EPU. A second dose of misoprostol may need to be administered.

For women who opt for inpatient medical management, repeated doses of misoprostol may be considered if no vaginal bleeding occurs 3 to 4 hours after taking 800mcg of misoprostol. A maximum of 4 further doses of 400mcg of misoprostol may be administered buccally every 3 hours until pregnancy tissue passes (equating to a maximum of 2400mcg of misoprostol in 24 hours). See Appendix 5 for recommended medical management protocol.

Misoprostol is associated with several side-effects: very commonly diarrhoea (≥ 1/10 women), commonly nausea and vomiting (≥ 1/100 – <1/10 women) and uncommonly fever (≥ 1/1000 – < 1/100).[134] Women should be informed about these side-effects and provided with appropriate analgesia (paracetamol and/or ibuprofen) in addition to an anti-emetic medication if indicated. If bleeding is excessive (i.e. changing a pad soaked with blood clots every 15 minutes over 1 hour or 4 soaked pads over 1 hour) and there are signs of haemorrhagic shock, women should seek urgent medical attention.

Written information about what to expect, appropriate analgesia and contact information for their local EPU and maternity unit/hospital, and when to present to these services, should be provided to women.

Surgical Management

Surgical uterine aspiration, MVA or EVA, should be offered to women who prefer this option. Clinical indications for offering surgical management include persistent excessive bleeding, incomplete evacuation after conservative/medical management, haemodynamic instability, evidence of infected retained pregnancy tissue, suspected molar pregnancy and pregnancy tissue required for cytogenetic analysis. Surgical management should also be considering where the mean gestational sac diameter measures more than 30 mm and gestational age exceeds 9 weeks on ultrasound.

Surgical aspiration is typically managed as a day case and is completed in the operative theatre under general or spinal anaesthesia, local anaesthesia, or sedation. Transabdominal ultrasound may be utilised during the surgery to reduce risk of perforation and/or ensure complete evacuation.

In the outpatient setting, uterine aspiration is performed under local anaesthesia and may be appropriate in the following clinical circumstances:

- Haemodynamically stable
- Women who express a preference for this method and can tolerate a speculum examination
- Availability of appropriate facilities and equipment
- Trained operator with necessary skillset

Irrespective of the setting, 400mcg of oral misoprostol is offered to women 3 to 4 hours (or buccally 1 hour) pre-operatively to prime the cervix. Cervical priming decreases the need for manual cervical dilation resulting in shorter operating time, however women may experience some side-effects from misoprostol. Alternatively, mifepristone can be taken 12 to 24 hours pre-operatively in the presence of a doctor. Women should be counselled on the risks of surgery and informed written consent needs to be obtained. Risks that need to be addressed when obtaining consent include incomplete uterine evacuation, haemorrhage, uterine perforation, infection, intra-abdominal trauma, and cervical trauma. Women should be informed that bleeding can persist up until 7 to 10 days post-operatively. For women who are rhesus negative and undergo surgery, anti-D prophylaxis should be administered.

Overview of Management Options for Missed Miscarriage

Conservative Management	Medical Management	Surgical Management
Indication		
• Women's preference • Clinically stable	• Women's preference • Clinically stable • Cytogenetic sampling facilitated as inpatient management	• Women's preference • Haemodynamic instability • Septic miscarriage • Heavy bleeding • Previously unsuccessful treatment • Cytogenetic sampling
Complete uterine evacuation requiring no further treatment		
• 29-76%	• 83-91%	• 95%
Advantages		
• No medication side-effects • Facilitates outpatient management • Avoids potential surgical complications and/or hospital admission • Natural process	• Facilitates outpatient management if clinically appropriate • Avoids potential surgical complications and/or hospital admission	• Plan timing • Less pain in comparison to conservative and medical interventions • No follow-up ultrasound or HSUPT is required
Complications		
• Feeling faint (1-2/100) • Heavy bleeding (1/100) • Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (3-10/100) • Infection (1-3/100)	• Feeling faint (1-2/100) • Heavy bleeding (1/100) • Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (7/100) • Side-effects of misoprostol (≥ 1/10 diarrhoea, ≥ 1/100 – <1/10 nausea and vomiting, ≥ 1/1000 – <1/100 fever)	• Feeling faint (1-2/100 only if awake during surgery) • Heavy bleeding (1/100) • Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (1-3/100) • Infection (1-3/100) • Uterine perforation (1-4/1000) • Cervical trauma (1/100) • Ashermans Syndrome (1/100) • Anaesthesia risks (<1/1000)

* Table adapted from Musik *et al.* (2021) Treatment options after a diagnosis of early miscarriage: expectant, medical and surgical[135]

Recommendations

14. Conservative or medical management in the absence of excessive bleeding, infection, and haemodynamic instability are appropriate management options for miscarriage.
15. For medical management of missed miscarriage, we recommend pre-treatment with mifepristone 24 to 48 hours before misoprostol administration.
16. Misoprostol should be administered buccally, rather than orally, to improve treatment efficacy for medical management of miscarriage.
17. If vaginal bleeding has not started 48 hours after taking misoprostol, women should be advised to contact their local early pregnancy unit. A second dose of misoprostol may need to be administered.
18. For inpatient medical management, further doses of misoprostol may be considered if no bleeding is observed 3 to 4 hours after taking 800mcg of misoprostol. A total of 4 further doses of 400mcg of misoprostol may be administered buccally every 3 to 4 hours until pregnancy tissue passes.
19. Surgical management for miscarriage should be performed using either manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA) and this management option should be offered to women exceeding 9 weeks gestation on ultrasound or those with a gestational sac diameter measuring > 30 mm.

Clinical Question 2.6: What is the necessary follow-up after conservative and medical management to ensure miscarriage is complete?

Evidence Statement

Traditionally ultrasound has been the principal method to evaluate treatment outcome. However, a systematic review reported significant variation regarding the ultrasonographic criteria to define incomplete miscarriage potentially leading to diagnostic uncertainty and unnecessary intervention.[95] Furthermore there is no consensus on how and when to assess and define retained pregnancy tissue or quantity of retained pregnancy tissue requiring additional treatment.[95] Emerging evidence recognises the role of urine hCG follow-up after conservative and medical management after resolution of heavy vaginal bleeding.[106,117,136] Declination in serum β-hCG after medical management are comparable to the decline demonstrated in successful surgical management of miscarriage and TOP.[137,138] Although follow-up with urine hCG after conservative and medical management is acceptable, in some instances ultrasonographic follow-up may be indicated. Prolonged and persistent bleeding, irrespective of a negative urine hCG, is indicative of retained pregnancy tissue and requires ultrasound evaluation. In essence, clinical status, response to treatment, medical co-morbidities and women's preferences should be considered when determining the optimal mode of follow-up.

Conservative Management

Several observational studies evaluating success rates for conservative management of miscarriage found up to 75% of women experienced spontaneous resolution of miscarriage at 2 weeks and to extend this period beyond 2 weeks without intervention did not improve the efficacy of this management method.[96,139] Considering conservative management is dependent on the quantity of bleeding and these bleeding patterns may vary, medical review 2 weeks after initiating this management pathway is warranted. After miscarriage is diagnosed on ultrasound, NICE guidelines recommend completing a urine hCG 3 weeks after resolution of heavy bleeding.[7] However, this method of follow-up is not suitable for those who report mild or no bleeding. Such women require ultrasound follow-up 2 weeks after completing conservative management.

Medical Management

For women who underwent medical management percentage declination >87% in serial serum β-hCG levels over a 7 to 9 day interval was associated with complete gestational sac expulsion.[117] Furthermore, a percentage serum β-hCG change >94.5% obviated the need for surgery.[117] For women who report passage of pregnancy tissue after medical management, rapidly declining or negative serum β-hCG measurements typically indicate treatment completion.[62] Considering the efficacy of serum β-hCG follow-up, NICE guidelines recommend completion of a urine hCG test 3 weeks after medical management if miscarriage is considered complete.[7] However, follow-up should be individualised and some women may require ultrasound follow-up 3 weeks after completing medical management.

Surgical Management

Current clinical practice does not recommend urine hCG, serum β-hCG or ultrasound follow-up after surgical management, provided pregnancy tissue is obtained during surgery.[6,7] Ultrasonographic follow-up may be indicated in rare instances if incomplete surgical evacuation and/or uterine perforation are suspected.

Clinical Practice

Follow-up is an essential cornerstone of care for conservative and medical management. Determining the optimal mode of follow-up is dependent upon several factors: clinical status, response to treatment, bleeding patterns, medical/obstetric/gynaecological history, and women's preferences.

Conservative management

Women opting for conservative management should be advised to contact EPU in the following instances:

- Passage of pregnancy tissue followed by lightening or resolution of bleeding indicating complete miscarriage
- Prolonged heavy and/or abnormal vaginal bleeding persisting over the 2 week period

To confirm if miscarriage is complete:

- Ultrasound should be completed 2 weeks after cessation of bleeding
- Or if a woman declines ultrasound follow-up and is clinically well, HSUPT should be completed 3 weeks after cessation of bleeding. Ideally, each EPU should provide women with a HSUPT in this case.

If this HSUPT is positive, or a negative HSUPT with prolonged bleeding is reported, women should be advised to contact their local EPU for individualised care.

Persistent heavy and/or abnormal vaginal bleeding warrant immediate medical review and ultrasound follow-up.

For unsuccessful conservative management, discussion of the risks and benefits of each management option (continued conservative, medical, and surgical) should take place with the woman to allow her to make an informed decision.

Medical Management

A follow-up HSUPT or ultrasound is not indicated if miscarriage is considered complete by a healthcare professional (i.e. fetal tissue and/or pregnancy tissue are identified in obtained pregnancy tissue).

Follow-up is recommended 3 weeks after completing outpatient medical management with either a HSUPT or ultrasound. Relevant clinical factors and women's preferences should be considered when planning this follow-up.

For women who complete a HSUPT, and this test is positive after 3 weeks, or prolonged bleeding with a negative HSUPT is reported, women should be advised to contact their local EPU for individualised care.

Surgical Management

No follow-up ultrasound or HSUPT is indicated after uncomplicated surgical management. If histology demonstrates an intrauterine pregnancy, and excludes gestational trophoblastic disease, there is no role for serum β-hCG or HSUPT follow-up. If prolonged vaginal bleeding and/or pain is reported post-operatively or incomplete uterine evacuation at the time of surgery is suspected, ultrasound follow-up is indicated to exclude retained pregnancy tissue.

Recommendations

20. **A follow-up ultrasound scan is recommended 2 weeks after cessation of bleeding in women who undergo conservative management. Women who experience persistently heavy/abnormal vaginal bleeding during this 2-week period warrant immediate medical review and ultrasound assessment.**
21. **For women who undergo medical management, a HSUPT or ultrasound completed 3 weeks after initiating medical management is recommended.**
22. **If a woman opts to complete a HSUPT and this test is positive, or prolonged bleeding with a negative HSUPT is reported, women should be advised to contact their local early pregnancy unit for individualised care.**

Clinical Question 2.7: What are the recommended management options for incomplete miscarriage?

Evidence Statement

Conservative Management

Conservative management is an appropriate option for the management of incomplete miscarriage. This method has demonstrated higher efficacy for incomplete miscarriage compared to missed miscarriage, with reported success rates of 55 to 90%.[97-99] A Cochrane review compared conservative care with medical management, and found there was no difference in complete miscarriage rates (RR 1.23, 95% CI 0.72 to 2.10, 2 studies, 150 women) or need for emergency surgical evacuation (RR 0.62, 95% CI 0.17 to 2.26, 2 studies, 308 women).[140] Considering this evidence, conservative management should be available to women who are clinically stable and express a preference for this method.

Medical Management

Medical management is an efficient management option for incomplete miscarriage. Since the expulsion process has already started, priming with mifepristone is not required and treatment with 800mcg of misoprostol is usually sufficient. Medical management in the outpatient setting has reported success rates of 72 to 93%.[102,108] A Cochrane review found there was a slightly lower incidence of complete miscarriage with misoprostol compared to surgical evacuation (average RR 0.96, 95% CI 0.94 – 0.98, 15 studies, 3862 women), however success rates were high for both interventions.[140] Nausea and diarrhoea were more common after misoprostol (average RR 2.50, 95% CI 1.53 -4.09, 11 studies, 3015 women), however patient satisfaction was similar (average RR 1.0, 95% CI 0.99 – 1.0, 9 studies, 3349 women) for all management methods.[140] Although, this review deemed evidence to be of low quality, medical management with misoprostol alone, is considered as an appropriate alternative to surgery to manage incomplete miscarriage.

Surgical Management

Given the efficacy of conservative and medical management for incomplete miscarriage, surgical evacuation is usually reserved for previously unsuccessful treatment, haemodynamic instability, and women's preference.[140] For women who are clinically stable and meet the criteria, uterine aspiration in the outpatient setting may be appropriate.[131] Limited evidence indicates hysteroscopic resection of retained pregnancy tissue is a safe alternative to uterine aspiration and has the advantage of providing direct visualisation resulting in complete evacuation.[141] In comparison to traditional curettage, recent systematic reviews concluded that it is not clear which method is overall superior to manage retained pregnancy tissue due a scarcity of good quality comparative data.[142,143] A systematic review comparing conservative and surgical management found there was no significant difference in complete uterine aspiration rates between the two methods.[129] Importantly there was no significant difference in patient satisfaction for both management options.[129]

Clinical Practice

Conservative Management

Conservative management, for 2 weeks, is an appropriate first line treatment option for women diagnosed with incomplete miscarriage.

Women undergoing conservative management should be advised to contact EPU if:

- Passage of pregnancy tissue followed by lightening or resolution of bleeding is observed
- Heavy and/or abnormal vaginal bleeding persists over 2 weeks. Immediate medical review and ultrasound assessment is indicated.

To confirm if miscarriage is complete:

- Ultrasound should be completed 2 weeks after cessation of bleeding
- Or if a woman declines ultrasound follow-up and is clinically well, HSUPT should be completed 3 weeks after cessation of bleeding. If this HSUPT is positive, or a negative HSUPT with prolonged bleeding is reported, women should be advised to contact their local EPU for individualised care.

Medical Management

Medical management for incomplete miscarriage consists of 800mcg of buccal misoprostol (see Appendix 5). Typically bleeding occurs within 1 to 24 hours of taking this medication often peaking at 4 to 6 hours and then tapers off over 7 to 10 days. Women should be advised that bleeding is usually heavier than a period and should be advised to take over the counter analgesia as indicated.

Follow-up HSUPT or ultrasound should be offered to women 3 weeks after initiating medical management. Women who choose to complete a HSUPT should be advised to contact their local EPU if this test is positive or prolonged vaginal bleeding irrespective of HSUPT result is reported.

Surgical Management

Surgical management for incomplete miscarriage is usually indicated if a woman expresses preference for this method, there is evidence of haemodynamic instability, or there has been previous unsuccessful management. Informed consent should be obtained including a discussion of the benefits and risks associated with surgery. If persistent bleeding is reported after completing conservative or medical management, there should be a low threshold to perform surgical evacuation. For women who present with prolonged bleeding (i.e. 6 weeks or more in duration since miscarriage diagnosis), hysteroscopy or hysteroscopic resection should be considered. If a small quantity of retained pregnancy tissue is suspected, hysteroscopic resection enabling removal under direct vision may be considered as retained pregnancy tissue may be very adherent.

Overview of Management Options for Incomplete Miscarriage

Conservative Management	Medical Management	Surgical Management
Indication		
• Women's preference • Clinically stable	• Women's preference • Clinically stable	• Women's preference • Haemodynamic instability • Septic miscarriage • Previously unsuccessful treatment • Cytogenetic sampling
Complete uterine evacuation requiring no further treatment		
• 55-90% (97-99)	• 72-93% (102,108)	• 95%(102)
Advantages		
• No medication side-effects • Facilitates outpatient management • Avoids potential surgical complications and/or hospital admission • Natural process	• Facilitates outpatient management if clinically appropriate • Avoids potential surgical complications and/or hospital admission	• Plan timing • Less pain in comparison to conservative and medical interventions • No follow-up ultrasound or HSUPT is required
Complications		
• Feeling faint (1-2/100) • Heavy bleeding (1/100) Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (3-10/100) • Infection (1-3/100)	• Feeling faint (1-2/100) • Heavy bleeding (1/100) • Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (7/100) • Infection (1-3/100) • Side-effects of misoprostol (≥1/10 diarrhoea, ≥1/100 – <1/10 nausea and vomiting, ≥1/1000 – <1/100 fever)	• Feeling faint (1-2/100 only if awake during surgery) • Heavy bleeding (1/100) • Haemorrhage requiring blood transfusion (1/1000) • Retained pregnancy tissue requiring further treatment (1-3/100) • Infection (1-3/100) • Uterine perforation (1-4/1000) • Cervical trauma (10/1000) • Ashermans Syndrome (1/100) • Anaesthesia risks (<1/1000)

* Table adapted from Musik *et al.* (2021) Treatment options after a diagnosis of early miscarriage: expectant, medical and surgical[135]

Recommendations

23. In the management of incomplete miscarriage, conservative, medical and surgery are appropriate management options.
24. We recommend 800mcg of misoprostol, to be administered buccally for medical management of incomplete miscarriage.
25. Ultrasound should be offered 2 weeks after cessation of bleeding in women who opt for conservative management for incomplete miscarriage.
26. To ensure miscarriage is complete, follow-up with either a HSUPT or ultrasound 3 weeks after initiating medical management for incomplete miscarriage is recommended.

Clinical Question 2.8: What is the recommended management approach for a woman who presents with heavy vaginal bleeding or inevitable miscarriage?

Evidence Statement

The bleeding patterns after conservative and medical management vary until pregnancy tissue passes. Typically bleeding after conservative management is often more prolonged since the timing of pregnancy tissue expulsion can be highly variable in comparison to medical and surgical management.[118] Approximately 90% of women report bleeding up to 1 week after medical management, with one-third of these women reporting heavy bleeding that lightens after pregnancy tissue passes and half of women reporting persistence of bleeding for 15 to 30 days after intervention.[144] However, this bleeding rarely requires intervention.

Excessive or protracted bleeding necessitates medical evaluation in secondary care. Women who present with such bleeding with or without signs of haemodynamic compromise (tachycardia, hypotension, pallor and syncope) should be assessed using IMEWS.[38] Heavy bleeding requiring blood transfusion following conservative and medical management occurs in 1 to 2% of miscarriages.[118] The need for surgical intervention after conservative and medical management is estimated at 6% and 3% respectively.[118] Haemorrhage after surgical evacuation requiring blood transfusion is <1%, although this risk may be higher in women who undergo unplanned surgical intervention.[118,144]

Since primary haemorrhage in women who are diagnosed with miscarriage is usually caused by retained pregnancy tissue and rarely uterine atony, the benefit of uterotonic agents in such circumstances is limited. Secondary or delayed haemorrhage is typically a complication of infection or endometritis.[145] Rarely haemorrhage may arise as a result of a undiagnosed cervical or ectopic pregnancy.[146] The use of oxytocin in the first trimester is not recommended as there is a low number of oxytocin receptors in the uterus, limiting its efficacy.[147] For excessive bleeding leading to haemodynamic compromise, uterine evacuation is the definitive management.[88]

Clinical Practice

Following a miscarriage diagnosis, all women should be counselled and provided with the necessary information relating to bleeding patterns.

If bleeding soaks 4 pads over 1 hour women should attend their nearest maternity unit/hospital. Heavy bleeding which lightens and subsequently becomes heavy again warrants prompt clinical review.

At initial presentation, it is important to quantify bleeding and assess for symptoms of anaemia such as dizziness, and syncope. Tachycardia and hypotension secondary to hypovolaemia are often late signs of acute haemodynamic instability, however absence of these signs does not exclude significant haemorrhage. Where significant haemorrhage is identified or suspected, intravenous access should be established and urgent FBC, blood group and crossmatch for red cell transfusion should be completed. Intravenous fluids should be commenced to increase intravascular volume. Early support and evaluation by senior clinicians are key to provide adequate resuscitation and plan definitive management.

Sterile speculum examination is useful to identify retained pregnancy tissue protruding through the cervix and facilitate rapid removal potentially stopping bleeding. Following removal of pregnancy tissue, bleeding should become progressively lighter and obtained pregnancy tissue should be inspected, by a healthcare professional, to ensure miscarriage is complete (i.e. both fetal tissue and/or pregnancy tissue are present). If miscarriage is considered complete and the woman remains clinically well with a stable haemoglobin, no further follow-up (i.e. HSUPT or ultrasound) is indicated.

In instances where pregnancy tissue cannot be safely removed and the woman continues to bleed, urgent surgical evacuation is indicated. Further assessment for red cell transfusion should be considered intra-operatively and post-operatively.

Recommendations

27. **Delayed or protracted vaginal bleeding as a result of incomplete miscarriage or inevitable miscarriage warrants urgent medical assessment in secondary care.**
28. **Women who experience delayed or protracted bleeding and present with signs of haemodynamic instability should be resuscitated and assessed by senior clinicians before planning definitive management.**

Clinical Question 2.9: Do rhesus negative women who are diagnosed with a first trimester miscarriage require anti-D immunoglobulin?

Evidence Statement

Evidence from an observational study found that the risk of sensitisation in women diagnosed with first trimester miscarriage is 0.1 to 0.2%.[148] However, a recent prospective cohort study evaluating risk factors for rhesus immunisation before or during pregnancy in women previously non-exposed or possibly exposed to the rhesus D-antigen found 35% (n=28/80) of these women had experienced a miscarriage beyond 10 weeks gestation ($P < 0.001$).[149] This risk of fetomaternal haemorrhage following surgical intervention increases to 4 to 5% following surgical intervention, potentially sensitising a rhesus negative woman leading to subsequent haemolytic disease of the fetus and newborn.[150]

Both NICE and the British Society of Haematology (BSH) guidelines recommend that all non-sensitised rhesus negative women who have surgical management for miscarriage should be offered anti-D immunoglobulin prophylaxis at a dose of 250 IU.[7,151]

For women who undergo conservative and medical management, both NICE and BSH guidelines state anti-D immunoglobulin prophylaxis is not indicated, considering there is insufficient evidence demonstrating maternal exposure to D-antigen.[7,151] However, BSH in their 2014 guidance recommended anti-D immunoglobulin prophylaxis should be considered in women who are less than 12 weeks gestation who present with repetitive and heavy vaginal bleeding in addition to vaginal bleeding associated with pain.[151] The BSH's website updates from 2020 refer to NICE and suggest that the NICE guidance is to be followed. NICE recommend that anti-D immunoglobulin not be given to women who have a threatened miscarriage.[7]

Clinical Practice

- All non-sensitised women who are rhesus negative should receive anti-D immunoglobulin prophylaxis when undergoing surgical management for first trimester miscarriage.
- Women who undergo conservative and medical management for first trimester miscarriage do not require anti-D immunoglobulin, given the risk of sensitisation is negligible.
- Women who are undergoing medical management should be counselled that there is a lack of consensus in international guidance about the use of Anti-D immunoglobulin in these situations.
- Anti-D immunoglobulin prophylaxis should be considered in women who present with repetitive and heavy vaginal bleeding or bleeding that is associated with pain, when the pregnancy is confirmed over 10 weeks' gestation.

Recommendations

29. All non-sensitised women who are rhesus negative should receive anti-D immunoglobulin prophylaxis if having surgical management for first trimester miscarriage.

Section 4: Histopathological Examination

Introduction

Routine histopathological examination of pregnancy tissue is currently recommended in Ireland, where pregnancy tissue is available after a miscarriage. This is most typically after surgery or inpatient medical management, and in women who meet the criteria for recurrent miscarriage and its investigation.

The potential presence of a fetus or embryonic/fetal cells in this pregnancy tissue means that there is a need to handle them with sensitivity, both at ward/theatre level and during examinations in the pathology laboratory. Parental expectations vary but considerations with regard to the potential sensitivity of these type of tissue samples also need to be kept in mind when planning for their ultimate disposal. Expectations and procedures may also vary depending on whether fetal tissue is visible by naked eye examination, by microscopic examination or not identified at all. The term disposal may not be thought to be appropriate and terms such as disposition or final management may be used as alternatives. The legal status of pregnancy tissue and practices in relation to the methods of ultimate disposal vary internationally and may include incineration, sensitive incineration, burial or cremation.[152,153] In this section we will use 'management of pregnancy tissue' to refer to the process whereby these specimens are handled with respect up to an including their ultimate disposal.

Clinical Question 2.10: What is the role of and recommended protocol for histopathological examination after miscarriage?

Evidence Statement

Histopathology examination of pregnancy tissue is usually completed to confirm the diagnosis of an intrauterine pregnancy and to exclude pathologies such as gestational trophoblastic disease.

Diagnosis of pathologies such as chronic histiocytic intervillositis (CHI) and massive perivillous fibrin deposition (MPFD) may be made in the first or second trimesters. As these conditions may recur in subsequent pregnancies, the histopathological diagnosis may be used to guide future pregnancy management.[154]

Although histopathology results can provide clinically useful information, women often report feeling unprepared for this discussion and the consent process around management of pregnancy tissue.[155] Inappropriate timing of this discussion is a common theme identified by women and is described in various contexts: timing on the day of treatment/surgery, timing during the miscarriage care pathway and in reference to gestational age.[155] A national audit conducted in the UK found that less than 55% of women reported being informed or consenting to decisions regarding pregnancy tissue management, while 42% of staff self-reported "seldom or only occasionally" discussing policies relating to pregnancy tissue management.[156] While it is acknowledged that early miscarriage is a subjective experience for every woman/couple and perceptions relating to this loss and pregnancy tissue burial/cremation differ, it is imperative a person-centred approach is adopted and standards relating to ethical management of pregnancy tissue are maintained.[157,158]

The National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death set out core principles around discussion of and consent for management of pregnancy tissue.[33] Sensitive and clear communication addressing the role of histopathology examination, procedures relating to the identification or absence of fetal tissue during this examination and consideration of women's/couple's wishes for burial or cremation of recognised fetal tissue is vital.

Clinical practice

At the time of miscarriage diagnosis or presentation to hospital at the time of or after miscarriage, procedures and policies relating to collection, identification and management of pregnancy tissue should be discussed with women/couples. During this discussion it is important to inform women/couples that fetal tissue is often too small to be identified in collected pregnancy tissue and that this examination is usually offered to confirm a intrauterine pregnancy and to exclude gestational trophoblastic disease.

In instances where pregnancy tissue is obtained, histopathological examination is routinely offered. However, this examination may not isolate fetal tissue, and women/couples should be informed that this examination often does not identify a cause for miscarriage. Women/couples who opt for this examination should be informed of the expected timeframe for when to expect results and how these results will be communicated. If pregnancy tissue is collected, hospital procedures and policies relating to management of pregnancy tissue must be discussed with women/couples.

Miscarriage in the community

- Some women miscarry in the community and may or may not collect pregnancy tissue. In instances where women contact their local EPU or maternity unit/hospital, staff should be aware of hospital procedures relating to pregnancy tissue collection and storage, in addition to providing practical information on how to bring collected pregnancy tissue to hospital.
- If a woman/couple bring pregnancy tissue to their local maternity unit/hospital, this tissue should be inspected to identify if any fetal tissue is present, and procedures should be in place for the management of this tissue.
- Collected tissue may be sent for histopathological examination unless the fully informed woman/couple have expressed any objection to this.

Miscarriage in the maternity unit/hospital

- Pregnancy tissue collected during surgical management is usually sent for histopathological examination, unless the woman does not consent to this.
- Pregnancy tissue may also be collected after medical management. Women should be advised to call a staff member when heavy bleeding commences. Measures should be put in place to collect pregnancy tissue.

Each maternity unit/hospital should have a specific protocol in place to communicate histopathological results with women/couples. Histopathological examination results should be communicated to women/couples in a timely manner and these results should be documented in the woman's healthcare record for follow-up and to guide future management.

If fetal tissue is identified/not identified this should be sensitively explained to women/couples. As noted previously, expectations and procedures may vary depending on whether fetal tissue is visible by naked eye examination, by microscopic examination or not identified at all. Women/couples should be provided with the opportunity to collect pregnancy tissue after examination and arrange their own personal burial/cremation if they desire. If women/couples do not want to collect pregnancy tissue, appropriate procedures should be in place for its management, for example with their consent, fetal tissue identified by naked eye examination may be sensitively and respectfully buried in a hospital cemetery plot in accordance with local practice

Recommendations

30. Histopathological Examination is usually performed where pregnancy tissue is available to exclude gestational trophoblastic disease.
31. Women should be informed of the procedures and hospital policies that relate to management of pregnancy tissue, including options around management of fetal tissue and/or return of pregnancy tissue. Specifically, women should be informed that often small quantities of pregnancy tissue are obtained, and it may not be possible to identify fetal tissue.
32. For women who experience miscarriage in the community and present to secondary care with the pregnancy tissue, each maternity unit/hospital should have an established care pathway for pregnancy tissue, including discussion of histological examination and management of fetal tissue. Relevant healthcare professionals should be aware of these procedures.
33. There is a need to review practice nationally in relation to the management of early pregnancy tissue, including its ultimate disposal, a view to providing guidance on best practice.

Section 5: Complications of Miscarriage and/or its Management

Introduction

Intermediate potential complications of miscarriage arise from infection and/or retained pregnancy tissue. Long-term potential complications caused by delayed pregnancy tissue expulsion can lead to chronic endometritis. Repetitive surgical evacuation can increase the risk of Asherman's Syndrome, potential infertility and rarely placenta accreta spectrum.

Clinical Question 2.11: What are the potential intermediate and long-term complications of early miscarriage?

Evidence Statement

Intermediate complications

Risk of infection after all miscarriage management options is as low at 1 to 3%.[118] Infection can arise as a consequence of retained pregnancy tissue and in rare instances lead to septic miscarriage.[118] If not recognised and managed promptly, maternal sepsis can ensue. Definitive management encompasses uterine evacuation with appropriate antibiotic therapy.[118] Since consensus relating to antibiotic prophylaxis before routine surgical evacuation is lacking, such treatment is not indicated before planned surgery.[159]

Retained pregnancy tissue is one of the most common causes for prolonged and irregular bleeding patterns after miscarriage. Up to 18% and 6% of women who undergo conservative and medical management respectively require unplanned surgical evacuation for retained pregnancy tissue.[118] However, the addition of mifepristone increases expulsion rates and reduces the need for unplanned surgical evacuation by 60%.[100]

Long-term complications

Evidence indicates delayed expulsion of pregnancy tissue is associated with chronic endometritis potentially effecting fertility.[160,161] Evaluation of endometrial biopsy results demonstrated that 62% of women with retained pregnancy tissue developed chronic endometritis in comparison to 30% of women without retained tissue.[145] On further utilisation of endometrial biopsy results, it was shown that 7% of women diagnosed with recurrent miscarriage subsequently developed chronic endometritis.[162] If treated efficiently with antibiotics, cure rate was 100% leading to a subsequent cumulative birth rate of 88% for this group.[162,163]

Risk of intrauterine adhesions or Asherman's Syndrome is considered a rare complication of excessive or repetitive uterine curettage and is as low as 0.7%.[164] Although uterine aspiration reduces the occurrence of intrauterine adhesions,[164] women identified with adhesions as a result of surgical evacuations are more likely to have poorer reproductive outcomes specifically recurrent miscarriages, fewer ongoing pregnancies and a lower live birth rate.[165]

Repetitive uterine curettage is a risk factor for abnormal placental invasion in subsequent pregnancies, potentially leading to placental accreta spectrum.[166]

Clinical Practice

Intermediate complications

Women should be counselled about the signs and symptoms of infection. Malodourous vaginal discharge, pain, temperature, nausea, and vomiting are common symptoms that indicate medical review.

The assessing clinician should perform a thorough clinical examination including abdominal and sterile speculum examination. Investigations including full blood count (FBC), renal and liver function, CRP and high vaginal swab for culture and sensitivity should be completed. If sepsis is suspected, a septic screen should be completed, and the sepsis six protocol should be initiated. Antibiotics should be prescribed in accordance with local antimicrobial guidelines. Response to resuscitation and input from senior clinicians will determine the management course.

For women who present with persistent and irregular bleeding after miscarriage diagnosis, retention of pregnancy tissue must be considered. This is particularly important where heavy bleeding becomes lighter and subsequently heavier.

Clinical assessment should consist of sterile speculum examination, investigations including full haematological and biochemical work-up. Ultrasound assessment is recommended to identify retained tissue. The quantity of retained tissue, clinical parameters and preferences of the woman should be considered when planning further management. Surgical evacuation or hysteroscopic resection may be indicated if a large quantity of retained tissue is identified or there is a prolonged interval since initial management. If minimal retained tissue is identified and the woman is clinically stable, outpatient conservative or medical management may be appropriate. Women who opt for these options should be followed up at two-week intervals.

Long-term complications

Women with chronic endometritis may be asymptomatic or present with generalised symptoms such as abdominal pain, irregular vaginal bleeding, or discharge. Antibiotics should be prescribed and review by a senior clinician is indicated to plan definitive management. Intrauterine adhesions should be suspected in women who have a history of uterine surgery and present with secondary amenorrhoea, infertility, and pelvic pain. Hysteroscopy is the definitive method to diagnose intrauterine adhesions and hysteroscopic resection may be completed if deemed necessary.

Recommendations

34. **Infection and retained pregnancy tissue are intermediate complications of delayed or unsuccessful management of miscarriage, while chronic endometritis often presents later. Intrauterine adhesions are a rare complication from excessive and/or repetitive uterine curettage.**

Section 6: Bereavement and Supportive Care

Introduction

Healthcare professionals should be aware of the psychological sequalae associated with miscarriage which may lead to more significant long-term mental health conditions if the necessary supports are not provided. It is therefore important to provide a holistic approach towards care for women/couples who experience early pregnancy loss.

Clinical Question 2.12: What are the psychological needs and necessary support for women/couple who experience miscarriage?

Evidence Statement

It is recognised pregnancy loss is associated with psychological morbidity including anxiety, depression and post-traumatic stress disorder, in addition to feelings of grief and loss. Approximately 8 to 20% of women report moderate depressive symptoms and 18 to 32% report anxiety, with resolution of symptoms after one year.[24] Partners also exhibit these signs, although to a lesser extent.[24]

Women with known mental health conditions or previous miscarriage may be at a higher risk of psychological distress, and symptoms of anxiety and depression may reoccur during subsequent pregnancies.[25,26] A Cochrane review evaluating the benefits of psychological interventions, such as counselling, demonstrated equivocal results.[167] It is therefore necessary to provide supportive care tailored to each individual woman's needs.

Quality of care received and interactions with healthcare professionals at the time of miscarriage is a major determinant of women's/couple's emotional and psychological wellbeing.[27,28]

To ensure implementation of best practice, the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death addresses key measures to promote best quality care to bereaved women/couples.[33] Provision of sufficient information, appropriate and sensitive communication, privacy in the hospital environment and formal follow-up have been identified as important components of care.[27,28,33]

The standards state that all hospital staff who care for women diagnosed with an early pregnancy loss should receive the necessary training appropriate to their role, particularly in relation to effective and sympathetic communication.[33] Some women may need more than one ultrasound scan to diagnose a miscarriage. This care should be provided in a quiet and private environment to support women after breaking bad news and to allow time to reflect on the diagnosis.[33] If inpatient care is required, women should be admitted to non-obstetric wards and prioritised for surgery if indicated.[33] Given the psychological morbidity associated with miscarriage, women/couples should have access to the specialist bereavement team at diagnosis and/or afterward if deemed necessary.[24,33]

Clinical Practice

Healthcare professionals should aim to incorporate the standards addressed in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death when caring for women/couples who have experienced an early pregnancy loss.

Care at the time of miscarriage diagnosis

- All healthcare professionals who are breaking bad news should sensitively communicate to women/couples in a private room considering the individual needs of each woman/couple.
- Following the diagnosis of miscarriage, women/couples should be allowed sufficient time to reflect on the diagnosis, discuss management options and ask questions.
- Relevant information leaflets/booklets (such as the Miscarriage Booklet developed by the Pregnancy Loss Research Team and NWHIP https://www.ucc.ie/en/pregnancyloss) and contact details of the local bereavement team should be provided.
- All healthcare professionals should be aware of the psychological sequalae following early pregnancy loss. Women/couples should be made aware of the availability of the bereavement specialist team (e.g. Clinical Midwife Specialist in Bereavement, Chaplain, and Medical Social).

Care following hospital admission (if relevant)

- For women who opt for inpatient management, a system of prompt ward admission such as the use of a direct admission card should be provided by all hospitals.
- Women should be admitted to a gynaecology or non-obstetric ward.
- Priority should be given to scheduling elective surgical procedures for miscarriage at the beginning of a theatre list.

Care after discharge

- Discharge letters outlining the woman's diagnosis, management and relevant follow-up should be communicated to the woman's GP and any other relevant community specialties. All future antenatal clinic and antenatal appointments should be cancelled within one working day following miscarriage diagnosis.
- For women/couples who require individualised follow-up and care, bereavement and/or psychological support or counselling should be offered, and relevant contact details should be provided.
- Women, and their partners, should be provided with written information of appropriate national and local support groups and organisations. Relevant information can be found at www.pregnancyandinfantloss.ie and from the Miscarriage Association of Ireland at www.miscarriageassociation.ie.

Recommendations

35. Healthcare professionals should be aware of the psychological sequalae associated with miscarriage which can affect women/couples and may contribute to long-term mental health morbidity if the necessary supports are not provided. Signposting to appropriate supports including psychological counselling, bereavement services and informal supportive resources may be indicated.
36. Standards described in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death relating to sensitive communication, compassionate care, dignity and respect should be followed when caring for women/couples who have experienced miscarriage.

Section 7: Follow-up and Future Pregnancy Planning

Introduction

Comprehensive follow-up after miscarriage relating to the medical and psychological needs of each woman in addition to future pregnancy planning and/or contraception options is important. Follow-up is necessary for women who have had recurrent miscarriages, including review of any available histopathological results to guide management for any future pregnancies, in addition to women who may require sub-specialised care.

Clinical Question 2.13: What is the recommended follow-up and approach to future pregnancy planning after miscarriage?

Evidence Statement

Qualitative evidence indicates that women/couples desire access to reliable and accurate information specifically relating to cause(s) and prevalence of miscarriage, in addition to appropriate treatment options and information relevant to future pregnancy planning.[21,28,168] In practice accessibility to bereavement care, psychological support/counselling and relevant clinical information (e.g. histology results and relevant investigations) are essential for follow-up.

No consensus for optimal interpregnancy interval after a miscarriage exists. A systematic review including 16 studies found an interpregnancy interval less than 6 months after miscarriage was not associated with adverse outcomes in the next pregnancy.[169] Further meta-analysis demonstrated conceiving within this interval was associated with a significant reduction in overall miscarriage (risk ratio 0.82 95% CI 0.78, 0.86) and preterm birth risk (risk ratio 0.79 95% CI 0.75, 0.83).[169] To provide reassurance in a subsequent pregnancy after miscarriage, early ultrasound scans should be offered, as these scans are often valued by women/couples.[170]

Some women may not wish to pursue a further pregnancy after miscarriage. Fertility often resumes rapidly after an early pregnancy loss, with ovulation frequently occurring 14 days after miscarriage, therefore reliable contraception is essential.[171] Contraceptive options should be prescribed in accordance with recommendations outlined in UK medical eligibility criteria (UKMEC) guideline.[172]

Recent national guidelines recommend that investigations for women who experience recurrent miscarriage should be initiated in the community.[1] These investigations include antiphospholipid antibodies, thyroid function, and transvaginal pelvic ultrasound.[1] Given fetal aneuploidy is the most common cause of sporadic and recurrent miscarriage, cytogenetic and parental karyotype testing may be indicated after individual risk stratification.[3] Further guidance for investigation and management of recurrent miscarriage is available in the National Guideline on Recurrent Miscarriage.[1]

Ideally women who experience recurrent miscarriage should receive the necessary care and follow-up, in dedicated recurrent miscarriage clinics. Provision of these clinics varies nationally and there is also variation in referral criteria, location of clinics, genetic counselling and recording of subsequent pregnancy-related outcomes.[173] It is envisaged that implementation of the National Guideline Recurrent Miscarriage will standardise practice to provide best quality care.[1]

Clinical Practice

As part of their follow-up, women/couples should receive the necessary information on:

- Appropriate bereavement and psychological support and follow-up. This should be tailored to each woman/couple's needs. Ideally, this would be written information with a documented follow-up plan.
- Histopathology results. These results should be available on the woman's healthcare record for future pregnancy planning.
- Histopathology demonstrating gestational trophoblastic disease. Women should be referred to the National Gestational Trophoblastic Disease for specialised follow-up.
- Future pregnancy planning and contraceptive advice if indicated. Following a first menstrual period after miscarriage, women/couples should be advised it is safe to attempt conception if a future pregnancy is desired. If, however, a pregnancy is not desired, contraceptive options should be discussed and prescribed in accordance with UKMEC guidelines.
- Accessibility of early pregnancy ultrasound scans in a subsequent pregnancy after miscarriage. It is recommended that this is completed at 8 weeks gestation in EPU.
- Referral criteria and availability of recurrent miscarriage (or pregnancy loss) clinics. Women who have two or more consecutive miscarriages, should be referred in a timely manner to the local recurrent miscarriage (or pregnancy loss) clinic or gynaecology clinic depending on local service availability.
- Necessary information relating to recurrent miscarriage as outlined in the National Recurrent Miscarriage booklet developed by the Pregnancy Loss Research Group and the National Women and Infants Health Programme (NWIHP) https://www.ucc.ie/en/pregnancyloss.
- Relevant investigations should be decided after appropriate counselling considering each individual woman/couple's history and risk factors. Investigations that can be completed in the community include antiphospholipid antibodies, thyroid function tests, and pelvic ultrasound.
- Women who experience recurrent miscarriage, should have appropriate management plans should be put in place for potential further pregnancy loss, e.g. if cytogenetic testing on pregnancy tissue is indicated, surgical management should be facilitated for subsequent miscarriage.

Recommendations

37. Follow-up care after miscarriage should be tailored to each individual woman specifically relating to bereavement and psychological needs and communication of histopathological results. Written information outlining appropriate supports and follow-up plans should be provided to women/couples.
38. Future pregnancy and family planning after miscarriage are important components. Women should be counselled appropriately in relation to future pregnancy planning and/or contraceptive options.
39. For women who experience recurrent miscarriage, guidance should be sought from the National Clinical Practice Guideline: Recurrent Miscarriage for definitions, relevant investigations and management options for these women.

Section 8: Organisation And Provision Of Services

Introduction

Early pregnancy units (EPUs) facilitate continuation of care for women who experience early pregnancy complications. This service allows rapid access to clinical assessment, ultrasound, and measurement of serum β-hCG if indicated.[174]

Clinical Question 2.14: How should the care of women/couples with miscarriage be organised?

Evidence Statement

After the review of misdiagnosis of miscarriage conducted in Ireland in 2010, the review committee recommended that every maternity unit/hospital in Ireland should have a dedicated EPU service.[92] Subsequently, both the National Standards for Safer Better Maternity Services and National Maternity Strategy were launched to address deficits in the safety and quality of maternity services.[175,176] The former provides a framework addressing domains relating to safety, quality of care, service capacity and capability.[175] Although these recommendations have yet to be implemented, they represent a useful standard for EPU services. The National Maternity Strategy states that all women have easy and appropriate access to well-resourced early pregnancy units in all maternity units/hospitals.[176]

Since 2010 each maternity unit/hospital has established an EPU service. Each EPU should comprise of dedicated spaces for clinical assessment, ultrasonography, counselling and a waiting area. These units are cost effective, reduce hospital admissions for early pregnancy complications, and shorten the length of time to reach diagnosis ultimately improving quality of care.[177]

Qualitative studies evaluating women's perception of EPU services report that availability of individualised care, respect for women's opinions, effective communication and provision of necessary clinical information using appropriate terminology is essential.[60] Further recommendations suggested by women attending these clinics to improve service provision and care include: separation of EPU from general maternity services, removal of barriers to accessibility (e.g. difficulty obtaining appointments) and a sensitive and compassionate approach to patient management (e.g. automatic cancellation of antenatal ultrasounds) following pregnancy loss.[178]

Clinical Practice

EPU is a dedicated outpatient service that provides clinical assessment, management and support for women/couples who experience miscarriage.

The following are important components of care.

Staffing/expertise

- Healthcare professionals competent to diagnose and care for women with pain and/or bleeding in early pregnancy (Obstetricians/Gynaecologists/Specialist midwives) should staff EPU.
- Sonographers who are appropriately trained should be available to diagnose and care for women with early pregnancy complications.
- Accessibility to trained and qualified staff (bereavement specialist team/psychologist/medical social worker), if necessary, should be available.

Location/facilities/equipment

- The EPU should be in a separate clinical space that is not located close to an antenatal clinic, antenatal ward, or other areas where pregnant women may attend.
- At minimum, each EPU should have at least one properly furnished single room to ensure the woman's/couple's privacy is maintained.
- The EPU service should have access to the necessary haematological and biochemistry laboratories.

Service provision

- EPU services should be accessible during opening hours Monday to Friday with sufficient capacity and staffing to manage local needs in addition to providing ultrasounds on the next working day following presentation with suspected miscarriage.
- There should also be facilities to perform serum β-hCG testing and follow-up of these measurements.
- A system should be in place to enable women who are referred to EPU to contact the service within 24 hours if clinically indicated. If a woman warrants assessment outside working hours, ensure local maternity emergency services are available and accessible.

Recommendations

40. **All women who experience early pregnancy complications should be referred to a dedicated early pregnancy clinic for centralisation and coordination of care.**
41. **Each early pregnancy unit should be accessible with sufficient staffing and facilities to provide appropriate clinical assessment, management and support for women/couples who experience miscarriage.**

Section 9: Education

Introduction

All healthcare professionals who care for women with early pregnancy complications should be supported through training and have access to education to fulfil their roles and responsibilities.

Clinical Question 2.15: What are the necessary training requirements, educational resources, and support services available to healthcare professionals?

Evidence Statement

This Guideline should be complemented with ongoing education, training and assessment for all healthcare specialties involved in caring for women who experience miscarriage. The educational and training needs of healthcare professionals warrants careful consideration in an effort minimise the level of distress and grief this type of pregnancy loss can bring. To optimise patient care and provide a holistic service, staff should be knowledgeable of local and national policies relating to bereavement care.[122]

The Misdiagnosis of Miscarriage review identified staff training and experience as necessary components of care to avoid misdiagnosis.[92] In response to this recommendation, University College Dublin (UCD) devised a formal training programme for healthcare professionals who chose to specialise in early pregnancy ultrasound.

While this programme is not mandatory for doctors in training, the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) training committee recommend doctors training in obstetrics and gynaecology should have the basic skills to perform and interpret early pregnancy ultrasound.[179] Evidence indicates that time spent in ultrasound units developing clinical experience and skills improves confidence.[180] Ultrasound simulators are further adjuncts that improve competence and skills yet, may have associated costs.[181] To compliment training, an Irish tertiary maternity unit demonstrated that a low-cost structured teaching programme improved confidence in both performance and interpretation of early pregnancy ultrasound.[182]

Clinical Practice

Implementation of recommended training standards and accessibility to necessary educational and support resources is essential for healthcare professionals who care for women diagnosed with miscarriage.

Training and Education

- All doctors training in obstetrics and gynaecology must be able to demonstrate completion of training in early pregnancy ultrasound before performing unsupervised ultrasound assessments. Doctors enrolled on both the basic and higher specialist training programmes should maintain a record of encountered early pregnancy cases in accordance with training requirements.

- To diagnose first trimester miscarriage, clinicians and midwives must hold a recognised postgraduate certificate or equivalent, demonstrating competency in performing both transabdominal and transvaginal ultrasound. Recognised certificates/formal training programmes offered by UCD School of Medicine include the Professional Certificate in Early Pregnancy Ultrasound Graduate Taught Programme.
- Each maternity unit should provide structured training and education to all healthcare professionals who are involved in the care of women diagnosed with miscarriage.
- All healthcare professionals are required to undergo regular continuous professional development (CPD) to achieve the necessary competence to deliver safe and effective care. A log of trained staff should be available with ongoing accreditation and attendance at courses, local, national, and international educational/training days and conferences.
- Healthcare professionals should have access to the relevant educational resources. Relevant guidelines and protocols are available at www.pregnancyandinfantloss.ie/guidelines

Recommendations

42. **Healthcare professionals who care for women with early pregnancy complications should be supported through training and have access to education to fulfil their roles and responsibilities.**

Clinical Question 2.16: How can healthcare professionals who care for women/couples diagnosed with miscarriage be supported?

Evidence Statement

Caring for women who experience miscarriage can have an emotional impact on healthcare professionals who work in maternity care. Qualitative evidence indicates that breaking bad news, particularly for inexperienced healthcare professionals is a stressful experience and learning is “a continuum” which progresses throughout training.[183] Staff delivering bad news often felt responsible for women/couple’s distress and described the experience as “emotionally exhausting, physically draining and sometimes unrelenting”.[184]

To provide optimal care to women/couples who experience miscarriage, while avoiding fatigue and burnout among healthcare professionals, each unit should provide appropriate supports. A supportive work environment facilitating development of clinical experience, formal training and talks from patient representatives have been identified as important factors to improves skill set and confidence.[183-185] Peer support is considered as the most prominent factor in mitigating burnout and disengagement.[185] It is therefore essential that each maternity unit considers initiatives to promote the availability of resources for all staff members. The National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death detail recommendations that each maternity unit should implement to optimise staff training and support. [33]

Clinical Practice

A formal policy on staff support for those working in early pregnancy loss should be devised and made available. Standards addressed in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death should be included in this policy outlining a range of support options including supervision, individual debriefing, peer group support and services of a professional counsellor.

Reliable information should be supplied to each staff member to enable each member to take personal responsibility for his/her self-care and access the HSE Employee Assistance Programme if necessary.

Staff should be informed that necessary support information is available on the National Pregnancy and Infant Loss website at www.pregnancyandinfantloss.ie, NWIHP https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/ and RCPI websites (https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/)

Recommendations

43. **A formal policy on staff support for those working in early pregnancy loss should be available and should outline a range of supports as described in the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death. Support options including supervision, individual debriefing, peer group support and services of a professional counsellor such as the HSE Employee Assistance Programme to mitigate burnout and fatigue.**

Chapter 3: Governance And Approval

3.1 Literature search strategy

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

Research databases including PUBMED, Google Scholar and the Cochrane Library were reviewed to locate suitable resources. Generic terms including “miscarriage” and “early pregnancy loss” and “early pregnancy complications” were utilised alone or in combination with specific terms depending upon the clinical question. For example, to compile evidence relating to the management of miscarriage terms such as “conservative management”, “expectant management”, “medical management”, “mifepristone”, “misoprostol”, “surgical management”, “surgical evacuation” “manual vacuum aspiration” and “electrical vacuum aspiration” were utilised individually or in combination. Searches were restricted to humans and the English language.

The search window extended from 1972 to 2023. The literature review extended from April 2023 to October 2023 and included studies published over the last 34 years. Published texts were reviewed and included or excluded after critiquing the presenting evidence. Priority was given to randomised control trials, meta-analysis and systematic reviews. In circumstances where such evidence was not available, cohort studies were evaluated. Qualitative studies were examined to gather evidence surrounding service users and employee support requirements and needs.

Relevant national and international guidelines were reviewed and appraised, including previous National Clinical Practice Guidelines Ultrasound Diagnosis and Management of Early Pregnancy Miscarriage in addition to international guidance provided by the National Institute for Health and Care Excellence (NICE) Ectopic pregnancy and miscarriage: diagnosis and initial management and American College of Obstetricians and Gynaecologists (ACOG) Early Pregnancy Loss. The latter two guidelines were updated in 2023 and 2018 respectively, and provide recommendations based on research that is currently implemented in clinical practice in most maternity units/hospitals (e.g. inclusion of mifepristone for medical management of missed miscarriage). Further guidance was sought from the Society of Radiographers (SOR) and British Medical Ultrasound Society (BMUS) Guidelines for Professional Ultrasound Practice and the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) Practice Guidelines: performance of first trimester fetal ultrasound scan for practice standards pertaining to early pregnancy ultrasound scanning. To glean information regarding quality and safety of maternity service provision, the HIQA National Standards for Safer Better Maternity Services and the National Maternity Strategy 2016-2026 were consulted. Recommendations derived from the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death relating to bereavement care during early miscarriage are included in this guideline.

3.2 Appraisal of evidence

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

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

A number of evidence-based recommendations for the assessment and management of first trimester miscarriage were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (Appendix 6) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for guideline developers', 2019[19].

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

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

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two. At the inception of the guideline, a list of clinical questions were agreed by the Guideline Development Group. A systematic literature search was conducted, and each clinical question was addressed and discussed accordingly. Dr Ciara McCarthy reviewed relevant evidence and provided recommendations specific to management of miscarriage in the primary care setting. Dr Clare Crowley and Dr Deirdre Hayes-Ryan performed a similar review of relevant evidence specific to secondary care. Ms Louise Dooley provided further recommendations, particularly in relation to ultrasound miscarriage diagnosis, and devised the necessary algorithms. Ms Lynsey Manning also reviewed relevant literature and completed clinical question discussing audit. Ms Niamh Spillane contributed to clinical question 2.15. Submitted clinical questions were compiled and reviewed by the principal writer, Dr Clare Crowley. All contributing authors reviewed the finalised guideline. The guideline was further reviewed and edited by the clinical lead/ supervisor, Professor Keelin O'Donoghue, who also managed consultations with other stakeholders.

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

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations.[20]

While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[21] (Appendix 7)

3.6 Future research

An important outcome of the Guideline development process is in highlighting gaps in the evidence base.

Some suggested questions of relevance to this Guideline include:

- Healthcare staff experiences of caring for women who are diagnosed with first trimester miscarriage, and the educational needs/resources required to fulfil gaps in care.
- Organised and structured teaching for doctors in training to improve knowledge, communication and awareness of miscarriage care and management.
- Evaluation of EPU clinics at national and local levels to assess service provision and needs around service improvement.
- Women's experiences and perceptions of services and care provided in EPU.
- Women's acceptability and experiences relating to outpatient uterine aspiration within the Irish setting.
- Prevalence of pelvic floor dysfunction (urinary and faecal symptoms/incontinence and dyspareunia) after experiencing a first trimester miscarriage.
- Explore whether miscarriage exacerbates pre-existing pelvic floor dysfunction or causes new onset of symptoms secondary to relaxin hormonal effects.
- Development of a national patient information booklet describing specific information relating to pelvic floor dysfunction, role of pelvic physiotherapy services and gradual return to exercise after miscarriage.

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

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

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 (GPT). 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[22] for developing Policies, Procedures, Protocols and Guidelines (2023) and under supervision of the Guideline Programme Team.

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 8 for list of CAG members.

22 Health Service Executive (2023). How to develop HSE National Policies, Procedures, Protocols and Guidelines (PPPGs).

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[23].

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 are also instrumental in the circulation of new and updated guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline available to all employees through standard networks as well as storing it in the online PPPG repository.

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

In the case of this Guideline, a plain language summary should be available for people who experience miscarriage. We will distribute this guideline to the Irish Institute of Obstetricians (IOG) of the Royal College of Physicians Ireland (RCPI) and Irish College of General Practitioners (ICGP) to disseminate to their members. Lastly recommendations from this guideline will also be available in the National Patient Information Booklet and relevant websites (HSE.ie, Mychild.ie, Miscarriage Association of Ireland).

23 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 Guideline 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.

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

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

6.2 Education plans required to implement the Guideline

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

This Guideline's education plan could include:

- A formal launch of the Guideline
- The presentation of the Guideline locally
- The availability of structured educational sessions for staff with facilitated attendance
- The promotion of Guideline awareness through medical and patient accessible media platforms including websites such as RCPI, NWIHP, https://pregnancyandinfantloss.ie/ and https://www.ucc.ie/en/pregnancyloss/.

6.3 Barriers and facilitators

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

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

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

Potential external barriers include:

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

In the case of this Guideline, 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.

Since the National Review of Misdiagnosis of Miscarriage in 2010, each maternity unit has introduced a dedicated EPU service optimising the care of women who have experienced an early pregnancy loss or complication. Although implementation of these review recommendations has enhanced patient care, particularly relating to ultrasound diagnostic criteria, deficits still exist at local levels and these often relate to structural, organisational, and individual factors.

Lack of dedicated spaces separate from antenatal clinics/wards is often identified as a barrier to care. Provision of private spaces staffed with healthcare professionals who have the necessary skillset to diagnose miscarriage and communicate findings in an appropriate manner is the recommended standard of care. Addressing this is not only dependent upon necessary resource and training provisions but also infrastructural change and service prioritisation to optimise service provision which requires investment at a both a national and local level.

Given previous national guidelines recommended misoprostol only for medical management of missed miscarriage, some units may still prescribe this regime without mifepristone pre-treatment. It is envisaged that the national dissemination of this guideline will standardise care. Provision of this guideline should be supported through local champions with accessibility to the relevant resources to promote standardised practice.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement process in each maternity unit/hospital. They 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, funding and staffing are required to develop services in each maternity unit/hospital. Currently not all maternity units/hospitals have equitable access to maternal mental health care services, with limited access to psychology and counselling services and this requires investment.

To the meet the unique care needs of women/couples who experience miscarriage, each maternity unit/hospital should appoint dedicated midwives with a special interest in miscarriage to provide holistic and evidence-based care to these women/couples. It is envisaged that these midwives will act as advocates for women/couples, provide education and training to staff in addition to partaking in audit/research to enhance care.

Most units have access to specialised ambulatory hysteroscopy units, which may be utilised to expand service provision to offer MVA procedures during dedicated sessions.

Considering current evidence, healthcare resources and the individual needs of women who experience recurrent miscarriage, recommendations specifically relating to structure of care, counselling and supportive care, relevant investigations and future pregnancy planning, as described in the National Clinical Practice Guideline Recurrent Miscarriage, should be implemented to standardise care.

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. Maternity units/hospitals and health professionals are encouraged to develop and perform 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.

It is envisaged the implementation of this guideline will standardise care of first trimester miscarriage. It is important that services for women/couples experiencing early pregnancy loss continue to be enhanced and that clinical outcomes are audited locally and nationally. At a national level, audit should be undertaken to evaluate consistency of practice across all maternity units. To maintain the highest standards of care, it is vital each EPU regularly audits its services and outcomes. Each EPU should have a method to record clinical outcomes to compare to a national standard.

7.2 Auditable standards

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

Auditable standards for this Guideline include:

1. The number of initial/new presentations to EPU compared to follow up presentations.
2. From the proportion of women who are diagnosed with miscarriage within this guideline definition, what number of these women are diagnosed with a spontaneous complete miscarriage.
3. The number of women who chose each management option: conservative management, medical management and surgical management.
4. For women who are diagnosed with missed miscarriage and chose medical management, quantify the proportion of women who receive the recommended regime (mifepristone followed by misoprostol).
5. The proportion of women who attend out of hours as an emergency to secondary care with an early pregnancy complication (i.e. bleeding, infection, generally unwell) following outpatient conservative and/or medical management.
6. The proportion of women who undergo unsuccessful management requiring further treatment (i.e. unsuccessful conservative management requiring medical or surgical management).

Care Experience Survey

There is no national survey evaluating early pregnancy loss bereavement experience. Due to the variety of care settings and management options, women's maternity care experiences of early pregnancy loss were outside of the scope of Ireland's first National Maternity Bereavement Experience Survey.[34] However, surveys at a local level could provide useful information and insights to improve standards of care.

Areas to explore include women and/or couples experience with:

1. Acknowledgement of the pregnancy loss
2. The physical hospital environment
3. Quality of interactions with healthcare professionals
4. The quality of written information provided
5. Follow up support services provided by the hospital.

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[24].

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

24 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.[25]

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

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

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

8.2 Method for amending the Guideline

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

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

a) 3 years since the Guideline was published

b) 3 years since last review was conducted

c) Update required as a result of new evidence

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

25 Health Service Executive (2023). How to develop HSE National Policies, Procedures, Protocols and Guidelines (PPPGs).

Chapter 9: **References**

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2. Regan L, Rai R, Saravelos S, Li T, Royal College of Obstetricians and Gynaecologists. Recurrent Miscarriage Green-top Guideline No. 17. BJOG: An International Journal of Obstetrics and Gynaecology. 2023 Jun 19. 2023.

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Supporting Evidence

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

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

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

Glossary

AGREE Appraisal of Guidelines for Research and Evaluation

ACOG American College of Obstetricians and Gynaecologists

ART Artificial Reproductive Technologies

hCG Beta-Human Chorionic Gonadotrophin

BSH British Society of Haematology

CAG Clinical Advisory Group

CHI Chronic Histiocytic Intervillositis

CMS

CRL Crown Rump Length

DOH Department of Health

EAG Expert Advisory Group

EP Ectopic Pregnancy

EPC Early Pregnancy Clinic

EPAU Early Pregnancy Assessment Unit

EPU Early Pregnancy Unit

ER Emergency Room

ET Endometrial Thickness

EVA Electrical Vacuum Aspiration

FIGO International Federation of Gynaecology and Obstetrics

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

GTD

HIQA Health Information and Quality Authority

HSE Health Service Executive

HSUPT High Sensitivity Urinary Pregnancy Test

IMEWS Irish Maternity Early Warning Score

IOG Institute of Obstetricians and Gynaecologists

ISUOG International Society of Ultrasound in Obstetrics and Gynaecology

IV Intravenous

LMP Last Menstrual Period

LSUPT Low Sensitivity Urinary Pregnancy Test

MPFD Massive Perivillous Fibrin Deposition

MTOP Medical Termination of Pregnancy

MVA Manual Vacuum Aspiration

NCEC National Clinical Effectiveness Committee

NICE The National Institute for Health and Care Excellence

NWIHP National Women and Infants Health Programme

PPPG Policy, Procedures, Protocols and Guidelines

PUL Pregnancy of Unknown Location

PUV Pregnancy of Uncertain Viability

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

RM Recurrent Miscarriage

SOP Standard Operating Procedure

TOP Termination of Pregnancy

Appendix 1:
Expert Advisory Group Members 2021-

Member	Profession	Location
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Dr Nicholas Barrett	Consultant Anaesthesiologist, Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Venita Broderick	Consultant Obstetrician and Gynaecologist	National Maternity Hospital Dublin
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women and Infants University Hospital
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Niamh Connolly-Coyne *And* Ms Mandy Daly *(Shared nomination)*	Board of Directors Members	Irish Neonatal Health Alliance
Ms Sinéad Curran	Dietician Manager	National Maternity Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital
Ms Georgina Cruise	National Manager	Patient Advocacy Service
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology and SWEC Fellow	St George Hospital, Sydney, Australia
Ms Alana Dineen	Senior Clinical Pharmacist	Cork University Maternity Hospital
Prof. Maeve Eogan	Consultant Obstetrician and Gynaecologist	National Clinical Lead SATU (HSE) Rotunda Hospital Dublin
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital

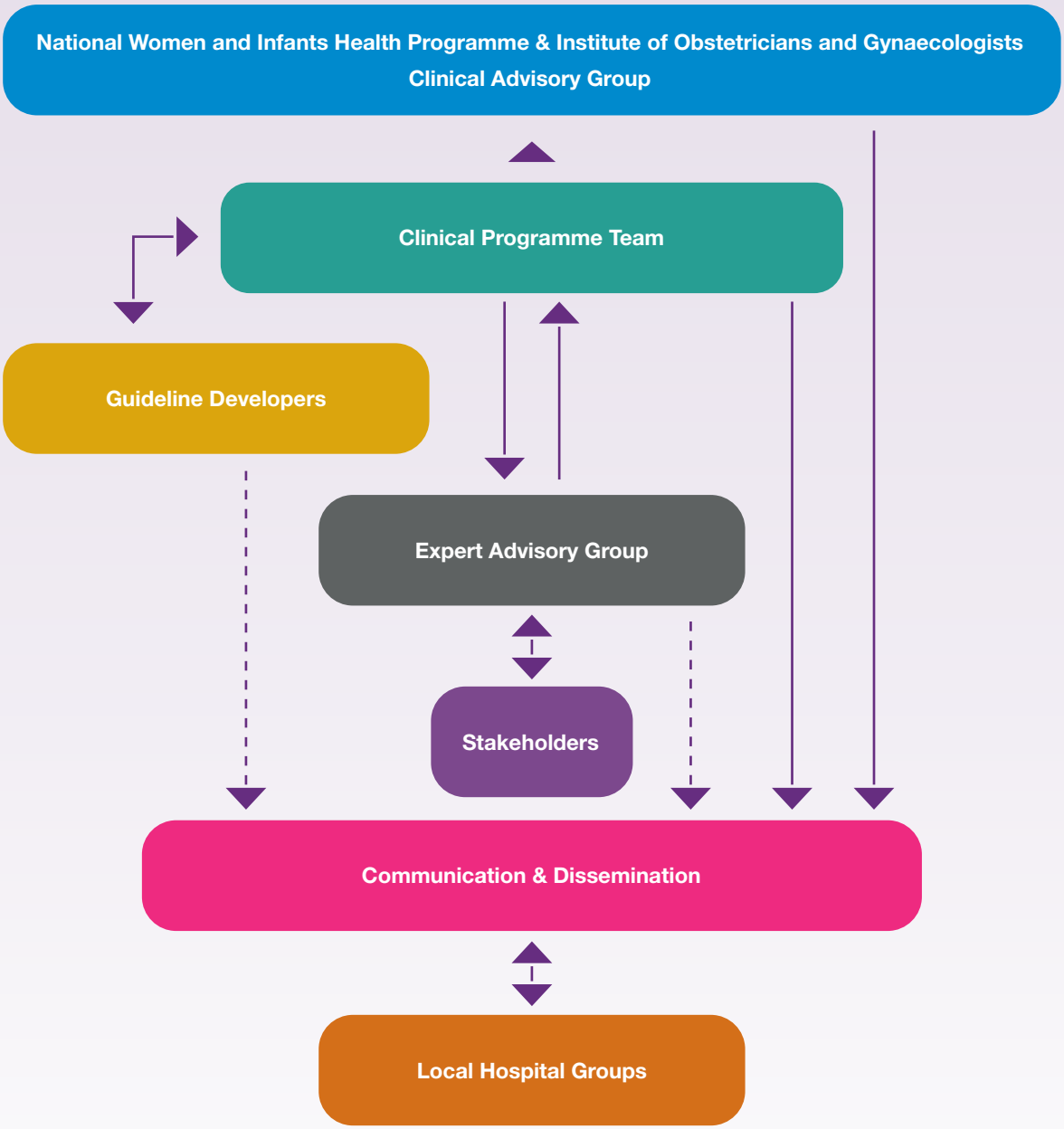
Member	Profession	Location
Dr Daniel Galvin	Specialist Registrar, Obstetrics and Gynaecology	Cork University Maternity Hospital
Ms Stacey Grealis	Patient Research Partner	Independent Living Movement Ireland
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Laura Harrington	Principal Medical Social Worker	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Chaitra Jairaj	Consultant Perinatal Psychiatrist	Coombe Women and Infants University Hospital, Dublin Midland Regional Hospital Portlaoise
Dr Cathy Monteith	Consultant Obstetrician and Gynaecologist	Our Lady of Lourdes Hospital Drogheda
Prof. John Murphy	Consultant Neonatologist	Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology National Women and Infants Health Programme
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford
Dr Jill Mitchell	Specialist Registrar, Obstetrics and Gynaecology	Cork University Maternity Hospital
Dr Aisling McDonnell	Specialist Registrar, Obstetrics and Gynaecology	Mater Misericordiae University Hospital Dublin
Dr Ciara McCarthy	General Practitioner	ICGP and NWIHP Women's Health Lead Irish College of General Practitioners
Ms Orla McCarthy	Clinical Specialist Physiotherapist in Pelvic Health	Cork University Hospital

Member	Profession	Location
Dr Donough J. O'Donovan	Director Neonatal Intensive Care Unit Consultant Neonatologist/Paediatrician	University College Hospital Galway
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 and Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Dr Gillian Ryan	Consultant Obstetrician and Gynaecologist	University Hospital Galway
Prof. Valerie Smith	Chair of Midwifery	University College Dublin
Ms Nora Vallejo	Advanced Midwife Practitioner	Coombe Women and Infants University Hospital, Dublin

Member 2021-2023	Profession	Location
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist	University Hospital Galway
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women and Infants University Hospital, Dublin
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Prof. Declan Keane	Consultant Obstetrician, Gynaecologist, *Professor of* Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Ms Áine Kelly	Physiotherapy Manager	Coombe Women and Infants University Hospital, Dublin
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist	Cork University Maternity Hospital, University College Cork
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **Checklist for Emergency Room staff | First Trimester Miscarriage**

This is a sensitive discussion. Acknowledge any potential upset/distress that the person may be feeling from the outset.

Reason for call
What is your reason for concern/this phone call – pain and/or bleeding?
Pregnancy
Is this your first pregnancy? [Probe: What no. pregnancy is this; how many children at home?]
Have you had a positive pregnancy test?
How many weeks are you?
Have you been to the Early Pregnancy Unit (EPU) in this pregnancy? If yes, what was said?
Have you had a scan in this pregnancy?
Was this a spontaneous, or fertility-assisted pregnancy?
When was your last previous pregnancy? [If applicable]
Have you had a previous miscarriage? If yes, when [if not volunteered]; were there any complications?
Have you had a previous ectopic pregnancy?
Bleeding
How long has bleeding gone on?
Was the bleeding brought in by anything in particular/Is the bleeding provoked, i.e. postcoital?
Is the bleeding fresh red, pink or brown?
How heavy is the bleeding? What is it like compared with your usual period?
Are you soaking through a maternity pad? How quickly? (15 mins = heavy)
Any clots? Bad smell?

Pain
Have you pain that you can't control with paracetamol at home?
Pain score out of 10?
Where is the pain?
Have you any shoulder tip pain?
Overall well-being
Have you any significant medical history (e.g. type 1 diabetes, history of recurrent miscarriage, infertility)?
Support needs
Are you alone, or do you have a support person with you? Can someone bring you to hospital (if needed)?
Consider: do they need an ambulance transfer? (Bad pain, heavy bleeding, alone)

POSSIBLE ACTIONS (1 or 2)

1. Come to Emergency Room (ER) If they have: • Heavy bleeding • Severe pain • Gastrointestinal symptoms • Ongoing pregnancy of unknown location management with change in symptoms New symptoms or complications post-medical or surgical management of miscarriage or expectant or medical management of ectopic pregnancy.	Advise: Purpose of attending the ER is to ensure that they are clinically well and safe for outpatient management or, if unwell, that their care needs are to be escalated and they require admission and further investigation/ treatment
	Advise: What might happen in the ER: may or may not include scan (often too early, staff not certified to perform); what they need to bring with them (clothes; pregnancy tissue, if applicable); they may be waiting for a long time (depends on triage), with other pregnant women – this may be difficult
2. Arrange an appointment for Early Pregnancy Unit (EPU) [contact EPU or seek GP referral, depending on processes in place] **and/or referral triaged by EPU staff**	Advise that if anything changes, they can always phone again/come straight to the ER
	Explain procedure for making EPU appointment from ER – and timeframe chosen

* Developed by the Pregnancy Loss Research Group https://www.ucc.ie/en/pregnancyloss/. For more information/support: www.pregnancyandinfantloss.ie.

Appendix 4: **Early Pregnancy Ultrasound Scan Template**

Patients NAME/MRN	**Date of scan**
DOB	
Name of sonographer	
Indication for ultrasound	
Date of referral	
Ultrasound Machine	☐ Transabdominal ☐ Transvaginal
View	☐ Sufficient ☐ Good view ☐ Suboptimal view
Previous History	Gravida Parity Previous CS ☐ Yes ☐ No Previous EP ☐ Yes ☐ No Previous uterine surgery ☐ Yes ☐ No

Dating		**Pregnancy**	
LMP		**Date of first positive UPT**	
Cycle	☐ Regular ☐ Irregular ☐ Uncertain ☐ Unknown	**Number of fetuses**	
Cycle length in days		**Type of gestation**	☐ Singleton pregnancy ☐ Twin pregnancy ☐ Triplet pregnancy
Agreed dating			

Assessment	
Number of gestational sacs	☐ Visualised ☐ Not visualised ☐ Uncertain ☐ Too early to identify
Location of gestational sac	☐ Intrauterine normally sited ☐ Intrauterine abnormally sited ☐ Probably intrauterine (too early to determine) ☐ Uncertain location ☐ Not applicable ☐ Mean gestational sac diameter (MGSD)
Presence/absence – yolk sac (mandatory)	☐ Visualised ☐ Not visualised ☐ Uncertain ☐ Not applicable
Presence/absence – embryo	☐ Visualised ☐ Not visualised ☐ Uncertain ☐ Not applicable
Presence/absence – cardiac activity	☐ Present ☐ Absent ☐ Not applicable ☐ Uncertain ☐ Too early to determine
Fetal heart rate recorded (M mode)	
Crown rump length in mm	

Pelvic Anatomy			
Uterus	☐ Anteverted ☐ Retroverted ☐ Axial ☐ Other	**Cervix**	☐ Visualised ☐ Not visualised **If visualised** ☐ normal ☐ polyp noted ☐ cerclage visualised ☐ hypervascularity ☐ increased echogenicity
Endometrial thickness (mm)			

Ovary			
Right	☐ Visualised ☐ Not visualised **If visualised** ☐ appears normal ☐ appears abnormal **Corpus Luteum** ☐ present ☐ Not present	**Left**	☐ Visualised ☐ Not visualised **If visualised** ☐ appears normal ☐ appears abnormal **Corpus Luteum** ☐ present ☐ Not present

Adnexa			
Right	☐ Visualised ☐ Not visualised **If visualised** ☐ appears normal ☐ appears abnormal	**Left**	☐ Visualised ☐ Not visualised **If visualised** ☐ appears normal ☐ appears abnormal
Pouch of Douglas free fluid	☐ Visualised ☐ Not visualised **If visualised** ☐ anechoic ☐ echogenic ☐ mixed echogenicity	**Other findings**	

Scan Report conclusion	
Diagnosis from ultrasound	
☐ Complete TOP ☐ Incomplete TOP ☐ Viable intrauterine pregnancy ☐ Pregnancy of uncertain viability ☐ Missed miscarriage ☐ Incomplete miscarriage	☐ Complete miscarriage ☐ Pregnancy of unknown location ☐ Probable ectopic pregnancy ☐ Definite ectopic pregnancy ☐ Probable molar pregnancy
Plan for follow up	
☐ For medical review ☐ Serum β-hCG ☐ Repeat ultrasound recommended	☐ Routine dating scan ☐ Discharged from EPU ☐ Copy of report sent to GP
Comment	
Sign off final report/name(s)/grade(s)	
Second sign off/second opinion (if relevant)	

Images	
Include in report	Image of gestational sac Image of embryo/fetal pole if present Image of CRL with measurement Image of any pathology if present
Store and archive	• 'Global' view of uterus and bladder/adnexa showing the gestational sac in the uterus and in the endometrial cavity • Gestational sac with measurements if no embryo/fetal pole present • Yolk sac • Embryo/fetal pole if present • CRL with measurement if embryo/fetal pole present • Cardiac activity (using M Mode) • Right ovary – measurements in 3 planes (displayed in split screen) • Right ovarian cyst with measurements (if present) and image with colour (e.g. to show it is a corpus luteal cyst if has peripheral vascularity) • Left ovary – measurements in 3 planes (displayed in split screen) • Left ovarian cyst with measurements (if present) and image with colour as above • Pouch of Douglas • Any other pathology (e.g. adnexal masses) • If multiple pregnancy: CRL x 2 measurements and cardiac activity x 2 • Image of both gestational sacs containing yolk sac(s) to demonstrate how chorionicity has been diagnosed

Purpose of the early pregnancy ultrasound scan is to:

1. locate an early pregnancy (normally sited versus ectopic)
2. determine the gestational age of the pregnancy
3. determine whether a pregnancy is single or multiple
4. establish whether a pregnancy is ongoing (early or live versus miscarriage)
5. identify any co existing pelvic pathology that is present
6. identify the cause of the presenting symptoms

More information regards Early Pregnancy Ultrasound Standards/Guidelines is available at:

https://www.aepu.org.uk/professional-standards/

https://www.bmus.org/static/uploads/resources/2021_SoR_and_BMUS_guidelines_v1.0_.pdf

https://www.isuog.org/static/uploaded/4daa1ea7-bc64-4c24-b81b17df5a684a38.pdf

https://www.isuog.org/static/uploaded/b670e097-7101-46fe-9ddc30a67a1b2052.pdf

https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Ectopic-pregnancy

https://www.aium.org/docs/default-source/resources/guidelines/aium-practice-parameter-for-documentation-of-an-ultrasound-examination.pdf?sfvrsn=3135b66_3

https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/the-diagnosis-and-management-of-ectopic-pregnancy-2024-.pdf

Appendix 5:
Protocol for Medical Management of First Trimester Miscarriage

	Mifepristone	Misoprostol
Missed Miscarriage	Mifepristone 200mg PO	Misoprostol 800mcg buccal/PV Outpatient Medical Management • Consider repeat dosing after 48 hours if no response to first dose Inpatient Medical Management • If no response to the first dose after 3 to 4 hours consider further doses of misoprostol. • Up to maximum of 4 further doses of 400mcg of misoprostol every 3 hours is recommended
Incomplete Miscarriage		Misoprostol 800mcg buccal/PV • Consider repeat dosing after 48 hours if no response to first dose

Appendix 6: **AGREE II checklist**[26]

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	

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

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

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

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

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

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

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

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

Appendix 7: **GRADES of Recommendation**[27]

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomized, 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…

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

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomized, 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…
1C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomized, 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 randomized, 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 randomized, 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 randomized, 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 8: **NWIHP/IOG CAG (2024-)**

Dr Cliona Murphy (Chair, 2023-). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith (2023-). Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Dr Venita Broderick (2024-). Clinical Lead Gynaecology, National Women and Infants Health Programme.

Dr Brian Cleary (2023-). Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

Ms Angela Dunne (2023-). Director of Midwifery, National Women and Infants Health Programme.

Prof. Seán Daly (2023-). Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof. Maeve Eogan (2023-). Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Prof. Richard Greene (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof. John Higgins (2023-). Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Prof. Shane Higgins (2023-). Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Dr Mendinaro Imcha (2023-). Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof. John Murphy (2023-). Clinical Lead Neonatology, National Women and Infants Health Programme.

Dr Aoife Mullaly (2023-). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof. John Morrison (2023-). Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Mr Kilian McGrane (2023-). Director, National Women and Infants Health Programme.

Prof. Keelin O'Donoghue (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Dr Suzanne O'Sullivan (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof. Mike O'Connell (2023-). Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Ms Davinia O'Donnell (2024-). General Manager | National Women and Infants Health Programme

Office of the Chief Clinical Officer, Health Service Executive

Dr Vicky O'Dwyer (2023-). Consultant Obstetrician and Director of Gynaecology, Rotunda Hospital.

Dr Mairead O'Riordan (2024-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital.

Ms Danielle Prenderville (2024-). Senior Executive Assistant – Master's Office.

Prof. Nóirín Russell (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Dr Carmen Regan (April 2024). Clinical Lead Obstetrics, National Women and Infants Health Programme.

Dr Orla Shiel (2024-). Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Ms Clare Thompson (2023-). Consultant Gynaecological Oncologist, The Mater, Dublin.