Early Pregnancy Unit Guideline

Document Type:	Clinical Guidelines
Ref:	(For Non-Clinical References – Contact: CTM_Corporate_Governance@wales.nhs.uk For Clinical References – Contact: CTM_ClinicalPolicies@wales.nhs.uk
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Executive Sponsor:	Executive Medical Director
Approved By:	**Health Board**
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Version:	1

Target Audience:

People who need to know about this document in detail	All health care professionals working in the Early Pregnancy Unit / Gynaecology
People who need to have a broad understanding of this document	Womens health directorate team. Board Members, Management Board. Senior Leaders. Board Committees.)
People who need to know that this document exists	All staff involved in the development of Health Board Policies.

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:

CTM_Corporate_Governance@wales.nhs.uk

Or visit the Policy Author Page on SharePoint:

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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 provide a standardised approach to miscarriage management across CTMUHB

Scope

For all staff, medical and nursing, to provide uniformity in the care and treatment of women being administered with hormonal implants.

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
- 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.

Equality Impact Assessment Statement

This policy has been screened for relevance to Equality. No potential negative impact has been identified.

Introduction

Early Pregnancy Assessment Clinics are held in Royal Glamorgan Hospital (South) and Prince Charles Hospital (North) and Princess of Wales (West) daily. They accept self- referrals or via GP/community midwife from 6 to 12+6 weeks gestation with:

- Low abdominal pain
- PV bleeding
- Previous miscarriage
- Previous ectopic pregnancy
- Previous molar pregnancy

This is the basic criteria that is followed, but the unit will triage every woman who contacts the department to assess eligibility.

The service is there to assess location and viability of an early pregnancy.

N.B Referrals for 13 to 15+6 weeks gestation must be made via GP to the on-call gynae team

16 weeks gestation is referred to maternity services

Miscarriage

First trimester miscarriage is pregnancy loss within the first 13 weeks of conception. This guideline will cover management of pregnancy loss up to 15+6 weeks as managed with gynaecology**.**
1 in 4 pregnancies will miscarry and the majority occur in the first trimester. Women should be seen in appropriate setting and counselled sensitively, whilst being treated with respect and maintaining dignity.

Risk Factors for Miscarriage

- Maternal age >40
- Medical comorbidities- diabetes, renal disease, hypertension, thyroid disease, autoimmune conditions
- Previous recurrent miscarriage/ pregnancy loss
- Uterine abnormalities
- Chromosomal abnormalities
- Smoking
- Alcohol intake
- Drug use

Classification of types of Miscarriage

Threatened miscarriage	Patient presents with pain and or vaginal bleeding but cervical os closed and USS shows ongoing pregnancy.
Missed miscarriage	USS findings diagnose miscarriage with no symptoms prior (PVB or pain)
Septic miscarriage	USS findings diagnose miscarriage with associated pyrexia, abnormal discharge, abdominal pain, bleeding
Complete miscarriage	Vaginal bleeding and pain resolved, and pregnancy tissue all passed.
Incomplete miscarriage	Vaginal bleeding ongoing, pain ongoing, cervical os open and USS shows retained pregnancy tissue.

Diagnosis criteria

Miscarriage requires a formal ultrasound diagnosis, by an appropriately trained user and confirmed by a 2nd Sonographer, before treatment is commenced.

Transvaginal ultrasound is used in practice for pregnancies under 9 weeks gestation and the transabdominal for over 9 weeks gestation.

There must be evidence of an intrauterine pregnancy seen, whether this is gestation sac only, or progression to yolk sac and fetal pole.

Transvaginal ultrasound is preferable to diagnosis miscarriage or early pregnancy complications- if women choose not to undergo transvaginal ultrasound then transabdominal should be performed, but its limitations explained to the patient.

Transabdominal USS

Visible Fetal cardiac activity	Reassurance of viable pregnancy	Discharge EPAU if no other concerns
No visible fetal cardiac activity	CRL <32mm	1. Rescan 14 days or 2. Perform TVS
No visible fetal cardiac activity	CRL >/=32mm	Diagnose miscarriage Offer treatment options
Gestational sac seen with no fetal pole		1.Rescan 14 days or 2. Perform TVS

Transvaginal USS

Visible Fetal Cardiac activity	Reassurance of viable pregnancy	Discharge EPAU if no other concerns
Fetal pole seen with no visible fetal cardiac activity	CRL <7mm	Offer rescan 7 days
Fetal pole seen with no visible fetal cardiac activity Comment- seek a second opinion on the viability of the pregnancy **and/or** perform a second scan a minimum of 7 days after the first before making a diagnosis. **[2012]**	CRL >/=7mm	Diagnose miscarriage
GS seen with no fetal pole	MSD <25mm	Offer rescan 7 days

These measurements are for patients who have not previously had an USS in this pregnancy. If a previous USS has shown a viable intrauterine pregnancy, then miscarriage can be diagnosed if no cardiac activity seen on subsequent USS.

Cyclogest- progesterone pessaries can be used in women who have experienced a previous miscarriage who present with bleeding but are found to have an ongoing viable pregnancy on USS. Dose of 400mg twice daily (PV or PR) up to 16/40.

Management of Miscarriage

Options of miscarriage treatment include:

- Expectant
- Medical
    a. Ambulatory -as outpatient
    b. As in patient
- Surgical

Expectant management

Women diagnosed with miscarriage can be offered expectant management for up to 14 days after diagnosis.

This option is not suitable for women with risks of infection, bleeding (coagulopathies/ anticoagulated/ declining blood transfusion) or other concerns.

Must be able to access emergency care if needed.

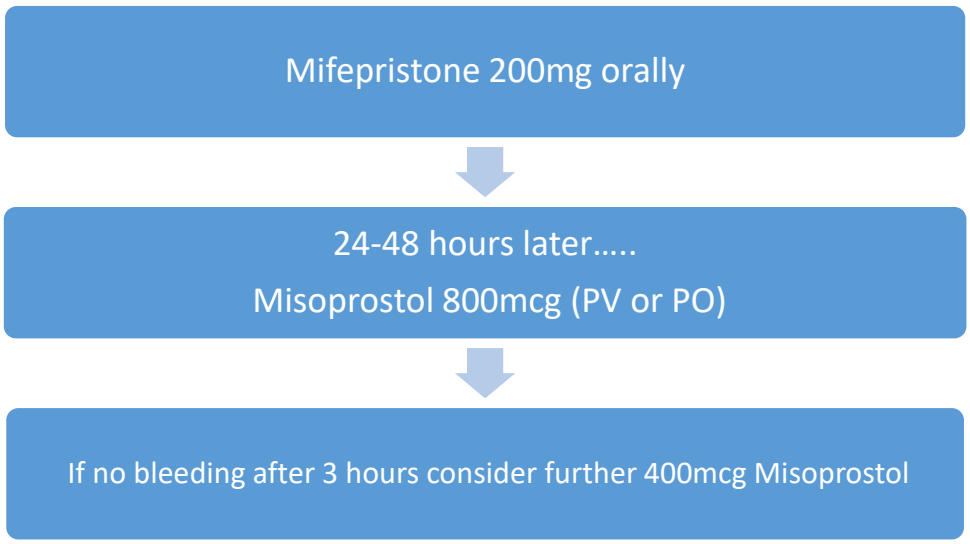
A urine pregnancy test should be done 3 weeks after diagnosis of miscarriage.

A repeat USS may be required if:

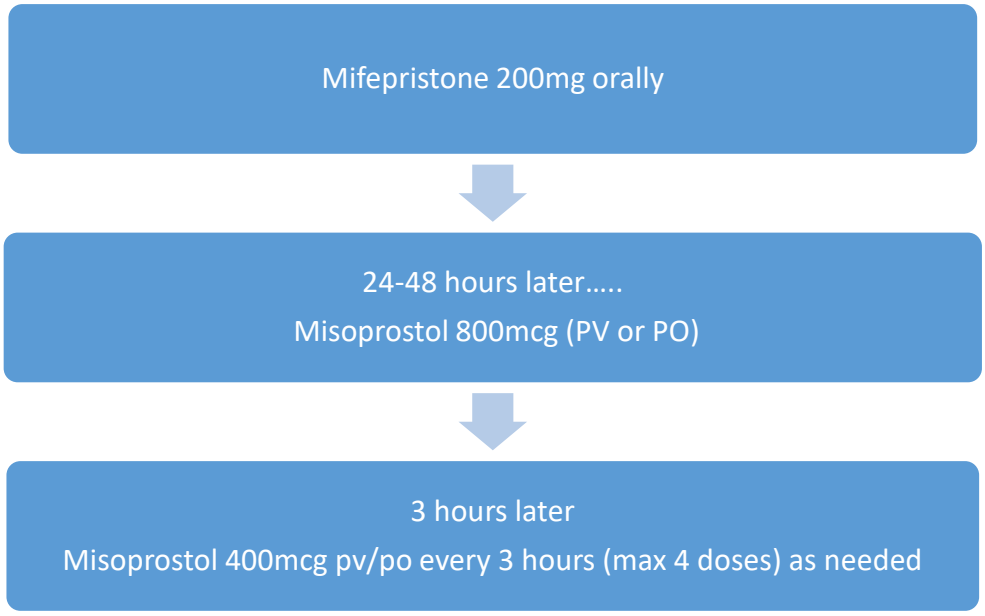
- No pregnancy tissue has been passed with no/ minimal bleeding vaginally
- Urine pregnancy test positive after 3 weeks

Medical Management of Miscarriage

Up to 9+6 (can be considered as outpatient)



From 10/40 gestation (In patient management only)



Outpatient management of miscarriage should be offered if women are suitable.

- Less than 10/40
- Access to services in an emergency (can access hospital)
- Suitable adult with them at appropriate residence during treatment
- No medical contraindication or risk of bleeding
- Aged 18 years or over
- Hb >100

Medical Management of Incomplete Miscarriage

Do not offer mifepristone as a treatment for incomplete miscarriage

Treatment with Misoprostol only 800mcg stat dose

- Can be managed as outpatient if stable and no contraindications
- Patient to contact EPAU for review +/- further USS if no bleeding or tissue passed after one week
- Urine pregnancy test to be performed after 3 weeks of diagnosis. If positive for EPAU review and further USS.

If failed medical management or incomplete medical management:

- Senior clinician to review case.
- A further ultrasound may be required to confirm failed treatment.
- Women can then be offered Surgical management or repeated medical management -after 24 hour rest period.

Surgical Management

This is offered for miscarriage up to 12 weeks

Surgical Management (Suction evacuation of retained products of conception) is offered under General anaesthetic as part of the Emergency CEPOD list, daily in Prince Charles and Princess of Wales Hospital. This is not offered in Royal Glamorgan Hospital as a planned procedure.

Cervical preparation may be offered to reduce the risk of cervical trauma, or if nulliparous to help prepare the cervix.

Misoprostol 400mcg PV/ sublingual approximately 2-3 hours pre-operatively

Post-Operative Surgical Considerations

Anti-D Immunoglobulin

Offer anti-D rhesus prophylaxis at a minimum dose of 250 IU (50 micrograms) to all rhesus-negative women who have a surgical procedure to manage an ectopic pregnancy or a miscarriage.
Do not use a Keilhauer test for quantifying feto-maternal haemorrhage.

Histology and Cytogenetics

Ensure that POC are seen and documented at the time of surgical evacuation.

If histology is required (Molar pregnancy suspected, abnormality, prolonged RPOC, patient request) Please send a complete sample with completed histology form and PLR (Pregnancy Loss Remains) form ensuring patient has been fully informed, understands and consents to this.

Inform the patient that by undertaking histology, there will be a delay of up to 6- 8 weeks for results to return and therefore a delay in the chosen disposal method.

If this is the third consecutive miscarriage, the patient should be offered for the products of conception to be sent for cytogenetic testing.

This must be sent with a cytogenetics request form, signed by the counselling clinician and a Maternal FBC sample included. They must not be sent in formalin and the remaining sample is to be sent for histology.

Please complete a referral to Recurrent Miscarriage clinic if the patient has not already been referred.

How to take a cytogenetics sample

- Please send a fresh tissue sample once pregnancy tissue has been passed / removed surgically
- Approx. size of 5p piece (<0.5cm)
- Do not store in formalin or saline but send sample in sterile pot
- Send maternal FBC sample with the specimen
- Ensure form is completed correctly

POSTMORTEM SAMPLES				
SAMPLE TYPE	**VOLUME/ QUANTITY**	**CONTAINER INFORMATION**	**TRANSPORT REQUIREMENTS**	**CONDITIONS IF STORED PRIOR TO TESTING**
Products of conception (POCs)	Unfixed subsample the maximum size of 5 pence piece, preferably fetal material	Transport medium* or sterile saline	Urgent postage, ideally within 24 hours	Fridge (4°C) not frozen
Fetal tissue	Cord/Peripheral blood in 4ml LiHep; Skin/Placenta/Other - Unfixed subsample the maximum size of 5 pence piece			
Infant (sudden death) tissue biopsy	Unfixed subsample the maximum size of 5 pence piece			
****Samples that do not comply with the laboratory recommendations may not be processed. Solid tissues greater in size than a 5 pence piece are inappropriate and will not be processed.**				

*Transport media is available upon request from the laboratory
** Requesters are responsible for the collection of inappropriate samples from the laboratory. Failure to comply with the sample requirements could impose an unnecessary clinical risk. **For any samples received which are of an inappropriate size, the laboratory will contact the sender who will need to arrange transport for the sample to be returned to the source of origin within a week of receipt by the laboratory.** We would be pleased to receive the returned sample once it meets our sample requirements.

Management of Retained Products of Conception

Retained products of conception may be seen on ultrasound during the process of miscarriage. This can be managed expectantly unless

- there is clinical suspicion of infection
- the patient has ongoing pain and vaginal bleeding for more than 2 weeks
- the urine pregnancy test remains positive after 3 weeks

Highly vascular appearance of retained products of conception indicates this will be unlikely to resolve without treatment.

Treatment options for Retained Products of Conception

Conservative

Women who have retained products of conception initially, asymptomatic have the option of expectant or conservative management. They should be advised about risk of infection with prolonged retained products of conception and asked to repeat pregnancy test 3 weeks later.

Medical

Women may be offered a single dose of vaginal Misoprostol 800mcg. This can be offered as outpatient if there are no other concerns with bleeding or infection and patient is suitable for outpatient management (As with miscarriage management).

They should be advised to contact EPAU to arrange a follow-up appointment if they have had no bleeding within 7 days or develop signs of infection.

Surgical

Surgical treatment for retained products should not be offered first line. Where medical treatment has failed, surgical evacuation under general anaesthetic will be offered.

Hysteroscopy+/- resection with Myosure device may be required with chronic or prolonged retained products of conception, or high vascularity increases suspicion.

These cases must be discussed with Consultant on call and procedure performed by senior clinician.

The choice of management of miscarriage is ultimately up to the women but all options should be offered and counselled appropriately.

Treatment option	Risks	Benefits
Expectant	Infection, Bleeding, failure	No medical procedure
Medical	Infection, bleeding, pain, incomplete/ failed treatment, need for SMM	Avoid prolonged management/ ongoing bleeding
Surgical	GA, pain infection bleeding, uterine perforation, incomplete, scarring/ adhesions	Avoids prolonged follow up/ prolonged bleeding

Manual Vacuum Aspiration can be used as surgical management of miscarriage or Retained products of conception under local anaesthetic

	ERPC	MVA
Average pain score /10 during procedure	n/a as under anaesthetic	2.6
Average pain score /10 after procedure	3.8	3.9
Failed procedures or repeat procedure needed %	10	2.5
% admitted to hospital or stayed longer	0	13.9
Patient satisfaction rate %	94	98

Management of Recurrent miscarriage will be covered elsewhere within another clinical guideline.

Management of Pregnancy of Unknown Location (PUL)

Please see Appendix 1
N.B this is to be used in conjunction with clinical assessment and concern. This is to be a guide and if clinically further follow up is warranted, then this is appropriate.

References

- NICE Clinical Guideline 154: Ectopic Pregnancy and Miscarriage guidance.nice.org.uk/cg154
- Qureshi, H. et al. (2014) "BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn," Transfusion Medicine, 24(1), pp. 8–20. Available at: https://doi.org/10.1111/tme.12091.
- Royal College of Obstetrics and Gynaecologists (RCOG Green Top Guideline 22,revised March). (2011) The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis.
- http://www.nice.org.uk/guidance/ng126
- AWMGS - Home www.medicalgenomicswales.co.uk

Appendix 1: Management of PUL Pathway