Clinical Guidance Document

NHS Fife

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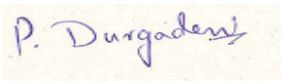

Early Pregnancy Clinic Guidelines

Target Patient Population: All women with bleeding or pain in early pregnancy
Target Staff Population: All staff managing women with early pregnancy bleeding or pain

Diagnosis of viable intrauterine pregnancy and of ectopic pregnancy

Using ultrasound for diagnosis

Offer women who attend an early pregnancy assessment service a transvaginal ultrasound scan to identify the location of the pregnancy and whether there is a fetal pole and heartbeat.

Consider a transabdominal ultrasound scan for women with an enlarged uterus or other pelvic pathology, such as fibroids or an ovarian cyst.

If a transvaginal ultrasound scan is unacceptable to the woman, offer a transabdominal ultrasound scan and explain the limitations of this method of scanning.

Inform women that the diagnosis of miscarriage using 1 ultrasound scan cannot be guaranteed to be 100% accurate and there is a small chance that the diagnosis may be incorrect, particularly at very early gestational ages.

When performing an ultrasound scan to determine the viability of an intrauterine pregnancy, first look to identify a fetal heartbeat. If there is no visible heartbeat but there is a visible fetal pole, measure the crown–rump length. Only measure the mean gestational sac diameter if the fetal pole is not visible.

If the crown–rump length is less than 7.0 mm with a transvaginal ultrasound scan and there is no visible heartbeat, perform a second scan a minimum of 7 days after the first before making a diagnosis. Further scans may be needed before a diagnosis can be made.

If the crown–rump length is 7.0 mm or more with a transvaginal ultrasound scan and there is no visible heartbeat:

- seek a second opinion on the viability of the pregnancy **and/or**
- perform a second scan a minimum of 7 days after the first before making a diagnosis.

If there is no visible heartbeat when the crown–rump length is measured using a transabdominal ultrasound scan:

- record the size of the crown–rump length **and**
- perform a second scan a minimum of 14 days after the first before making a diagnosis.

If the mean gestational sac diameter is less than 25.0 mm with a transvaginal ultrasound scan and there is no visible fetal pole, perform a second scan a minimum of 7 days after the first before making a diagnosis. Further scans may be needed before a diagnosis can be made.

If the mean gestational sac diameter is 25.0 mm or more using a transvaginal ultrasound scan and there is no visible fetal pole:

- seek a second opinion on the viability of the pregnancy **and/or**
- perform a second scan a minimum of 7 days after the first before making a diagnosis.

If there is no visible fetal pole and the mean gestational sac diameter is measured using a transabdominal ultrasound scan:

- record the size of the mean gestational sac diameter **and**
- perform a second scan a minimum of 14 days after the first before making a diagnosis.

Inform women that the date of their last menstrual period may not give an accurate representation of gestational age because of variability in the menstrual cycle.

Inform women what to expect while waiting for a repeat scan and that waiting for a repeat scan has no detrimental effects on the outcome of the pregnancy.

Give women a 24-hour contact telephone number (Early Pregnancy Clinic on ext 29069 /Ward 32 ext 29332) so that they can speak to someone with experience of caring for women with early pregnancy complications who understands their needs and can advise on appropriate care.

When diagnosing complete miscarriage on an ultrasound scan, in the absence of a previous scan confirming an intrauterine pregnancy, always be aware of the possibility of ectopic pregnancy. Advise these women to return for further review if their symptoms persist.

Management of miscarriage

Expectant Management

Use expectant management for 7–14 days as the first-line management strategy for women with a confirmed diagnosis of miscarriage. Explore management options other than expectant management if:

- the woman is at increased risk of haemorrhage (for example, she is in the late first trimester) **or**
- she has previous adverse and/or traumatic experience associated with pregnancy (for example, stillbirth, miscarriage or antepartum haemorrhage) **or**
- she is at increased risk from the effects of haemorrhage (for example, if she has coagulopathies or is unable to have a blood transfusion) **or**
- there is evidence of infection.

Offer medical management to women with a confirmed diagnosis of miscarriage if expectant management is not acceptable to the woman.

If the resolution of bleeding and pain indicate that the miscarriage has completed during 7–14 days of expectant management, advise the woman to take a urine pregnancy test after 3 weeks, and to return for individualised care if it is positive.

Offer a repeat scan if after the period of expectant management the bleeding and pain:

- have not started (suggesting that the process of miscarriage has not begun) **or**
- are persisting and/or increasing (suggesting incomplete miscarriage).

  Discuss all treatment options (continued expectant management, medical management, and surgical management) with the woman to allow her to make an informed choice.

Review the condition of a woman who opts for continued expectant management of miscarriage at a minimum of 14 days after the first follow-up appointment.

Medical management

Mifepristone is no longer required as a treatment for missed/incomplete miscarriage.

Offer vaginal misoprostol for the medical treatment of missed or incomplete miscarriage. Oral administration is an acceptable alternative if this is the woman's preference.

For women with a missed miscarriage, use a single dose of 800 micrograms of misoprostol.

Medical management is being offered on an inpatient basis presently. Refer to the respective guideline.

Advise the woman that if bleeding has not started 24 hours after treatment, she should contact Early Pregnancy Clinic (EPC)/ Ward 32 to determine ongoing individualised care.

Offer all women receiving medical management of miscarriage pain relief and anti-emetics as needed.

Inform women undergoing medical management of miscarriage about what to expect throughout the process, including the length and extent of bleeding and the potential side effects of treatment including pain, diarrhoea and vomiting.

Advise women to take a urine pregnancy test 3 weeks after medical management of miscarriage unless they experience worsening symptoms, in which case advise them to contact EPC (Monday-Friday 0900 – 1700 hrs) or Ward 32, Victoria Hospital out of hours.

Advise women with a positive urine pregnancy test after 3 weeks to return for a review by EPC to ensure that there is no molar or ectopic pregnancy.

Surgical management

Suction evacuation if offered under general anaesthetic in our unit. Pre-procedure cervical preparation with misoprostol (600mcg) is advocated as this reduces the risk of injury to uterus & cervix and also the risk of increased bleeding.

Provide oral and written information to all women undergoing surgical management of miscarriage what to expect during and after the procedure.

Remember prescribing anti D in women who are rhesus negative.

Symptoms and signs of ectopic pregnancy and initial assessment

Refer women who are haemodynamically unstable, or in whom there is significant concern about the degree of pain or bleeding, directly to A&E.

Be aware that atypical presentation for ectopic pregnancy is common.

Be aware that ectopic pregnancy can present with a variety of symptoms. Even if a symptom is less common, it may still be significant. Symptoms of ectopic pregnancy include:

- common symptoms:
    - abdominal or pelvic pain
    - amenorrhoea or missed period
    - vaginal bleeding with or without clots
- other reported symptoms:
    - breast tenderness
    - gastrointestinal symptoms
    - dizziness, fainting or syncope
    - shoulder tip pain
    - urinary symptoms
    - passage of tissue
    - rectal pressure or pain on defecation.

Be aware that ectopic pregnancy can present with a variety of signs on examination by a healthcare professional. Signs of ectopic pregnancy include:

- more common signs:
    - pelvic tenderness
    - adnexal tenderness
    - abdominal tenderness
- other reported signs:
    - cervical motion tenderness
    - rebound tenderness or peritoneal signs
    - pallor
    - abdominal distension
    - enlarged uterus
    - tachycardia (more than 100 beats per minute) or hypotension (less than 100/60 mmHg)
    - shock or collapse
    - orthostatic hypotension.

Exclude the possibility of ectopic pregnancy, even in the absence of risk factors (such as previous ectopic pregnancy), because about a third of women with an ectopic pregnancy will have no known risk factors.

Management of ectopic pregnancy

Offer systemic methotrexate as a first-line treatment to women who are able to return for follow-up and who have all of the following:

- no significant pain
- an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat
- a serum hCG level less than 1500 IU/litre
- no intrauterine pregnancy (as confirmed on an ultrasound scan).

Offer surgery where treatment with methotrexate is not acceptable to the woman.

Offer surgery as a first-line treatment to women who are unable to return for follow-up after methotrexate treatment or who have any of the following:

- an ectopic pregnancy and significant pain
- an ectopic pregnancy with an adnexal mass of 35 mm or larger
- an ectopic pregnancy with a fetal heartbeat visible on an ultrasound scan
- an ectopic pregnancy and a serum hCG level of 5000 IU/litre or more.

Offer the choice of either methotrexate or surgical management to women with an ectopic pregnancy who have a serum hCG level of at least 1500 IU/litre and less than 5000 IU/litre, who are able to return for follow-up and who meet all of the following criteria:

- no significant pain
- an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat
- no intrauterine pregnancy (as confirmed on an ultrasound scan).

Obtain baseline blood samples for HCG, LFTs and Us & Es before administering methotrexate. Advise women who choose methotrexate that their chance of needing further intervention is increased and they may need to be urgently admitted if their condition deteriorates.

For women with ectopic pregnancy who have had methotrexate, take 2 serum hCG measurements in the first week (days 4 and 7) after treatment and then 1 serum hCG measurement per week until a negative result is obtained. If hCG levels plateau or rise, reassess the woman's condition for further treatment.

GUIDANCE TO CALCULATE THE DOSAGE OF METHOTREXATE

Chart 1 DOSE OF METHOTREXATE IN MILLIGRAMS (50MG/M^2 BODY SURFACE AREA)

Weight (kg)	Height (cm)												
	70	**80**	**90**	**100**	**110**	**120**	**130**	**140**	**150**	**160**	**170**	**180**	**190**
10	21	23	25	27									
15	24.5	27	29.5	32	34.5	36.5	38.5						
20	28	31	33.5	36	39	41.5	43.5	46	48.5				
30	33	36.5	40	43	46	49	52	55	57.5	60.5	63		
40					52	55.5	58.5	62	65	68.5	71.5	74.5	
50							64.5	68	71.5	75	78.5	81.5	85
60							70	73.5	77.5	81	84.5	88.5	92
70								78.5	82.5	86.5	90.5	94.5	98
80									87.5	91.5	96	100	104
90										96.5	100.5	105	109
100										101	105.5	110	114
110											109.5	114.5	119
120											114	118.5	123.5
130											117.5	122.5	127.5

DOSE BANDING FOR METHOTREXATE (MTX) –
FOR MEDICAL MANAGEMENT OF UNRUPTURED ECTOPIC PREGNANCY

EFFECTIVE FROM 16/08/2016

Following is the chart for calculation of methotrexate dosage.
Please follow the chart for Body Surface Area (BSA) calculation

BSA	**Dose**	**Stock Level- see note**
1.30 – 1.35	65mg/2.6ml	-
1.36 – 1.45	70mg/2.8ml	-
1.46 – 1.55	75mg/3.0ml	1
1.56 – 1.65	80mg/3.2ml	2
1.66 – 1.75	85mg/3.4ml	3
1.76 – 1.85	90mg/3.6ml	3
1.86 – 1.95	95mg/3.8ml	2
>1.96	100mg/4ml	2

If patient is obese, select a site of least adipose tissue as MTX is water-soluble and may not be absorbed/ released from a fatty site.
Maximum dose is 100mg regardless of BSA.

METHOTREXATE CHECKLIST

PATIENT ADDRESSOGRAPH

CONTACT NOS
PATIENT
NEXT OF KIN

COUNSELLING Y / N

Information leaflet Y/ N

Consent Y/N

Blood Group ....

Chlamydia ....

	FBC	B hCG	U&Es, LFTS	S/ S, Obs. (P, BP)
Day 0	....	....	....	....
Day4	....	....		....
Day7	....	....	....	....

(HCG fall day4 – day7 greater than 15% weekly bloods till HCG less than 5IU/L

If falls less than 15% then reassess criteria, rescan and discuss with Consultant regarding repeat dose. If repeated follow up Day 11)

Day 11	....	....	....	....
Day 14	....	....	....	....

(If second dose of methotrexate was given day – day14 fall greater than 15% then weekly HCG, If not discuss with consultant on call)

Day21	....	....		....
Day 28	....	....		....
Day 35	....	....		....

Anti D

Post treatment counselling

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MEDICAL TREATMENT OF ECTOPIC PREGNANCY

Information Leaflet

Ectopic pregnancy can be treated either by medication or an operation to remove the ectopic pregnancy.

Methotrexate is a drug used to dissolve the pregnancy. It is successful in approximately 90% of treatments. If it is unsuccessful we may need to consider further injection or an operation to remove the ectopic pregnancy.

You may experience some side effects like nausea, diarrhoea and sore mouth. It is common to experience some abdominal discomfort and some bleeding in the first couple of weeks. If the pain is sharp or is getting worse you should contact the early pregnancy unit or the gynaecology ward immediately.

During the treatment you need to attend the hospital regularly in order to ensure that the treatment is working by checking your blood hormone levels. This would mean a visit every two to three times a week initially followed by blood tests once or twice a week till the pregnancy hormone in your blood has disappeared.

While on treatment we advise you to avoid:

- Alcohol
- Folic acid
- Intercourse (as it can cause the ectopic pregnancy to rupture)

If you are on any other medications please inform the staff nurse or the doctor.

It is very important that after methotrexate treatment you should avoid pregnancy for two months.

Allow yourself time to recover physically and emotionally before trying for another pregnancy. If you wish any support to deal with your feelings do not hesitate to contact .....

The possibility of ectopic pregnancy in future pregnancy is approximately 1:10. It still means that you have a greater chance of having a pregnancy inside your womb.

We advise you to do a pregnancy test if you miss your period. Please contact your GP if you are pregnant. He will be able to refer you to the Early Pregnancy Unit for an early scan and monitoring.

Anti-D rhesus prophylaxis

Offer anti-D rhesus prophylaxis at a dose of 250 IU (50 micrograms) to all rhesus negative women who had surgical management of miscarriage or surgery for an ectopic pregnancy.

Do not offer anti-D rhesus prophylaxis to women who:

- receive solely medical management for an ectopic pregnancy or miscarriage **or**
- have a threatened miscarriage **or**
- have a complete miscarriage **or**
- have a pregnancy of unknown location.

Do not use a Kleihauer test for quantifying feto–maternal haemorrhage.

Early Pregnancy Loss Under 12 Weeks

Discuss options with Mother regarding the disposal of remains.

Forms 1+2 to be completed

Mother wishes to take remains home.
Form1

NHS provide collective cremations. If parents specifically request individual cremation this can be accommodated.

Form 2 to be Completed

Mother wishes to be informed of date and time of Service of Remembrance.
Give leaflet -
Ensure form 2 is Completed

Mother does not wish to be informed of choices.

Ensure form 2 is Completed

Ensure that a copy of Form 1 is placed within the case notes and a copy given to the patient.

Pregnancy loss must be kept in an approved 'specimen collective device' and placed into a clear plastic bag with a copy of **Form 1** and **Form 2** and any other documentation required.

Arrange for collection and transfer to the Laboratory within 24 hours as per local arrangements.

Where requested, funeral director phones and writes to the mother with details of the service of remembrance.

Service of Remembrance last Thursday of every month at 3.45pm at Kirkcaldy Crematorium.

Collective remains scattered in the Baby Garden of Remembrance at Kirkcaldy Crematorium.

Women with pregnancy of unknown location

There is no evidence of an intra-uterine or extra-uterine pregnancy on transvaginal ultrasound scan in women 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. Depending on the quality of the ultrasound service provided, anything between 10 and 30% of pregnancies of unknown locations will subsequently be diagnosed as an ectopic pregnancy.

Do not use serum hCG measurements to determine the location of the pregnancy.

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.

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

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.

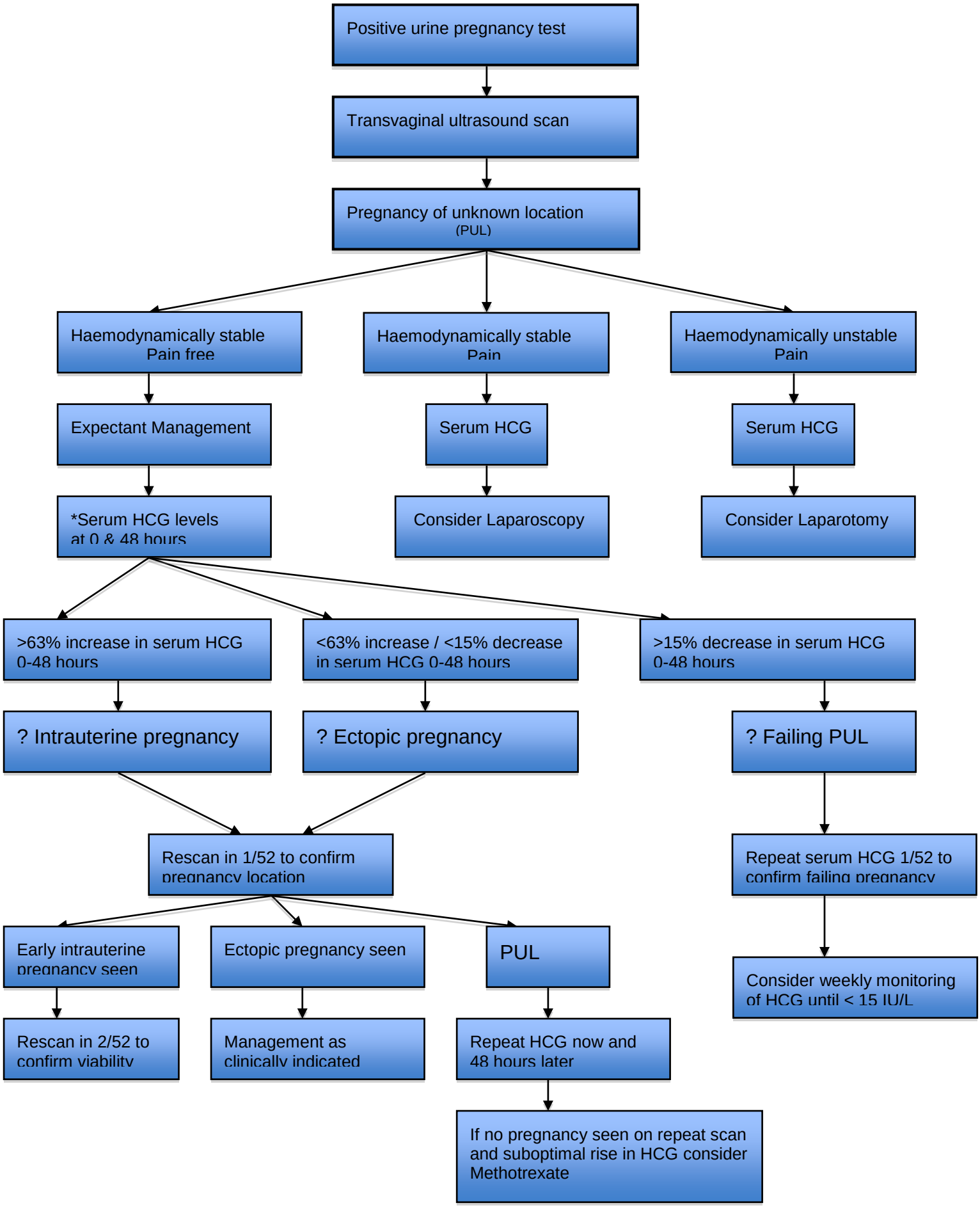
For a woman with an increase in serum hCG concentration greater than 63% after 48 hours:

- 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 14 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, refer her for immediate clinical review by a senior gynaecologist.

For a woman with a decrease in serum hCG concentration 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 **and**
- ask her to take a urine pregnancy test 14 days after the second serum hCG test, and explain that:
    - if the test is negative, no further action is necessary
    - if the test is positive, she should return to the early pregnancy assessment service for clinical review within 24 hours.

For a woman with a change in serum hCG concentration between a 50% decline and 63% rise inclusive, refer her for clinical review in the early pregnancy assessment service within 24 hours.


Positive urine pregnancy test
Transvaginal ultrasound scan
Pregnancy of unknown location
(PUL)
Haemodynamically stable
Pain free
Haemodynamically stable
Pain
Haemodynamically unstable
Pain
Expectant Management
Serum HCG
Serum HCG
*Serum HCG levels
at 0 & 48 hours
Consider Laparoscopy
Consider Laparotomy
>63% increase in serum HCG
0-48 hours
<63% increase / <15% decrease
in serum HCG 0-48 hours
>15% decrease in serum HCG
0-48 hours
? Intrauterine pregnancy
? Ectopic pregnancy
? Failing PUL
Rescan in 1/52 to confirm
pregnancy location
Repeat serum HCG 1/52 to
confirm failing pregnancy
Early intrauterine
pregnancy seen
Ectopic pregnancy seen
PUL
Consider weekly monitoring
of HCG until < 15 IU/L
Rescan in 2/52 to
confirm viability
Management as
clinically indicated
Repeat HCG now and
48 hours later
If no pregnancy seen on repeat scan
and suboptimal rise in HCG consider
Methotrexate

Summary of references

NICE Guidelines (CG154): Ectopic pregnancy & Miscarriage; Diagnosis & Initial Management in early pregnancy & miscarriage December 2012

Rhesus D prophylaxis: The use of Anti D – immunoglobulin (Green Top Guideline No 22; RCOG)

AEPU Guidelines

Membership: Women & Children's Health Directorate

Contact Lead: Dr P Durgadevi