Guideline

Pain and Bleeding in Early Pregnancy

the women's
the royal women's hospital
victoria australia

1. Purpose

Some pain and/or vaginal bleeding is common in the first trimester. Women with these symptoms may need emotional support in addition to accurate information and appropriate clinical care.

Any woman with severe pain, heavy vaginal bleeding and/or haemodynamic instability should be assessed in the Women's Emergency Care (WEC) for urgent care.

If pain and bleeding are not severe, vaginal ultrasound examination is the cornerstone of diagnosis; it should be timed to give the maximal likelihood of being diagnostic. If prompt ultrasound examination is not available, vaginal examination to determine the level of suspicion of ectopic pregnancy, and therefore urgency of further assessment, should be considered.

Those with non-urgent symptoms are encouraged to attend the Early Pregnancy Assessment Service (EPAS), which provides coordinated assessment, scanning, diagnosis and management-planning for women who experience pain and/or bleeding in early pregnancy.

The conditions to be distinguished are ectopic pregnancy, pregnancy of unknown location, miscarriage, hydatidiform mole and live intrauterine pregnancy. Diagnosis is important because:

- ectopic pregnancy can be life-threatening
- when a pregnancy is of unknown location, ectopic pregnancy is not excluded
- miscarriage is usually distressing; however it seldom leads to serious physical harm without warning symptoms of increasing bleeding and pain
- live ongoing pregnancy is usually (but not always) welcome news for women; however there may be considerable anxiety associated with pain and bleeding in early pregnancy.

The purpose of this document is to guide the initial assessment, investigation and referral process and support safe, supportive and consistent provision of care for women with pain and bleeding in early pregnancy.

2. Definitions

EPAS (Early Pregnancy Assessment Service): This service runs a weekday morning clinic within the Women's Emergency Care (WEC) for women with pain and/or bleeding in early pregnancy. EPAS does not conduct dating scans or manage hyperemesis.

Early pregnancy: all gestations up to 13 weeks+6 days gestation.

POC (Products of Conception): this term may be used with colleagues, but another expression, such as 'pregnancy tissue' should be used with women and their families.

3. Responsibilities

Not applicable.

4. Guideline

4.1 Assessment

Refer below for the:

Assessment Algorithm: SIMPLE pain and bleeding

Assessment Algorithm: COMPLEX pain and bleeding

Assessment Algorithm: SIMPLE pain and bleeding

Shaded boxes represent pathway endpoints

Initial assessment:
- referral information
- gestation (LMP and pregnancy symptoms)
- history of pain and bleeding
- confirmed pregnancy? (UHCG)
- vital signs, abdominal examination
- blood for βHCG, group, Rh, Abs, usually FBE
- urine or cervical swab for Chlamydia for all <25, query ectopic

↓

Is the woman:
- haemodynamically stable
- without an acute abdomen
- uterus not palpable abdominally and
- <14 weeks gestation?

No → If the woman is:
- haemodynamically unstable
- has an acute abdomen
- has a uterus palpable abdominally or
- is assessed as at least 14 weeks

Refer to:
Complex pain and bleeding pathway (4B)

Yes ↓

Current heavy vaginal bleeding >2 soaked pads per hour?

Yes →
- prompt speculum examination to view and remove any POC in cervix (send to pathology)
- swabs for chlamydia (age <25) and M&C if indicated.
- If POCs found treat as miscarriage (refer to CPG).
- If no POCs, gynae review re: urgency of ultrasound/admission

No ↓

Pain?

Yes →
- VE for uterine size and signs of ectopic pregnancy e.g. adnexal mass +/or tenderness, cervical excitation
- Note: if immediate credentialed ultrasound examination available, this may be done prior to VE.

Positive for ectopic → If suggestive of ectopic pregnancy, admit for observation/clinical management until ultrasound examination can be arranged

Negative for ectopic → Vaginal bleeding with no pain or negative VE for ectopic?

No ↓

Vaginal bleeding with no pain or negative VE for ectopic?

Yes ↓

Plan ultrasound examination

↓

Ectopic risk factors:
- previous ectopic, IUD in situ, PID in history, IVF/ART, use of progesterone only contraception (including emergency contraception)

Yes → Ultrasound by credentialed person if available in WEC, or next EPAS for ultrasound

No ↓

>6 weeks gestation?

Yes → Ultrasound by credentialed person if available in WEC, or next EPAS for ultrasound

No ↓

βHCG>10000 IU/L?

Yes → Ultrasound by credentialed person if available in WEC, or next EPAS for ultrasound

No ↓

Repeat βHCG in 48-72 hours in EPAS, US if slow rising or when >10,000 IU/L

If risk factors, clinical findings or βHCG pattern suggestive of ectopic, needs US regardless of βHCG level.
In normal early pregnancy, a sac is usually identifiable (excludes ectopic) on TV US once βHCG reaches 1,500IU/L
If βHCG <10,000IU/L, US unlikely to distinguish miscarriage from early pregnancy with uncertain viability..

Assessment Algorithm: COMPLEX pain and bleeding

Shaded boxes represent pathway endpoints

Initial assessment
- Referral information
- Gestation (LMP and pregnancy symptoms)
- History of pain and bleeding
- Confirmed pregnancy? (UHCG)
- Vital signs, abdominal examination
- Blood for βHCG, group, Rh, Abs, usually FBE
- Urine or cervical swab for Chlamydia for all <25, query ectopic

↓

Haemodynamically unstable

Yes →
- Urgent assessment and resuscitation
- IV access and fluids
- Urgent gynae review

No ↓

Acute abdomen?

Yes →
- Urgent gynae review; may require diagnostic laparoscopy ± prior US (e.g. ovarian cyst /ectopic/appendicitis). If US would cause delay, act on clinical grounds.
- Would US change management? Only gynae registrar or consultant should call in ultrasound consultant after hours, only after direct assessment by gynae registrar and usually discussion with gynae consultant on call; gynae registrar to attend scan.

No ↓

Uterus palpable abdominally or known to be 14+ weeks?

Yes → Doppler for fetal heart detection

- FH found → Obstetric review and follow up as indicated
- FH not found → Clinical assessment confirms 14+ weeks
  - Yes → Obstetric review and follow up as indicated
  - No → Current heavy vaginal bleeding >2 soaked pads per hour

No ↓

Current heavy vaginal bleeding >2 soaked pads per hour

Yes →
- Prompt speculum examination to view and remove any POC in cervix (send to pathology)
- Swabs for chlamydia (age <25) and M&C if indicated
- if POCs found treat as miscarriage (see CPG)
- if no POCs, gynae review re urgency of US/admission

No ↓

Return to main pathway:
Assessment Algorithm: SIMPLE pain and bleeding

4.2 Clinical features

Discuss the diagnosis with the woman

- Inform the woman of the assessment findings and diagnosis, and provide consumer information
- Provide reassurance, and be aware of the potential for psychological trauma - adequate time should be allowed for the woman to make decisions
- Provide access to formal counseling when necessary. Appropriate support can result in significant positive psychological gain.

Management planning

- **Ectopic pregnancy**: see guideline: Ectopic Pregnancy: Management
- **Missed miscarriage**: see guideline: Miscarriage: Management
- **Incomplete miscarriage**: see guideline: Miscarriage: Management
- **Complete miscarriage**: see guideline: Miscarriage: Management
- **Unsited pregnancy**:
  - Raised ßhCG level without ultrasound evidence of intrauterine or extrauterine pregnancy or retained products of conception
  - Perform vaginal examination if not already done, to exclude adnexal mass or tenderness
  - Arrange clinical review if indicated by symptoms or vaginal examination findings
  - Advise to make contact with EPAS or WEC or present to WEC if worsening pain or heavy bleeding
  - Review if symptoms develop or worsen
  - Repeat ßhCG in no less than 48 hours (usually in EPAS)
    - If ßhCG doubles and findings consistent with gestation, repeat scan when anticipate ßhCG > 1500IU/L to confirm intrauterine or >10,000IU/L to confirm viability (depending on clinical story/ectopic risk); review at any time if indicated by symptoms
    - If ßhCG rises slowly, plateaus, fluctuates or falls, reassess clinically re likelihood of miscarriage or ectopic pregnancy (gynae team) and decide re further serial ßhCG and/or US timing and/or clinical review
    - monitor to ßhCG <5IU/L if ectopic possible (use post MTX frequency ie ßhCG day 4,and day 7, then weekly if falling satisfactorily as per CPG: Ectopic Pregnancy: Management); if miscarriage likely clinically may reduce frequency
- **Inconclusive (confirmed intrauterine) pregnancy**:
  - Check the need for Anti-D (usually not indicated: see Anti-D Immunoglobulin Use in Maternity Patients in appendix 3)
  - If consistent with gestational age, may treat as live and review only if further symptoms
  - Otherwise arrange repeat scan in EPAS after 7-10 days
  - Advise woman of what symptoms to expect and act on.
- **Live pregnancy**:
  - Check the need for Anti-D (usually not indicated <12 weeks: see Anti-D Immunoglobulin Use in Maternity Patients in appendix 3)
  - Reassure and discharge to antenatal care provider or PAS as requested
  - Arrange urgent or specialist follow up if indicated for medical or obstetric complication
  - If bleeding recurs, ensure woman aware of need for speculum examination for incidental causes if not already done; also clinical review for rare pregnancy complications.

Ultrasound Diagnostic Algorithm

- Pregnancy Test
  - Negative → Investigate + refer
  - Positive → POC passed (send to pathology)
    - Yes → Incomplete or complete miscarriage. Manage clinically ±US see Miscarriage CPG
    - No → Transvaginal US IU sac*
      - No → Adnexal mass
        - Yes → Suspected Ectopic#
        - No → POC passed (send to pathology)
          - No → Unsited pregnancy (early, complete misc, ectopic or “PUL”)
          - Yes → POC in uterus on ultrasound
            - No → Complete miscarriage
            - Yes → Incomplete miscarriage
      - Yes → Fetal pole on TV US
        - Yes → Fetal heart detected
          - Yes → Live intrauterine pregnancy*
          - No → Fetal pole >7mm
            - Yes → Missed miscarriage
            - No → Inconclusive (confirmed intrauterine)
        - No → Sac > 25mm
          - No → Inconclusive (confirmed intrauterine)
            - Early pregnancy?
            - Missed miscarriage?
            - Repeat ultrasound in 7-10 days
          - Yes → Missed miscarriage

*Consider heterotopic pregnancy if symptoms warrant this (1:40,000 pregnancies, 1:1,000 ART pregnancies).
#Differential diagnosis may include early intrauterine pregnancy with ovarian cyst or other pathology.
Hydatidiform mole may be seen with or without a fetal pole.

4.3 Clinical features

Ectopic pregnancy

Definitive diagnosis:

- surgical
- live ectopic pregnancy on ultrasound examination.

Presumptive diagnosis:

- Ultrasound findings of empty uterus and adnexal mass with elevated HCG.

Clinically likely if (in early pregnancy):

- shoulder pain
- fainting episodes
- severe pain
- tender adnexum
- cervical excitation
- acute abdomen ± shock.

Differential diagnosis includes early intrauterine pregnancy with bleeding corpus luteum or other pathology.
Need to exclude ectopic if:

- risk factors in history: previous ectopic, IUCD in situ, progestogen contraception, infertility/IVF treatment, PID
- mild pain especially if unilateral
- suspicion on clinical examination.

Miscarriage

Definitive diagnosis:

- passage of confirmed POC; fibrous clot/decidual cast can be difficult to differentiate
- vaginal ultrasound findings of sac >25mm without fetal pole, CRL>7mm without fetal heart motion or lack of growth (sac or fetus) over defined period (ASUM criteria).

Clinically likely (but not diagnostic) if:

- increasing vaginal bleeding with clots and crampy lower abdominal pain
- decrease/disappearance of pregnancy symptoms such as nausea and urinary frequency.

Possible (missed miscarriage) if:

- mild bleeding or spotting
- fundal size less than expected for gestation
- asymptomatic (incidental finding on ultrasound examination).

Hypotension with bradycardia may occur due to vagal stimulation caused by cervical dilatation on passage of POC. In this situation hypotension may be out of proportion to observed blood loss and is rapidly improved by removing any POC from the cervix (speculum examination).

Unsited pregnancy

Raised ßhCG level without ultrasound evidence of intrauterine or extrauterine pregnancy or retained products of conception. Often referred to as pregnancy of unknown location (PUL) especially when the evolving picture is suggestive of ectopic pregnancy.
Differential diagnosis:

- normal early pregnancy (until around 5 weeks gestation).
- ectopic pregnancy
- early failing pregnancy
- complete miscarriage.

Importance:

- ectopic pregnancy is not excluded until location is identified or complete miscarriage confirmed.

Results must therefore be interpreted in the context of the best estimate of gestation, the woman's symptoms and serial HCG levels.
The clinical picture can sometimes indicate treatment, including laparoscopy or methotrexate, without confirming location of pregnancy.

Live intrauterine pregnancy

Definitive diagnosis:

- ultrasound examination demonstrating a live intrauterine embryo, usually seen on transvaginal scan after 6 weeks gestation or with HCG level >10,000IU/L
- birth.

Presumptive diagnosis:

- continuing uterine growth
- detection of a fetal heart by Doppler (after about 14 weeks).

Clinically miscarriage is less likely but not excluded if:

- continuing pregnancy symptoms with light or resolved bleeding.

May need to consider heterotopic pregnancy if pain persists in the presence of confirmed live intrauterine pregnancy, especially following ovulation induction or assisted reproduction.

Hydatidiform mole

Usually diagnosed by typical ultrasound findings or histologically after passage of hydropic tissue; may coexist with a live pregnancy. May be accompanied by exceptionally high HCG levels and hyperemesis. Gynae team need to arrange appropriate follow up.

4.4 HCG patterns in early pregnancy

HCG patterns must be considered together with clinical picture:

- doubling every 48 hours: normal (does not exclude ectopic or miscarriage)
- sustained fall; suggestive of miscarriage (does not exclude ectopic)
- plateau/slow rise or fall; suggestive of miscarriage or ectopic pregnancy
- fluctuating levels; highly suggestive of ectopic pregnancy.

If there is a high level of confidence that the woman has an intrauterine pregnancy of at least 7 weeks with positive urinary HCG, US examination may be arranged without βHCG level.
Correlation between HCG and ultrasound findings in normal pregnancy:

- small intrauterine sac likely to be visible on TVS when HCG >1,500IU/L, yolk sac may not be visable
- small embryo with visible heart motion likely to be detectable on TVS when HCG > 10,000IU/L.

After approximately 7 weeks gestation, short term changes in HCG levels are unlikely to be helpful (with the exception of catastrophic falls); HCG levels peak in the late first trimester, after which they plateau and fall in normal pregnancy.

4.5 Ultrasound examination

Indications for ultrasound examination:

- **to detect embryonic cardiac activity**: if at least 6 weeks and/or HCG>10,000mIU/L
- **to diagnose ectopic pregnancy** (adnexal mass and 'empty' uterus): if high level of clinical suspicion, (regardless of HCG level) or abnormal HCG pattern, including slow rise, plateau or fluctuation
- **to exclude ectopic pregnancy** (by identifying intrauterine sac >5weeks); if HCG>1500mIU/L and ectopic risk factors or low to moderate level of clinical suspicion present
- May be indicated **to differentiate complete from incomplete miscarriage** if there is a history of heavy bleeding and passage of clots/POC; if passage of POC has been confirmed clinically, management may be clinically determined without US examination (see management of miscarriage).

Timing ultrasound examination/follow up

- If HCG <10,000, pain and bleeding are mild and there is a low level of clinical suspicion of ectopic pregnancy; schedule visit to **EPAS at 48-72 hours, for repeat HCG level**; US can be done then if indicated. If the visit is at <48 hours, the change in HCG level may be difficult to interpret
- For all other women, schedule a visit at the **next EPAS clinic**; this includes women with a moderate level of suspicion of ectopic pregnancy, women who have had (but stopped) heavy vaginal bleeding and women with slow rising or plateauing HCG levels. They must be given advice about what to do if pain and/or bleeding worsen prior to review. If it is >24 hours until the next EPAS, it is especially important to be confident that ectopic risk is low; vaginal examination should usually be done to exclude significant tenderness/cervical excitation.

If (1) suspicion of ectopic pregnancy is low, (2) pain and bleeding are mild **and** (3) HCG level is doubling normally, US will be most informative after at least 6 weeks gestation and HCG>10,000IU/L, when it is likely to detect a fetal heart if present. Earlier US in these circumstances is likely to be inconclusive, to aggravate anxiety and to need repeating.

Ultrasound examination outside EPAS hours

WEC is not staffed to provide routine non-urgent ultrasound examination outside EPAS hours, but if a suitably experienced/credentialed staff member is available (see appendix 1) and workload permits, it may be done, rather than refer the woman to a further EPAS appointment. She may still need to attend EPAS for follow up and management.
If there is a medium to high level of suspicion of ectopic pregnancy and the US department is open, referral should be discussed with the US supervisor.
After US department hours, the course of management will depend on the clinical situation, options being:

- US by credentialed staff member if available
- refer to next EPAS clinic as per guidelines above, if satisfied risk of acute ectopic complication is low
- admit for observation and departmental US following morning if not convinced discharge is safe
- urgent US by ultrasonologist on call; this should only be done after review by the gynaecological registrar and if it will change management; decision for laparoscopy/surgery will usually be determined by clinical findings and may not be affected by US, which is often difficult in these circumstances and may not be diagnostic anyway.

Refer to Appendix 1: Guidelines for the use of the Ultrasound Machine in WEC.

Ultrasound Scan

- The Ultrasound scan should only be performed by clinicians who are appropriately qualified or credentialed in first trimester scanning (see appendix 1)
- Findings as follows must be entered into Viewpoint:

1. The mean gestation sac diameter	7. The presence / absence of fetal heart activity
2. The number of sacs / fetal number	8. The appearance of the ovaries
3. The regularity of the outline of the sac	9. The presence of any ovarian cysts
4. The presence of a yolk sac	10. The presence and size of any tubal mass
5. The presence of a fetal pole	11. The presence of haematoma/other anatomy
6. The CRL / gestational dates	12. The presence of any fluid in the P.O.D

If the ultrasound images are difficult to interpret, or a second opinion is required, contact the ultrasound supervisor to view the images prior to making diagnosis; they can be emailed to a consultant who is not in the Hospital.
For criteria required to accept external scans, see appendix 2.

4.6 Records and data collection

- The *EPAS Record* sheet should be used to document details of the attendance. This should be filed in the woman's medical record
- Ultrasound findings should be recorded onto Viewpoint and the report printed, signed by Sonologist and filed in the woman's medical record
- Additional progress notes can be added to the medical record
- Referring doctors should be sent an attendance letter including investigations performed and management plan.

5. Evaluation, monitoring and reporting of compliance to this guideline

Not applicable.

6. References

Women's policies, guidelines and procedures:

- Miscarriage: Management
- Ectopic Pregnancy Management.

Women's fact sheets:

- Pain and bleeding in early pregnancy
- Pain and bleeding in early pregnancy - understanding your results.

7. References

1. Bourne T, Condous G. Handbook of Early Pregnancy Care. Informa Healthcare, 2006
2. Royal College of Obstetricians and Gynaecologists (RCOG). Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. NICE clinical Guidelines, December 2012. https://www.rcog.org.uk/en/guidelines-research-services/guidelines/ectopic-pregnancy-an-miscarriage-nice-clinical-guideline-154/

3. Guidelines for the Performance of First Trimester Guidelines. ASUM Guidelines, Policies & Statements, D11. Revised August 2014.

8. Legislation/Regulations related to this guideline

Not applicable.

9. Appendices

Appendix 1: Guidelines for the use of the ultrasound machine in WEC

Appendix 2: Minimum requirements for accepting external ultrasound reports

Appendix 3: Anti-D Immunoglobulin Use in Maternity Patients (intranet link to procedure)

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Appendix 1

Guidelines for the Use of the Ultrasound Machine in WEC

The ultrasound machine in WEC is primarily for the use of EPAS.

These guidelines relate to the use of this WEC/EPAS ultrasound machine out of regular working hours.

Who can use the WEC/EPAS ultrasound machine?

1. All credentialed staff. Credentialed staff who have either completed their Ultrasound module required for FRANZCOG, or have completed the ultrasound training in EPAS
2. All Radiologists , Ultrasonologists and Ultrasonographers of the P-G Imaging Centre
3. Any Obstetrician with a COGU, MFM, DDU or RANZCOG credentialing
4. Any person currently training for their EPAS credentialing or their Ultrasound module who have a credentialed person available to actually supervise them
5. Note: it is expected that all credentialed staff will make their skills available to other staff out of hours if they are on duty and have the time and competence to complete the request.

Reporting

All scans performed in WEC must be reported on Viewpoint. Part of the credentialing process is to show competency in reporting on Viewpoint.

It is important to document on Viewpoint even if diagnosis cannot be made e.g. even if the clinician-cannot find the uterus he/she should still acknowledge that a vaginal scan was performed but was uninformative and so the patient was referred (or treated accordingly). This should not be regarded as a failing but as a duty of care to the patient.

Private patients

A private patient can be scanned by their own doctor out of hours using the WEC/EPAS ultrasound machine if it is available. It is not the responsibility of WEC staff to do this scan.

Appendix 2

Minimum Requirements for Accepting External Ultrasound Reports

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1. Clinician with DDU or COGU qualification
2. Live pregnancy:
    - presence of fetal heart
    - CRL or BPD measurement
    - EDD.
3. Failed pregnancy
    - sac dimensions or at least a mean gestational sac diameter
    - a comment on presence or absence of yolk sac and/or fetal pole (presence will exclude the GS being a pseudosac)
    - size of fetal pole (and estimated gestational age)
    - absence of fetal cardiac pulsations
    - 2 sequential scans at least 7 days apart if first scan was inconclusive (CRL <7 mm or MGS <25 mm)
    - if only GS present, there should be a comment on free fluid, adnexal masses and both ovaries should have been visualized.
4. Ectopic pregnancy
    - absence of intrauterine pregnancy
    - localisation
    - presence/absence of GS, fetal pole, cardiac activity
    - size
    - presence of free fluid or clots.
5. Pregnancy of unknown location (PUL)
    - any PUL should be rescanned in the department.