EARLY PREGNANCY UNIT POLICIES AND GUIDELINES

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Signed

……………………………………………………………………

Jacqui Tingle
Chair of the WCQGG

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1. INTRODUCTION/BACKGROUND

General Aims of EPAU
- To provide a service dedicated to diagnosing and managing early pregnancy problems and to facilitate reductions in hospital admissions and length of in-patient stay.
- To effectively diagnose and guide the management of ectopic pregnancies in order to reduce maternal morbidity and mortality.
- To provide reassurance to women with a history of previous significant pregnancy complications e.g. recurrent miscarriages and previous ectopics.
- To provide support and counselling for women and their partners.
- To be actively involved in medical education and research into early pregnancy problems.

2. PURPOSE
To ensure all women are supported and managed appropriately.

3. SCOPE OF POLICY
This guideline applies to all clinical staff.

4. DUTIES AND RESPONSIBILITIES

Managers
It is the responsibility of the managers to ensure that the nurses are aware of the guidelines and their application to practice. They will also review and update them in line with the latest evidence as required, or at least every 3 years.

Clinical Staff
All clinical staff have a duty to be familiar with this policy and to use it to guide their practice. Specific roles and responsibilities of various staff groups are set out in section 6.

Local Policy Officer
The Local Policy Officer has a duty to ensure the policy is compliant with the Trust Policy on Policies. The Local Policy Officer must ensure this policy is reviewed within the designated time period or as changes in national guidance arise. The policy should comply with the current base of evidence and best practice guidance and be current and in date.
5. SUBJECT MATTER OF WORKING DOCUMENT

5.1 Indications for EPAU assessment

Women can be referred if they:

- Have a positive pregnancy test, are less than 14 weeks gestation and are experiencing lower abdominal pain and/or bleeding.
- Have a history of 2 or more consecutive miscarriages (recurrent miscarriage), previous ectopic, stillbirth or molar pregnancy. A scan will be offered at 7/40, unless the woman is symptomatic of pain and/or bleeding.
- Have hyperemesis.
- Have abnormal uterine bleeding following recent pregnancy (eg. TOP, SMM).
- Are symptomatic and had recent fertility treatment.

5.2 Opening Times

The EPAU runs from Monday to Friday from 0830 to 1630.

- The ultrasound service, in the Early Pregnancy Assessment Unit (EPAU) currently operates on Monday to Friday from 09.00 to 13.00 with consultant scan sessions on Tuesday, alternate Wednesday, Thursday and Friday afternoon from 1400 – 1700.
- Outside of EPAU opening times, including weekends, patients will be seen by the on-call team and triaged either for admission, if deemed necessary, or discharged with a referral made to EPAU (as outlined in section 1.5).
- Any EPAU scans that are done out of hours should be reported on Viewpoint.

5.3 Referral Method

- RSCH EPAU does not provide a walk-in service.
- Referrals are made via a referral form from GPs, A&E, midwives and other health professionals (see Appendix 1: Referral Form).
- Out-of-hours including the weekend, the gynaecology on-call team or A&E team can either fax a referral or fill in an ultrasound request form to be handed over to the triage Nurse in EPAU the following morning by 0900 or on Monday by 0900 if it is over the weekend. The fax number is on the referral form (refer to Appendix 14.1)
- The EPAU triage nurse will contact the patients with an appointment slot after triaging.
- The referral form must be completed correctly, with current information from the patient including LMP date, gestation, presenting symptoms and any risk factors for ectopic pregnancy.
- Patient must be informed that they will receive a call from EPAU. The nurse will discuss symptoms further with the patient, and book them for assessment at an appropriate time. Patients should not be told just to turn up to EPAU for a scan.
• Self-referrals are only accepted from women with recurrent miscarriages, previous ectopic, stillbirth or molar pregnancy.

5.4 Triage Protocol

The EPAU team will triage all referrals received, and book them for assessment in order of priority and severity. The following should be adhered to:

• All the EPAU referrals should be triaged by EPAU staff nurse who should also take overall responsibility of supervising, support and offering training to band 5 nurses in EPAU.
• All urgent referrals including in patient admission and A&E patients take priority over the EPAU scan list and must be scanned within 24hrs. In the event of unavailable slots the EPAU staff nurses/sister must review scan lists and rearrange non urgent scans such as dating, reassurance scans, and follow up for pregnancy of uncertain viability, to accommodate emergency scans. If this is not possible EPAU consultants should be informed on the days that they are allocated in EPAU.
• 5
  o Monday am, Tues pm CK
  o Wed alt pm, Thurs pm OA
  o Friday pm, AR
• Outside these days, the on call consultant should be informed. No patient should be turned away without discussing with the consultants.
• The person triaging referrals should document the following:
  o Date and time when the referral was received
  o Date and time it was actioned, and the action taken and by who
  o Should sign and document their name
• A summary of all telephone advice should be documented.

5.4.1 Immediate or urgent assessment

• All pregnant women with heavy bleeding and those with severe pain with or without haemodynamic instability need to be seen and assessed by the on-call team before referral to EPAU.
• Junior doctors should seek immediate advice from their seniors (ST3+ and Consultants) in these cases.

5.4.2 At least within 24 hours if there is:

• A history lower abdominal pain with/without bleeding
• A previous ectopic, history of tubal damage, in vitro fertilisation, multiple caesarean sections- all with pain and/or bleeding
• Women with heavy vaginal bleeding (see above also)
• Patients admitted with acute onset of severe lower abdominal pain, or pelvic inflammatory disease unresponsive to antibiotic treatment.
5.4.3 Between 24-72 hours

- PV spotting/ brownish pv discharge and pain free
- Hyperemesis gravidarum (to rule out molar or multiple pregnancy)

5.4.4 Routine assessment

- Recurrent miscarriage (from 7/40 gestational age).
- Reassurance scans in women with previous poor obstetric outcome eg late miscarriage, stillbirth or complex medical history requiring an early viability scan, or previous traumatic experience.
- Dating scan.

5.5 Consultation, Examination and Ultrasound Procedure

- Assessments should be performed in rooms with screens designed to protect patients’ privacy while being examined.

- There should be two members of staff present during the consultation and examination; at least one member must be female. Women should be given the option of inviting partners or other accompanying persons to join them during the examination, but these people should not be used as chaperones. **Chaperones should always be present regardless of the sex of the examiner.**

- No person should enter the room during the examination apart from a senior member of staff who may be invited to check the ultrasound findings or discuss management options. The patient should be informed of this in advance.

- A concise history should be taken and the details entered on the computer (refer to Viewpoint guidelines in the RSCH Obstetric Ultrasound policy). The aim and the process of the examination, as well as likely findings, should be discussed with the patient. An explicit verbal consent should be obtained before any intimate examination is undertaken.

- The vast majority of women attending the unit will undergo a transvaginal scan. An abdominal scan should be offered to virgins, women with psychosexual problems and to those women who refuse a vaginal scan. These patients will need to fill their bladder and should be instructed to drink two pints of water. The scan should be performed when the bladder is uncomfortably full. Abdominal scans without a full bladder can be useful in women with pregnancies beyond nine weeks gestation and in those with large palpable abdominal masses. A transrectal scan may be useful if a woman is virgo intacta and a suboptimal view is obtained transabdominally.
- Vaginal scans are performed in the lithotomy position. Women should be given the option of viewing the screen.

- The vaginal ultrasound probe has to be cleaned and disinfected before and after every examination. The guidelines for cleaning and handling the probe are in the *RSCH Obstetric Ultrasound policy* and their implementation is closely monitored.

- Some patients will also require a vaginal examination in addition to a scan. Women presenting with recurrent or post-coital bleeding should have a speculum examination to exclude cervical pathology, polyps or prolapsed fibroids. A speculum examination may also be required for the purposes of performing smears & swabs.

- All sonographers must be aware of the BMUS safety guidelines and adhere to the ALARA principles.

<table>
<thead>
<tr>
<th>Application</th>
<th>Values to monitor (A)</th>
<th>Thermal index value</th>
<th>Mechanical index value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 - 0.7</td>
<td>0.7 - 3.0</td>
<td>&gt;3.0</td>
</tr>
<tr>
<td>Obstertrics up 10 weeks after LMP (and gynaeology when pregnancy is possible)</td>
<td>TIS and MI</td>
<td>(B) restrict time to</td>
<td>Scanning of an embryo or fetus is not recommended, however briefly</td>
</tr>
<tr>
<td></td>
<td>0.7×TIS≤1.0 : 60 min</td>
<td>1.0×TIS≤1.5 : 30 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.5×TIS≤2.0 : 15 min</td>
<td>2.0×TIS≤2.5 : 4 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5×TIS≤3.0 : 1 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(C) risk of cavitation with contrast agents</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Under no circumstances should a probe with a used condom be left on the ultrasound machine.

- Findings must be explained to the patient and a copy of the scan report or discharge summary should be sent to the referring clinician or GP.

- The purpose of the unit is not only to provide an ultrasound imaging service, but clinical assessment and advice on the patient’s management.
5.6 EARLY PREGNANCY DIAGNOSIS

5.6.1. Clinical History - Current Pregnancy

- Last menstrual period: certainty, length of cycle
- Was it a spontaneous conception?
- If IVF, what was the embryo transfer date?
- If unplanned, is the pregnancy wanted? What type of contraception, if any was used?
- Symptoms: Bleeding- duration and amount. Pain- duration and character.

5.6.2. Past Obstetric History

- Number and mode of deliveries
- Miscarriages with gestation and treatment
- Ectopic pregnancies and treatment
- Terminations and any complications

5.6.3. Past Gynaecology History

- Risk factors predisposing to ectopic; Pelvic Inflammatory Disease (PID), endometriosis, surgery.
- Last cervical smear test

5.7. Ultrasound Diagnosis of Normal Early Pregnancy

_Please read in conjunction with RSCH Obstetric Ultrasound Policy_

5.7.1. Key Points

- The gestation sac must be visualised below the endometrium and surrounded by myometrium. Longitudinal section showing the sac as well as cervix is essential. _These are all important to avoid mis-diagnosing ectopics as intrauterine pregnancies_ particularly in those that are interstitial, cervical or abdominal.
- Even in normal pregnancy, always examine the adnexae to screen for ovarian pathology and to exclude the rare cases of heterotopic pregnancy.
- Be aware of the morphological differences between an early intrauterine pregnancy and pseudosac- refer to Table 1.
Table 1: Characteristics of a pseudosac vs an early intrauterine gestation sac

<table>
<thead>
<tr>
<th></th>
<th>Pseudosac</th>
<th>Early IUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Along the cavity line, between the endometrial layers</td>
<td>Below the midline echo buried into the endometrium</td>
</tr>
<tr>
<td>Shape</td>
<td>May change during scan, usually ovoid</td>
<td>Steady, usually round</td>
</tr>
<tr>
<td>Borders</td>
<td>Single layer</td>
<td>Double ring</td>
</tr>
<tr>
<td>Doppler flow</td>
<td>Avascular</td>
<td>High peripheral flow</td>
</tr>
</tbody>
</table>

5.7.2. Landmarks for diagnosis

Table 2: Landmarks for diagnosis

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4+3 to 5+0</td>
<td>A small gestation sac (2-5mm) is seen within the endometrium. The sac is spherical, regular in outline and eccentrically situated towards the fundus. It is implanted just below the surface of the endometrium (midline echo) and is surrounded by echogenic trophoblast.</td>
</tr>
<tr>
<td>5+1 to 5+5</td>
<td>Yolk sac becomes visible within the chorionic cavity. This should be seen in all pregnancies with a mean gestational sac diameter of &gt;12mm. If it is not, the diagnosis of blighted ovum can be made.</td>
</tr>
<tr>
<td>5+6 to 6+0</td>
<td>The embryonic pole is visible and measures 2-4mm in length. Heart action is also detectable. An embryo is usually visible with a mean GS of &gt;18mm.</td>
</tr>
<tr>
<td>6+1 to 6+6</td>
<td>The embryo changes from being a straight line at the top of the yolk sac to being kidney bean shaped, with the yolk sac separated from the embryo by the vitelline duct. The crown-rump length measures 4-10mm.</td>
</tr>
<tr>
<td>7+0 to 7+6</td>
<td>The CRL measures 11-16mm. The rhombencephalon becomes distinguishable as a diamond shaped cavity, enabling distinction of cephalad and caudal. The spine is seen as double echogenic parallel lines. The amniotic membrane becomes visible defining the amniotic cavity from the chorionic cavity. The umbilical cord can also be seen.</td>
</tr>
<tr>
<td>8+0 to 8+6</td>
<td>CRL measures between 17-23mm. The forebrain, midbrain, hindbrain and skull are distinguishable. Limb buds are also visible. Midgut hernia is present. The amniotic cavity expands and the umbilical cord and vitelline duct lengthens.</td>
</tr>
<tr>
<td>9+0 to 10+0</td>
<td>CRL length 23-32mm. The limbs lengthen and hands and feet are seen. Embryonic heart rate peaks at 170-180bpm</td>
</tr>
</tbody>
</table>

(Adapted from: Jurkovic, Davor, Valentin, Lil, and Vyas, Sanjay, eds. Gynaecological Ultrasound in Clinical Practice : Ultrasound Imaging in the Management of
5.8 β-hCG and progesterone

**β-hCG (human Chorionic Gonadotrophin)**
- β-hCG is a hormone specifically produced by placental tissue. The level of β-hCG correlates well with the amount of viable trophoblast.
- Most commercially available monoclonal antibody-based urine pregnancy tests can detect the presence of β-hCG at a level above 25 IU/l which corresponds to day 24-25 of regular 28-day cycle.
- In normal very early pregnancy the level doubles every 48 hrs until 1200 IU/l and every 72 hours thereafter. (Pittaway DE et al. Doubling times of human chorionic gonadotrophin increase in early viable intrauterine pregnancies. Am J Obstet Gynecol 1985;152:299)

**Progesterone**
- In very early pregnancy <7 weeks progesterone is produced almost exclusively by the corpus luteum.
- The production of progesterone is determined by the slope of β-hCG rise. The level of serum progesterone in maternal serum thus reflects the speed of trophoblastic proliferation, which can be used to assess the pregnancy viability. (Hahlin M et al. The expectant management of early pregnancies of uncertain site. Hum Reprod 1995; 10:1223)
- The use of serum biochemistry in the management of specific pregnancy complications is discussed under Pregnancy of Unknown Location (section 5.10.3) and Ectopic Pregnancy (section 5.10.4).
5.9 Multiple Pregnancies

- In early pregnancy the chorionic and amniotic cavities are not fused, so the number of each should be recorded as well as the number of yolk sacs.

- The final diagnosis of chorionicity/amnionicity should not be made before the 7th week (Jurkovic et al 2009) especially when defining monochorionic twins. This is the gestation at which amnionicity is clear.

- All women with a twin pregnancy should be offered an ultrasound examination between 11+0 weeks and 13+6 weeks of gestation (crown–rump length 45–84 mm) to assess fetal viability, gestational age and chorionicity, and to exclude major congenital malformations.

Diagnosis of chorionicity and amnionicity in early twin pregnancy

\[ (O = \text{chorionic cavity} \quad O = \text{amniotic cavity}, \quad \bullet = \text{embryo}) \]

<table>
<thead>
<tr>
<th>Gestational age (weeks)</th>
<th>Dichorionic diamniotic</th>
<th>Monochorionic diamniotic</th>
<th>Monochorionic monoamniotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>6</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>7</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

- In higher multiples, the same principles are applied. Beware of unusual combinations such as dichorionic, diamniotic triplets.

- In very early pregnancy the diagnosis of monochorionic twins is difficult, and often one or more embryos are missed on examination. The number of yolk sacs in monochorionic pregnancies is variable, and should not be used for diagnosis (Monteagudo A et al. Early and simple determination of chorionic and amniotic type in multifetal gestations in the first fourteen weeks by high-frequency transvaginal sonography. Am J Obstet Gynecol 1994; 170:824).

- Please do not refer to dichorionic twins as non-identical. Approximately 15% of dichorionic twins are monozygotic (Moore and Persaud, The Developing Human: Clinically Oriented Embryology, Seventh Ed, Saunders 2003). Examining the ovaries for the number of corpora lutei may provide an insight into the possible zygosity.
• If two live embryos are seen at 6-10 weeks gestation in a DC twin pregnancy in our population, 75% of pregnancies will result in a livebirth of two babies. (Prediction of outcome in dichorionic twin pregnancies at 6-10 weeks’ gestation. Papaioannou GI et al. Am J Obstet Gynecol. 2011 Oct;205(4):348).

• Unfavourable features associated with pregnancy loss in twins are a large discrepancy in the crown rump lengths (ie >20%), oligohydramnios in one twin or a discrepancy in gestational sac diameter of>30%. (Prediction of outcome in dichorionic twin pregnancies at 6-10 weeks’ gestation. Papaioannou GI et al. Am J Obstet Gynecol. 2011 Oct;205(4):348).

• Vanishing twin phenomenon which was often described on transabdominal scan is a rarely seen transvaginally due to increased ability to differentiate between intrauterine haematoma and an empty sac (Jauniaux E et al. Clinical and morphological aspects of the vanishing twin phenomenon. Obstet Gynecol 1988; 72:577).

• The significance is that it is thought to be associated with increased risks of very preterm delivery, very low, and low birth weight babies (van Oppenraaij et al 2009). In relation to early pregnancy, ‘vanished twin syndrome’ can affect the levels of free β-hCG and (pregnancy associated plasma protein A) PAPP-A, used in screening for Down’s syndrome (Chasen et al 2006). It is important to document this finding on the Viewpoint report before Nuchal scan is performed.

• Monochorionic pregnancies have much less favourable outcomes than dichorionic and careful follow up is necessary as early as 12-14 weeks to detect an early onset of twin-to-twin transfusion syndrome which develops in 25% of cases (Hecher K et al. Doppler studies of the fetal circulation in twin-to-twin transfusion syndrome. Ultrasound Obstet Gynecol 1995; 5:318).
5.10 ABNORMAL EARLY PREGNANCY:

5.10.1 MISCARRIAGE

Background

Miscarriage or pregnancy failure occurs when there is failure of embryonic development or when a previously viable embryo/fetus dies. It affects approximately 20% of all pregnancies. It can be asymptomatic, but is typically associated with bleeding with/without pain.

Risk of miscarriage

Clinical history, including past reproductive history is useful in the determination of risk of miscarriage. Maternal age is the most important factor determining the risk of miscarriage.


<table>
<thead>
<tr>
<th>Maternal age</th>
<th>Miscarriage risk (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-20</td>
<td>15</td>
</tr>
<tr>
<td>21-25</td>
<td>11</td>
</tr>
<tr>
<td>26-30</td>
<td>12</td>
</tr>
<tr>
<td>31-35</td>
<td>17</td>
</tr>
<tr>
<td>36-40</td>
<td>30</td>
</tr>
<tr>
<td>41-45</td>
<td>60</td>
</tr>
</tbody>
</table>

The risk of miscarriage can also be estimated based on a combination of clinical symptoms and ultrasound findings.


- Ultrasound indicators of a pregnancy at a high risk of miscarriage are:
  1. small gestation sac diameter in proportion to CRL
  2. small CRL
  3. bradycardic embryo (< 90 bpm).
  4. large yolk sac

- Unless a woman is uncertain of her dates, then do not re-date the pregnancy from a single CRL measurement. If there is a discrepancy between the dates and size of the embryo, rescan in 1-2 weeks and only then re-date.

- If you see free fluid or blood in the uterine cavity, then counsel the woman to anticipate more discharge/bleeding. There is no conclusive evidence to support an association between the size of subchorionic haematoma and miscarriage (Johns J et al Obstetric outcome after threatened miscarriage with and without a hematoma on ultrasound. Obstet Gynecol 2003; 102(3): 483-7).

- Although the morphology of the yolk sac is often abnormal in cases of missed miscarriage, this has not shown to be a useful predictor of miscarriage in prospective studies (Reece EA et al. Prognostic significance of the human yolk sac assessed by ultrasonography. Am J Obstet Gynecol 1988; 159:1191).

**Clinical Definitions and Diagnosis of Miscarriage**

**Threatened Miscarriage**
- Amenorrhoea followed by slight vaginal bleeding
- No pain
- The uterus is the correct size for dates
- The internal cervical os is closed

**Inevitable Miscarriage**
- Amenorrhoea followed by heavy vaginal bleeding
- Pain usually follows bleeding
- The uterus may be small, large or correct size for dates
- The cervix is dilating and products of conception may be passing through the cervical os.

**Incomplete Miscarriage**
- An ultrasound criterion to diagnose incomplete miscarriage is variable and therefore there is no single accepted criterion (Jurkovic, 2013).
- It can be difficult to differentiate blood from retained products but generally retained products have mixed echogenic features representing fluid mixed with solid components, with or without a disorganised gestation sac.
- Sonographers will often measure endometrial thickness displaying some or all of these features. Cut-off levels have ranged between 5 and 15mm (Nielson & Hahlin 1995).
**Complete Miscarriage**
- Amenorrhoea followed by symptoms seen in inevitable miscarriage, followed by variable amounts of bleeding which has stopped.
- The uterus is smaller than expected.
- The cervix is closed.
- A complete miscarriage indicates that all products of conception have been spontaneously expelled from the uterine cavity and ultrasound fails to identify any pregnancy tissue. The endometrium is thin and smooth. The cavity may sometimes become distended with blood clots.
- The diagnosis can be confidently made in women who had an intrauterine pregnancy seen in a previous scan. If this is the first scan the pregnancy should be described as pregnancy of unknown location and followed up (see below).

**Missed miscarriage (Early embryonic demise)**
- This is an ultrasound diagnosis in women with minimal or no symptoms in which a scan (transvaginal ultrasound) finds an intrauterine pregnancy which has failed on the basis of the following criteria (NICE CG154)
  - Mean Gestational Sac diameter of 25.0mm or more with no visible fetal pole
  - Crown-rump-length 7.0mm or more with no visible heartbeat.
- If these are found on a first scan, then diagnosis must be confirmed by:
  - A second assessment by a different sonographer during the first scan
  - A follow up scan should be arranged in 7 days for both transvaginal and transabdominal scans.

Experienced sonographers are allowed to make the diagnosis of missed miscarriage at the initial visit when there is an empty intrauterine sac measuring >25 mm in mean diameter or when there is an embryonic pole with CRL>7mm and no visible heart action, according to RCOG 2011 addendum to Greentop Guideline No 25 Oct 2006: The Management of Early Pregnancy Loss. However, the clinical picture needs to be taken into account and women are unlikely to come to harm by waiting a week for a repeat scan rather than risk misdiagnosis.

- Any deviation from this will have to be at the discretion of the EPAU consultant

**Management of Miscarriage**

**Threatened Miscarriage**
- Always manage expectantly.
- Woman to contact EPAU for further assessment if bleeding worsens or persists beyond 14 days.
- If no further bleeding then she can continue routine antenatal care.
All Other Miscarriages

Expectant

- Offer to all ladies with incomplete miscarriage as first line management unless there is significant bleeding with haemodynamic compromise that requires surgery or if the lady refuses or if there is known coagulopathy.
- Those with early embryonic demise or missed miscarriage can also be managed expectantly.
- Careful counselling is important. Success rates range from 55% to 86% for incomplete and 29-42% in those with missed miscarriage (Jurkovic et al 2013).
- Give verbal and written information about what to expect, including pain relief and when to get emergency assessment.
- Chances of successful spontaneous miscarriage are better with increased length of follow up.
- If bleeding and pain have resolved within 14 days of expectant management women should be advised to take a pregnancy test. If positive they will need to contact EPAU for advice.
- If bleeding and pain have not started or if symptoms are increasing or unresolved then a repeat scan should be offered after 14 days (earlier if bleeding is significant and not tolerated by the woman).

Medical (See Guideline on Medical Management of Miscarriage)

Surgical

Offer as an elective procedure for women who prefer this method and for those in whom conservative management is unsuccessful.

See Appendix 2 for integrated care pathway for booking the patient for the procedure and Appendix 14.5 for surgical management checklist.

Emergency surgery should be the treatment of first choice in:

- Those with excessive bleeding
- Haemodynamically unstable
- Signs of infected retained products of conception
- Have a provisional diagnosis of gestational
- Trophoblastic disease.
5.10.2 Intrauterine Pregnancy of Uncertain Viability (IPUV)

- This refers to pregnancies in which an ultrasound scan shows features consistent with an intrauterine gestation sac but with no visible embryonic cardiac activity. It is also used when a scan shows only typical looking gestation sac with or without a yolk sac.

- **If there are any doubts about the presence of an intrauterine pregnancy in cases where only an intrauterine fluid filled structure is seen without any other features of pregnancy within it, then a pregnancy of unknown location should be described.** However if the sonographer is clear that the features meet the criteria for a gestation sac (refer to section 5.6) and the adnexae have been clearly visualised then an IPUV can still be described.

- In IPUV, a follow up scan should be arranged in 7 to 10 days for TV scan and 14 days if scanned TA after initial scan.

- **Below is the criteria for transvaginal ultrasonographic diagnosis of pregnancy failure in a woman with an Intrauterine pregnancy of uncertain viability**

(Society of Radiologists in Ultrasound Multispecialty Consensus Conference on Early First Trimester Diagnosis of Miscarriage and Exclusion of a Viable Intrauterine Pregnancy, October 2012. (Doubilet et al 2014))
<table>
<thead>
<tr>
<th>Findings Diagnostic of Pregnancy Failure</th>
<th>Findings Suspicious for, but not Diagnostic of, Pregnancy Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crown–rump length of ≥7 mm and no heartbeat</td>
<td>Crown–rump length of &lt;7 mm and no heartbeat</td>
</tr>
<tr>
<td>Mean sac diameter of ≥25 mm and no embryo</td>
<td>Mean sac diameter of 16–24 mm and no embryo</td>
</tr>
<tr>
<td>Absence of embryo with heartbeat ≥2 wk after a scan that showed a gestational sac without a yolk sac</td>
<td>Absence of embryo with heartbeat 7–13 days after a scan that showed a gestational sac without a yolk sac</td>
</tr>
<tr>
<td>Absence of embryo with heartbeat ≥11 days after a scan that showed a gestational sac with a yolk sac</td>
<td>Absence of embryo with heartbeat 7–10 days after a scan that showed a gestational sac with a yolk sac</td>
</tr>
<tr>
<td>Absence of embryo ≥6 wk after last menstrual period</td>
<td>Absence of embryo 7–10 days after a scan that showed a gestational sac with a yolk sac</td>
</tr>
<tr>
<td>Empty amnion (amnion seen adjacent to yolk sac, with no visible embryo)</td>
<td>Empty amnion (amnion seen adjacent to yolk sac, with no visible embryo)</td>
</tr>
<tr>
<td>Enlarged yolk sac (&gt;7 mm)</td>
<td>Enlarged yolk sac (&gt;7 mm)</td>
</tr>
<tr>
<td>Small gestational sac in relation to the size of the embryo (&lt;5 mm difference between mean sac diameter and crown–rump length)</td>
<td>Small gestational sac in relation to the size of the embryo (&lt;5 mm difference between mean sac diameter and crown–rump length)</td>
</tr>
</tbody>
</table>

**Summary of ultrasound follow up in definite or suspected pregnancy failure**

<table>
<thead>
<tr>
<th>Ultrasound Findings</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational Sac &gt;25mm with no embryo or yolk sac</td>
<td>Repeat scan in one week (Or second assessment at initial scan)</td>
</tr>
<tr>
<td>Crown-rump-lump &gt;7mm with no heart action</td>
<td>Repeat scan in one week (Or second assessment at initial scan)</td>
</tr>
<tr>
<td>Gestational sac &lt;15mm or CRL&lt;7mm</td>
<td>Repeat scan in two weeks</td>
</tr>
<tr>
<td>Intrauterine Pregnancy of Uncertain Viability</td>
<td>Repeat scan in 7-14 days</td>
</tr>
</tbody>
</table>
5.10.3 Pregnancy of Unknown Location

G:\Shared\Surgery\ObsGynae\EPAU\M6 PUL

A diagnosis of ‘Pregnancy of Unknown Location’ (PUL) is made when at an initial visit to EPAU, the woman has a positive pregnancy test but the scan shows no clear evidence of intrauterine nor extrauterine pregnancy.

Most women with pregnancies of unknown location have spontaneously resolving pregnancies (70%), or very early intrauterine pregnancies which are below the resolution capability of ultrasound scan (25%). Surgical intervention is required in approximately 5% of women, the majority of whom will have tubal ectopics. (Banerjee S et al. Expectant management of early pregnancies of unknown location: a prospective evaluation of methods to predict spontaneous resolution of pregnancy. Br J Obstet Gynecol 2001; 108:158-63)

Those with presumed RPOC on first scan should still be classified as PUL.

The diagnosis should only be made following assessment with a transvaginal scan. If there is any uncertainty, then a second opinion scan should be obtained preferably from an EPAU consultant or Supervising sonographer on the same day.

PUL should NOT be applied to:

- Women with an early pregnancy sac-like structure within the cavity requiring follow up. In such cases a scan can be repeated within 7 to 10 days.
- Women with an adnexal mass which is a suspected ectopic
- Women with haemoperitoneum with no visible adnexal mass. In such cases a second opinion must be sought by an EPAU Consultant or supervising sonographer.
- Those with significant haemoperitoneum who are clinically stable or unstable. The on-call Consultant and team should be informed as these women require surgical intervention.
Management of a Pregnancy of Unknown Location (PUL)

Recent research comparing serial β-hCG has found that the β-hCG ratio (the serum β-hCG after 48 hours/serum β-hCG at presentation) is the most sensitive diagnostic model in predicting failing pregnancy (Guha et al; 2014).

Progesterone can help to improve the sensitivity. A systematic meta-analysis assessing single progesterone measurements to diagnose ectopics found that this alone cannot diagnose ectopics for certain however it is has good discriminative capacity for diagnosing failing pregnancies from viable intrauterine pregnancies (Mol 1998)

- Take 2 serum hCG measurements as near as possible to 48 hours apart (but no earlier) to determine subsequent management. Take further measurements only after review by an EPAU Consultant or On-call Consultant.

- Take a single progesterone measurement at initial visit.

- If repeat βHCG is to be taken outside of EPAU working hours, then direct the patient to Emergency Assessment Unit (EAU), and hand over to SHO on call. See Appendix 4.

- All PULs will be recorded in the PUL folder which should be looked at daily by the Consultant covering EPAU.

- Inform women to access emergency care if they experience any new or worsening symptoms. Advise women to return if there are new symptoms or if existing symptoms worsen.

- If a patient is symptomatic, she needs to be assessed by the on-call team and discussed with the Consultant. Clinical symptoms outweigh blood results in any management decision.
Protocol for the Management of PUL (See Appendix 4 for flowchart)

The current protocol for management is defined below. Our Unit is part of a multi-centre prospective audit looking at a new model for triaging PULs. Currently this model is to be used as a decision support tool for the EPAU team and does not replace the management described below. PLEASE DO NOT take third (3rd) serum hCG unless discussed with a Consultant.

**Interpreting initial hCG and Progesterone and guide to management** *(Adapted from Banerjee S et al 2001)*:

<table>
<thead>
<tr>
<th>Progesterone nmol/l</th>
<th>hCG IU/L</th>
<th>Likely Diagnosis</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2</td>
<td>&gt;25</td>
<td>Resolving Pregnancy</td>
<td>Pt to repeat Urine PT in 2 weeks</td>
</tr>
<tr>
<td>10-20</td>
<td>&gt;25</td>
<td>Likely Resolving Pregnancy</td>
<td>Repeat Serum hCG in 48 hours</td>
</tr>
<tr>
<td>20-60</td>
<td>&gt;25</td>
<td>Ectopic or miscarriage requiring intervention</td>
<td>Serum hCG in 48 hours</td>
</tr>
<tr>
<td>&gt;60</td>
<td>&lt;1000</td>
<td>Normal intrauterine Pregnancy</td>
<td>Repeat Scan when hCG&gt;1000 Repeat scan same day by a senior examiner +/- Laparoscopy</td>
</tr>
<tr>
<td>&gt;60</td>
<td>&gt;1000</td>
<td>Ectopic</td>
<td></td>
</tr>
</tbody>
</table>
## Guide on how to manage Serial hCGs

<table>
<thead>
<tr>
<th>hCG after 48 hours</th>
<th>Advise</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase greater than 63%</td>
<td>Likely to have a developing intrauterine pregnancy (although the possibility of an ectopic pregnancy cannot be excluded).</td>
<td>TV scan between 7 and 14 days later. Consider an earlier scan for women with a serum hCG level greater than or equal to 1500 IU/litre.</td>
</tr>
</tbody>
</table>
| Decrease greater than 50% | Pregnancy is unlikely to continue but that this is not confirmed | Patient to do a urine pregnancy test 14 days after the second serum hCG test.  
- Negative; no further action is necessary  
- Positive; she should return for clinical review within 24 hours  
- |
| Between a 50% decline and 63% rise inclusive | | Clinical review by doctor within 24 hours |
| hCG less than 20 | Pregnancy Loss. Refer to Miscarriage section of these guidelines | Discharge. |
5.10.4 ECTOPIC PREGNANCY

BACKGROUND
An ectopic pregnancy is any pregnancy implanted outside of the endometrial cavity. In the UK, the incidence is approximately 11/1000 pregnancies, with an estimated 11 000 ectopic pregnancies diagnosed each year. The incidence of ectopic pregnancy in women attending early pregnancy units is 2–3%. Advancement in diagnostic transvaginal ultrasound, dedicated early pregnancy units and biochemical markers have led to a fall in the associated mortality rate. However, it is still the third most common cause of direct maternal deaths in the most recent Triennnial Report, “Saving Mother’s Lives”.

Any patient with pain and bleeding in early pregnancy in whom the ultrasound demonstrates free fluid in the pouch of Douglas or an adnexal mass in the absence of an intrauterine pregnancy should be discussed with the EPAU or on-call consultant.

TYPES OF ECTOPIC PREGNANCIES
1. TUBAL
2. NON TUBAL
   a. CERVICAL
   b. CAESAREAN SCAR
   c. INTERSTITIAL
   d. CORNUAL
   e. OVARIAN
   f. ABDOMINAL
   g. HETEROTOPIC

RISK FACTORS:
• Previous ectopic pregnancy
• Previous tubal surgery
• History of pelvic inflammatory disease / sexually transmitted disease
• IUCD in-situ
• Assisted conception management
• Exposure of diethylstilbestrol in-utero
• Use of post-coital contraception
CLINICAL FEATURES

Amenorrhoea – in many cases, abnormal bleeding is mistaken by the patient as a menstrual period and she may give no history of amenorrhoea. Hence a high degree of suspicion is necessary to diagnose this condition.

Abdominal pain – in the majority of cases the pain is unilateral and mild to moderate in the lower abdomen. In the case of significant intraperitoneal haemorrhage or tubal rupture, the pain is sudden and severe and many patients may present in a collapsed condition. Please bear in mind that a significant proportion of women may present with minimal or no symptoms.

Vaginal Bleeding – usual presentation is with light or prolonged intermittent bleeding. At times the bleeding may be heavy and the passage of decidualised endometrium (decidual cast) is commonly mistaken for ‘products of conception’. Histological evaluation of the decidual cast will show no chorionic villi.

Atypical Symptoms – at times, women present with gastrointestinal symptoms (e.g. nausea and vomiting) and the clinical diagnosis might be gastroenteritis rather than ectopic pregnancy.

Abdominal tenderness – may be mild to severe

Adnexal mass / tenderness – it is advisable NOT to perform a bimanual vaginal examination to elicit the above signs as a pelvic scan is usually performed for the diagnosis except for women presenting shocked. Furthermore, a vaginal examination may cause tubal rupture.

DIAGNOSIS CRITERIA AND MANAGEMENT OF ECTOPIC PREGNANCIES

1. TUBAL ECTOPIC PREGNANCY

Ultrasound diagnosis

Transvaginal ultrasound is the diagnostic tool of choice for tubal ectopic pregnancy. Tubal ectopic pregnancies should be positively identified, if possible, by visualising an adnexal mass that moves separate to the ovary.

- The majority of tubal ectopic pregnancies should be visualised on transvaginal ultrasound. Transvaginal ultrasound has reported sensitivities of 87.0–99.0% and specificities of 94.0–99.9% for the diagnosis of ectopic pregnancy.
- The majority of ectopic pregnancies will be visualised on the initial ultrasound examination.
• The remainder will initially be classified as a PUL. Not all ectopic pregnancies initially classified as a PUL are ‘missed’ on the initial scan. Some of these ectopic pregnancies are just too small and too early in the disease process to be visualised on the initial ultrasound examination.

• Laparoscopy is no longer the gold standard for diagnosis. False-negative laparoscopies (3.0–4.5%) have been reported when the procedure is performed too early in the development of an ongoing ectopic pregnancy.

Ultrasound features

• An inhomogeneous or noncystic adnexal mass is the most common finding in around 50–60% of cases.
• An empty extrauterine gestational sac will be present in around 20–40% of cases. While an extrauterine gestational sac containing a yolk sac and/or embryonic pole that may or may not have cardiac activity will be present in around 15–20% of cases.
• There is no specific endometrial appearance or thickness to support a diagnosis of tubal ectopic pregnancy.
• In up to 20% of cases, a collection of fluid may be seen within the uterine cavity, classically referred to as a ‘pseudosac’.
• The key is to distinguish this from an early intrauterine gestational sac. The intradecidual and double decidual signs can be used to diagnose an early intrauterine pregnancy. The intradecidual sign is described as a fluid collection with an echogenic rim located ‘within a markedly thickened decidua on one side of the uterine cavity’.
• The double decidual sign is described as an intrauterine fluid collection surrounded by ‘two concentric echogenic rings’. However, in practice, it can be very difficult to distinguish a ‘pseudosac’ which is just a collection of fluid in the endometrial cavity from an early intrauterine sac.
• The presence of a ‘pseudosac’ alone cannot be used to diagnose an ectopic pregnancy and in fact, a small anechoic cystic structure is more likely to be an early sac rather than a ‘pseudosac’. A study has shown that a woman with a positive pregnancy test, an intrauterine smooth-walled anechoic cystic structure and no adnexal mass has a 0.02% probability of ectopic pregnancy, while the probability of intrauterine pregnancy in such a patient is 99.98%.
• Free fluid is often seen on ultrasound, but is not diagnostic of ectopic pregnancy. A small amount of anechoic fluid in the pouch of Douglas may be found in both intrauterine and ectopic pregnancies. Echogenic fluid has been reported in 28–56% of ectopic pregnancies. It may signify tubal rupture, but most commonly is due to blood leaking from the fimbrial end of the fallopian tube.

Biochemical investigations

A serum progesterone level is not useful in predicting ectopic pregnancy.

A serum beta-human chorionic gonadotrophin (β-hCG) level is useful for planning the management of an ultrasound visualised ectopic pregnancy.
• A meta-analysis has confirmed that a single β-hCG level cannot be used in isolation to predict an ectopic pregnancy.
• There is a common misconception that a single low serum β-hCG level (e.g. less than 1000 iu/l) means that an ectopic pregnancy is unlikely. However, this is a false assumption and in modern practice many ectopic pregnancies have a β-hCG value below this level.
• The initial serum β-hCG level is a key prognostic indicator for the success of conservative management (expectant and medical) in cases of ultrasound visualised tubal ectopic pregnancies.

1. MANAGEMENT OF TUBAL ECTOPIC PREGNANCY
• SURGICAL
• PHARMACOLOGICAL
• CONSERVATIVE

SURGICAL MANAGEMENT OF TUBAL ECTOPIC PREGNANCY
A laparoscopic surgical approach is preferable to an open approach.
• Laparoscopic approach is the treatment of choice in a stable woman who is medically fit, with an appropriate BMI. Advantages include significantly less blood loss, lower analgesic requirements, shorter hospital stay and quicker postoperative recovery time. Adhesions develop significantly less often after laparoscopy than after laparotomy. The laparoscopic approach is also associated with significantly lower costs.

• Evidence, however, suggests that there is no difference in terms of health benefits between laparoscopy and laparotomy, including the key outcome of subsequent successful pregnancy.

• All cases must be supervised by an appropriately trained surgeon. No trainee should perform surgery unsupervised without prior assessment by a senior clinician. The Consultant on-call must be informed when the patient is taken to theatre.

• Laparotomy is reserved for cases of severe haemorrhage and collapse (or difficulty in accessing the pelvis laparoscopically). It is important that if a patient has haemorrhagic shock, she must be operated on as rapidly as possible by the most expedient method. In such circumstances, open laparotomy will be the preferred operation.

• Where severe haemodynamic compromise exists, the presence of senior/consultant cover is desirable. The must speak to the consultant and commence the procedure prior to the arrival of the Consultant. In such circumstances, surgery may be performed even before blood loss has been replaced.
• If the surgeon has insufficient operative laparoscopic experience and/or the quality of the laparoscopic equipment is inadequate, laparotomy may be necessary.

In the presence of a healthy contralateral tube, salpingectomy should be performed in preference to salpingotomy.

• In women with a history of fertility-reducing factors (previous ectopic pregnancy, contralateral tubal damage, previous abdominal surgery, previous pelvic inflammatory disease), salpingotomy should be considered.

• If a salpingotomy is performed, women should be informed about the risk of persistent trophoblast with the need for serum β-hCG level follow-up. Persistent trophoblastic disease occurs in up to 11% of salpingotomy cases and consequently these women need serum follow up. They should also be counseled that there is a small risk that they may need further treatment in the form of systemic methotrexate or salpingectomy.

• Women undergoing salpingotomy should have a serum β-hCG level taken 7 days after surgery and then weekly until a negative result is obtained(levels <5IU/L)

• Salpingotomy is reasonable when there is only one tube. The patient may still request that the Fallopian tube be preserved if possible despite the above recommendations in this case the discussion and patient request must be fully documented in the notes.

In cases of negative laparoscopy

Uterine Curettage

• Uterine curettage at the time of surgery for an ectopic pregnancy is not routinely indicated. The uterus should not be instrumented until the diagnosis of an ectopic pregnancy is confirmed at laparoscopy to avoid disruption to an early intrauterine pregnancy. The patient should be advised that vaginal bleeding might occur postoperatively.

• Uterine curettage is recommended in the event of a negative laparoscopy if serum hCG has consistently demonstrated a suboptimal increase. This may help to confirm a failing intrauterine pregnancy. This should be discussed with the consultant in charge of the case prior to proceeding with the operation.

• It is important that the histology results are followed-up to confirm the diagnosis and exclude trophoblast abnormality.

• In a small percentage of women(5%), there is lack of histological confirmation of sonographically diagnosed and surgically confirmed ectopic pregnancies. Clinicians should be aware of this when
counselling women with tubal ectopic pregnancies with surgical management. A follow up serum BCG should be arranged in such cases through EPAU (Farahani et al., 2017)

Anti-D Ig
Anti-D should be given to non-sensitised rhesus negative women following surgery for an ectopic pregnancy (see Anti-D policy).

Fertility outcomes following surgical management of tubal ectopic pregnancy

- There is no confirmed evidence that salpingotomy improves infertility rates when the other tube appears normal. A multicentre randomised controlled trial (RCT) on 446 women with a laparoscopically confirmed tubal ectopic pregnancy and a healthy contralateral tube has found that the cumulative ongoing pregnancy rate was 60.7% after salpingotomy and 56.2% after salpingectomy.

- Recurrent ectopic pregnancy rate is higher in women who undergo linear salpingotomy (up to 8%) compared with salpingectomy (5%).

- Higher rates of subsequent intrauterine pregnancy have been found if salpingotomy is performed rather than salpingectomy in women with a history of fertility-reducing factors (previous ectopic pregnancy, contralateral tubal damage, previous abdominal surgery, previous pelvic inflammatory disease). One study found subsequent intrauterine pregnancy rates of 75% with salpingotomy and 40% with salpingectomy in such women. However, subsequent intrauterine pregnancy rates were greater than 90% in both groups in women without fertility-reducing factors.

Care-pathway for surgical management of ectopic pregnancy

Should patient require surgery

- **Admit** – contact duty bed manager
- **A wide bore intravenous cannula** must be inserted and blood taken for
  - **FBC** · **Group and save +/- crossmatch 2 units**
  - **Clotting screen if haemodynamic compromise**
- The patient must be made **nil by mouth** and the last time they ate and drank ascertained.
- The on-call Consultant, SpR on duty and SHO should be notified.
- Consent should be taken by the doctors
- The SHO should add patient to the emergency theatre list ASAP and notify the on call anaesthetist
- Patients who are in significant pain and who have signs of haemodynamic collapse must have 2 wide bore (16G) IV cannulae inserted and IV fluids
commenced and a request for cross matched blood sent urgently. The consultant on call should be alerted immediately.

- **Post-surgery prior to discharge**
  - The patient should be debriefed on the findings and surgical procedure that has been done and arrange a GOPD follow up in 6 weeks under the admitting consultant on call or the consultant that performed the procedure.
  - The on call or gynaecological SHO doing the discharging summary must ensure that information on the findings, procedure performed and any complications has been passed over to the EPAU staff nurses to be recorded in the database.

**PHARMACOLOGICAL MANAGEMENT OF TUBAL ECTOPIC PREGNANCY WITH METHOTREXATE**

*Whilst ruptured ectopic pregnancy can be life threatening, up to 70% of all ectopic pregnancies can be managed non-surgically.*

*Systemic methotrexate may be offered to suitable women with a tubal ectopic pregnancy. It should never be given at the first visit, unless the diagnosis of ectopic pregnancy is absolutely clear and a viable intrauterine pregnancy has been excluded.*

*Consultant on call or EPAU consultant must be informed on all cases of medical management of ectopic pregnancy prior to commencement of treatment.*

**Methotrexate**

- **Women** should be told that medical management of ectopic pregnancy is carried out using a drug known as methotrexate (MTX).
- **Randomised controlled trials comparing methotrexate with laparoscopic surgery** have shown methotrexate to be equally successful to surgery in certain cases of tubal ectopic pregnancy (Elson CJ et al. 2016)
- **Methotrexate (MTX)** is a folic acid antagonist which prevents growth of rapidly dividing cells by interfering with DNA synthesis and is partially metabolised by the liver and primarily excreted by the kidney. MTX has been used extensively for the treatment of gestational trophoblastic disease (RCOG Management of Gestational Trophoblastic Disease)
- **It can be administered systemically** (IV, IM or orally) or by local injection under USS or laparoscopic guidance and by hysteroscopically inserted intra-tubal catheters.
- **The most commonly used systemic route in management of ectopic pregnancy** is IM because of ease of administration.
- **Dosage** is related to the patient's body weight or surface area. A single dose regime of 50 mg/m² IM is widely used and in the majority of cases is adequate for
successful treatment in the region of 65–95%. 15% of women may require a second dose (Elson CJ et al. 2016).

- An initial βHCG level is taken. This is primarily as a reference for subsequent monitoring. However if the level is very high (>10,000iu/l) there is a greater risk of tubal rupture – up to 30% in one series.

Counseling for women receiving methotrexate

- Women should be counseled that the side effects of methotrexate are dose dependent and common after multiple doses. Serious side effects are rare following a single dose of MTX.
- If multiple doses are required, a calcium folinate rescue dose should be considered to reduce the incidence of side effects. With a single dose of MTX, calcium folinate rescue treatment is not necessary. The rescue dose should be prescribed as a single oral stat dose of 30mg of calcium folinate to be taken 24 hours after the second methotrexate injection only.
- Women should be counseled that in a small percentage of women the treatment may not work and may require either a repeat dose (15%) or surgery (10%), (Elson CJ et al. 2016).
- Women must be counseled about the length of time for follow (sometimes it can take 6 – 8 weeks) while undergoing medical treatment of ectopic pregnancy.
- Women should be warned to avoid alcohol, sexual intercourse and vitamin preparations containing folic acid.
- Women should be counseled about experiencing abdominal pain – this is the most common side effect of MTX and occurs in up to 60% of women. Crampy abdominal pain usually starts 3-14 days following treatment. Pain is likely to be aggravated by gas producing foods like cabbage and leek and women should be informed to avoid these foods (Elson CJ et al. 2016). Women should be advised to attend accident and emergency if in significant pain.
- Vaginal examination should be avoided unless strongly clinically indicated. This should be discussed with registrar or consultant on call.
- Women should also be advised to avoid pregnancy for at least three months after the last methotrexate injection to ensure that it will have no effect on a future pregnancy.
Table 1. Contraindications and cautions to methotrexate – please refer to the summary of product characteristic (SPC) for methotrexate

<table>
<thead>
<tr>
<th>Contra-indications</th>
<th>Cautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemodynamic instability</td>
<td>Avoid concurrent use with Aspirin and other NSAIDs as these drugs may increase risk of drug toxicity. If NSAID use is necessary, the patient should omit NSAID doses from 24 hours before the methotrexate and not restart till 48 hours after.</td>
</tr>
<tr>
<td>Severe liver impairment</td>
<td></td>
</tr>
<tr>
<td>Severe renal impairment (CrCl less than 20mL/min)</td>
<td></td>
</tr>
<tr>
<td>Pre-existing blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anaemia</td>
<td></td>
</tr>
<tr>
<td>Ulcers of the oral cavity and known active gastrointestinal ulcer disease</td>
<td></td>
</tr>
<tr>
<td>Presence of an intrauterine pregnancy</td>
<td></td>
</tr>
<tr>
<td>Concurrent vaccination with live vaccines</td>
<td></td>
</tr>
<tr>
<td>Serious, acute or chronic infections such as tuberculosis, HIV or other immunodeficiency syndromes</td>
<td></td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity to methotrexate or to any other component of the product</td>
<td></td>
</tr>
<tr>
<td>If unable to comply with follow-up</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Side effects of methotrexate (see summary of product characteristics on http://www.medicines.org.uk for full list of side effects from methotrexate)

<table>
<thead>
<tr>
<th>Side effects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea, vomiting, diarrhoea, excessive flatulence and bloating due to intestinal gas formation</td>
<td></td>
</tr>
<tr>
<td>Tiredness</td>
<td></td>
</tr>
<tr>
<td>Dermatitis, stomatitis, skin rashes, photosensitivity</td>
<td></td>
</tr>
<tr>
<td>Pneumonitis, bone marrow suppression, hepatotoxicity</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain, vaginal bleeding</td>
<td></td>
</tr>
</tbody>
</table>

Exclusion criteria for management of ectopic pregnancy with methotrexate

- **Uncertain diagnosis** – MTX should only be given where the diagnosis is certain (ie no IUP and visualisation of adnexal mass). If the diagnosis is not certain, further follow up with βHCG and TVS should be arranged (and discuss with EPAU consultant / consultant on call).
- **Haemodynamically unstable**
• Severe abdominal pain
• Live tubal ectopic (relative contraindication as cervical or cornual or interstitial pregnancies are best managed medically)
• Large adnexal mass (>35cm) with significant free fluid in the pelvis and associated with significant pain.
• Active lung, liver or kidney disease, bone marrow impairment
• Heterotopic pregnancy

Inclusion criteria for management of ectopic pregnancy with methotrexate

• Certain diagnosis
• No intrauterine pregnancy (as confirmed on ultrasound scan)
• Haemodynamically stable
• No significant pain
• Adnexal mass <35cm (not absolute)
• A low serum β-hCG, ideally less than 1500 iu/l but can be up to 5000 iu/l
• No contraindications to methotrexate
• Normal platelets, WBC, U&E’s, LFT’s
• Able to attend follow-up

Predictors of successful medical treatment of ectopic pregnancy with methotrexate

• Initial serum β-hCG level

  Success rates are higher with lower β-hCG levels. Success rates of 81–98% have been reported if serum β-hCG levels are less than 1000 iu/l, compared with only 38% if β-hCG levels are greater than 5000 iu/l.

• Ultrasound appearance of the ectopic pregnancy

  The presence of a yolk sac, fetal pole and/or fetal cardiac activity are significant predictors of failure. Success rates are higher when no gestational sac is visualised.

• Pre-treatment changes in serum β-hCG levels

  The smaller the increase in β-hCG level prior to administration of methotrexate, the higher the chance of successful medical management. A β-hCG increase of up to 11–20% over 48 hours prior to the administration of methotrexate has been associated with higher rates of success.
• Decrease in β-hCG levels from day 1 to day 4 after methotrexate

Success rates of 88–100% have been reported if the serum β-hCG level decreases from day 1 to day 4 post administration of methotrexate, compared with only 42–62% if the serum β-hCG level increases.

Management protocol for treatment with methotrexate

For prescription, ordering and administration of methotrexate for the management of ectopic pregnancy follow the Methotrexate for Management of Ectopic Pregnancy: Prescription and Administering Policy.

Pre-treatment

• Once diagnosis of ectopic pregnancy has been made, EPAU staff nurse must inform the on call SHO and Registrar.
• The case must be discussed with EPAU consultant or consultant on call.
• The doctors should discuss treatment options with the patient and check that the patient is eligible for medical management with methotrexate and has no contraindications to methotrexate.
• Patient should be counseled about common side effects of methotrexate and the follow up process. Methotrexate patient information leaflet must be given to the patient.
• A written consent form for medical treatment of ectopic pregnancy with methotrexate should be obtained by the doctors.
• The EPAU staff nurse must complete the pre-treatment check list for the medical management of ectopic pregnancy with methotrexate.
• Prior to commencing treatment ensure the following blood tests have been done and are within normal range
  ▪ FBC
  ▪ Group and Save
  ▪ LFT
  ▪ U/E
  ▪ Serum β-hCG

Day 0 of treatment:

• Once admitted to the medical day unit, the oncology nurse must check that the patient has seen, read and understood the information leaflet provided.
• The approved NHS consent form must be signed as testimony to this informed consent. The patient must have agreed to the treatment and signed the consent form prior to administration of the methotrexate.
• The oncology nurse administers the intramuscular methotrexate injection as a bolus into the gluteal muscle in line with trust policy for safe handling of cytotoxic agents. In this policy this is counted as day 0 of treatment.
• GP information sheet is sent to the GP by EPAU staff nurses
• Follow up protocol for subsequent blood tests and reviews are arranged by the EPAU staff nurses.

Day 4 and day 7 post treatment:

• Patient must attend EPAU or, if over the weekend, EAU for their day 4 and 7 serum β-hCG.
• Serum β-hCG often goes up initially between days one and 4 following administration of MTX – this is likely to be a normal response to MTX.
• If the serum β-hCG level decreases by more than 15% between days 4 and 7, β-hCG levels are then measured weekly until less than 15 iu/l.
• If the serum β-hCG level does not decrease by 15% on day 7 or levels are rising, a repeat transvaginal ultrasound should be considered to exclude ectopic fetal cardiac activity and the presence of significant haemoperitoneum.
• Consideration may then be given to administration of a second dose of methotrexate. This should be discussed by the EPAU consultant or on call consultant.
• If multiple doses are required, calcium folinate acid rescue should be considered to reduce the incidence of side effects. This should be prescribed as a single oral stat dose of 30mg of calcium folinate to be taken 24 hours after the second methotrexate injection.

Acute abdominal pain following medical and conservative management of ectopic pregnancy

• Abdominal pain is the most common side effect of IM MTX occurring in nearly 50% of the cases. Most of the time pain is mild to moderate and crampy requiring no or simple analgesia only. Such cases do not require admission.
• About 20 – 25% of women experience significant pain requiring in-patient observation and IM / IV analgesia. Abdominal pain in a haemodynamically stable patient is not necessarily an indication for surgical intervention. All such cases must be discussed with the consultant on call.
• Differential diagnosis of abdominal pain include side effect of MTX Intraperitoneal bleeding from a leaking ectopic pregnancy / tubal miscarriage / tubal rupture.
• Admit for in-patient observation if pain is moderate to severe requiring analgesia. Doctors must clinically assess the patient for haemodynamic stability (no vaginal examination).
• Check FBC and repeat 4-6 hours later if necessary to check for continuing intraperitoneal bleeding.
• TVS – to look for free fluid and signs of rupture.
• Haemodynamic instability or falling haemoglobin or haematocrit is an urgent indication for surgical intervention.
CONSERVATIVE /EXPECTANT MANAGEMENT OF TUBAL ECTOPIC PREGNANCY

Expectant management is an option for clinically stable women with an ultrasound diagnosis of ectopic pregnancy and a decreasing β-hCG level initially less than 1500 iu/l.

- Expectant management is a reasonable option for appropriately selected and counseled women. They must be willing and able to attend for follow-up.
- Reported success rates range from 57–100% and are very dependent on case selection.
- Women should be counseled about avoiding sexual intercourse & vaginal examination.
- Women should be advised of symptoms and signs of possible tubal rupture.
- Women should have open access to and be advised to attend EPAU during working hours or Accident and Emergency for out of hours and over the weekend if symptoms worsen. In cases of history of collapsing at home, women should be advises to call for an ambulance on 999.
- Women should be counseled on the need for medical or surgical management should expectant management fail.
- Women should be counseled about the risk of subsequent ectopic pregnancy 10-15% following one previous ectopic and should contact EPAU for an early scan in their subsequent pregnancies.
- All cases of expectant management must be approved by the EPAU consultant or consultant on call.

Inclusion criteria:
- Patients able to understand the implication of this form of management and who are likely to comply with follow-up.
- Clinically stable with minimal symptoms.
- If the 0 hour serum β-hCG is <1500 iu/l and two follow-up β-hCG 48 hours apart are decreasing.
- The diameter of the ectopic pregnancy on TVS is less than 3.5cm.
- There are no signs of rupture or haemoperitoneum on TVS.

Management:
- Serial β-hCG every 48 hours until there is a fall of more than 20% is documented on 2 occasions.
- Weekly serum β-hCG thereafter until levels reaches 15 iu/l.
- TVS immediately if pain develops or 6 weeks after resolution of β-hCG.
- TVS at 6 weeks following return of the serum β-hCG to non-pregnant values to assess resolution of the ectopic mass.
- Anti-D immunoglobulin should be given to non-sensitised rhesus negative women who are managed conservatively for an ectopic pregnancy.
2. NON-TUBAL ECTOPIC PREGNANCIES

All cases of suspected non-tubal ectopic must be discussed with the EPAU consultant.

a) Interstitial ectopic pregnancy

This is where the pregnancy occurs high at the fundus in the myometrial portion of the tube. The gestational sac invades the myometrium and is separate from the endometrium. Fibroids can make the diagnosis difficult and in some cases the ectopic can be misdiagnosed as a fibroid.

- Ultrasound criteria
  - Empty uterine cavity, products of conception/gestational sac located laterally in the interstitial (intramural) part of the tube and surrounded by less than 5 mm of myometrium in all imaging planes, and presence of the ‘interstitial line sign’.
  - The ‘interstitial line sign’, which is a thin echogenic line extending from the central uterine cavity echo to the periphery of the interstitial sac. The ‘interstitial line sign’ has been shown to have a sensitivity of 80% and a specificity of 98% for the diagnosis of interstitial ectopic pregnancy.
  - Sonographic findings in two-dimension can be further confirmed using three-dimensional ultrasound, where available, to avoid misdiagnosis with early intrauterine or angular (implantation in the lateral angles of the uterine cavity) pregnancy.
  - Supplementation with MRI can also be helpful in the diagnosis of interstitial pregnancy.

- Serum β-hCG
  - A single serum β-hCG should be carried out at diagnosis to help with management. In some cases, a repeat serum β-hCG in 48 hours may be useful in deciding further management.

- Treatment options
  - Nonsurgical management is an acceptable option for stable interstitial pregnancies.
  - Expectant management is only suitable for women with low or significantly falling β-hCG levels in whom the addition of methotrexate may not improve the outcome.
  - A pharmacological approach using methotrexate has been shown to be effective, although, there is insufficient evidence to recommend local or systemic approach. For our unit follow the methotrexate protocol for tubal ectopic pregnancy.
  - Surgical management by laparoscopic cornual resection or cornuostomy is an effective option.
  - Techniques to minimise blood loss include before cornuostomy or resection.
b) **Cervical ectopic pregnancy**

- Cervical pregnancies are rare, accounting for less than 1% of all ectopic gestations.
- The 'sliding sign' enables cervical ectopic pregnancies to be distinguished from miscarriages that are within the cervical canal. When pressure is applied to the cervix using the probe, in a miscarriage, the gestational sac slides against the endocervical canal, but it does not in an implanted cervical pregnancy.

**Ultrasound criteria**

- Empty uterine cavity.
- A barrel-shaped cervix.
- A gestational sac present below the level of the internal cervical os.
- The absence of the 'sliding sign'.
- Blood flow around the gestational sac using colour Doppler.

**Serum β-hCG**

- A single serum β-hCG should be carried out at diagnosis.
- A single serum β-hCG carried out at the time of ultrasound diagnosis is useful in deciding management options. A serum β-hCG level greater than 10 000 iu/l is associated with a decreased chance of successful methotrexate treatment.

**Treatment options**

- **Medical management with methotrexate**
  
  - Early, accurate diagnosis is the key factor in the conservative management of cervical pregnancies.
  - Reported success rate is approximately 91%.
- Gestational age more than 9\(^0\) weeks, \(\beta\)-hCG levels greater than 10 000 iu/l, crown–rump length greater than 10 mm and fetal cardiac activity were shown to be associated with a higher risk of primary failure of the treatment of cervical ectopic pregnancy with systemic methotrexate.
- Follow the methotrexate protocol for tubal ectopic pregnancy.

- **Surgical methods of management are associated with a high failure rate and should be reserved for those women suffering life-threatening bleeding.**
  - Dilatation and Curettage of the cervical ectopic
    - Carries higher rates of excessive bleeding necessitating hysterectomy
    - This should be restricted to those women for whom alternative measures are unsuitable
  - Combination of uterine artery embolisation and hysteroscopic resection of the cervical ectopic
    - None of the women in this recent case series of 5 patients required blood transfusion or additional techniques. However, women should be counseled that UAE is associated with complications and there have been no long-term follow-up studies of these women
  - Combination of uterine artery ligation with systemic methotrexate or combination of uterine artery embolisation with systemic methotrexate
    - Case series report success with these methods in combination with intracervical or systemic methotrexate, but the number of cases reported is small and associated complications include infection, uterine infarction, sciatic nerve injury, and necrosis of the bladder or rectum.

**c) Caesarean scar ectopic pregnancy**

- Caesarean scar pregnancy is defined as implantation into the myometrial defect occurring at the site of the previous uterine incision.
- The prevalence of caesarean scar pregnancy is estimated to be approximately 1 in 2000 pregnancies and these pregnancies may be ongoing potentially viable pregnancies or miscarriages within the scar.
- Clinicians should be aware that ultrasound is the primary diagnostic modality, using a transvaginal approach supplemented by transabdominal imaging if required.
- The diagnostic criteria have not been subject to validation and are derived from descriptive case series, so to minimise the risk of false-positive diagnosis, we recommend that all non-emergency cases of suspected scar pregnancy are referred to a nearest regional centre to confirm the diagnosis.
• **Transvaginal scan diagnostic criteria**
  - Empty uterine cavity
  - Gestational sac or solid mass of trophoblast located anteriorly at the level of the internal os embedded at the site of the previous lower uterine segment caesarean section scar.
  - Thin or absent layer of myometrium between the gestational sac and the bladder.
  - Evidence of prominent trophoblastic/placental circulation on Doppler examination
  - Empty endocervical canal.

• **Magnetic resonance imaging (MRI) can be used as a second-line investigation if the diagnosis is equivocal and there is local expertise in the MRI diagnosis of caesarean scar pregnancies.**
  - The MRI features of caesarean scar pregnancy are essentially the same as those described on ultrasound, but ultrasound is more readily available and cheaper.

• **Serum β-hCG**
  - No biochemical investigations are needed routinely.
  - A serum β-hCG level may be useful as a baseline prior to monitoring if conservative treatment is contemplated, but it does not have a role in the diagnosis of caesarean scar pregnancy.

• **Treatment options for first trimester scar ectopics**
  - Women diagnosed with caesarean section scar pregnancies should be counseled that such pregnancies are associated with severe maternal morbidity and mortality.
    - To date, there are 35 cases of ongoing caesarean section scar pregnancies that were diagnosed in the first trimester where the women chose to continue with the pregnancy. There were 27 live births and 22 pregnancies ended with emergency hysterectomy, at gestational ages ranging from 15 to 38 weeks, due to haemorrhage and morbidly adherent placentas (*Timor-Tritsch, et al., 2015*).
    - There have also been numerous small case series and case reports of intra-abdominal rupture and severe vaginal haemorrhage at the point of diagnosis or following intervention.
    - There were six maternal deaths due to haemorrhage in women with a history of caesarean section in the 2006–08 Centre for Maternal and Child Enquiries report, although, the site of implantation was not always identified.
  - There is insufficient evidence to recommend any one specific intervention over another for caesarean scar pregnancy in the first trimester, but the current literature supports a surgical rather than medical approach as the most effective.
o **Medical treatment with methotrexate**
  - Local injection into the gestational sac under ultrasound guidance or systemically by intramuscular injection.
    1. Local injection seems to be a more effective means of terminating the pregnancy.
    2. The disadvantage of using medical treatment is that the trophoblast remains in situ; there is a risk of hemorrhage as the retained, often very vascular, placental tissue degenerates, so some authors have advocated using suction evacuation in addition to methotrexate to hasten resolution and reduce the risk of unpredictable haemorrhage in the follow-up period.

o **Surgical treatment with or without additional haemostatic measures should be considered in women with first trimester caesarean scar pregnancy.**
  - Suction evacuation of the pregnancy
    1. Most frequently described procedure.
    2. Can be combined with either: cervical cerclage, Foley catheter insertion or UAE as additional haemostatic measures.
    3. Should be done under ultrasound guidance.
  - Excision of the pregnancy as an open, laparoscopic or hysteroscopic procedure.
    1. Excisional techniques have the advantage of incorporating a repair of the scar, but these procedures are technically more difficult and invasive, and it is not known whether scar repair reduces the risk of recurrent caesarean scar pregnancy or scar rupture in future pregnancies.

o **Expectant/conservative management**
  - Suitable for women with small, nonviable scar pregnancies.
  - May be considered if the pregnancy is partially implanted into the scar and grows into the uterine cavity, provided that the woman is counseled regarding the associated potential risks, haemorrhage and morbidly adherent placentation, and she declines termination of the pregnancy.

**Second trimester caesarean scar ectopic**

- The management is complex and challenging with a high risk of maternal morbidity and hysterectomy whichever approach is taken.
- In these cases, the risk of surgical intervention must be balanced with the risks of allowing the pregnancy to continue with the aim of reaching a potentially viable gestational age. An MDT plan should be in place for all women with such pregnancies and including a care package for
morbidly adherent placenta, with a plan for emergency intervention should haemorrhage or rupture occur.

d) **Cornual pregnancy**
Cornual pregnancy is the rarest form of ectopic pregnancy with a reported incidence of 1 in 76,000 pregnancies

- **Ultrasound criteria** - the following must be seen:
  - Visualisation of a single interstitial portion of fallopian tube in the main uterine body.
  - Gestational sac/products of conception seen mobile and separate from the uterus and completely surrounded by myometrium.
  - A vascular pedicle adjoining the gestational sac to the unicorneate uterus.

- **Serum β-hCG**
  - A single serum should be carried out at diagnosis to help with management.
  - In some cases with the consultant input a repeat serum β-hCG in 48 hours may be useful in deciding further management.

- **Treatment options**
  - Cornual pregnancies should be managed by excision of the rudimentary horn via laparoscopy or laparotomy.
  - The laparoscopic technique is safe, but attention needs to be paid to the possibility of urinary tract anomalies, which can be associated with unicorneate uteri.
  - The technique involves excision of the fibrous band that attaches the rudimentary horn to the unicorneate uterus with removal of the rudimentary horn through the secondary port.
  - Methotrexate and potassium chloride injection may be given prior to later laparoscopic rudimentary horn excision.

e) **Ovarian ectopic pregnancy**

- **Ultrasound diagnostic criteria**
  - There are no specific agreed criteria for the ultrasound diagnosis of ovarian ectopic pregnancy.
  - Findings suggestive of an ovarian ectopic pregnancy on transvaginal ultrasound with an empty uterus are a wide echogenic ring with an internal anechoic area on the ovary. A yolk sac or embryo is seen less commonly.
  - It is not possible to separate the cystic structure or gestational sac from the ovary on gentle palpation (negative sliding organ sign).
  - The corpus luteum should be identified separate from the suspected ovarian pregnancy.
  - Colour Doppler may aid detection of a fetal heart pulsation within the ovary. A complex echogenic adnexal mass with free fluid in the pouch of Douglas can represent a ruptured ovarian ectopic pregnancy.
• Serum β-hCG
  o A single serum β-hCG should be carried out at diagnosis to help with management. In some cases, a repeat serum β-hCG in 48 hours may be useful in deciding further management.

• Treatment options
  o Definitive surgical treatment is preferred if laparoscopy is required to make the diagnosis of ovarian ectopic pregnancy.
    ▪ Enucleation or wedge resection
    ▪ Haemostasis by electrocautery or suturing.
    ▪ Oophorectomy is occasionally required when there is coexisting ipsilateral ovarian pathology or excessive bleeding
  o Systemic methotrexate can be used to treat ovarian ectopic pregnancy when the risk of surgery is high or postoperatively in the presence of persistent residual trophoblast or persistently raised β-hCG levels.

f) Abdominal ectopic pregnancy
• Ultrasound diagnostic criteria
  o Absence of an intrauterine gestational sac.
  o Absence of both an evident dilated tube and a complex adnexal mass.
  o A gestational cavity surrounded by loops of bowel and separated from them by peritoneum.
  o A wide mobility similar to fluctuation of the sac, particularly evident with pressure of the transvaginal probe toward the posterior cul-de-sac.
• MRI can be a useful diagnostic adjunct in advanced abdominal pregnancy
• Serum β-hCG
  o A high index of suspicion is based upon an elevated serum β-hCG level in combination with ultrasound findings.
• Treatment options
  o Laparoscopic removal is an option for treatment of early abdominal pregnancy.
    ▪ Laparoscopic treatment is a safe and effective option for the management of abdominal pregnancy when the diagnosis is made early and the site of implantation does not involve a vascular area.
    ▪ Laparoscopic management has been associated with reduced operative time, blood loss and length of hospital stay when compared with laparotomy
  o Possible alternative treatment methods would be systemic methotrexate with ultrasound-guided fetocide.
  o Methotrexate has also been used as an adjunctive treatment to surgery.
  o Advanced abdominal pregnancy should be managed by laparotomy.
    ▪ Advanced abdominal pregnancy is associated with significant maternal and fetal morbidity and mortality and once diagnosed, a laparotomy should be undertaken promptly.
    ▪ The surgical approach should be planned to avoid incision of the placenta.
- The placenta may be left in situ if the vascular attachment involves major vessels or vital structures, and spontaneous resorption awaited.
- Preserving the placenta (or ‘its retention’) is associated with significant morbidity (ileus, bowel obstruction, fistula formation, haemorrhage, peritonitis), but the mortality is lower than with its removal.
- Adjuvant treatments with methotrexate and selective arterial embolisation have been described.

g) Heterotopic pregnancy

Heterotopic pregnancies are very rare. The reported incidence in spontaneous pregnancy is around one in 30,000. In the case of assisted reproduction, however, the rate increases to 1 in 100 pregnancies.

Ultrasound diagnosis

- **A heterotopic pregnancy is diagnosed when the ultrasound findings demonstrate an intrauterine pregnancy and a coexisting ectopic**
  - Heterotopic pregnancy should be considered in all women presenting after assisted reproductive technologies,
  - Women with an intrauterine pregnancy complaining of persistent pelvic pain
  - Women with a persistently raised β-hCG level following miscarriage or termination of pregnancy.
- **Serum β-hCG level is of limited value in diagnosing heterotopic pregnancy.**
  - A higher than expected level of serum β-hCG in relation to gestational age may be suspicious of heterotopic gestations, although, the presence of a complete or partial mole must also be considered. However, in a case series of 20 heterotopic pregnancies following assisted reproductive technology, the mean β-hCG level at the time of pregnancy test was no higher than in nonheterotopic pregnancies.
- **Treatment options**
  - The intrauterine pregnancy must be considered in the management plan.
  - **In women with a viable pregnancy who do not wish to continue with the pregnancy, the Abortion Act regulations will apply.**
  - Methotrexate should only be considered if the intrauterine pregnancy is nonviable or if the woman does not wish to continue with the pregnancy.
  - Local injection of potassium chloride or hyperosmolar glucose with aspiration of the sac contents under ultrasound guidance is an option for clinically stable women.
  - Ultrasound follow-up is necessary in these women to ensure resolution of the ectopic pregnancy as β-hCG levels cannot be used.
This approach has been described for interstitial, caesarean scar and cervical heterotopic pregnancies.

- Surgical removal of the ectopic pregnancy is the method of choice for haemodynamically unstable women and is also an option for haemodynamically stable women.
- Care should be taken at the time of laparoscopy to avoid cannulation or manipulation of the uterus
- Expectant management is an option in heterotopic pregnancies where the ultrasound findings are of a nonviable pregnancy.

5.10.5 Molar Pregnancy (refer to RCOG guideline of Gestational Trophoblastic Disease)

The majority of molar pregnancies present as a first trimester miscarriage. Charing Cross Hospital found that 79% of complete moles and 29% partial moles were suspected on ultrasound prior to histological diagnosis (Fowler et al 2006).

Complete moles are diploid and the genes are entirely paternal in origin. They often present with minimal bleeding. Partial moles are triploid and usually occur following dispermic fertilisation of an ovum.

The risk of persistent trophoblastic disease following a molar pregnancy is 15-30% and 1-10% for complete and partial moles respectively. The risk of recurrent molar pregnancy of any type is 1-2% (Sebire et al 2003).

Suspected moles should be managed surgically for histological confirmation.

5.11 Recurrent miscarriage (Refer to the RCOG guideline)

Recurrent miscarriage is defined as loss of 3 or more consecutive pregnancies.

Couples with recurrent miscarriage should have fortnightly scans from six to ten weeks since reassurance and support given in early pregnancy may be beneficial.

In those with three or more miscarriages, products of conception can be sent for cytogenetic analysis. This is performed at the Wessex Regional Genetics Laboratory.
Parental karyotyping is no longer performed in our region in line with RCOG evidence.

5.12 Anti-D Prophylaxis (Refer to Anti-D guidelines)

500IU of Anti-D should be given to all non-sensitised Rhesus negative women in the following situations.

- Threatened miscarriage less than 12 weeks only if bleeding is repeated and heavy or accompanied by abdominal pain.
- Threatened miscarriages ≥ 12 weeks.
- Complete spontaneous miscarriage ≥ 12 weeks.
- Surgical and medical evacuation of retained products.
- Molar pregnancies.
- All ectopic pregnancies regardless of management.

Following potentially sensitising events, anti-D Ig should be administered as soon as possible and always within 72 hours of the event. If, exceptionally, this deadline has not been met some protection may be offered if anti-D Ig is given up to 10 days after the sensitising event.

A test for fetomaternal haemorrhage (FMH) is not required for pregnancies under 12 weeks.

6 TRAINING

Any necessary training will be provided to all relevant staff and the Consultant Leads in EPAU and Acute Gynaecologists.

7 IMPLEMENTATION

The processes described within this policy are already in place.
8 MONITORING COMPLIANCE WITH AND EFFECTIVENESS OF THIS POLICY

Monitoring compliance with and effectiveness of this policy

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9 REVIEW, RATIFICATION AND ARCHIVING

The policy will be reviewed every 3 years, or earlier if national policy or guidance changes are required to be considered. The review will then be subject to review and re-ratification.

- The Central Policy Officer or Local Policy Officer is responsible for ensuring that archive copies of superseded working documents are retained in accordance with the Records Management: NHS Code of Practice, 2009. (Refer to Policy Development and Management: including policies, procedures, protocols, guidelines, pathways and other procedural documents).

- Please note the authors’ responsibilities for archiving superseded copies. The author will ensure that a review of the document is carried out in the event of a change in circumstances or immediately prior to the expiry date.

10 DISSEMINATION AND PUBLICATION

- Dissemination of the final policy is the responsibility of the author. They must ensure the policy is uploaded to the Trust’s Central Library (TrustNet) either via their Local Policy Officer or submitted directly to the Central Policy Officer.

- The Head of Communications is responsible for the Trust-wide notification of new and revised working documents.

- Clinical Directors, Associate Directors, Specialty Business Unit (SBU) or supporting services management teams, Ward Managers and Heads of Department as applicable are responsible for distributing this policy and ensuring that all staff under their management (including bank, agency, contracted, locum and volunteers) are aware of the policy.
11 EQUALITY IMPACT ANALYSIS

The author of this policy has undertaken an Equality Impact Analysis and has concluded there is no impact identified. The Equality Analysis Initial Screening has been archived and is available via the Central Policy Officer.

12 ASSOCIATED DOCUMENTS

12.1 Consent form for disposal and examination of foetal remains

[Consent Form for Disposal of Fetal Remains]

12.2 Policy for pregnancy loss: termination of pregnancy for foetal abnormality

[Medical Termination of Pregnancy for Fetus]

12.3 Methotrexate for management of ectopic pregnancy: Prescription and administering policy

[METHOTREXATE FOR MANAGEMENT OF ECTOPIC PREGNANCY PRESCRIPTION AND ADMINISTERING POLICY]
REFERENCES


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Mol et al 1998 Serum human chorionic gonadotropin measurement in the diagnosis of ectopic pregnancy when transvaginal sonography is inconclusive. Fertil Steril 70: 972–981


NICE CG154 Guideline. Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage www.nice.org.uk. Date Published: December 2012


Sebire et al 2003. Risk of recurrent hydatidiform mole and subsequent pregnancy outcome following complete or partial hydatidiform molar pregnancy. BJOG 110 (1): 22-26


14 APPENDICES

Appendix 14.1

EARLY PREGNANCY ASSESSMENT UNIT

Miss Chimwemwe Kalumbi – Early Pregnancy Lead
Mr Osama Abughazza – Acute Gynaecological Lead
Consultant Obstetricians & Gynaecologists

The Royal Surrey County Hospital
Egerton Road
Guildford
Surrey
GU2 7XX
Tel: 01483 571122 Ext: 2321
Direct Line: 01483 402792
Fax: 01483 406649

Team: Sisters Julie Johnston Elizabeth Connold, Sophie Moxey

DIRECT FAX REFERRAL TO EPAU FOR WOMEN WITH EARLY PREGNancy PROBLEMS

** The patient’s NHS number must be entered

Patient’s Details:                          **NHS Number.............................................
Name ........................................................... Hospital Number.................................
DOB ........................................................... Home Telephone.................................
Address ........................................................ Mobile...........................................
............................................................................ OK to leave message: YES / NO

Referred by: A/E GP SHO O&G Midwife Other

Name of referring clinician: .....................

Date and time seen ........................................ Place seen: ....................................

Urinary pregnancy test positive: Yes / No  Is scan urgent: Yes / No
Gravidity ......................... Parity ....................... LMP: ............

Gestation: ........ weeks ........ days (If less than 6wks please send HCG & progesterone sample)

IVF: YES / NO

Symptoms: Bleeding: Minimal / Moderate / Heavy
Pain None / Minimal Yes (please refer to on-call SHO Bleep 0301
Need to exclude ectopic)

Significant Past Medical History:
Recurrent miscarriage: Yes / No Previous ectopic: Yes / No

Vaginal examination: Cervical os: Closed / Open
Adnexal tenderness: Yes / No

Investigations done: FBC / Group+save / HCG (if appropriate) Please send HCG & progesterone sample

Suspected diagnosis: Threatened Miscarriage/Incomplete/Missed miscarriage/Ectopic pregnancy
Other (please specify) .................................................................
Appendix 14.2

INTEGRATED CARE PATHWAY
PATIENTS UNDERGOING
SURGICAL MANAGEMENT OF MISCARRIAGE
(SMM/ERPC)

Suffering a miscarriage can be a very sad, scary or lonely experience. A miscarriage can have a profound emotional impact, not only on the woman herself, but also on her partner, friends and family. It is imperative that women and their partners and family are supported during this period. It is unacceptable for women who have opted for surgical management of miscarriage to wait days and days for their treatment. These women will automatically be booked on any consultant list within 24-48hrs.

This policy is therefore streamlines the process of booking women for surgical treatment of miscarriage (SMM).

EPAU nurses must ensure that all pre-operative assessment, consenting and necessary bloods and Anti D prescriptions are completed in EPAU prior to the patient attending for the procedure.

For complex cases – Consultant to Consultant handover is compulsory to ensure patient safety.

If subsequent follow up appointments are required, this will be arranged by EPAU nurses unless for follow up appointments that have arisen as a result of complications during surgery. These should be done under the surgeon doing the procedure or the consultant whose list the patient has been listed under.

All histology results for retained products of conception will be forwarded to the Consultant under whose list the patient is booked. Any results for patients undergoing surgical management of miscarriage under the CPOD list will be forwarded to the Consultant who is on call on the day that the procedure was carried out. Should any consents regarding any of the histology results should be directed to Miss Kalumbi or Mr Abughazza.

Theatre staff must ensure that all specimens for histology are sent with the consent form of examination and disposal of fetal remains. Specimen for cytogenetic analysis MUST NOT BE SENT IN FORMALIN. These must be put in dry leak-proof containers and correctly sealed.
Miscarriage Confirmed

Counselling on treatment options
Patient information leaflets given

Expectant Treatment
EPAU Staff book scan 2 weeks
Failed expectant management

Decides
Medical Treatment
Follow Medical Protocol
Failed medical management

By EPAU Nurse or Doctors
Surgical Treatment (ERPC/SMM)

a) Consenting
   1. Procedure
   2. Sensitive disposal of pregnancy remains
   3. Cytogenetic form
b) Bloods FBC, GP & Save
c) Pre op assessment

EPAU Nurses to contact Admissions Officer

Contact Details for EPAU
Early Pregnancy Assessment Unit, The Royal Surrey County Hospital, Egerton Road, Guildford, Surrey, GU2 7XX
Tel: 01483 571122 Ext 2321, Direct Line: 01483 402792, Fax: 01483 406649
### Appendix 14.3

#### Checklist for outpatient medical management – to be completed by the EPAU nurse and doctors

<table>
<thead>
<tr>
<th>Date and signature when completed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduce yourself, offer condolences</strong></td>
</tr>
<tr>
<td><strong>Assess for cautions and contraindications for misoprostol as per SECTION 4.2</strong></td>
</tr>
<tr>
<td><strong>Explain treatment and what to expect</strong></td>
</tr>
<tr>
<td><strong>Bleeding</strong></td>
</tr>
<tr>
<td>• can continue for up to 3 weeks, but the heaviest bleeding is usually for only a few days</td>
</tr>
<tr>
<td>• at the time of the miscarriage they may soak 4-6 sanitary towels in the first hour, then 1 pad hourly for the next 3-4 hours</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
</tr>
<tr>
<td>• will be severe period-like cramps</td>
</tr>
<tr>
<td>• will require regular painkillers as specified in the guideline</td>
</tr>
<tr>
<td><strong>Misoprostol (this will be supplied and administered in EPAU)</strong></td>
</tr>
<tr>
<td>• discuss contraindications and cautions</td>
</tr>
<tr>
<td>• advise women that it is used off-label</td>
</tr>
<tr>
<td>• generally well tolerated</td>
</tr>
<tr>
<td>• may experience abdominal pain, nausea, vomiting and diarrhoea</td>
</tr>
<tr>
<td><strong>General Information:</strong></td>
</tr>
<tr>
<td>A small proportion may require emergency admission due to heavy bleeding and may require surgical management of miscarriage</td>
</tr>
<tr>
<td><strong>Print out guidance for staff and patients on Medical Management of Miscarriage</strong></td>
</tr>
<tr>
<td><strong>Obtain written consent (see example in Appendix 4)</strong></td>
</tr>
<tr>
<td><strong>Take blood for FBC and G&amp;S (for Rhesus status)</strong></td>
</tr>
<tr>
<td>• If concerned regarding a patient’s bleeding, offer the patient inpatient management</td>
</tr>
<tr>
<td><strong>Check blood results</strong></td>
</tr>
<tr>
<td><strong>FBC: _____</strong></td>
</tr>
<tr>
<td><strong>Blood Group: _____ Rhesus Status: ____</strong></td>
</tr>
<tr>
<td><strong>Arrange administration of Anti-D for all Rhesus negative women</strong></td>
</tr>
<tr>
<td><strong>If IUCD/IUS in place, remove prior to administration of medication</strong></td>
</tr>
<tr>
<td><strong>Give misoprostol 800mcg pv</strong></td>
</tr>
<tr>
<td>• This should be administered vaginally, but can be administered orally if patient would prefer</td>
</tr>
<tr>
<td><strong>Give anti-emetics and analgesia as specified in the guideline</strong></td>
</tr>
<tr>
<td>• Analgesia</td>
</tr>
<tr>
<td>o Dihydrocodeine 30mg QDS PRN for 5 days</td>
</tr>
<tr>
<td>o Advise to buy paracetamol and Ibuprofen over the counter</td>
</tr>
</tbody>
</table>
- Paracetamol 1g QDS PRN
- Ibuprofen 400mg TDS PRN
- Antimetics
  - First line: Cyclizine 50mgs TDS for 5 days OR
  - Second line: Ondansetron 4-8 mg TDS for 5 days

Ensure the woman knows where to seek help
- If she needs advice to ring the Early Pregnancy Assessment Unit on 01483 571122 ext. 2321. EPAU is open Monday to Friday 9am to 1700pm. Out of hours in an emergency patient should be advised to contact NHS 111 or attend the nearest Accident and Emergency department. For general advice patient can ring directly to the gynaecology ward sister on Compton ward 01483571122 ext. 4941 or 6372. *(New contact details will be updated in due course)*
- Leaflet with EPAU telephone numbers, cover letter and a copy of her scan should be given to the woman.

Patient should be advised to take a pregnancy test in 3 weeks, if positive to contact the EPAU to arrange follow up.
Appendix 14.4

Checklist for inpatient medical management

At present inpatient management will be on Compton ward until further notice

This should only be offered after discussion with a Consultant. It may be patient preference to be admitted or there may be patients who want medical management in situations that are outside the criteria set out above.

This pathway assumes the woman is clinically stable and does not need immediate admission. Our aim should therefore be that all women are cared for in a side room with access to a private toilet on Compton ward

The EPAU staff nurse should arrange admission to Compton ward

<table>
<thead>
<tr>
<th>Checklist for outpatient medical management – to be completed by the EPAU nurse and doctors</th>
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</tr>
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<td>Introduce yourself, offer condolences</td>
<td></td>
</tr>
<tr>
<td>Assess for cautions and contraindications for misoprostol as per SECTION 4.2</td>
<td></td>
</tr>
<tr>
<td>Confirm that Consultant has agreed to inpatient medical management</td>
<td></td>
</tr>
<tr>
<td>Discuss with site managers about bed availability on Compton</td>
<td></td>
</tr>
<tr>
<td>Discuss with Compton to ensure side room will be available</td>
<td></td>
</tr>
<tr>
<td>Arrange with the woman where and when she will attend</td>
<td></td>
</tr>
<tr>
<td>Explain treatment and what to expect</td>
<td></td>
</tr>
<tr>
<td><strong>Bleeding</strong></td>
<td></td>
</tr>
<tr>
<td>• can continue for up to 3 weeks, but the heaviest bleeding is usually for only a few days</td>
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</tr>
<tr>
<td>• will require regular painkillers</td>
<td></td>
</tr>
<tr>
<td><strong>Misoprostol</strong></td>
<td></td>
</tr>
<tr>
<td>• 800 mcg pv to be administered on Compton ward</td>
<td></td>
</tr>
<tr>
<td>• discuss contraindications and cautions</td>
<td></td>
</tr>
<tr>
<td>• advise women that it is used off-label</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>A small proportion may require surgical management of miscarriage due to heavy bleeding</td>
<td></td>
</tr>
<tr>
<td><strong>Give leaflet – Medical Management of Miscarriage</strong></td>
<td></td>
</tr>
</tbody>
</table>
Obtain written consent (see example in Appendix 4)

Take blood for FBC and G&S (for Rhesus status)
If being admitted immediately, place a large bore cannula at the same time (minimum green, ideally grey)

Complete drug chart – after checking allergy status
Prescribe misoprostol 800mcg PV as a stat dose, if not miscarried after 24 hours, repeat dosage or surgical management
Prescribe regular oral ibuprofen and paracetamol
Prescribe regular 30mg oral dihydrocodeine QDS, 50mg cyclizine TDS PO/IM/IV or 4-8mg ondansetron TDS PO/IV
Prescribe PRN morphine sulphate oral solution 10mg PO or pethidine 50-100mg IM

If going home – ensure woman has the information leaflet, letter and scan results and is aware of how, why and where to seek help

On admission to the ward

| Ensure facilities are appropriate |
| Check that the clinical situation has not changed since last review |
| Is medical management still warranted and safe? |
| Check Hb and blood group results |
| FBC: _____ |
| Blood Group: _____ Rhesus Status: _____ |
| Administer of Anti-D within 72 hours of administration of misoprostol |
| Ensure patient has baseline observations |
| Ensure patient has intravenous access |
| Ensure any IUS/IUD has been removed |
| If woman is happy to proceed, administer misoprostol |
| The woman may choose to self-administer |
| The vaginal route is preferable to the oral route due to a better side effect profile |
| Ask woman to take low vaginal swab for NAAT (chlamydia) testing prior to giving medication. |
| Prior to discharge |
| • Ensure anti-D IM has been administered if Rhesus negative |
Appendix 14.5

Surgical Management of Miscarriage Checklist

Date: __________________________
Room patient in: __________________________ (Patient Label Here)
Time arrived: __________________________

1. Nurse to log SMM date, and note follow up call the following week in diary
   Check rhesus status
   Anti-D given if needed

2  SHO input:
   SHO to clerk patient
   SHO to consent patient

3  Follow up:
   Nurse to call patient following week.
   If Recurrent Miscarriage – GP letter recommending a Consultant referral
1 Booking patient for SMM, nurse to:

- Explain procedure and plan of care
- Give patient information leaflet 'Miscarriage' & 'SMM'
- MRSA swabs, Nose & Groin
- Discuss admission pack with patient. Patient to fill in PMH, allergies etc.
- Check Height, Weight, BMI, full set of observations
- Take bloods for: G&S, FBC
- Nurse to call admissions office to book patient onto a theatre list, or discuss beds for CEPOD with site nurse practitioner.

Admission letter given to patient

Call to SHO to attend EPAU.

Time call made:
Appendix 14.6: Defining a Missed Miscarriage: (circle and complete relevant pathway)

If the above criteria are not met, however it is felt it is clinically indicated to proceed to surgery, please obtain the responsible:

Consultant’s Name: ___________ management: ______________
Consultant’s Signature: ________________________________
Appendix 14.7: MANAGEMENT OF PREGNANCY OF UNKNOWN LOCATION

Give information

Take serum for hCG and Progesterone (Day 0)

Day 0 hCG>1000 and Prog >60
High risk for Ectopic

Repeat scan the same day by EPAU Consultant/senior examiner +/- Laparoscopy

Progesterone > 60 & hCG <1000
Or
Progesterone 10-60 & hCG > 25

Repeat hCG AT 48 HOURS

Patient to do urine pregnancy test in 2 weeks. Review in EPAU only if positive

Increase in hCG by 63% or more

Suboptimal change in hCG i.e. less than 50% decline or less than 63% increase

Clinical review within 24 hours (if this falls during the week-end, pt should be contacted and discussed with oncall Registrar/Consultant).

Repeat TV scan 7-14 days later (likely to have a developing intrauterine pregnancy)

Management can include a repeat scan by EPAU Consultant, repeat serum hCG at 72 hours or theatre if significantly symptomatic and/or developing haemodynamic compromise)

Decrease in hCG by >50%

Patient to do urine pregnancy test 14 days after second hCG

Negative
No further Action

Positive
Pt to return for clinical review in 24 hours

Decisions on further management to be decided by EPAU Consultant or Oncall Consultant.
Appendix 14.8: Medical Management of Ectopic Pregnancy – Methotrexate check list

Early Pregnancy Assessment Unit

Date: ______________
Consultant: ______________ (Patient label)
Patient’s telephone: ______________
Obstetric history: ________________________________________________________________
______________________________________________________________
LMP/gestation: ______________

<table>
<thead>
<tr>
<th>Action checklist</th>
<th>Sign</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloods taken as below day 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record height &amp; weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor to prescribe methotrexate on chemo drug chart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrange admission to Medical Day Unit (MDU) x2424</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Acute Oncology Nurses bleep 71-0727</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Aseptics x4588 &amp; take drug chart to them with blood results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order notes from Medical Records x4061</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add GP info sheet for MDU to send</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrange follow up βhCG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information sheet given to patient</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Monitoring:

<table>
<thead>
<tr>
<th>Date</th>
<th>Day</th>
<th>Bloods</th>
<th>Comments/plan</th>
<th>USS result</th>
<th>Sign</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>FBC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>U&amp;E</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>LFT</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>βhCG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 4</td>
<td>βhCG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 7</td>
<td>BhCG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Date of discharge: ______________
Signed: ______________
Designation: ______________
### Appendix 14.9: EPAU Handover

Please do not repeat a 3\textsuperscript{rd} hCG without Consultant input**

<table>
<thead>
<tr>
<th>Clinical History</th>
<th>Doctors actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Hospital number:</td>
<td></td>
</tr>
<tr>
<td>Contact number:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Hospital number:</td>
<td></td>
</tr>
<tr>
<td>Contact number:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Hospital number:</td>
<td></td>
</tr>
<tr>
<td>Contact number:</td>
<td></td>
</tr>
</tbody>
</table>

**Please do not repeat a 3\textsuperscript{rd} hCG without Consultant input**