Protocols for

Early Pregnancy Assessment Unit

Originator: Gynaecology Protocol Group
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Protocol- Early pregnancy unit

Site

☐ The EPU should be located in a dedicated area.
☐ The surroundings should be pleasant and comfortable with toilets nearby

Access

☐ The gold standard is to have a unit open seven days a week from 08:00hrs until 17:00hrs
☐ The minimum requirement would be to have a unit open for five days, mornings only from Monday to Friday.

Facilities

☐ Good quality ultrasound equipment
☐ Urine pregnancy testing
☐ Access to serum hCG assay with results within 24 hours
☐ Other investigations such as FBC and rhesus grouping as required
☐ Rhesus grouping and Anti-D considered if gestation is >12 wks
☐ It is important to bear in mind that some patients may require other gynaecological procedures such as vaginal swabs and occasionally removal of coils.

Staffing

Minimum requirement would be:
☑ a receptionist/secretary
☑ a nurse
☑ a gynaecologist and/or sonographer
☐ Attitude of the staff involved should be caring and sympathetic
☐ There should be access to formal counselling sessions where necessary (this may be needed by only a few)

Referral Guidelines

Who may be referred?

- Women in first trimester who have had a positive pregnancy test <13+6 weeks and >6 weeks)
  a) abdominal pain
  b) vaginal bleeding

- Post evacuation (medical/surgical) with persistent bleeding.

Gestational age for referral:
- 6-13+6 completed weeks of pregnancy
- Where clinically indicated the on-call registrar can discuss scan at earlier gestation.
  with the sonographer especially if b-HCG is high.

Reference:

Sources of Referral

- Primary Care Doctors
- Practice Nurses
- Midwives
- Accident and Emergency Departments
- Consultants
- Wards
- Antenatal Clinics

Referral Procedure

- Patients can either be referred via their GP or hospital doctor. After 5 pm and on weekends entries are made in the appointment book available on the gynaecology ward.
  - Details of patient’s name, address, date of birth, name of GP and reason for referral should be noted and an appointment time given

- Tell the patients that:
  a) a transvaginal scan is likely and
  b) as it is an emergency clinic the appointment time cannot be guaranteed and delays are likely

A patient information leaflet on what to expect should be available in the waiting area.

Caution

Women who are unwell, bleeding heavily or in whom an ectopic pregnancy is suspected should be advised to be admitted through the usual channels and not asked to wait for an appointment in an early pregnancy unit. There will also be a proportion of women who are frightened by the loss or who are geographically isolated and prefer admission.
Clinical Guidelines

General Patient Management

• A brief history is taken on the standardised proforma
  i) Previous obstetric history, LMP, urine pregnancy test in this pregnancy
  ii) Pain - description
  iii) Bleeding - amount
  iv) Passage of Products of conception (POC)

• Clinical examination should be considered if appropriate
• Transvaginal ultrasound scan (TVS) is performed if less than 7-8 weeks and also in some circumstances at more than 8 weeks, which provides the patient with the option of seeing what is visualised on the screen.
• The procedure and the reasons for the scan should be explained
• Patient’s wishes should be respected if she strongly declines a TVS and where the gender of the professional is particularly important to the patient
• A clear explanation should be given by the Gynaecologist/Sonographer performing the scan as to the possible or likely diagnosis/diagnoses
• Appropriate pictures are taken for the patient’s records. Pictures are not usually given to patients in EPAU unless requested by the patient
• A plan of management should be formulated based on the guidelines
• A pregnancy test should be performed if a pregnancy is not clearly visible
• Consideration for serum hCG assay should be given if a pregnancy test is positive
• Support should be given where the pregnancy is non-viable or the woman is upset - A quiet room should be available
• Follow up should be arranged before the woman leaves the clinic if required.
• Appropriate written advice and telephone numbers for contact should be given

Chaperone

Transvaginal ultrasound scanning (TVS) is found to be extremely well tolerated as a technique by most women. In the presence of a female chaperon most women feel comfortable even if the person doing the scan is male. For most women the mannerism and expertise of a professional is more important than the gender. A junior member of the staff should always be supervised until he/she has attained the required level of expertise in scanning.

Guidance on Ultrasound Images

It is not necessary to seek separate permission from the patient to make the recordings of Ultrasound images. Nor is consent required to use them for any purpose, provided that, before use, the recordings are effectively anonymised by the removal of any identifying marks.

References:
Guidelines for Ultrasound Scanning

RCOG Criteria

If the gestation sac has a mean diameter greater than 25mm, with no evidence of an embryo or yolk sac, this is highly suggestive of a Missed miscarriage.

If the embryo has a crown rump length greater than 7mm, with no evidence of heart pulsations, this is highly suggestive of a Missed miscarriage.

When the mean gestation sac is less than 25mm or the crown rump length is less than 7mm a repeat examination should be performed at least one week later both to assess growth of the gestation sac and embryo and to establish whether heart activity exists.

If the gestation sac is smaller than expected for gestational age the possibility of incorrect dates should always be considered, especially in the absence of clinical features suggestive of a threatened miscarriage.

In all of the above instances a repeat scan should be undertaken in 7 days. This is necessary to confirm the diagnosis.

All scans should be performed by experienced personnel.

Information should be recorded including:

i) number of sacs and mean gestation sac diameter
ii) regularity of the outline of sac
iii) presence of haematoma
iv) presence of a yolk sac
v) presence of a fetal pole
vi) CRL measurement (mm)
vii) presence of fetal heart pulsation
viii) extra uterine observations – ovaries, adnexal mass, fluid in the P.O.D.
ix) Measure diameter of tissues present in uterine cavity If incomplete miscarriage or retained POC
# A Brief Guide to Management of Early Pregnancy Features

## Ultrasound appearance

<table>
<thead>
<tr>
<th>Ultrasound appearance</th>
<th>Diagnosis</th>
<th>Plan of management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrauterine gestational sac (GS), embryo and cardiac activity (CA)</td>
<td>Viable pregnancy</td>
<td>Back to GP for referral to ANC</td>
</tr>
<tr>
<td>If actively bleeding</td>
<td></td>
<td>Admit for reassurance</td>
</tr>
<tr>
<td>If a significant haematoma noted</td>
<td></td>
<td>Rescan 1 week later</td>
</tr>
<tr>
<td>If &gt; 12 weeks</td>
<td></td>
<td>Check the need for Anti-D immunoglobulin</td>
</tr>
<tr>
<td>GS &lt;25mm – no fetal pole</td>
<td>Early gestational sac (EGS)</td>
<td>Rescan 1 week later</td>
</tr>
<tr>
<td>GS &gt;25mm – no fetal pole</td>
<td>Empty sac</td>
<td>If any doubt Rescan 1 week later If no change on second scan discuss management (see under management of nonviable pregnancy)</td>
</tr>
<tr>
<td>Crown Rump Length (CRL) &lt;7mm CA not demonstrated</td>
<td>Pregnancy of uncertain viability (PUV)</td>
<td>Rescan 1 week later</td>
</tr>
<tr>
<td>CRL &gt;7mm CA not demonstrated</td>
<td>Early fetal loss</td>
<td>Offer options, conservative, medical or surgical.</td>
</tr>
<tr>
<td>Empty uterus No adnexal abnormality</td>
<td>Pregnancy of unknown location (PUL) Serum hCG negative (&lt;5) complete miscarriage or never pregnant serum hCG positive possible early pregnancy possible ectopic pregnancy possible complete miscarriage</td>
<td>Repeat serum hCG 48 hours later. Rescan if necessary (see guidelines for β-hCG) Warn of the possibility of ectopic pregnancy. Give contact numbers to report if any pain.</td>
</tr>
<tr>
<td>Empty uterus Adnexal mass Fluid in Pouch of Douglas (POD) Pain</td>
<td>Ruptured ectopic pregnancy</td>
<td>Follow guideline on ectopic pregnancy</td>
</tr>
<tr>
<td>Empty uterus Adnexal mass &lt;3cm No other findings/symptoms</td>
<td>Unruptured ectopic pregnancy</td>
<td>Follow guideline on ectopic pregnancy</td>
</tr>
</tbody>
</table>
Endometrium/tissue diameter <15mm

**Complete miscarriage**

5.9% of cases diagnosed as complete miscarriage (heavy bleeding with passing clots and empty uterus on uss) found to be ectopic on follow up. Condous BJOG 2005. These cases should be dealt as PUL and BhCG done

Endometrium/tissue diameter >15mm

**Incomplete miscarriage**

Discuss management (see guidelines on management of incomplete miscarriage)

Homogeneous mass within the uterus

**Suspect trophoblastic disease Serum hCG assay**

Surgical evacuation (see guidelines for trophoblastic disease)

Pregnancy of Unknown Location (PUL)

**Diagnosis by exclusion**

Follow up with serial hCG See guidelines for ‘PUL’

Adequate time should be allowed for women to make decisions.

**References:**


**Rhesus Anti D Prophylaxis**

Prophylactic Anti D is not routinely required for rhesus negative with women bleeding below 12 weeks gestation. There is minimal evidence that administering Rh immune globulin for first trimester vaginal bleeding prevents maternal sensitization or development of haemolytic disease of the newborn.

**Threatened miscarriage:**

Anti-D Ig should be given to all non-sensitised RhD negative women with a threatened miscarriage after 12 weeks of pregnancy. Where bleeding continues intermittently after 12 weeks' gestation, anti-D Ig should be given at 6-weekly intervals (send EDTT to check for anti bodies prior to administering) (RCOG Grade C recommendation). However it may be prudent to administer anti-D where bleeding is heavy or repeated or where there is associated abdominal pain particularly if these events occur as gestation approaches 12 weeks (RCOG Grade C recommendation). The period of gestation should...
be confirmed by ultrasound. Review on an individual basis recommended.

**Spontaneous miscarriage:**
Anti-D Ig should be given to all non-sensitised RhD negative women who have a spontaneous complete or incomplete miscarriage after 12 weeks of pregnancy (RCOG Grade B recommendation).

The risk of immunisation by spontaneous miscarriage before 12 weeks' gestation is negligible when there has been no instrumentation to evacuate the products of conception and anti-D Ig is not required in these circumstances (RCOG Grade C recommendation).

**Ectopic pregnancy:**
Anti-D Ig should be given to all non-sensitised RhD negative women with a confirmed or suspected ectopic pregnancy (RCOG Grade B recommendation).

**ERPC and Therapeutic termination of pregnancy:**
Anti-D Ig should be given to all non-sensitised RhD negative women having a therapeutic termination of pregnancy, whether by surgical or medical methods, regardless of gestational age (RCOG Grade B recommendation).

**Recommended Dose 250 i.u. given IM into deltoid muscle** as injections into the gluteal region often only reach the subcutaneous tissues and absorption may be delayed.

**Reference:**

**Guidelines for Viable Intra-Uterine Pregnancy**

Definition: A normally sited gestation sac with clearly identified cardiac activity.

Demonstration of fetal heart activity is generally associated with a successful pregnancy rate of 85-97%, depending on the period of gestation.

About 25% of all pregnancies threaten to miscarry.

A **threatened miscarriage** is one in which:

- the women bleeds a little from the vagina
- cervical os is closed
- there is little abdominal pain and
- pregnancy is still viable.
All women attending EPAU receive a contact number.

Women will go back to GP for referral to ANC via the usual method.

Follow up appointment may be required in the following situations:

1. Significant vaginal bleeding and patient refusing to be admitted
2. Liquor volume is reduced
3. Fetal bradycardia
4. After IUCD removal in the EPAU

Reference:

Management of Non-Viable Pregnancy

1. Complete Miscarriage

Ultrasound scan - Endometrial thickness <15mm

Advise to report if bleeding persists longer than 2/52.

Patient should be advised to do a pregnancy test in 1 week, if pregnancy test is positive to contact EPU.

2. Incomplete Miscarriage

Ultrasound scan - Intrauterine tissue diameter 15 - 50mm

*Conservative method* should be offered as an option provided the bleeding is not heavy and a rescan arranged 2 weeks later or advice may be given to the women to report if bleeding persisted after 2 weeks.

Alternatively, *medical management* may be offered if patient is not willing to wait.

*Surgical evacuation* is arranged if a patient has a strong preference it.

*Surgical* method should be reserved for those who:

1. make a specific request for it
2. change their mind during the course of conservative management
3. have heavy bleeding and/or severe pain
4. Tissue diameter of > 50mm
5. have infected tissue
Conservative management of Incomplete Miscarriage has excellent success rate and evidence suggests that it is associated with lower rates of infection than surgical management.

3. Missed Miscarriage (empty sac/fetal loss)

Since the introduction of TVS, ‘missed miscarriage’ (previously described as ‘anembryonic pregnancy’, absent fetal echo, ‘blighted ovum’ in the past) are felt to reflect different aspects or stages of the same clinical process. The absence of a identifiable fetal pole should be referred to as an ‘empty sac’.

A previously identified fetal heart action followed by absence of heart activity should be referred to as a fetal loss. There is an approximately 5% chance of this happening after fetal heart action is seen at 7 weeks gestation (Brigham et al, 1998) and increases with advanced maternal age

Following the diagnosis of early pregnancy failure women should be offered the choices of conservative, medical or surgical methods of miscarriage management. Patient preference is important and should be acknowledged as a determining factor in management decisions.

**Conservative** management:
- Rescan 2-3 weeks later, if necessary follow up with further rescans at 2-weekly intervals.
- Give patient a contact number

**Medical** management may be offered if patient is not willing to wait.

**Surgical** method should be reserved for those:
- who make a specific request for it
- who change their mind during the course of conservative management
- where medical management fails

The incidence of gynaecological infection after surgical, expectant, and medical management of first trimester miscarriage is low (2-3%). There are small non-significant differences in haemorrhage rates (<3%) and surgical evacuation carries a small risk of uterine perforation. The RCOG has recently updated their guidelines for early pregnancy loss (2).

References:
Understanding hCG measurements

Urine Measurements
The urine test is simple and reliable enough to be used routinely to establish whether or not a woman is pregnant. A rapid and simple test should be available in the unit.

Serum Measurements
Measurement of hCG in Serum, permits more accurate quantification which may be useful in the following:

1 Screening in women at high risk of ectopic pregnancy
2 Determining the appropriate treatment for women with suspected ectopic pregnancy
3 Monitoring during expectant management or medical management of women with ectopic pregnancy
4 Evaluation of conservative surgical treatment of ectopic pregnancy

Serum hCG levels double approximately every two days in early (<8 weeks) normal intrauterine pregnancy; a lesser increase (<66% over 48 hours) is associated with ectopic pregnancy and miscarriage.

To find out whether or not a pregnancy is normal or pathological, the two useful clinical concepts of hCG measurement are the **hCG doubling time** and the **discriminatory hCG level**.

**hCG doubling time**
It refers to the time taken for the hCG level to double its original value. A hCG value of <5 IU/L is considered to be the non pregnant value.

The doubling time is particularly useful in early pregnancy i.e. before 5.5 weeks or when the serum hCG level is <5000IU/L. As pregnancy progresses the doubling time also lengthens.

However 15% of normal pregnancies will have abnormal doubling time and 13% of ectopic pregnancies will have a normal doubling time .

**Caution**
1 In multiple pregnancies the level of hCG on D2 would be a little higher, requiring an extra two or three days for a sac to become visible.
2 The possibility of a heterotopic pregnancy should be kept in mind (1 in 3000 – 4000 of spontaneous conceptions and 1% - 3% of assisted conceptions). – this is expected to be much less in the next few years as UK is moving to single embryo transfer(SET).
3

**Discriminatory hCG level**
It refers to a defined level of hCG above which the gestational sac of an intrauterine pregnancy should be visible on ultrasound. In women with an hCG result above the discriminatory level, but absence of an intrauterine gestational sac on ultrasound, ectopic pregnancy is a distinct possibility.

With the use of high resolution transvaginal ultrasound the discriminatory level has been reported to be around 1000IU/L IRP\(^4\). However the American Fertility Society suggested that in practice the level ought to be around 2400IU/L.

The discriminatory level may vary in different units and depends on three factors:

i) hCG assay

ii) quality of ultrasound

iii) the experience of the person performing the ultrasound

It usually lies between 1000 – 2400IU/L.

A diagnosis of ectopic pregnancy is more likely whenever intrauterine pregnancy is not detected by ultrasound at serum hCG concentration above 2400IU/L. This does not mean that you can not have an ectopic pregnancy below the discriminatory

References:


4 Caeciatore et al. (1990) Diagnosis of Ectopic Pregnancy by Vaginal Ultrasonography in Combination with a discriminatory serum hCG level of 1000IU/L (IRP). BJOG 97, 904-8.
**Directorate of Women & Child Health**

**Checklist for Clinical Guidelines being Submitted for Approval by Quality & Safety Group**

<table>
<thead>
<tr>
<th>Title of Guideline:</th>
<th>Protocol-early pregnancy unit</th>
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<tbody>
<tr>
<td>Name(s) of Author:</td>
<td>Zainab Khan</td>
</tr>
<tr>
<td>Chair of Group or Committee supporting submission:</td>
<td>Mr Andy Allman / Gynaecology Protocol Group</td>
</tr>
<tr>
<td>Issue / Version No:</td>
<td>1</td>
</tr>
<tr>
<td>Next Review / Guideline Expiry:</td>
<td>March 2014</td>
</tr>
</tbody>
</table>
| Details of persons included in consultation process: | Gynaecology consultants from Princess of Wales and Singleton hospital.  
                                                                                       | Senior incharge ultrasonographer |
| Brief outline giving reasons for document being submitted for ratification | Previous trust guideline was due for updating and recent changes in the RCOG scan criteria. |
| Name of Pharmacist      | Not applicable                                                   |
| (mandatory if drugs involved): |                                                        |
| Please list any policies/guidelines this document will supersede: | W&CH Mgmt Drive: Clinical Governance\Policies & Procedures etc - Ratified\Gynaecology |
| Keywords linked to document: | EPU, miscarriage, ectopic pregnancy, scan                     |
| Date approved by Directorate Quality & Safety Group: |                                                        |
| File Name: Used to locate where file is stores on hard drive | Jan 2012 EPU guideline                     |

* To be completed by Author and submitted with document for ratification to Clinical Governance Facilitator