1. **Aim/Purpose of this Guideline**

1.1. All clinical staff working in the Division of women, children & sexual health to provide evidence based guidance in the management of Ectopic Pregnancy.

1.2. This version supersedes any previous versions of this document.

1.3. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can’t rely on Opt out, it must be Opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

2. **The Guidance**

2.1. **Introduction**

Ectopic pregnancy remains one of the most common causes of pregnancy related deaths and is the most common direct cause of maternal mortality in the early pregnancy. In the 2003 – 2005 triennium, there were 10 deaths from ruptured ectopic pregnancies in the UK and 7 of these deaths were associated with substandard care.

2.1.1. Four of the woman had presented with a history of diarrhoea & vomiting preceding death and the diagnosis of ectopic pregnancy had not been considered. Thus the following recommendation has been made:

**In women of reproductive age who present to practitioners with diarrhoea and vomiting and/or fainting, the possibility of ectopic pregnancy should be considered.**

2.1.2. One death occurred in a woman with a modestly raised $\beta$HCG, an empty uterus and pelvic mass compatible with an ectopic pregnancy on scan who was an inpatient awaiting repeat $\beta$HCG, another occurred in a woman with a known ectopic pregnancy who was being treated medically and when she became symptomatic had difficulty seeking appropriate help. Thus the following recommendation has been made:
Medical treatment of ectopic pregnancy should be based on strict adherence to protocols, with women having immediate access to inpatient facilities if complications occur.

2.1.3. The incidence of ectopic pregnancy is 11/1000 pregnancies and this figure has remained static since 1994. The majority (>95%) of ectopic pregnancies are located in the Fallopian tube, 2-4% are in rarer sites (interstitial, cornual, Caesarean section scar, cervical, ovarian or abdominal implantation).

2.1.4. This guideline is going to cover primarily the diagnosis & management of TUBAL ectopic pregnancy. USS criteria & recommended management of non-tubal ectopic pregnancies is covered extensively in the RCOG Green Top Guideline ‘Diagnosis & Management of ectopic Pregnancy No 21, Nov 2016’.

2.1.5. Urine HCG assays are very sensitive, however there is a small false negative rate with urine pregnancy tests, therefore if there is any discrepancy between clinical history and urine pregnancy test (e.g. woman sure she is pregnant, but urine pregnancy tests negative), a serum βHCG should be sent.

2.2. Risk factors for ectopic pregnancy

- Previous ectopic pregnancy
- Known tubal damage e.g. due to pelvic inflammatory disease
- Assisted reproductive techniques
- Previous tubal surgery including tubal sterilisation & reversal of sterilization
- Pregnancy with IUCD in situ
- Smoking

However, the majority of women with ectopic pregnancies have no identifiable risk factors.

2.3. 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.
- **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.

### 2.4. Investigations

2.4.1. Urine pregnancy test – this needs to be done on all women with suspected ectopic pregnancy, indeed consider this test in all women with unexplained abdominal pain, whether or not she has missed a period or had abnormal bleeding.

2.4.2. Pelvic ultrasound scan – almost all women undergo a transvaginal ultrasound scan (TVS) to exclude an intrauterine pregnancy (IUP). The aim is to make a positive diagnosis by identification of a mass that moves separately to the ovary – this should be possible in the majority of cases and the woman may need to be referred for a second scan if no ectopic identified (discuss with consultant lead for EPU or consultant on call).

2.4.3. Other ultrasonographic features of an ectopic pregnancy are:

- Free fluid in the pelvis (please measure depth)

- Pseudogestation sac (secondary to bleeding in the endometrium) – can be distinguished from an early gestation sac by
  - central location in the cavity
  - absence of a yolk sac
  - absence of hyperechoic thickened endometrium seen in IUP

2.4.4. The adnexal mass has a very variable appearance and may present as a tubal ring with a live / dead embryo and / or yolk sac, an empty gestation sac or an echogenic, complex or ill-defined mass.

2.4.5. **NB.** Unless a gestation sac and yolk sac are identified in the adnexa on scan, the diagnosis of ‘Pregnancy of unknown location possible ectopic’ should be selected and serum bHCG arranged. This is to ensure the mass seen is not an atypical corpus luteum or other
ovarian / paraovarian mass and that the pregnancy is not earlier than expected.

2.4.6. In rare cases (1 in 10,000 to 50,000 spontaneous conceptions but more commonly following assisted reproductive techniques up to 1%) there may be a heterotopic pregnancy where there is a co-existing intra and extra uterine pregnancy. Check the adnexae carefully on a woman with an IUP and unilateral pain.

2.4.7. **Quantitative serum βHCG** – following TVS, if there is no evidence of an IUP, serial βHCGs should be performed according to the pregnancy of unknown location (PUL) algorithm – see PUL Guideline.

2.4.8. As a general rule, an intrauterine pregnancy can usually be seen at TVS with βHCG >1000 iu/l. However this may not be possible in some circumstances e.g. axial uterus, twin pregnancy. Therefore a cut-off of 2000 iu/l is probably safer.

85% of viable intrauterine pregnancies will show a 63% or greater rise in βHCG in every 48 hour period in the first 40 days of gestation. With an ectopic pregnancy or a non-viable IUP, the rise in βHCG is suboptimal or remains static. However 13 – 21% of all ectopic pregnancies will also show a 63% rise in βHCG in every 48 hour period. Serum progesterone levels may be helpful in the diagnosis and management of ectopic pregnancies, but should not be requested routinely but discussed with the consultant on an individual case basis.

2.4.9. **Laparoscopy** – was considered the gold standard for diagnosing ectopic pregnancy. However, with increasing quality and skills of TVS and availability of quantitative βHCG, the non-surgical diagnosis of ectopic pregnancy can be made in the vast majority of cases. Before arranging a laparoscopy for suspected ectopic pregnancy, discuss with consultant on call.

2.4.10. **Anti D Immunoglobulin**
All non-sensitised Rhesus negative women who have surgical treatment for an ectopic pregnancy should receive Anti D Immunoglobulin.

Do Not offer Anti D Immunoglobulin to women who have medical or expectant management for an ectopic pregnancy.

2.5. **Non-surgical management of ectopic pregnancy**

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

2.5.1. When an ectopic pregnancy is diagnosed / suspected, inform the consultant lead of EPU or the consultant on call to discuss proposed management.
2.5.2. **Exclusion criteria for non-surgical management of ectopic pregnancy:**

- Haemodynamically unstable
- Severe abdominal pain and suspected rupture
- Live tubal ectopic pregnancy
- Significant intraperitoneal bleeding
- Patient unable to attend for follow up

2.5.3. βHCG follow up is essential following non-surgical management and levels must be repeated weekly until negative. Ruptured ectopic pregnancies can occur even with declining or very low βHCGs. Rupture has even been reported with negative levels of serum βHCG. Therefore women who are not able to attend for follow up βHCG levels are NOT suitable for non-surgical management.

2.6. **Expectant management of ectopic pregnancy**

Expectant management can be an appropriate and successful management plan for those ectopic pregnancies that are destined to fail. The success rate largely depends upon the inclusion criteria for expectant management. Using the following inclusion criteria, up to 90% can be managed successfully without any further intervention (demonstrated by annual local audit).

2.5.4. **Inclusion criteria for expectant management of ectopic pregnancy:**

- Certain diagnosis
- Haemodynamically stable
- βHCG <2000 iu/l and falling on serial assessment
- Adnexal mass <4cm (not absolute)
- Patient able to attend for follow up (initially at 48 hours then weekly for bloods)

Intraperitoneal free fluid on TVS is not a contraindication, but need to assess the woman clinically to ensure haemodynamically stable.

2.5.5. **Counselling for woman having expectant management of ectopic pregnancy:**

- Avoid Sexual intercourse & VE (risk rupture)
• Advise of symptoms and signs of possible tubal rupture and give open access to EPU / Gynaecology ward if symptoms worsen

• Possible need for medical or surgical management fully discussed should expectant management fail – risk 10%

• Avoid pregnancy for at least two to three cycles

• Risk of subsequent ectopic pregnancy 10-15% following one previous ectopic

• Recommend USS in subsequent pregnancies at 6-7/40

2.5.6. Management

• Give RCHT patient information leaflet no. 974 entitled ‘Expectant management of your ectopic pregnancy’

• Arrange follow up appointments in EPU (or Gynaecology ward at weekends)

• Add to open access folder on Gynaecology ward

• Complete discharge letter (or viewpoint scan report) ensuring that the follow up arrangements, open access status and emergency contact numbers are written in the ‘Comments’ section

2.5.7. Follow up

• Repeat βHCG every 48 hours for the first week or at least until there is a fall of more than 20% in 48 hours

• Levels should then be checked weekly until <15iu/l

2.7. Medical management of ectopic pregnancy with methotrexate

Various agents have been used to treat ectopic pregnancy (including potassium chloride, hyperosmolar glucose, dactinomycin, misoprostol and mifepristone) but Methotrexate (MTX) is the most commonly used agent. It is a folic acid antagonist which prevents growth of rapidly dividing cells by interfering with DNA synthesis and is metabolised by the liver and excreted by the kidney.

MTX has been used extensively for the treatment of gestational trophoblastic disease and is not known to increase the risk of miscarriage, fetal malformations or secondary malignancies following treatment. 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 route is IM because of ease of administration. A single dose regime is used and in the majority of cases is adequate for successful treatment,
but in around 15% of cases a second dose may be required.

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

2.5.8. **Exclusion criteria for management of ectopic pregnancy with methotrexate**

- Uncertain diagnosis – MTX should only be given where the diagnosis is certain (i.e. 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 EPU consultant / consultant on call)

- Haemodynamically unstable

- Severe abdominal pain

- Live tubal ectopic (relative contraindication as cervical or cornual or interstitial pregnancies may be best managed medically)

- Large adnexal mass with significant free fluid in the pelvis and associated with significant pain

- Active lung, liver or kidney disease, bone marrow impairment

- Heterotopic pregnancy

2.5.9. **Inclusion criteria for management of ectopic pregnancy with methotrexate**

- Certain diagnosis

- Haemodynamically stable

- Adnexal mass <4cm (not absolute)

- βHCG >2000 iu/l or rising following expectant management

- Normal platelets, WBC, U&E’s, LFT’s

- Able to attend follow-up

2.5.10. **Management protocol for treatment with methotrexate**

- Discuss with EPU consultant or consultant on call

- Informed, written consent (use pre-printed consent forms found in EGU or on shared drive see Appendix 3)
• Check no contraindications (active kidney, liver or lung disease, bone marrow impairment, clinical signs of rupture)

• Dose 50mg/m² IM (to calculate this you need the height (cm) and weight (kg) of the woman and use the chart on the ward) to a maximum of 100mg dose (see Chart at Appendix 6). Doses should be rounded to the nearest 10mg as per the dose banding schedule below:

<table>
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<tr>
<th>SURFACE AREA (m²)</th>
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<tr>
<td>1.3 – 1.49</td>
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<tr>
<td>1.5 – 1.69</td>
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<tr>
<td>1.7 – 1.89</td>
<td>90mg</td>
</tr>
<tr>
<td>&gt; 1.9</td>
<td>100mg</td>
</tr>
</tbody>
</table>

• Repeat βHCG Day 4 & 7. βHCG often goes up initially between days one and 4 following administration of MTX – this is likely to be a normal response to MTX:
  o If fall >15% Day 4 to 7 – weekly βHCG to <25 iu/l
  o If rise βHCG or decline <15% - further dose MTX
  o If very high initial βHCG (>5,000 iu/l or doubling between day 1 and 4) consider a second dose of MTX on Day 4 (discuss with lead consultant for EPU / consultant on call)

• During follow up if there is no adequate fall in weekly βHCG, a further dose should be given

2.5.11. Counselling for women receiving methotrexate

• Side Effects (nausea, gastric disturbance, tiredness, abdominal pain, vaginal bleeding, dermatitis, stomatitis, skin rashes, photosensitivity, pneumonitis, bone marrow suppression, hepatotoxicity)

• Failure rate & need for surgery – 10%

• Length of time follow up required (sometimes 6 – 8 weeks)

• Possible need for repeat doses (around 15%)

• Avoid vitamin preparations containing folic acid, alcohol, sexual intercourse, vaginal examination & foods likely to cause gaseous abdominal distension (e.g. cabbage and leeks)

• Use effective contraception for at least 2 months after follow up is complete and at least 3 months after last injection
2.5.12. **Side effects of Methotrexate**

Side effects are dose dependent and common after multiple doses. Serious side effects are rare following single dose MTX. If multiple doses are required, folinic acid rescue should be considered to reduce the incidence of side effects. With single dose MTX, folinic acid rescue is not necessary.

- 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 patients are asked to avoid these foods
- Nausea, vomiting, stomatitis, dermatitis
- Skin rashes, photosensitivity, pneumonitis
- Bone marrow depression and hepatotoxicity – very rare and usually reversible

2.5.13. **Acute abdominal pain following non-surgical 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.

2.5.14. **Differential diagnosis of abdominal pain**

- Side effect of MTX
- Intraperitoneal bleeding – leaking ectopic pregnancy / tubal miscarriage / tubal rupture

2.5.15. **Management**

- Admit for in-patient observation if pain moderate to severe requiring analgesia
- Clinical assessment 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 indication for surgical intervention

2.5.16. Follow up arrangements

• Arrange follow up appointment for repeat bloods (EPU or Gynaecology ward at weekends)

• Add to ‘open access’ file on Gynaecology ward

• Complete a discharge letter (copy for patient) and clearly state follow up appointments and emergency contact numbers of the ward in the ‘comments’ section

• Give RCHT patient information leaflet No. 975 entitled ‘Medical Management of your ectopic pregnancy’

• Repeat βHCGs arranged Day 4 and 7 following first MTX dose and then weekly thereafter until the level is below 15 iu/l

• Open access to the ward / EPU

• Inform EPU consultant lead or consultant on call of any problems

2.5.17. Prescribing and supply of Methotrexate

• MTX should be prescribed via the out-patient module of EPMA by selecting the appropriate strength of “Methotrexate for ectopic pregnancy”

• All decisions to administer MTX should be made by the consultant (either Miss Verity as EPU lead or the consultant on call) and this needs to be documented in the patient notes. Once this has been done, the SHO / registrar may sign the prescription

• Contact the pharmacist Sabrina Tierney (Bleep 3238) to arrange supply by 12.00 noon

• The methotrexate is collected from main pharmacy and comes double wrapped in a rigid sealed container marked “CYTOTOXIC DRUGS”

• If the drug is not to be given return the unopened box to pharmacy immediately but note that it has an expiry of 24 hours

2.5.18. Handling and administration of MTX

All persons handling and administering Methotrexate must have been trained in the safe storage and handling of the drug and be suitably dressed in protective clothing, (Long sleeved gown, nitrile gloves, protective eye wear). If you have not been trained, there are a
number of nurses on the ward who have, so please seek help.

NB. The drug should not be handled by anyone who is pregnant, trying to get pregnant or breast feeding.

The woman receiving the drug should be informed of the reasons, why protective clothing and precautions are required:

Assemble all equipment on an empty trolley:

- Disposable Nitrile gloves
- Long sleeved disposable gown
- Plastic apron
- Protective eye wear
- Small Sharps container
- Tape marked cytotoxic
- Disposable injection tray
- 2 x 21G X 1half needles
- Cotton wool balls
- Prescription sheet

At the bedside:

- put on protective clothing
- check the woman’s identity
- check the drug and dosage according to guidelines
- prepare injection by removing the syringes from the container and wrapping
- remove protective cap and attach sterile needle ( luer lock )
- Give one injection into the buttock by deep intra-muscular injection
- sign prescription sheet and complete documentation as appropriate

NB If spillage occurs then refer to the RCHT Health and Safety Guidelines - available on the Intranet Document Library – under Health & Safety then "Arrangements for Cytotoxic Drugs". A cytotoxic spillage kit is available
on the ward.

2.5.19. Following administration

- Place used syringe straight into the sharps container without touching the needle
- LOCK the container and seal with tape marked cytotoxic (supplied). Dispose of as SPECIAL CYTOTOXIC WASTE.
- The nurse should be aware of all necessary precautions required when using Methotrexate or caring for a woman who has been treated with Methotrexate Personnel handling patient samples, including blood, urine and faeces should take the same precautions as those required for infection control i.e. gloves and apron.

2.8. Surgical Management of Ectopic pregnancy

When surgical management of an ectopic pregnancy is decided (see indications below) laparoscopic salpingectomy is the surgical operation of choice in a haemodynamically stable women. It is important to ensure that the whole length of the tube is removed to prevent another ectopic in the proximal stump. Salpingotomy may be considered if there are other risk factors for infertility (e.g. contralateral tubal damage) or if the woman requests this. Laparotomy should be performed if woman is haemodynamically unstable or complications occur at laparoscopy. Always comment in the operative notes on the state of the contralateral tube noted at surgery. This can help to give important information of future fertility outcome.

2.5.20. Indications for surgery

- Haemodynamically unstable – immediate surgery indicated to stop the intraperitoneal bleeding
- Severe abdominal pain – suspected tubal rupture
- Live tubal ectopic pregnancy – high risk of rupture
- Patient not suitable for MTX (abnormal LFTs, U&Es, active lung/liver/kidney disease or women unable to attend for follow up)
- Large complex adnexal mass with significant free fluid and moderate to severe abdominal pain
- Recurrent ectopic pregnancy of same tube (increased risk for further ectopic pregnancy, though not an absolute contraindication)
- Patient choice (e.g. family complete)
• Known severe tubal damage (high risk of recurrence)

Consent for surgery should be obtained using the pre-printed consent forms available in EGU or on the shared drive (see Appendix 4). Include discussion of preservation/removal of tube and include risks:

• Infection
• Bleeding
• Damage to adjacent structures e.g. bladder, bowel, blood vessels
• Laparotomy
• Oophorectomy
• Sensitive disposal of pregnancy tissue

Where the tube has been preserved (salpingotomy / ‘milking’ of the tube), there is a risk (up to 1 in 5) of persistent trophoblastic activity and need for further treatment (methotrexate or salpingectomy). Follow up βHCGs should be arranged weekly until <15 iu/l.

If a salpingectomy is done, please advise the patient to undertake a urine pregnancy test at 3 weeks following the surgery and ring EGU if still positive.

Give RCHT patient information leaflet No 976 entitled ‘surgical management of your ectopic pregnancy’.

2.5.21. Specimen

The specimen should be sent for histological evaluation accompanied by a signed & fully completed collective cremation form (see Appendix 5) once written informed consent for this has been obtained (covered in the standard pre-printed consent form – Appendix 2). If the woman declines collective cremation, contact the bereavement office for further advice.

2.9. Future Fertility

Future fertility is impaired in women who’ve had a previous ectopic pregnancy. The rates of successful IUP depend upon whether the tube was removed/conserved and the condition of the other tube. Overall, we can counsel for an approximately 60% chance of successful IUP but up to 15% chance of subsequent ectopic pregnancy.

Therefore all women should be counseled to have an early scan (around 6/40) in a subsequent pregnancy. This currently should be arranged in the main USS department not the EPU.
3. **Monitoring compliance and effectiveness**

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Review of all cases using the ectopic audit proforma</th>
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<tr>
<td>Lead</td>
<td>Miss Lisa Verity, Consultant O&amp;G</td>
</tr>
<tr>
<td>Tool</td>
<td>Ad hoc monitoring of EGU / EPU database as part of routine activity</td>
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<td>Frequency</td>
<td>Biannual review presented at the monthly EGU &amp; EPU MDT</td>
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<td>Reporting arrangements</td>
<td>EGU / EPU MDT Dashboard Women’s &amp; Newborn Audit meeting</td>
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<td>Acting on recommendations and Lead(s)</td>
<td>EGU &amp; EPU MDT</td>
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<td>Change in practice and lessons to be shared</td>
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4. **Equality and Diversity**

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘*Equality, Inclusion & Human Rights Policy*’ or the *Equality and Diversity website*.

4.2. **Equality Impact Assessment**
The Initial Equality Impact Assessment Screening Form is at Appendix 2.
**Appendix 1. Governance Information**

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<th>Ectopic Pregnancy Diagnosis and Management Clinical Guideline V2.0</th>
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<tr>
<td>Date Issued/Approved:</td>
<td>October 2019</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>January 2020</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>January 2023</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Miss Lisa Verity Consultant O&amp;G</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252685</td>
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<tr>
<td>Brief summary of contents</td>
<td>All clinical staff working in the Division of women, children &amp; sexual health to provide evidence based guidance in the management of ectopic pregnancy</td>
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<tr>
<td>Suggested Keywords:</td>
<td>Ectopic Pregnancy, methotrexate, salpingectomy</td>
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<td>RCHT</td>
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<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>October 2019</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Ectopic Pregnancy - Clinical Guideline V1.1</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Obstetric &amp; Gynaecology Directorate meeting</td>
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<tr>
<td>Care Group General Manager confirming approval processes</td>
<td>Debra Shields</td>
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<tr>
<td>Name and Post Title of additional signatories</td>
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<tr>
<td>Name and Signature of Care Group/Directorate Governance Lead confirming approval by specialty and care group management meetings</td>
<td>{Original Copy Signed}</td>
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<tr>
<td>Name: Caroline Amukusana</td>
<td></td>
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<tr>
<td>Signature of Executive Director giving approval</td>
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<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
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<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical / Gynaecology</td>
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### Links to key external standards

1. Ectopic pregnancy & miscarriage: Diagnosis and initial management. NICE clinical guideline 154. Dec 2012

### Related Documents:

- Ectopic pregnancy & miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy & miscarriage. NICE clinical guideline 154. Dec 2012

### Training Need Identified?

No

### Version Control Table

<table>
<thead>
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<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<td>V1.0</td>
<td>Initial Issue</td>
<td>Lee Azancot Data Administrator</td>
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<tr>
<td>11/04/2017</td>
<td>V1.1</td>
<td>Minor changes</td>
<td>Lisa Verity Consultant</td>
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All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry. This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
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<th>Ectopic Pregnancy Diagnosis and Management Clinical Guideline V2.0</th>
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<td>Directorate and service area:</td>
<td>Gynaecology</td>
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<tr>
<td>New or existing document:</td>
<td>Existing</td>
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<tr>
<td>Name of individual completing assessment:</td>
<td>Miss Lisa Verity</td>
</tr>
<tr>
<td>Telephone:</td>
<td>01872 252685</td>
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</tbody>
</table>

1. **Policy Aim***
   - Who is the strategy / policy / proposal / service function aimed at?
   - All clinical staff working in the Division of women, children & sexual health to provide evidence based guidance in the management of ectopic pregnancies

2. **Policy Objectives***
   - As above

3. **Policy – intended Outcomes***
   - As above

4. *How will you measure the outcome?
   - See section 3

5. **Who is intended to benefit from the policy?**
   - All obs & gynae patients

6a. Who did you consult with
   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other

<table>
<thead>
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<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
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   **Please record specific names of groups**
   - Obstetrics and Gynaecology Specialty meeting

   **What was the outcome of the consultation?**
   - Guideline approved

7. **The Impact**
   - Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

   | Are there concerns that the policy could have differential impact on: |
   | --- | --- | --- | --- | --- |
   | Equality Strands: | Yes | No | Unsure | Rationale for Assessment / Existing Evidence |
   | Age | x | | | |

Ectopic Pregnancy Diagnosis and Management Clinical Guideline V2.0
Page 18 of 29
<table>
<thead>
<tr>
<th><strong>Sex (male, female, trans-gender / gender reassignment)</strong></th>
<th>x</th>
<th>Any information provided should be in an accessible format for the patient’s needs – i.e. available in different languages if required/access to an interpreter if required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race / Ethnic communities /groups</strong></td>
<td>x</td>
<td>Those patients with any identified additional needs will be referred for additional support as appropriate - i.e. to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family’s needs e.g. easy read, audio etc.</td>
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<tr>
<td><strong>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</strong></td>
<td>x</td>
<td>All staff should be aware of any beliefs that may impact on the decision to treat, and respond accordingly.</td>
</tr>
<tr>
<td><strong>Religion / other beliefs</strong></td>
<td>x</td>
<td>All staff should be aware of any beliefs that may impact on the decision to treat, and respond accordingly.</td>
</tr>
<tr>
<td><strong>Marriage and Civil partnership</strong></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>Pregnancy and maternity</strong></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</strong></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

**You will need to continue to a full Equality Impact Assessment if the following have been highlighted:**
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. | Yes | No | x

9. If you are **not** recommending a Full Impact assessment please explain why.

<table>
<thead>
<tr>
<th><strong>Date of completion and submission</strong></th>
<th>16/10/2019</th>
<th>Members approving screening assessment</th>
<th>Policy Review Group (PRG)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>‘APPROVED’</td>
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</tbody>
</table>

*This EIA will not be uploaded to the Trust website without the approval of the Policy Review Group.*

A summary of the results will be published on the Trust’s web site.*
Appendix 3. Medical Management of Ectopic Pregnancy of Unknown Location with Methotrexate Consent Form

CONSENT FORM 1 (Patient copy)
Procedure Specific Patient Agreement

Medical management of ectopic pregnancy or pregnancy of unknown location (presumed ectopic pregnancy) with Methotrexate and attending follow up appointments

To treat ectopic pregnancy or pregnancy of unknown location

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient, in particular, I have explained the intended benefits and summarised the risks, as below:

- To treat ectopic pregnancy or pregnancy of unknown location with an injection of medication called methotrexate

Significant, unavoidable or likely to occurinig risks:
- Side effects of methotrexate (abdominal pain, vaginal bleeding, nausea, vomiting)
- Need for a repeat dose (1 in 10)
- Bleeding into the abdomen after failure of treatment requiring surgery (1 in 10 cases)

Uncommon but major or serious risks:
- Rarer side effects of methotrexate (dermatitis, stomatitis, skin rash, photosensitivity, pneumonitis, bone marrow depression, hepatotoxicity)

Any extra procedures which may become necessary during the procedure:
- Blood transfusion
- Other procedure (please specify)
- Surgery - laparoscopy (keyhole surgery) or laparotomy (open operation) if bleeding into the abdomen suspected

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust’s approved patient information leaflet for this procedure, reference number CHA975, along with a copy of this consent

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve:
- General anaesthesia
- Local anaesthesia
- Sedation

Health Professional signature: ________________________________ Date: ________________

Name (PRINT): ________________________________ Job title: ________________________________

STATEMENT OF INTERPRETER (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ________________________________ Name (PRINT): ________________________________ Date: ________________
## CONSENT FORM 1 (Patient copy)

### Procedure Specific Patient Agreement

Medical management of ectopic pregnancy or pregnancy of unknown location (presumed ectopic pregnancy) with Methotrexate and attending follow up appointments

### STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page one which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment describe on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to avoid serious harm to my health.

I understand that tissue samples may only be taken in relation to the procedure explained to me. No samples will be taken for research, clinical education or teaching purposes.

I have been told about all the procedures which may become necessary during my treatment. I have listed below all the procedures which I do not wish to have carried out without further discussion.

I have received a copy of the Consent Form Patient Information leaflet CHA975 which forms part of this document.

Patient signature: ______________________________ Name (PRINT): ______________________________ Date: ______________________________

A witness should sign below if this patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see guidance notes).

Witness signature: ______________________________ Name (PRINT): ______________________________ Date: ______________________________

### CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: ______________________________ Date: ______________________________

Name (PRINT): ______________________________ Job title: ______________________________

### Important notes (tick if applicable):

- [ ] See advance decision to refuse treatment
- [ ] Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ______________________________ Name (PRINT): ______________________________ Date: ______________________________
CONSENT FORM 1 (file copy)
Procedure Specific Patient Agreement

Medical management of ectopic pregnancy or pregnancy of unknown location (presumed ectopic pregnancy) with Methotrexate and attending follow up appointments

To treat ectopic pregnancy or pregnancy of unknown location

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- To treat ectopic pregnancy or pregnancy of unknown location with an injection of medication called methotrexate

Significant, unavoidable or frequently occurring risks:

- Side effects of methotrexate (abdominal pain, vaginal bleeding, nausea, vomiting)
  Need for a repeat dose (1 in 5).
  Bleeding into the abdomen or failure of treatment requiring surgery (1 in 10 cases).

Uncommon but more serious risks:

- Rarer side effects of methotrexate (cellulitis, skin rash, photosensitivity, pneumonitis, bone marrow suppression, hepatic failure)

Any extra procedures which may be necessary during the procedure:

- Blood transfusion
  - May be necessary
- Other procedure (please state - e.g. surgery, laparoscopy, video surgery) or laparotomy (open operation) if bleeding into the abdomen suspected

I have also discussed with the patient the procedure is likely to involve the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given the patient information leaflet for this procedure, reference number CHA975, along with a copy of this consent

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve:

General and/or regional anaesthesia  □ Local anaesthesia  □ Sedation  □

Health Professional signature: □
Name (PRINT): □
Job title: □

Date: □

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: Name (PRINT): Date: □
**CONSENT FORM 1 (File copy)**

Procedure Specific Patient Agreement

**Medical management of ectopic pregnancy or pregnancy of unknown location (presumed ectopic pregnancy) with Methotrexate and attending follow up appointments**

**STATEMENT OF PATIENT**

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page one which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask—we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment describe on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described in this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for research, clinical education or teaching purposes.

I have been told about additional procedures which may be considered necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet CHA975 which forms part of this document.

**Patient signature:**

**Name (PRINT):**

**Date:**

A witness should sign below if this patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see guidance notes).

**Witness signature:**

**Name (PRINT):**

**Date:**

**CONFIRMATION OF CONSENT** (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

**Health Professional signature:**

**Date:**

**Name (PRINT):**

**Job title:**

**Important notes (tick if applicable):**

- [ ] See advance decision to refuse treatment
- [ ] Patient has withdrawn consent (ask patient to sign/date here)

**Patient signature:**

**Name (PRINT):**

**Date**
Appendix 4. Laparoscopic Treatment of Ectopic Pregnancy-Removal of Ectopic and/or Damaged Fallopian Tube Consent Form

CONSENT FORM 1 (Patient copy)
Procedure Specific Patient Agreement

Laparoscopic treatment of ectopic pregnancy - removal of ectopic and/or damaged Fallopian tube
use of keyhole surgery to investigate and treat ectopic pregnancy

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy):

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- To treat ectopic pregnancy and remove damaged Fallopian tube

Significant, unavoidable or frequently occurring risks:

- Bruising, shoulder tip pain, wound gaging, wound infection
- Inability to identify an obvious cause for presenting complaint
- Persistent trophoblastic tissue

Uncommon but more serious risks:

- The overall risk of serious complications from laparoscopy is approximately 1 in 1000
- Damage to bladder, bowel, or major blood vessels which may require immediate repair by laparoscopy or laparotomy (excision); up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy
- Failure to gain entry to abdominal cavity and complete operation
- Three to eight women in every 100,000 undergoing laparoscopy could die as a result of complications
- Hemia at site entry

Any extra procedures which may become necessary during the procedure:

- Blood transfusion required in around 1%
- Other procedure (please specify): laparotomy, repair of damage to bowel, bladder, uterus or blood vessels

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust’s approved patient information leaflet for this procedure, reference number CHA976, along with a copy of this consent

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve:
- General and/or regional anaesthesia [X] Local anaesthesia [ ] Sedation [ ]

Health Professional signature: __________________________ Date: __________________________

Name (PRINT): __________________________ Job title: __________________________

STATEMENT OF INTERPRETER (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: __________________________ Name (PRINT): __________________________ Date: __________________________
Laparoscopic treatment of ectopic pregnancy - removal of ectopic and/or damaged Fallopian tube

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page one which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment describe on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand tissue samples may be taken for analysis and kept as part of my patient record. Any sample arising from a pregnancy will be treated with dignity and respect. The hospital will arrange for collective cremation of the tissue on conception (unless otherwise indicated here that a separate consent has been taken).

I have been told about all other procedures which may become necessary during my treatment. I have listed below all procedures which I do not wish to be carried out without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet CHA976 which forms part of this document.

Patient signature: Name (PRINT): Date:

A witness should sign below if this patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see guidance notes).

Witness signature: Name (PRINT): Date:

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: Date:

Name (PRINT): Job title:

Important notes (tick if applicable - ask patient to sign/date here):
- See advance decision to refuse treatment
- Patient has withdrawn consent

Patient signature: Name (PRINT): Date
Laparoscopic treatment of ectopic pregnancy - removal of ectopic and/or damaged Fallopian tube

use of keyhole surgery to investigate and treat ectopic pregnancy

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- To treat ectopic pregnancy and remove damaged Fallopian tube

Significant, unavoidable or frequently occurring risks:
- Bruising, shoulder tip pain, wound going, wound infection
- Difficulty in identifying an obvious cause for presenting complaint
- Persistent trophoblastic tissue

Uncommon but more serious risks:
- The overall risk of serious complications from laparoscopy is approximately 2 in 1000
- Damage to bladder, bowel, uterus or major blood vessels which would require immediate repair by laparoscopy or laparotomy (uncommon): up to 15%
- Bowel injuries might not be diagnosed at the time of laparoscopy
- Failure to gain entry to abdominal cavity and complete operation
- Three to eight women in every 1000 undergoing laparoscopy could develop one or more complications
- Hematoma at site of entry

Any extra procedures which may become necessary during the procedure:
- Blood transfusion rate: approx 10%
- Other procedures which may be required: Laparotomy, repair of damage to bowel, bladder, uterus or blood vessels

I have also explained that the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment), and all particular concerns of this patient.

I have given and discussed the Trust’s approved patient information leaflet for this procedure, reference number CHA976, along with copies of this consent.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve:
- General anaesthesia
- Local anaesthesia
- Sedation

Health Professional signature: ___________________________ Date: ____________

Name (PRINT): ___________________________ Job title: ___________________________

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient in the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ___________________________ Name (PRINT): ___________________________ Date: ____________
CONSENT FORM 1

Ectopic Pregnancy Diagnosis and Management Clinical Guideline V2.0

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Appendix 5. Certificate of Medical Practitioner or Midwife in Respect of Foetal Remains

Certificate of Medical Practitioner or Midwife in Respect of Fetal Remains

(The products of conception expelled from the uterus before 24 weeks gestation which showed no visible signs of life)

I hereby certify that I have examined the fetal remains whose details are shown below:
Delivered on ........................................ (Date) at ...................................... am/pm of .................................. weeks gestation and which at no time showed any visible signs of life. Place of delivery ..................................................

I have no reason to suspect that the duration of pregnancy was shortened by violence, poison or any unlawful act and I knew of no reason why any further examination or enquiry should be made.

Tick one box

I confirm that informed written consent for collective cremation has been obtained. (Complete sections A & B) 

I confirm that informed written consent for a private funeral has been obtained. The mother/parents understand that they may contact the Hospital Bereavement Office to discuss the options available and/or any financial concerns they may have. (Complete sections A & C)

A) Doctor/Midwife details

Print Name .................................................. Signature ..................................................

Registered qualifications .................................. Date ..................................................

Workplace .................................................. Tel ..................................................

(Mother's details to be removed by bereavement office if remains are for collective cremation)

Funeral Arrangements

As explained these are the options available to you, please indicate your preference below:

B) The mother/parents would like the hospital to arrange collective cremation by means of a monthly collective cremation together with other issue of conception only.

C) The mother/parents would like to make private funeral arrangements. They will instruct a funeral director and advise the bereavement office accordingly within one month.

Affix Patient Label

Procedure for the sensitive disposal of pre-24 week fetal tissue
## Appendix 6. Body Surface Area Chart

<table>
<thead>
<tr>
<th>Height in Centimetres</th>
<th>Wt in Kg</th>
<th>140</th>
<th>142</th>
<th>144</th>
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