Royal Cornwall Hospitals NHS Trust

Policy Under Review

Please note that this policy is under review. It does, however, remain current Trust policy subject to any recent legislative changes, national policy instruction (NHS or Department of Health), or Trust Board decision. For guidance, please contact the Author/Owner.

Information Category	Detailed Information
Document Title:	Ectopic Pregnancy Diagnosis and Management Clinical Guideline V3.1.
This document replaces (exact title of previous version):	Ectopic Pregnancy Diagnosis and Management Clinical Guideline V3.0.
Date Issued / Approved:	December 2023.
Date Valid From:	December 2023.
Date Valid To:	March 2026.
Author / Owner:	Sarah Eddy Advanced Nurse Practitioner EGU/ EPU.
Contact details:	01872 252686 rch-tr.egu@nhs.net
Brief summary of contents:	All clinical staff working in the Women, Children and HIV Care Group to provide evidence based guidance in the management of ectopic pregnancy.
Suggested Keywords:	Ectopic Pregnancy. Methotrexate. Salpingectomy.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Gynaecology Specialty Meeting.
Manager confirming approval processes:	Caroline Chappell.

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Information Category	Detailed Information
Name of Governance Lead confirming consultation and ratification:	Melanie Gilbert.
Links to key external standards:	1. Ectopic pregnancy and miscarriage: Diagnosis and initial management. NICE clinical guideline 154. Dec 2012. 2. Diagnosis and Management of Ectopic Pregnancy, RCOG Green Top Guideline No. 21. Nov 2016.
Related Documents:	Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. NICE clinical guideline 154. Dec 2012.
Training Need Identified:	No.
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Ectopic Pregnancy Diagnosis and Management Clinical Guideline

V3.1

December 2023

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1. Aim/Purpose of this Guideline

1.1. All clinical staff working in the Women, Children and HIV Care Group to provide evidence based guidance in the management of ectopic pregnancy.

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

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

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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 women had presented with a history of diarrhoea and 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 βHCG, an empty uterus and pelvic mass compatible with an ectopic pregnancy on scan who was an inpatient awaiting repeat βHCG, 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 in-patient 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 and management of TUBAL ectopic pregnancy. USS criteria and recommended management of non-tubal ectopic pregnancies is covered extensively in the RCOG Green Top Guideline 'Diagnosis and 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 and reversal of sterilization.
- Pregnancy with IUCD (intrauterine contraceptive device) 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

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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 (Emergency Pregnancy Unit) or consultant on call).

2.4.3. Other ultrasonographic features of an ectopic pregnancy are:

- Free fluid in the pelvis (please measure depth).

- Pseudo gestation 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. N.B., 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%)

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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. **Quantative 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 quantative 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.

2.4.0. When an ectopic pregnancy is diagnosed / suspected, inform the consultant lead of EPU or the consultant on call to discuss proposed management.

2.4.1. Exclusion criteria for non-surgical management of ectopic pregnancy:

- Haemodynamically unstable.
- Severe abdominal pain and suspected rupture.

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- Live tubal ectopic pregnancy.
- Significant intraperitoneal bleeding.
- Patient unable to attend for follow up.

2.4.2. 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).

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

- Certain diagnosis.
- Haemodynamically stable.
- βHCG <1000iu/l (or consider <1500iu/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.

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

- Avoid Sexual intercourse and 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.

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

2.4.2. 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.

2.4.3. 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 to ensure the patient is suitable for medical management, methotrexate. This is primarily as a reference for subsequent monitoring. With BhCG levels of >5000iu/l, there is greater risk of tubal rupture, so surgical management is the first line of recommended treatment.

2.7.1. 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).

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- 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.
- BhCG >5000 iu/l.

2.7.2. **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 and E's, LFT's.
- Able to attend follow-up.

2.7.3. **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:

SURFACE AREA (m^2)	DOSE
1.3 – 1.49	70mg
1.5 – 1.69	80mg
1.7 – 1.89	90mg
> 1.9	100mg

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- Repeat βHCG Day 4 and 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:
    - If initial βHCG doubles between days 1 and 4 discuss with lead consultant / consultant on-call and consider surgical management or a second dose of MTX on Day 4.
    - If fall >15% Day 4 to 7 – weekly βHCG to <25 iu/l.
    - Between days 4 to 7, if there is a rise in βHCG or decline <15% - then discuss with the lead consultant / consultant on call and consider the patient's suitability for MTX or give a second dose on day 7.
- During follow up if there is no adequate fall in weekly βHCG, a further dose of MTX should be given should be given.

2.7.4. 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 and 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, and 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.

2.7.5. 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.

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- Nausea, vomiting, stomatitis, dermatitis.
- Skin rashes, photosensitivity, pneumonitis.
- Bone marrow depression and hepatotoxicity – very rare and usually reversible.

2.7.6. 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.

2.7.7. Differential diagnosis of abdominal pain

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

2.7.8. 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’.

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- 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.

2.7.9. **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.

2.7.10. **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.

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- 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 and Safety then "Arrangements for Cytotoxic Drugs". A cytotoxic spillage kit is available on the ward.

2.7.11. **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

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(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.

2.8.1. 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 and 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

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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'.

2.8.2. Specimen

The specimen should be sent for histological evaluation accompanied by a signed and 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 counselled 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

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Review of all cases using the ectopic audit proforma.
Lead	Sarah Eddy Advanced Nurse Practitioner EGU / EPU.
Tool	Ad hoc monitoring of EGU / EPU database as part of routine activity.
Frequency	Biannual review presented at the monthly EGU and EPU MDT.
Reporting arrangements	EGU / EPU MDT. Dashboard. Women's and Newborn Audit meeting.

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Information Category	Detail of process and methodology for monitoring compliance
Acting on recommendations and Lead(s)	EGU and EPU MDT.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

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 Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

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Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Ectopic Pregnancy Diagnosis and Management Clinical Guideline V3.1.
This document replaces (exact title of previous version):	Ectopic Pregnancy Diagnosis and Management Clinical Guideline V3.0.
Date Issued/Approved:	December 2023.
Date Valid From:	December 2023.
Date Valid To:	December 2025.
Directorate / Department responsible (author/owner):	Sarah Eddy Advanced Nurse Practitioner EGU/ EPU.
Contact details:	01872 252686 rch-tr.egu@nhs.net
Brief summary of contents:	All clinical staff working in the Women, Children and HIV Care Group to provide evidence based guidance in the management of ectopic pregnancy.
Suggested Keywords:	Ectopic Pregnancy. Methotrexate. Salpingectomy.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Gynaecology Specialty Meeting.
General Manager confirming approval processes:	Caroline Chappell.
Name of Governance Lead confirming approval by specialty and care group management meetings:	Melanie Gilbert.
Links to key external standards:	3. Ectopic pregnancy and miscarriage: Diagnosis and initial management. NICE clinical guideline 154. Dec 2012. 4. Diagnosis and Management of Ectopic

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Information Category	Detailed Information
	Pregnancy, RCOG Green Top Guideline No. 21. Nov 2016.
Related Documents:	Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. NICE clinical guideline 154. Dec 2012.
Training Need Identified?	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical/ Gynaecology.

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Date	Version Number	Summary of Changes	Changes Made by
11 Jun 14	V1.0	Initial Issue.	Lee Azancot, Data Administrator
11/04/2017	V1.1	Minor changes.	Lisa Verity, Consultant
20/04/2019	V2.0	Full review. Updated pharmacy section and addition of dose banding for methotrexate. Formatting updated.	Lisa Verity, Consultant. Sabrina Tierney, Pharmacist.
November 2022	V3.0	Updated conservative management BhCG values.	Sarah Eddy, ANP
November 2023	V3.1	Section 2.7.1 updated. Formatting updated.	Sarah Eddy, ANP

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All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

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Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

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Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Ectopic Pregnancy Diagnosis and Management Clinical Guideline V3.1.
Directorate and service area:	Gynaecology.
Is this a new or existing Policy?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Sarah Eddy Advanced Nurse Practitioner EGU/ EPU.
Contact details:	01872 252686 rch-tr.egu@nhs.net

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	All clinical staff working in the Women, Children and HIV Care Group 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 each outcome?	See section 3.
5. Who is intended to benefit from the policy?	All obstetrics and gynaecology patients.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No

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Information Category	Detailed Information
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Gynaecology Specialty Meeting
6c. What was the outcome of the consultation?	Approved- 28 November 2023
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	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.
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	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.
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat and respond accordingly.

UNDER REVIEW

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Sarah Eddy; Advanced Nurse Practitioner EGU/ EPU

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

UNDER REVIEW

Appendix 3. Medical Management of Ectopic Pregnancy of Unknown Location with Methotrexate Consent Form

CHA4531: Consent Form 1 - Medical management of ectopic pregnancy or pregnancy of unknown location (presumed ectopic pregnancy) with Methotrexate and attending follow up appointments (cornwall.nhs.uk)

UNDER REVIEW

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

CHA4533: Consent Form 1 - Laparoscopic treatment of ectopic pregnancy - removal of ectopic and / or damaged Fallopian tube (cornwall.nhs.uk)

UNDER REVIEW

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

Histology Case Number		Collective Number
Crematorium Number		

CORNWALL COUNCIL

Cornwall Council
PENMOUNT CREMATORIUM, TRURO
Tel 01872 272871

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 know 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 tissue 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
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Appendix 6. Body Surface Area Chart

	HEIGHT IN CENTIMETRES																				
Wt in Kg	140	142	144	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180
44	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
46	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
48	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
50	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
52	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
54	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
56	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7
58	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7
60	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
62	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8
64	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8
66	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8
68	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8
70	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9
72	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9
74	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9
76	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
78	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2
80	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2
82	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2
84	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2
86	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2.1	2.1	2.1
88	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1
90	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1
92	1.9	1.9	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
94	1.9	1.9	1.9	2	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2
96	1.9	1.9	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2
98	2	2	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2
100	2	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2
102	2	2	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3
104	2	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3
106	2	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3
108	2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3
110	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
112	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4
114	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4
116	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4
118	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4
120	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4