Medical Management of First Trimester Miscarriage (<13weeks)

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Approved By:	**Health Board**
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Target Audience:

People who need to know about this document in detail	All staff providing care for the medical management of first trimester miscarriage
People who need to have a broad understanding of this document	Care Group Directors Chief Operating Officer Executive Medical Director
People who need to know that this document exists	*All staff providing care for the medical management of first trimester miscarriage*

Integrated Impact Assessment:

Equality Impact Assessment Date & Outcome	**Date:** **Outcome:**
Welsh Language Standard	Choose an item.
Date of approval by Equality Team:	(00/00/0000)
Aligns to the following Wellbeing of Future Generation Act Objective	Choose an item.

Disclaimer:
If the review date of this document has passed please ensure that the version you are using is the most up to date version either by contacting the author or CTM_Corporate_Governance@wales.nhs.uk

COMPONENTS:

A policy must contain the following components and must also be written to include the values and behaviours of the organisation wherever relevant:

It is accepted that for Clinical Policies and or other Written Control Documents (Procedures, Guidance etc.) the policy components below may not all be relevant.

For guidance on Clinical Policy Development please contact:

CTM_ClinicalPolicies@wales.nhs.uk

For guidance on Non Clinical Policy Development please contact:

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BACKGROUND

Guideline Definition

Clinical guidelines are systemically developed statements that assist clinicians and patients in making decisions about appropriate treatments for specific conditions.

They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.

Purpose

To assist medical and nursing staff in the use of Misoprostol for the medical management of miscarriage.

Many complaints come from poor communication and contradictory advice.

The guideline aims to minimise this by standardising the information, advice and treatment that we provide to those couples who suffer early pregnancy loss and require medical treatment.

Scope

For all staff, medical, nursing and clerical, to provide uniformity in the management of patients diagnosed with a first trimester miscarriage.

Roles and Responsibilities

In seeking further advice on any uncertainties contained in this document, or if you feel that there is new or more updated advice it is your responsibility to contact the guideline author or Approval Group manager so that any amendments can be made.

The guideline Approval Group is responsible for disseminating this guideline to all appropriate staff.

The guideline author or a named alternative is responsible for updating the guideline with any amendments that they become aware of or are highlighted to them.

All health professionals are responsible to ensure that the guideline is utilised effectively, and to ensure that they are competent and compassionate in the implementation of it.

Training Requirements

There is no mandatory training associated with this guideline.

Monitoring of Compliance

- By audit and review of complaints relating to miscarriage diagnosis and management.
- The Governance Department will collate any complaints and distribute to the relevant individuals for comments, and share any learning points.
- The Service Lead will oversee any governance issues, make relevant recommendations to the directorate, and advise the Clinical Director or the directorate of any matters that require implementation.
- The Health Board reserves the right, without notice, to amend any monitoring requirements in order to meet any statutory obligations or the needs of the organisation

Complaints

All complaints should try to be resolved with the patient during any contact to avoid escalation. There concerns should be listened to and documented. If it is not possible to address any concerns at the time, or if the complaint is of a serious nature, the patient's complaint should be discussed with the consultant in charge for the day, or the patient should be given details of how to raise a formal complaint via the local governance department.

Related Guidelines

Diagnosis and Management of First Trimester Miscarriage (<13 weeks)

MEDICAL MANAGEMENT

Definition and Background

This protocol guides the use of misoprostol in the medical management of miscarriage (mainly incomplete/missed miscarriage) in the first trimester, up to 13 weeks of pregnancy (CRL= 84mm). Misoprostol is a synthetic prostaglandin analogue that induces uterine contractions resulting in the evacuation of uterine contents. Read this protocol in conjunction with the *Management of First Trimester Miscarriage (<13 weeks).*

Miscarriage occurs in 10−20% of pregnancies and can lead to significant psychological distress. Poor communication is a recurring cause of complaint from women experiencing miscarriage. All patients must be counselled sensitively, with empathy and patience. The correct terminology should be used when counselling and for documentation. The following topics must be covered during counselling, and should documented in the notes:

- Information on diagnosis and follow-up including oral and written information about what to expect throughout the process and advice on pain relief.
- Miscarriage information leaflet given to the patient
- The patient and partner/companion have no further questions
- When and how to seek help if symptoms worsen or change, and providing a 24 hour contact number(s).
- Advice when conception can next be attempted. There is usually no reason to wait more than one cycle
- The Early Pregnancy and Gynaecology Assessment Unit (EPGAU) has experienced nurses who can provide additional counselling if necessary.

Safety Net Advice and Urgent Referral

It is important to provide contact details of the EPGAU, its opening time, and any other emergency contact details so as to allow women to be able to seek advice should they be worried. Advise all women to seek advice or medical assistance should they have:

- Heavy bleeding sufficient to soak a sanitary towel every 20 minutes or they are feeling faint or unwell
- Passage of large clots that they are concerned about (e.g. clots that cover are large area of their palm)

- Prolonged heavy bleeding for >3 days that is not subsiding
- Persistent bleeding more than 21 days, or persistent bleeding of any duration sufficient to cause fainting or fatigue
- Pain not controlled with simple analgesia
- Prolonged or severe side effects
- Any issue for which they are concerned or worried about

KEY MESSAGE:

- **Refer women who are haemodynamically unstable, or in whom there is significant concern about the degree of pain or bleeding, directly to A&E.**

GENERAL INFORMATION AND COUNSELLING

Who Should Be Offered Medical Management

Medical management of missed miscarriage should be offered as a treatment option in addition to offering expectant and surgical management (SMM). Expectant management still generally remains the recommended management choice, particularly with incomplete miscarriage.

KEY MESSAGE:

- **No difference in the duration of pain or bleeding cf. expectant management**
- **No difference in infection rates (1-3%) cf. expectant and surgical management.**
- **No difference in future pregnancy rates cf. expectant and surgical management.**

Women Unlikely To Benefit From Medical Management

- After failed expectant management - especially where the POC have a strong vascular blood supply.
- Gestations over 10 weeks (CRL >31mm by ultrasound) - due to risk of heavy bleeding than during SMM.
- Those with incomplete miscarriage - **do not routinely offer** medical management for incomplete miscarriage in the first trimester. There is no advantage over expectant management (no difference in time to resolution). During expectant management of incomplete miscarriage, the miscarriage is usually complete (80%) within 3 days.
- **This does not mean that medical management is contraindicated.** Some women will have a strong preference for medical management despite counselling. Under these circumstances discuss with the consultant on call for possible medical management.

Advantages and Disadvantages of Medical Management

Advantages

- Fewer patients require SMM (20%) compared to those undergoing expectant management (30%).
- Fewer emergency admissions than expectant management.
- Avoids surgical/anaesthetic risks.
- Bleeding usually starts within 24 hours of medical management. This makes it faster, more predictable commencement of bleeding (after administration of drugs) than expectant management for missed miscarriage.

Disadvantages

- Medical management is less likely to be successful after failed expectant management.
- Gestations over 10 weeks (CRL >31mm by ultrasound) are more like to experience severe pain and heavy bleeding particularly when compared to SMM.
- **Should not routinely offer medical management for incomplete miscarriage in the first trimester** because there is no advantage over expectant management (no difference in time to resolution). During expectant management of incomplete miscarriage, the miscarriage is usually complete (80%) within 3 days. The final decision resides with the woman after appropriate counselling.
- Greater side effect profile than expectant and surgical management.
- Longer duration of pain and bleeding than SMM.

Contraindications to Medical Management

- Active heavy bleeding (subjective assessment by clinician)
- Haemoglobin <10g/dl (bleeding risk for expectant/medical management)
- Current severe abdominal/pelvic pain
- Pyrexia > 38°C (possible infected products of conception)
- IUCD in-situ *(coil must be removed before administration of misoprostol)*
- Anti-coagulant therapy or clotting problems (bleeding risk)
- Porphyria
- Severe Asthma
- Mitral stenosis

Information for Women

- **PROVIDE 24-HOUR CONTACT NUMBER FOR EPGAU**
- Ensure that safety net advice (see above) is given to the woman and any family members.
- Medical management shortens the time to commencement of missed miscarriage but not the time to completion.
- Even during successful medical management, light bleeding may persist for up to 3 weeks.
- Expect heavy bleeding and cramping pains for 24-48 hours after misoprostol administration. If ambulatory management has been decided, a member of the nursing staff will call the next day to confirm the onset of bleeding and check well-being.

- As products of conception pass through the cervix they may cause the woman to feel faint (due to fall in BP)

Misoprostol side effects are fairly common and include:

- Nausea and vomiting, resolve within 2-6hr
- Diarrhoea, resolves within 24 hours
- Pyrexia and fever, resolve within 12 hours Skin rash, resolves within 2-3 days

Unlicensed (off-label) Prescribing of Misoprostol

- Advise women that Misoprostol, is not licensed (off-label) for medical management of miscarriage (but is licenced for treating gastric ulcers).
- Explain that off-label treatments are fairly common (most medicines administered to children are off-label) in medicine, and that misoprostol is effective and safe in selected women. It is also recommended by NICE.
- **The doctor must document that the woman is aware that misoprostol is not licensed for the treatment of miscarriage, and obtain the woman's written consent**.

MEDICAL MANAGEMENT OF MISCARRIAGE PATHWAY

First Dose Pathway

There are two pathways that can be open to women when medically managing miscarriage depending on their gestation and the woman's wishes:

1. OUTPATIENT - Ambulatory – preferred when gestation LESS THAN 9 weeks
2. INPATIENT - Hospital – preferred when gestation MORE THAN 9 weeks or it is the woman's preference

Regardless of the pathway chosen, the following counselling should be undertaken:

- Counsel women on the advantages, disadvantages and alternatives to medical management.
- Provide information leaflets on miscarriage and medical management.
- Give the woman time to decide and the option to return at a later date for treatment. ○ Ideally, treatment should be commenced Monday – Wednesday as this allows appropriate follow on a weekday while the EPGAU is active, and also reduces potential inpatient admission over the weekend.

For Women Who Agree On Medical Management

KEY MESSAGE:

- **DO offer mifepristone for missed miscarriage (gestation sac present) 200mg orally 48 hours prior to misoprostol 800 micrograms (PO, PV, SL).**
- **DO NOT offer mifepristone as treatment for incomplete miscarriage (gestation sac absent). Instead prescribe 800 micrograms only of misoprostol (PO, PV, SL)**
- **Vaginal misoprostol is believed to be more effective than the other routes**
- **ENSURE that the woman has a responsible person with her at all times during the treatment if she chooses to have treatment at home – DOCUMENT IN NOTES**
- **DO NOT offer ambulatory home treatment if the pregnancy is > 9 weeks**
- **EXPLAIN what products of conception are likely to look like**

- Obtain written consent for medical management to include:
  - Failure / SMM rates (approx. 20%)
  - Misoprostol is unlicensed for this indication (but recommended by NICE)
  - Side effects (Pain, heavy bleeding, bowel upset [n&v&d], fever, skin rash, shortness of breath)
- Basic observations (BP/HR/Temp) should be taken along with bloods (FBC/G&S).
  - If the patient is an inpatient, MEWS observations should be taken on admission and continued every 4 hours. If any changes occur in the patient's clinical condition then the frequency of the MEWS must be reassessed.
- If the patient is to be admitted arrange a side room to maintain privacy and dignity.
- Anti-D **should not** be administered to women undergoing medical management of miscarriage under 13 weeks.
- For the first dose, prescribe 800µg (micrograms) misoprostol for the woman to be administered vaginally at home, or to be administered by nursing staff prior to discharge depending on the woman's choice, ideally Mon-Wed.
  - The 800µg misoprostol tablets can be taken orally but may be less effective than the vaginal route.
  - Consider the sublingual route for women who are actively bleeding heavily as this has a rapid onset of action but is often associated with headache.
- Pass urine before inserting misoprostol with fingers (a woman may find self-insertion of misoprostol easier using a tampon to ensure the correct placement. DO NOT LEAVE THE TAMPON IN SITU).
- Eat and drink as normal.
- Use sanitary towels rather than tampons after inserting misoprostol.
- Lie down for 30-60 minutes after vaginal insertion.
- Reinsert tablets vaginally if they fall out (or contact the EPGAU if the tablets are vomited)

- Paracetamol and ibuprofen can be taken for pain relief if no contraindications.
- If nausea and vomiting are severe, the woman may call and return for anti-emetics.
- If POC have not been passed:
    - INPATIENT – repeat dose after **3 hours**
    - OUTPATIENT – repeat dose after **24 hours**
- If the woman is on the outpatient/ambulatory pathway she should be called at home to determine if any progress has been made with respect to the passage of fetal tissue, and also to determine if the woman feels well or has not experienced any significant or worrying side effects or complications.

Second Dose Pathway

Inpatient Care

If the first dose treatment has not resulted in the passage of products of conception after 3 hours, a further second dose of **600µg** Misoprostol tablets should be given **after 3 hours**.

Patients can be discharged once the products of conception are passed, bleeding is not heavy, and observations are stable.

If no products of conception are seen and any pain or bleeding have settled, the woman may be allowed home with an ultrasound scan in the EPGAU within 48 hours, or as soon as reasonably possible.

If second dose medical management fails surgical management (SMM) may be offered.

Outpatient/Ambulatory Care

The EPGAU staff should contact the woman at home after 24 hours to discuss any preceding events, and to check that the patient is well.

If the first dose treatment has not resulted in the passage of products of conception after 3 hours, a further second dose of **600µg** Misoprostol tablets should be given **after 24 hours** in the hospital. This is particularly important to ensure the correct placement of the vaginal medication where the woman has previously self-administered.

A full set of observations should be taken as previously stated.

If the woman is on the ambulatory pathway, and has support available at home, she can be allowed to leave the hospital if bleeding is not heavy, and observations are stable.

The EPGAU staff should contact the woman at home after 24 hours to discuss any preceding events, and to check that the patient is well.

If no products of conception are seen within the next 24 hours, and any pain or bleeding have settled, the EPGAU staff must arrange an ultrasound scan in the EPGAU within 48 hours, or as soon as reasonably possible. If second dose medical management fails surgical management (SMM) may be offered,

Anti-D Immunoglobulin

Do not offer anti-D rhesus prophylaxis to women who:

- receive solely medical management for an ectopic pregnancy or miscarriage LESS THAN 13 weeks **or**
- have a threatened miscarriage **or**
- have a complete miscarriage **or**
- have a pregnancy of unknown location.

Do not use a Kleihauer test for quantifying feto-maternal haemorrhage.

(Offer anti-D rhesus prophylaxis at a dose of 250 IU (50 micrograms) to all rhesus-negative women who have a surgical procedure to manage an ectopic pregnancy or a miscarriage.)

Management of Fetal Remains (POC)

Following Passage of POC

If POC have been passed, advise women to take a urine pregnancy test 3 weeks after medical management of miscarriage, or up to three weeks after POC are passed, unless they experience worsening symptoms (see safety net advice above), in which case advise them to return to the EPGAU sooner for further review and advice. Advise women with a positive urine pregnancy test after 3 weeks to return for a review in the EPGAU in order to exclude molar or ectopic pregnancy. **If home urine pregnancy testing is being requested, provide the woman with a pregnancy test kit.**

Inform women that should there are choices available to them in how they wish to manage any fetal tissue. The following options should be discussed:

- Should a woman deliver away from the hospital, she may bring the fetal remains to the hospital. The hospital will arrange a shared cremation with her consent, which is carried out at the crematorium in a sensitive and respectful manner. If the woman would like details of when this will happen, this can be given to her.
- If the woman wishes an individual cremation/burial, she may of course make her own arrangements but the hospital is unable to contribute to the costs.
- In all cases, the staff will ensure that the woman's cultural and/or religious needs are respected.
- The woman is also legally allowed to take the pregnancy remains home to bury herself. There are certain legal requirements that must be adhered to if she wishes to do this, which are as follows:
    - The burial must not cause any danger to others.
    - It must not interfere with any rights other people may have on the land.
    - There must be no danger to water supplies or watercourses. ○ There must be no chance of bodily fluids leaking onto adjoining land. ○ The remains must be buried to a depth of at least 18 inches (45cm) ○ Permission must be obtained from the landowner if you do not own the land.
    - Careful thought needs to be given when considering burial in a garden, taking into account what would happen if you choose to move.

Products of Conception Histology and Cytogenetics

Ensure that POC are seen and documented at evacuation.

Depending on the woman's wishes for the sensitive disposal of fetal remains and PLR guidelines, send an adequate sample to histology to confirm intrauterine pregnancy and exclude molar pregnancy. If unsure, or if minimal sample is obtained, the surgeon should empty the suction trap and send the entire sample.

It is the doctor's responsibility to chase the histology result of all POC samples. This is essential if minimal or no sample is obtained (risk of ectopic pregnancy), or there is a risk of molar pregnancy.

If this miscarriage is the third consecutive miscarriage, offer for the POC to be sent for cytogenetics, if this has not already been done in the past. You must add '*testing for cytogenetics'* to the consent form. If POC are being sent for cytogenetics, they must **not** be sent in formalin and some POC must still be sent for histology.

Post SMM Admin

Provide a contact number for queries relating to potential post-op complications.

Complete the electronic discharge letter.

GP should provide routine follow-up care.

Follow Up

After an early pregnancy loss, offer the woman the option of a follow-up appointment with a healthcare professional of her choice.

OTHER CONSIDERATIONS

What Should We Tell Patients With Retained POC After Two-Weeks?

Although NICE strongly advocate expectant management, Cochrane evidence states: moderate-certainty evidence shows that, compared with expectant management, surgical evacuation reduced the number of women with early pregnancy loss who retained products of conception **at two weeks** (on average, 102 vs 406 per 1000 women) and at six to eight weeks (on average, 33 vs 84 per 1000 women), as well as the number of women who went on to additional or unplanned surgical evacuation (on average, 55 vs 402 per 1000 women).

High-certainty evidence shows that surgical evacuation also reduces the requirement for blood transfusion, although event rates were low in both groups (0% vs 14%). Evidence suggests that women experienced less pain with surgical evacuation than with expectant management, with 177 versus 445 per 1000 women requiring additional analgesia. Researchers found no clear differences between groups in localized infection, complications, or subsequent fertility (live births), but some of these analyses were underpowered to detect differences. COMMENT: Therefore, if POC shows significant vascular attachment, SMM may be a better option compared to expectant management.

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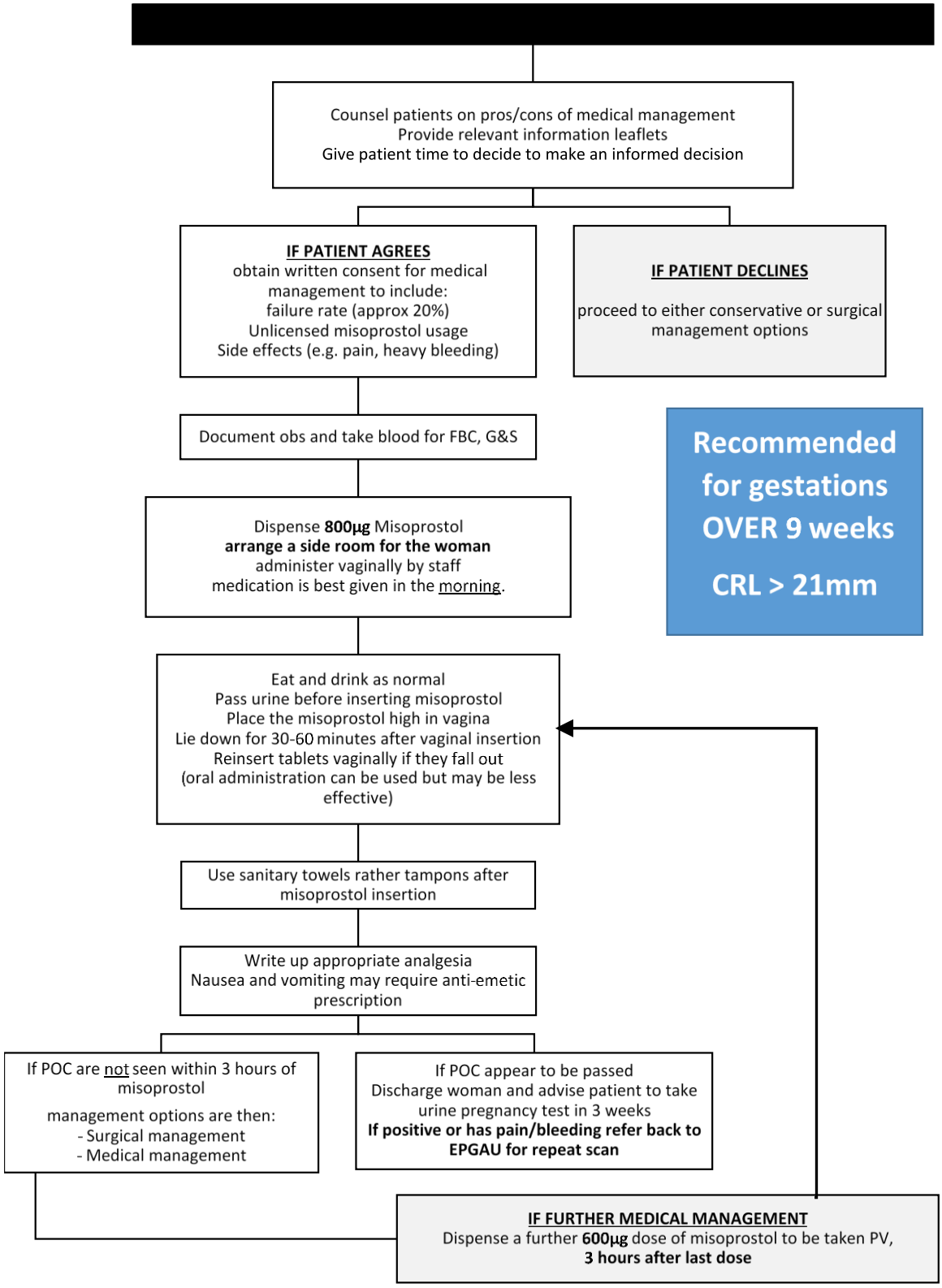
Appendices and Flowcharts

Flowchart on Inpatient Medical Management of Miscarriage (>9 weeks or Patient Preference)



Flowchart on Ambulatory Outpatient Medical Management of Miscarriage (<9 weeks)

[redacted]

Counsel patients on pros/cons of medical management
Provide relevant information leaflets
Give patient time to decide to make an informed decision
THE WOMAN MUST HAVE SOMEONE WITH HER AT ALL TIMES

IF PATIENT AGREES
obtain written consent for medical management to include:
failure rate (approx 20%)
Unlicensed misoprostol usage
Side effects (e.g. pain, heavy bleeding)

IF PATIENT DECLINES

proceed to either conservative or surgical management options

Document obs and take blood for FBC, G&S

Determine if Mifepristone needed

Recommended for gestations UNDER 9 weeks

CRL < 21mm

Dispense **800µg** Misoprostol
Patient to administer vaginally at home, or to be given by staff prior to discharge depending on patient choice. Medication is best given in the morning **Monday to Wednesday**

Eat and drink as normal
Pass urine before inserting misoprostol
Using fingers or tampon place misoprostol high in vagina
Lie down for 30-60 minutes after vaginal insertion
Reinsert tablets vaginally if they fall out
(oral administration can be used but may be less effective)

Use sanitary towels rather tampons after misoprostol insertion

Paracetamol +/- ibuprofen analgesia
Nausea and vomiting may require anti-emetic prescription

If POC are not seen in the first 24 hours after taking PV misoprostol call the EPGAU for further advice.

If POC appear to be passed
Discharge woman and advise patient to take urine pregnancy test in 3 weeks
If positive or has pain/bleeding refer back to EPGAU for repeat scan

Inform senior doctor - management options are then:
- Surgical management
- Medical management

IF FURTHER MEDICAL MANAGEMENT
Dispense a further **600µg** dose of misoprostol to be given PV in the morning, hospital**, 24 hours after last dose**

Table of Different Miscarriage Treatment Options

Expectant (conservative)	Medical	Surgical (SMM/ERPC)
There is no difference in infection rates (1-3%) between any of the modes of management for miscarriage		
The primary advantage of allowing the miscarriage to resolve 'naturally' is the avoidance of surgical and anaesthetic risks.	Medical management is likely to be most useful when used for women with missed miscarriage.	SMM, previously known as ERPC, should be an option offered (rather than recommended) to women with incomplete or missed miscarriage.
Approximately 30% (20% for medical management) of women will require surgical evacuation following expectant management of miscarriage.	Approximately 20% (30% for expectant management) of women will require surgical evacuation following medical management of miscarriage.	The only advantages over expectant management: a) Predicable start and end point b) No follow up required
Expectant management is by far the most cost effective mode of management.	Medical management is less likely to be successful after failed expectant management.	Where infection is suspected, delaying surgical intervention for 12-24 hours is recommended to allow local policy intravenous antibiotic administration.
Advise women that SMM is be preferable to expectant management after 10 weeks gestation (ultrasound dates rather than menstrual dates) or a tissue diameter >50mm, as pain and bleeding may be severe.	It is preferable to SMM for second trimester miscarriage.	Indications for SMM: • Woman's preference • Persistent excessive bleeding/pain • Haemodynamically unstable • US tissue diameter of > 50mm • (increased risk of excessive bleeding) • US dates >10weeks gestation • (increased risk of excessive bleeding) • Evidence of infected retained tissue (proceed after 6-24h IV antibiotics) • Suspected gestational trophoblastic • disease • Failed medical/ surgical management
Well-informed women experience less anxiety and are less likely to be readmitted.	**The doctor must document that the woman consents to the use of misoprostol, which is unlicensed for medical management of miscarriage**. This is because it is sold for a different indication (gastric ulcers).	Book as an elective day case on a future list (unless emergency indication). VTE assessment MRSA swabs, FBC, Rhesus group & save

Advice on analgesia at home and what to expect during the miscarriage process aid this. It is helpful to give a broad indication of the likely degree of pain and blood loss (strong pain, heavy blood loss, passage of fetal remains).	Explain that off-label treatments are fairly common (most medicines administered to children are off-label) in medicine.	In addition to SMM consent, women should also consent to: • Laboratory analysis to confirm the diagnosis and exclude molar pregnancy • Mortuary blessing and cremation. Women have the right to keep their products of conception (refer to sensitive disposal of early pregnancy remains pathway) • Swabs for Chlamydia and gonorrhoea when indicated
Time to completion of the miscarriage process is unpredictable.	Explain that misoprostol is effective and safe in selected women and is recommended by NICE.	• Haemorrhage (<3%) • Infection (2-3%) - no increase over expectant /medical management. • Incomplete evacuation requiring • possible further ERPC <1% • Uterine perf (<1%), cervical tears • Bowel / bladder trauma (<1%) • Intrauterine adhesions (<5%) • No additional risk to fertility
Expectant management may be continued for as long as the woman is willing provided there are no signs of infection or excessive blood-loss. Routine follow-up for missed miscarriage 2-3 weeks later.	Routine follow-up for missed miscarriage 2-3 weeks later.	Pre-op cervical preparation is indicated for missed and most incomplete miscarriages (closed internal os on bimanual examination).