NHS
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Ectopic Pregnancy and Pregnancy of Unknown Location – Diagnosis and Management - Full Clinical Guideline

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1. Introduction

This document provides guidance on the assessment and management of women presenting with suspected ectopic pregnancy and pregnancy of unknown location (PUL). The rate of ectopic pregnancy is 11 per 1000 pregnancies. There were 9 maternal deaths resulting from ruptured ectopic pregnancy in the UK and Ireland during the period 2009 - 2014 (MBRRACE).

Ectopic pregnancy remains the commonest cause of maternal mortality in early pregnancy. Only a minority of cases of ectopic pregnancy present with classical symptoms of amenorrhoea, lower abdominal pain and/or irregular vaginal bleeding. Other reported symptoms associated with ectopic pregnancy include gastrointestinal symptoms, dizziness and fainting, shoulder tip pain, urinary symptoms, rectal pressure or pain on defecation. A urine pregnancy test should be considered in any woman of reproductive age with unexplained abdominal pain – recommend catheterisation if necessary, to obtain a urine sample. Full clinical assessment should be supplemented with transvaginal ultrasound scan and serum hCG measurement to ascertain the location of pregnancy in women with a positive urine pregnancy test.

2. Purpose & Scope

The purpose of this policy is to increase the early detection of ectopic pregnancy whilst minimising the number of laparoscopies performed per case diagnosed, by:

- Defining which women require immediate surgical treatment and where it is more appropriate to wait for the results of ultrasound and hCG measurements.
- Defining the timing and interpretation of serial hCG measurements and ultrasound scans in the diagnosis of ectopic pregnancy and pregnancy of unknown location.· Providing guidance on different management options for ectopic pregnancy, i.e. expectant, medical or surgical management of ectopic pregnancy.

3. Abbreviations

A&E - Accident & Emergency Department
AEPU - Association of Early Pregnancy Units
CEMACH - Confidential Enquiry in Maternal & Child Health
FBC - Full Blood Count
G & S - Group & Save
hCG - Human Chorionic Gonadotrophin
IUCD - Intra Uterine Contraceptive Device
IU/L - International Units per Litre
IV - Intravenous
LFT - Liver Function Tests
MBRRACE Mothers and Babies: Reducing Risk though Audits and Confidential Enquiries across the UK.
PID - Pelvic Inflammatory Disease
PUL - Pregnancy of Unknown Location
RCOG - Royal College of Obstetricians and Gynaecologists
U&E - Urea & Electrolytes

4. Definitions

Ectopic Pregnancy

Ectopic pregnancy is a pregnancy that implants outside the uterine cavity. Ninety eight percent of ectopic pregnancies occur in the fallopian tube. The clinical features often overlap with other gynaecologic conditions; hence a high index of suspicion is required. Lower abdominal pain, especially unilateral, a positive pregnancy test, +/-amenorrhoea, +/-abnormal vaginal bleeding +/presence of risk factors should raise the suspicion of ectopic pregnancy. Patients with clear signs of abdominal haemorrhage (tachycardia, hypotension, abdominal tenderness or signs of collapse) need immediate surgery to stop haemorrhage. The majority of patients will need further tests to make a diagnosis. Investigations used to aid diagnosis are transvaginal ultrasound scan and serum hCG measurement. Risk factors for ectopic pregnancy include a history of previous ectopic pregnancy, tubal surgery, PID, concurrent IUCD use, and assisted conception.

Serum hCG

hCG is a hormone produced by the developing pregnancy. It is detectable in the serum as early as 7 days after conception and in the urine by the time the first period would have been missed. An hCG value of <5 IU/L is considered to be the non- pregnant value. In pregnancy serum hCG levels rise rapidly in the first 12 weeks then plateau and fall during later pregnancy. The hCG doubling time refers to the time taken for the hCG level to double its original value and is particularly useful in early pregnancy, i.e. before 6 weeks or when serum hCG level is <5000 IU/L. 85% of normal viable pregnancies will show a doubling or a rise of more than two thirds (>66%) every 48 hours. However a slower rise is also reported in a minority of viable intrauterine pregnancies. In tubal ectopic pregnancy hCG levels typically rise slowly (<66% rise), however 15% of ectopic pregnancies will have a normal doubling time.

The discriminatory hCG level (1500 IU/L) refers to a level of hCG above which a gestational sac of an intrauterine pregnancy should be visible on ultrasound. **The discriminatory level needs to be treated with caution** as it is highly dependent on the quality of ultrasound machine, experience of the sonographer, presence of physical factors, e.g. uterine fibroids.

A serum hCG level is also useful for planning the management of an ultrasound visualised ectopic pregnancy.

A single measurement of serum progesterone as an adjunct to serum hCG will not help with the diagnosis of viable intrauterine pregnancy or ectopic pregnancy. However a very low level is highly specific of a non-viable pregnancy (< 10 nmol/L) but does not exclude an ectopic pregnancy.

Ultrasound Scan
Transvaginal ultrasound scan is the imaging method of choice in the diagnosis of early pregnancy problems because it allows earlier identification of intrauterine pregnancy and better views of the adnexae. It should be possible to see an intrauterine gestation sac as early as 4-5 weeks, which corresponds roughly to a serum hCG of more than 1000-1500 IU/L. An intrauterine pregnancy can be confirmed by the presence of a fetal pole and/or yolk sac.

When carrying out a transvaginal ultrasound scan in early pregnancy, look for these signs indicating *there is* a tubal ectopic pregnancy:

- an adnexal mass, moving separate to the ovary, comprising a gestational sac containing a yolk sac **or**
- an adnexal mass, moving separately to the ovary, comprising a gestational sac and fetal pole (with or without fetal heartbeat).

When carrying out a transvaginal ultrasound scan in early pregnancy, look for these signs indicating a *high probability* of a tubal ectopic pregnancy:

- an adnexal mass, moving separately to the ovary, with an empty gestational sac (sometimes described as a 'tubal ring' or 'bagel sign') **or**
- a complex, inhomogeneous adnexal mass, moving separate to the ovary.

If these features are present, take into account other intrauterine and adnexal features on the scan, the woman's clinical presentation and serum hCG levels before making a diagnosis.

When carrying out a transvaginal ultrasound scan in early pregnancy, look for these signs indicating a *possible* ectopic pregnancy:

- an empty uterus **or**
- a collection of fluid within the uterine cavity (sometimes described as a pseudo-sac).

If these features are present, take into account other intrauterine and adnexal features on the scan, the woman's clinical presentation and serum hCG levels before making a diagnosis.

When carrying out a transabdominal or transvaginal ultrasound scan in early pregnancy, look for a moderate to large amount of free fluid in the peritoneal cavity or pouch of Douglas, which might represent haemoperitoneum.

When carrying out a transabdominal or transvaginal ultrasound scan during early pregnancy, scan the uterus and adnexae to see if there is a heterotopic pregnancy.

Management Algorithm for Tubal Ectopic Pregnancy

Confirmed tubal ectopic pregnancy

Features of ruptured tubal ectopic?

- Haemodynamic instability
- Large volume of fluid in POD
- Diarrhoea
- Shoulder tip pain
- Significant tenderness

YES

Urgent senior gynaecology review (registrar or consultant)

Preparation for theatre IV

access and fluid resus

Cross match

NO

Measure serum hCG and undertake clinical assessment.

Discuss management with consultant gynaecologist on call

Offer surgical management to women who are unable to return for follow up or who have any of the following:

- Ectopic pregnancy and significant pain
- Ectopic pregnancy and adnexal mass 35mm or larger and/or visible fetal heart beat visible on TVUSS
- Ectopic pregnancy and hCG of 5,000 IU/L or more

Offer expectant management to women who

- are clinically stable and pain free **and**
- have an unruptured tubal ectopic < 35mm with no visible heartbeat on TVUSS **and**
- have hCG less than 1,000 IU/L **and**
- are able to return for follow up

Consider expectant management for women who

- are clinically stable and pain free **and**
- have an unruptured tubal ectopic < 35mm with no visible heartbeat on TVUSS **and**
- have hCG between 1,000 – 1500 IU/L **and**
- are able to return for follow up

Offer methotrexate to women who

- have no significant pain **and**
- have an unruptured ectopic < 35mm with no visible heartbeat on TVUSS **and**
- have hCG less than 1500 IU/L **and**
- do not have an intrauterine pregnancy **and**
- are able to return for follow up

Offer methotrexate or surgery to women who

- have no significant pain **and**
- have an unruptured ectopic < 35mm with no visible heartbeat on TVUSS **and**
- have hCG 1500-4999 IU/L and
- do not have an intrauterine pregnancy **and**
- are able to return for follow up

5. Management of Tubal Ectopic Pregnancy

A woman with a suspected ectopic pregnancy and deteriorating symptoms should be urgently reviewed directly by a senior gynaecologist. Repeated presentation of a woman with abdominal and/or pelvic pain, or pain requiring opiates in a woman known to be pregnant should be considered 'red flag' signs (MBRRACE 2014).

If the patient is in significant discomfort, she should be admitted to the ward. If she is clinically stable with no discomfort she may be allowed home to return for follow up. Consider where she lives, i.e how far away she lives from the hospital.

The direct contact telephone numbers for the Gynaecology Assessment Unit and Gynaecology Ward should be given and the patient asked to attend at any time if her condition deteriorates. Depending on clinical symptoms and signs, ultrasound findings and serum hCG levels, patients are offered management options of expectant, medical (i.e. methotrexate) or surgical treatment for ectopic pregnancy – see management algorithm above.

Give all women with an ectopic pregnancy oral and written information about:

- the treatment options and what to expect during and after treatment
- how they can contact the Early Pregnancy Assessment Unit (Ward 30) for advice after treatment if needed.
- where and when to get help in an emergency.

Expectant management
For women with a tubal ectopic pregnancy being managed expectantly, repeat hCG levels at 48 and 96 hours after the original test and:

- if hCG levels drop by 15% or more from the previous value, then repeat weekly until a negative result (less than 20 IU/L) is obtained **or**
- if hCG levels do not fall by 15%, stay the same, or rise from the previous value, review the woman's clinical condition and seek advice from the consultant gynaecologist on call to help decide further management or
- by the time the third serial HCG is performed it would be advisable to get input from the consultant on call

Advise women that, based on limited evidence, there seems to be no difference following expectant or medical management in:

- the rate of ectopic pregnancies ending naturally
- the risk of tubal rupture
- the need for additional treatment, but that they might need to be admitted urgently if their condition deteriorates
- health status, depression or anxiety scores.

Advise women that the time taken for ectopic pregnancies to resolve can take several weeks and future fertility outcomes are likely to be the same with either expectant or medical management.

Methotrexate Treatment
Methotrexate should only be offered on a first visit when there is a definitive diagnosis of an ectopic pregnancy, and a viable intrauterine pregnancy has been excluded.

If hCG levels are rising on serial measurement, you must positively exclude intrauterine pregnancy before starting methotrexate treatment.

Contraindications to methotrexate

- Any possibility of an intra-uterine pregnancy
- Hepatic dysfunction
- Women who are breastfeeding
- Thrombocytopenia (i.e. platelets <150 x 109 /L), Blood dyscrasia (WCC<3 x 109/L), Significant anaemia, Bone Marrow Hypoplasia
- Difficulty or unwillingness of patient for prolonged follow up (average follow up 35 days).
- Women on concurrent corticosteroids
- Sensitivity / allergy to methotrexate
- Renal impairment
- Alcohol abuse
- Serious, acute or chronic infections such as tuberculosis, HIV or other immunodeficiency syndromes,
- Concurrent vaccination with live vaccines.
- Ulcers of the oral cavity and known active gastrointestinal ulcer disease

Methotrexate treatment protocol

- Provide information leaflet about medical management of ectopic pregnancy
- Obtain written informed consent from patient
- Take blood for FBC, U&E, LFT, blood group
- Measure patient's height and weight, document on EPMA system. BSA will automatically be calculated in Lorenzo/ Meditech.
- Prescribe dose of methotrexate based on 50mg/m^2, rounded to nearest dose band as per table 1, using appropriate order set on Lorenzo (RDH), or Meditech (QHB).

Table 1: Dose banding table for available doses of methotrexate

Body Surface Area (BSA) range (m2)*	Dose Band Methotrexate:	Number of mLs to be administered intra muscularly	Number of syringes supplied for total dose
1.5 - 1.7	80mg	3.2 mLs	1
1.7 - 1.9	90mg	3.6 mLs	1
1.9 - 2.1	100mg	4.0 mLs	1
>2.1**	110mg	4.4 mLs	2
*N.B. For patients with a BSA outside of the above ranges, please contact pharmacy for dosing advice			
** Not routinely stocked at QHB			

- Contact pharmacist holding the gynaecology bleep (RDH) / ward 30 bleep (QHB) to organise supply (typically available within 2 hour period).
- Check blood results, give methotrexate intramuscularly in buttock.
- Rest for up to one hour, check for any local reaction. If local reaction noted consider antihistamine or steroid cream (very rare).

Arrange **<u>follow up</u>** in EPAU / ward 30:

- Day 1: serum hCG and methotrexate
- Day 4: serum hCG
- Day 7: serum hCG, FBC, U&E, LFT. Consider second dose of methotrexate after discussion with consultant gynaecologist on call if hCG decreases <15% day 4-7. 15% of women having medical treatment will require second dose.

A rise between day 1 and 4 is acceptable.

If hCG decreases >15%, repeat hCG weekly until less than 20 IU/L.

Up to 75% women experience pain on days 3-7, due to tubal miscarriage/placental separation.

Side effects of the methotrexate are minimal but may include loss of appetite, nausea, vomiting, diarrhoea, gastrointestinal discomfort, stomatitis, anaemia, leucopenia, thrombocytopenia, chest pain, cough, dyspnoea, drowsiness, fatigue, fever, headache, skin reactions and throat complaints.

Patients are advised to maintain ample fluid intake, avoid alcohol and folic acid-containing vitamins during treatment, abstain from sexual intercourse (risk of rupture), and avoid exposure to sunlight.
Avoid pregnancy for 3 months following methotrexate because of a possible teratogenic effect. Patients may use reliable barrier method or hormonal contraception.

Outcome of Medical Treatment
90% successful treatment with single dose regime, recurrent ectopic rate 10-20%, tubal patency approximately 80%.

Surgical Treatment of Ectopic Pregnancy
In patients with haemodynamic instability, perform surgery by most expedient way, which in most cases is by a laparotomy. In stable patients, surgery should be performed laparoscopically whenever
possible as it is associated with reduced blood loss, shorter hospital stay, and quicker recovery.

Salpingectomy and Salpingotomy
Offer a salpingectomy to women undergoing surgery for an ectopic pregnancy unless they have other risk factors for infertility.

Consider salpingotomy as an alternative to salpingectomy for women with risk factors for infertility (such as contralateral tube damage, previous abdominal surgery or pelvic inflammatory disease).

Inform women having a salpingotomy that up to 1 in 5 women may need further treatment. This treatment may include methotrexate and/or a salpingectomy.

For women who have had a salpingotomy, take 1 serum hCG measurement at 7 days after surgery, then 1 serum hCG measurement per week until a negative result is obtained.

Advise women who have had a salpingectomy that they should take a urine pregnancy test after 3 weeks. Advise women to return for further assessment if the test is positive.

Consider whether VTE prophylaxis is required for 7 days post-salpingectomy.

Any patient who has an ectopic pregnancy managed medically or surgically must be discussed with a consultant and this should be documented.

6. Management of Suspected Ectopic Pregnancy in the Emergency Department

Consider ECTOPIC pregnancy if: Positive pregnancy test and lower abdominal pain (especially unilateral) ± abnormal vaginal bleeding.

A diagnosis of ectopic pregnancy should be considered in any woman of reproductive age presenting to the emergency department with collapse, acute abdominal/pelvic pain or gastrointestinal symptoms, particularly diarrhoea, vomiting and dizziness, regardless of whether or not she is known to be pregnant. A bedside pregnancy test should be performed – catheterise if necessary to obtain a urine sample (MBRRACE 2014).

Risk factors: Previous ectopic pregnancy, history of PID, IUCD, assisted conception, previous tubal surgery.

SUSPECTED ECTOPIC PREGNANCY

Observations
IV access
FBC, G & S, serum I3HCG
Full Assessment of Patient

- **Haemodynamically stable**
- **No signs or peritonism**

- **Syncope or Haemodynamic compromise**
- **And / or signs of peritonism**

IN HOURS (09:00 – 17:00 daily)
- Transfer patient to EPAU for further assessment

OUT OF HOURS
- Contact Gynae Registrar on call to discuss case and arrange a EPAU appointment for the following day

- Summon Senior help Resuscitate in Resus
- Large-bore IV access x2
- IV fluids
- X-match 4U
- FAST scan - ?intra-abdominal haemorrhage
- Contact Gynae registrar (via bleep) to review patient in Resus

If no response from Gynae Registrar in 20 minutes (or significant expected delay), phone switchboard / Delivery suite / EPAU to locate them. If this fails, inform Gynae Nurse-in-Charge and contact Gynae Consultant on call to discuss case.

7. Pregnancy of Unknown Location (PUL)

The term Pregnancy of Unknown Location (PUL) is used when there is no sign of either intra- or extra-uterine pregnancy on ultrasound scan with a positive pregnancy test. Be aware that women with a pregnancy of unknown location could have an ectopic pregnancy until the location is determined.

PUL require follow up until a pregnancy (either intra-uterine or ectopic) is identified on ultrasound scan, or levels of hCG spontaneously decrease.

Failing PUL is the most common outcome (44-69%) which resolves spontaneously. Early intrauterine pregnancies are subsequently seen in one third (30-37%) of PULs. Ectopic pregnancy will be diagnosed in 10-30% of PULs.

Persisting PUL will be the outcome in a small subset of patients (2%), in which serum hCG levels fail to decline and have reached a plateau (doubling time of 7 days or more) and a pregnancy could not be located by meticulous scanning. The endometrial thickness should also be taken into account in management planning and to predict the location of the pregnancy in these uncommon scenarios.

In a woman with a pregnancy of unknown location, place more importance on clinical symptoms than on serum hCG results, and review the woman's condition if any of her symptoms change, regardless of previous results and assessments, in case a change in plan and/or laparoscopy is required.

Use serum hCG measurements only for assessing trophoblastic proliferation to help to determine subsequent management.

Management of Pregnancy of Unknown Location
Take 2 serum hCG measurements as near as possible to 48 hours apart (but no earlier) to determine subsequent management of a pregnancy of unknown location. Take further measurements only after discussion with the consultant gynaecologist on call.

Regardless of serum hCG levels, give women with a pregnancy of unknown location written information about what to do if they experience any new or worsening symptoms, including details about how to access emergency care 24 hours a day. Advise women to return if there are new symptoms or if existing symptoms worsen.

For a woman with an increase in serum hCG levels greater than 63% after 48 hours:

- Inform her that she is likely to have a developing intrauterine pregnancy (although the possibility of an ectopic pregnancy cannot be excluded).
- Offer her a transvaginal ultrasound scan to determine the location of the pregnancy between 7 and 10 days later. Consider an earlier scan for women with a serum hCG level greater than or equal to 1500 IU/litre.
    - If a viable intrauterine pregnancy is confirmed, offer her routine antenatal care.
    - If a viable intrauterine pregnancy is not confirmed, discuss the case with the consultant gynaecologist on call.

For a woman with a decrease in serum hCG levels greater than 50% after 48 hours:

- inform her that the pregnancy is unlikely to continue but that this is not confirmed **and**
- provide her with oral and written information about where she can access support and counselling services.
- repeat her serum HCG in 7 days and if further significant fall she can do a urine pregnancy test 14 days after the previous serum hCG test, and explain that:
    - if the test is negative, no further action is necessary
    - if the test is positive, she should contact the Early pregnancy Assessment Unit for review.

For a woman with a decrease in serum hCG levels less than 50%, or an increase less than 63%, discuss the case with the consultant gynaecologist on call.

For a woman with a change in serum βHCG concentration between a 50% decline and 63% rise inclusive, please refer to the diagnostic algorithm.

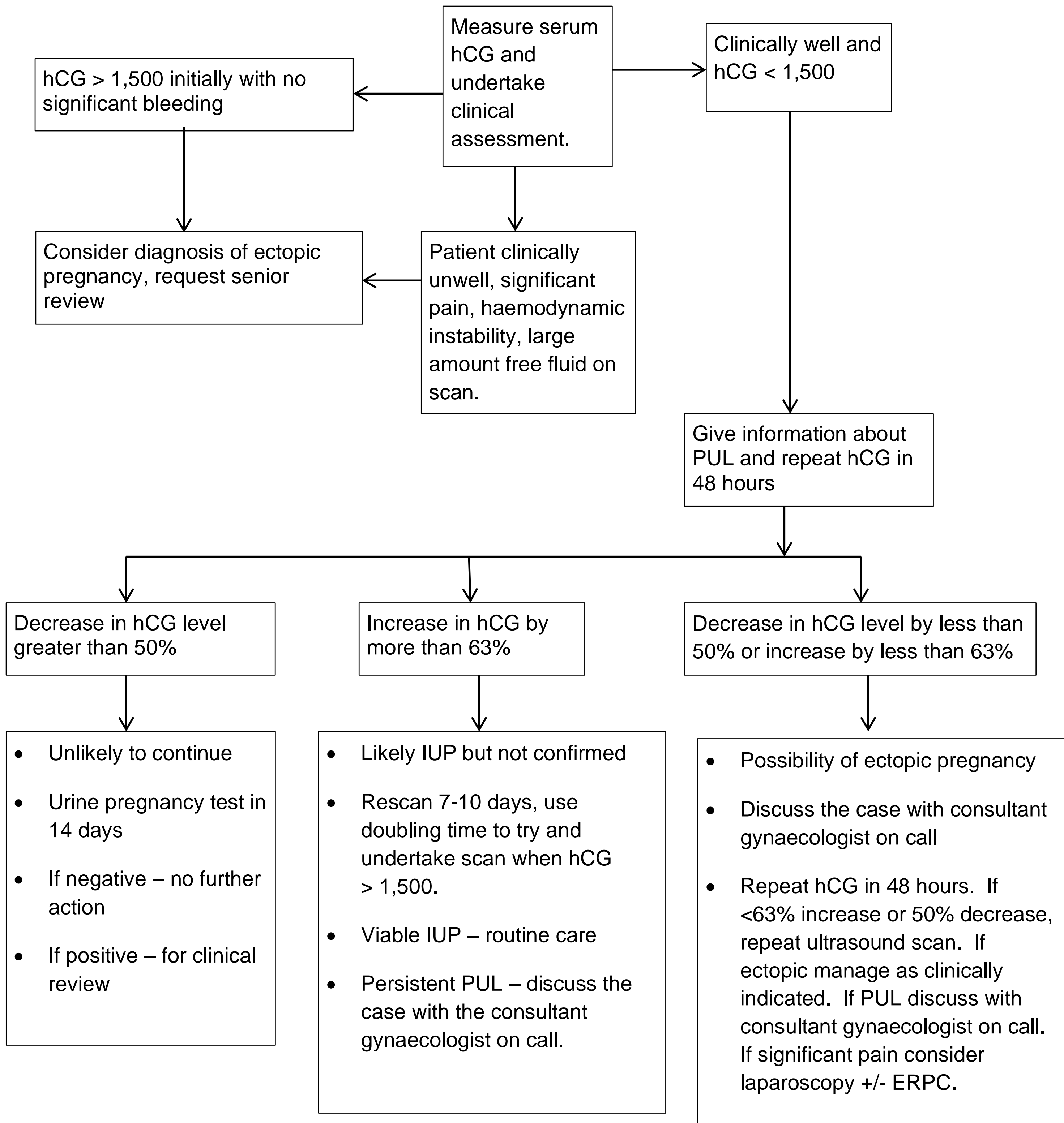
A third hCG measurement (or more) may be required followed by a carefully timed and meticulous transvaginal scan.

For women with PUL, do not use serum progesterone measurements as an adjunct to diagnose either viable intrauterine pregnancy or ectopic pregnancy.

Medical management (i.e. with methotrexate) of persisting PUL may only be considered after a confident diagnosis of absence of intrauterine pregnancy is made. The case must be discussed with the consultant gynaecologist on call before methotrexate is given.

PREGNANCY OF UNKNOWN LOCATION MANAGEMENT ALGORITHM

This algorithm is for patients who are clinically well only. If any symptoms of features of ectopic pregnancy/miscarriage develop then reassessment is indicated regardless of previous results.



8. Anti-D rhesus prophylaxis

Offer anti-D rhesus prophylaxis as per full guidelines click here for guidelines

9. Unusual Types of Ectopic Pregnancy

If the ultrasound scan reveals a non-tubal ectopic pregnancy, the treatment has to be individualized and based on the size and location of ectopic pregnancy. The less common types of ectopic pregnancy include:

- Cervical pregnancy
- Caesarean section scar pregnancy
- Interstitial pregnancy
- Cornual pregnancy
- Ovarian pregnancy
- Abdominal pregnancy
- Heterotopic pregnancy

A treatment plan should be made by the consultant gynaecologist on-call.

For further information on non-tubal ectopic pregnancy, consult Green-top Guideline No. 21 - Diagnosis and Management of Ectopic Pregnancy. RCOG/AEPU Joint Guideline November 2016.

In case of a suspected caesarean section scar pregnancy please follow the separate RDH guideline and Liaise with /seek advice and refer to Derby.

10. Support and Information Giving

Provide women with early pregnancy complications information and support in a sensitive manner, taking into account their individual circumstances and emotional response. Throughout a woman's care, give her and, with her agreement, her partner information in a variety of formats. This should include:

- When and how to seek help if existing symptoms worsen or new symptoms appear
- What to expect during the course of her care (including expectant management) such as the potential length of treatment and extent of pain and or bleeding, and possible side effects, as appropriate.

Women should be advised, whenever possible, of the advantages and disadvantages associated with each approach used for the treatment of ectopic pregnancy, and should participate fully in the selection of the most appropriate treatment.

Women should be made aware of how to access support via patient support groups, such as the Ectopic Pregnancy Trust, or local bereavement counselling services.

What are the long-term fertility prospects following an ectopic pregnancy?
In the absence of a history of subfertility or tubal pathology, women should be advised that there is no difference in the rate of fertility, the risk of future tubal ectopic pregnancy or tubal patency rates between the different management methods.

Women with a previous history of subfertility should be advised that treatment of their tubal ectopic pregnancy with expectant or medical management is associated with improved reproductive outcomes compared with surgery.

Women receiving methotrexate for the management of tubal ectopic pregnancy can be advised that there is no effect on ovarian reserve.

Advise women who have had an ectopic pregnancy to contact the Gynaecology Assessment Unit directly (Tel No 01332 785637) in any future pregnancy in order to arrange an early ultrasound scan (at approximately 5-6 weeks of pregnancy) to confirm the location of the pregnancy.

11. Monitoring Compliance and Effectiveness

As per agreed business unit audit forward programme

12. Useful web addresses

- http://earlypregnancy.org.uk
- www.nhs.uk
- www.rcog.org.uk/ectopic-pregnancy-information-for-you
- www.ectopic.org.uk
- www.bacp.co.uk/

13. References

Green-top Guideline No. 21 - Diagnosis and Management of Ectopic Pregnancy. RCOG/AEPU Joint Guideline November 2016

Saving Lives, Improving Mothers' Care - Surveillance of maternal deaths in the UK 2012-14 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-14

NICE Clinical Guideline 126: Ectopic Pregnancy and miscarriage (2019)

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	4	March 2018	Mr J Allsop Consultant Gynaecologist	NICE compliance
	5	Aug 2019	Dr J Davies – SpR Mr J Allsop Consultant Gynaecologist	NICE compliance & clarifying scan procedure
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