



## 1. Introduction

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 (6.1), pregnancy of unknown location (6.3), miscarriage (6.2), hydatidiform mole (6.5) and live 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; it seldom leads to serious physical harm without warning symptoms of increasing bleeding and pain
- live pregnancy is usually but not always welcome news for women; however there may be considerable anxiety associated with pain and bleeding in early pregnancy.

## 2. Purpose

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.

## 3. Definition of terms

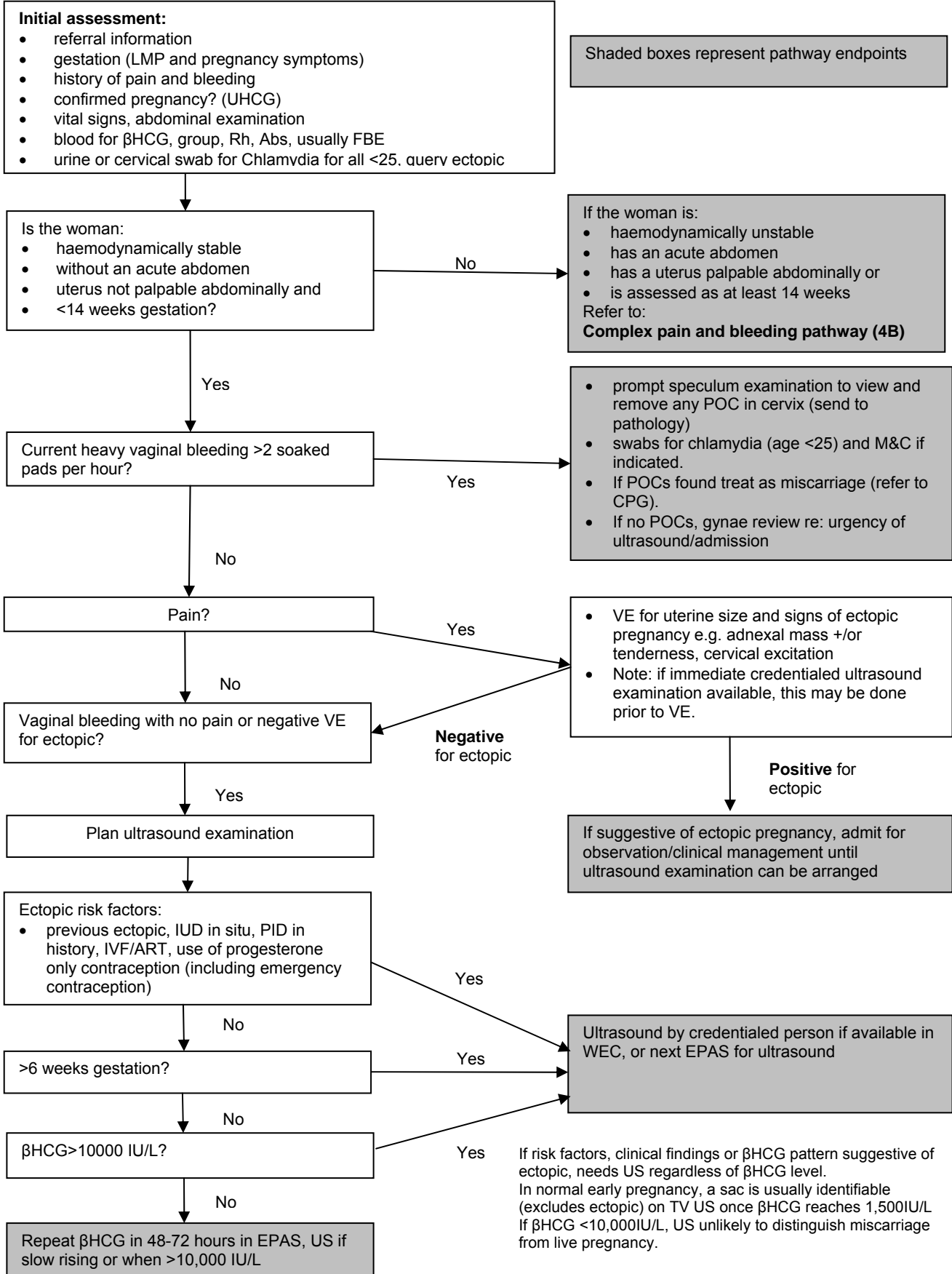
**EPAS** (Early Pregnancy Assessment Service): This service runs a weekday morning clinic within the Women's Emergency Care (WEC) for women with pain and/or bleeding in early pregnancy. EPAS does not conduct dating scans or manage hyperemesis.

**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.

## 4. Guideline

Refer to following pages.

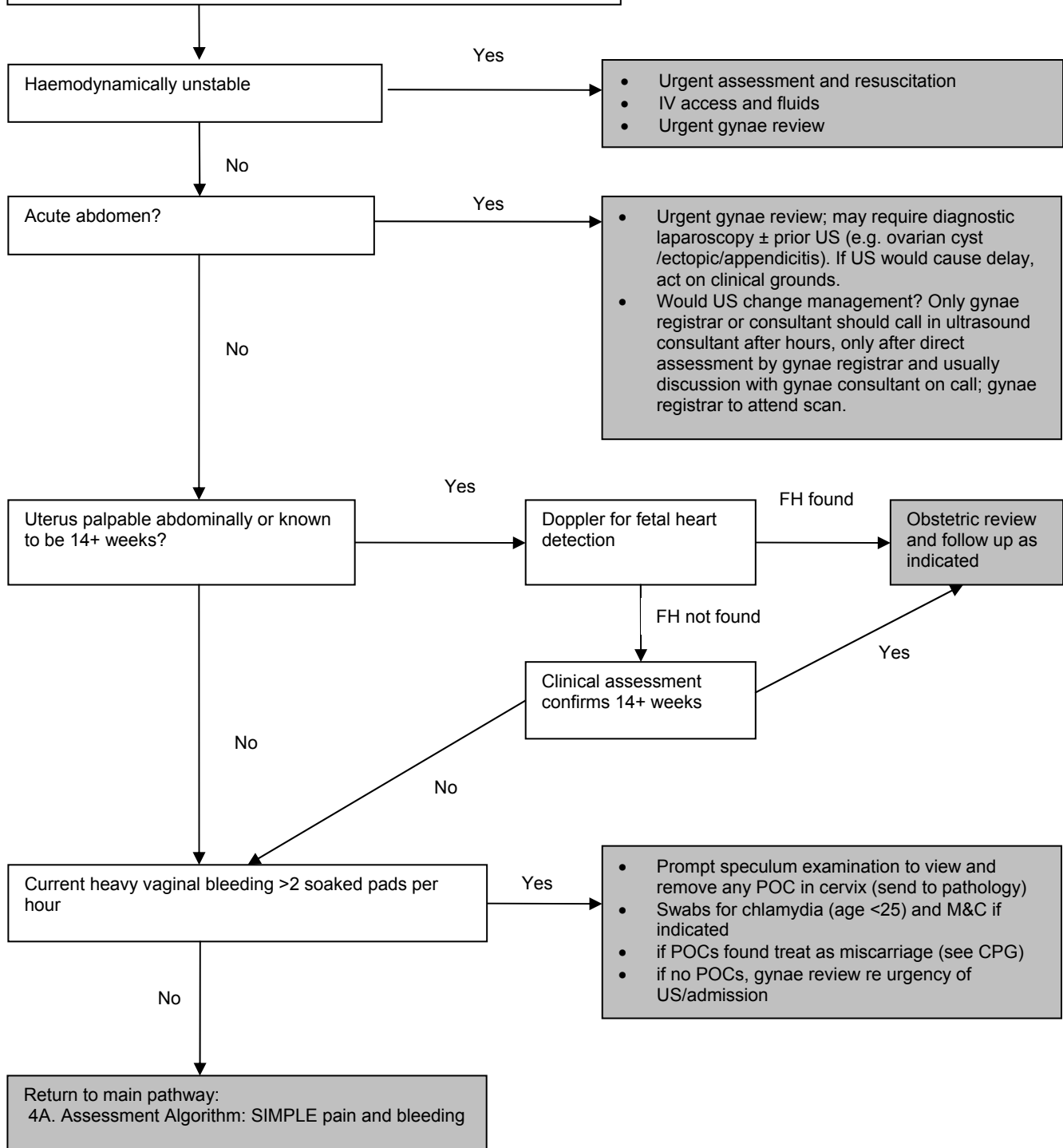




**Initial assessment**

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

Shaded boxes represent pathway endpoints



## 5. Management

### 5.1 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.

### 5.2 Management planning

- **Ectopic pregnancy:** see 6.1 and CPG: Ectopic Pregnancy: Management
- **Missed miscarriage:** see 6.2 and CPG: Miscarriage: Management
- **Incomplete miscarriage:** see 6.2 and CPG: Miscarriage: Management
- **Complete miscarriage:** see 6.2 and CPG: Miscarriage: Management
- **Unsited pregnancy:** see also 6 .3
  - Raised  $\beta$ hCG 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  $\beta$ hCG in 48 hours (usually in EPAS)
    - If  $\beta$ hCG doubles and findings consistent with gestation, repeat scan when anticipate  $\beta$ hCG > 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  $\beta$ hCG rises slowly, plateaus, fluctuates or falls, reassess clinically re likelihood of miscarriage or ectopic pregnancy (gynae team) and decide re further serial  $\beta$ hCG and/or US timing and/or clinical review
    - monitor to  $\beta$ hCG <5 if ectopic possible (use post MTX frequency ie +4, +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: awaiting revised CPG*)
  - 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:** see also 6.4
  - Check the need for Anti-D (*usually not indicated <12 weeks: awaiting revised CPG*)
  - 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.



# Clinical Practice Guideline

## Pain and Bleeding in Early Pregnancy



### 6 Clinical features

#### 6.1 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  $\pm$  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.

#### 6.2 Miscarriage

##### Definitive diagnosis:

- passage of confirmed POC; fibrous clot can be difficult to differentiate.
- vaginal ultrasound findings of sac  $>20\text{mm}$  without fetal pole, CRL  $>6\text{mm}$  without fetal heart 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).

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### 6.3 Unsited pregnancy

Raised  $\beta$ hCG 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.

### 6.4 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  $>10,000$  IU/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.

### 6.5 Hydatidiform mole

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



## 7. 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  $\beta$ HCG level.

Correlation between HCG and ultrasound findings in normal pregnancy:

- intrauterine sac likely to be visible on TVS when HCG >1,500IU/L
- fetal heart 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.**

## 8. Ultrasound examination

### 8.1 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).

### 8.2 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.

## Clinical Practice Guideline

# Pain and Bleeding in Early Pregnancy



### 8.3 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) 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.

### 8.4 Ultrasound Scan

- The Ultrasound scan should only be performed by clinicians who are appropriately qualified or credentialed in first trimester scanning (see appendix).
- 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**

## 9. 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.

## **10. Appendices**

### **10.1 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.

## 10.2 Appendix 2: Minimum requirements for accepting external ultrasound reports

### 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 <6 mm or MGS < 20 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.

## 11. References and resources

### Women's resources

- CPG: [Miscarriage: Management](#)
- CPG: [Ectopic Pregnancy: Management](#)

### Women's fact sheets

- [Pain and bleeding in early pregnancy](#)
- [Pain and bleeding in early pregnancy - understanding your results](#)

### References

Bourne T, Condous G. Handbook of Early Pregnancy Care. Informa Healthcare, 2006.

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