



Burton Hospitals NHS Foundation Trust

Early Pregnancy Assessment Unit Guideline (Care of a woman with bleeding and pain during early pregnancy)

Approved by:	Clinical Director, Women and Children's Services
On:	12 th June 2017
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Corporate / Directorate	Directorate
Clinical / Non Clinical	Clinical
Department Responsible for Review:	Obstetrics/Gynaecology
Distribution: • Essential Reading for:	All Gynaecology staff Emergency Department staff
 Information for: 	EPAU and Gynaecology staff All midwives
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Signature:	Chief Executive
Date:	

Burton Hospitals NHS Foundation Trust POLICY INDEX SHEET

Title:	Early Pregnancy Assessment Unit Guideline (Care of a woman with bleeding and pain during early pregnancy)
Original Issue Date:	June 2017
Date of Last Review:	December 2017
Reason for amendment:	Clarification on pathway for accessing methotrexate via oncology department
Responsibility:	Department of Obstetrics and Gynaecology
Stored:	Women & Children's Shared Drive File
Linked Trust Policies:	Criminal Records Bureau Policy Induction Policy Inoculation/ Sharps Injury Policy
E & D Impact Assessed	
Consulted	WC Business Unit Group All Obstetricians All Gynaecologists All Gynae Nurses ED Department

REVIEW AND AMENDMENT LOG

Version	Type of change	Date	Description of Change
1	New Document	June 2017	Not Applicable
2	Amendments for clarification	December 2017	Amendments to Appendix 5 to clarify pathway for accessing methotrexate via oncology department

OPENING TIMES:

EPAU

Ext:

Bleep:

Pathway for Pregnant women ≤ 15+6 weeks attending the Emergency Department

Assessment in ED by advance triage nurse or clinician should include:

- History and clinical examination findings (i.e. positive pregnancy test, pain, bleeding, febrile)
- Full set of observations- MEWS recorded
- Pad check to assess vaginal loss if any
- Significant bleeding OR suspected ectopic send FBC, G&S and βhcg (see below)

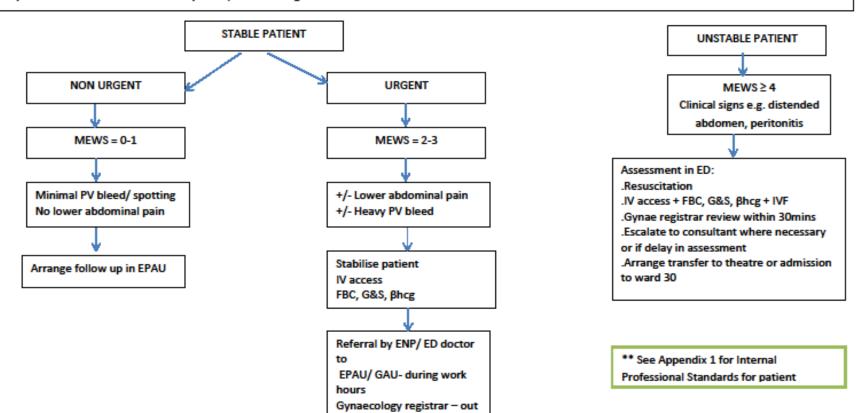
Above 15+6 weeks

Refer to obstetric guideline

Repeat attendances to ED- Refer to specialty doctor straight

NB

Consideration should be given to Domestic abuse and child protection issues



of hours

Pathway for Non Pregnant Women attending the Emergency Department

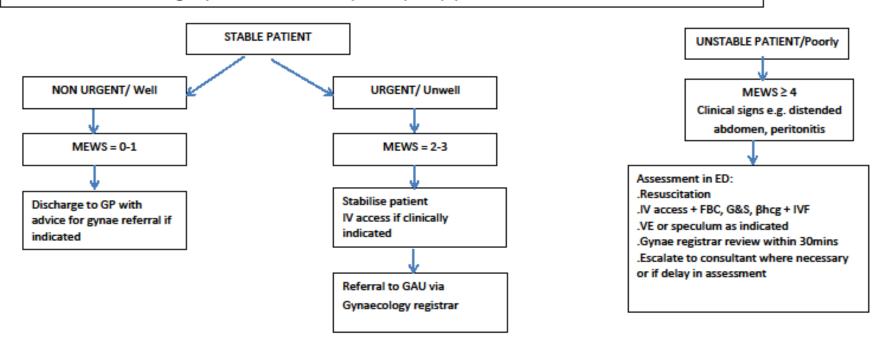
OPENING TIMES:

GAU Ext:

Bleep:

Assessment in ED by advance triage nurse or clinician should include:

- Negative urine pregnancy test/ negative bhcg
- History and clinical examination findings
- Full set of observations- MEWS recorded
- Pad check to assess vaginal loss if any
- Consider surgical pathology
- Discuss with ED middle grade/ consultant before referral; if seen by nurse, D/W doctor.



Burton Hospitals NHS Foundation Trust Division of Surgery Women and Children's Services

Early Pregnancy Assessment Unit Guideline (Care of a woman with bleeding and pain during early pregnancy)

1.0 Introduction

This guideline aims to reflect the best practice as per guidance issued by the National Institute of Clinical Excellence (NICE) and Royal College of Obstetricians and Gynaecologists (RCOG) on the management of pain and bleeding in early pregnancy.

Pain and bleeding in early pregnancy has adverse effect on the quality of life of many women. One in five pregnancies miscarry which can cause considerable distress to these women and family. Early pregnancy loss accounts for over 50,000 admissions in the UK annually. Ectopic pregnancies occur in 11 per 100 pregnancies with an estimated 11000 ectopic pregnancies diagnosed each year. Thus the incidence of ectopic pregnancies attending early pregnancy units is 2-3%. Unfortunately, women still die from ectopic pregnancy, with six maternal deaths reported between 2006 and 2008.

About two thirds of the deaths are associated with substandard care. Improvement in the diagnosis and management of early pregnancy problems is of vital importance in order to reduce the incidence of associated psychological morbidity and avoid unnecessary deaths of women.

2.0 Referral Criteria

Positive pregnancy test up to 16 completed weeks gestation AND at least one of the following

- Abdominal pain/ pain suggestive of ectopic pregnancy
- Active bleeding PV at greater than 6 weeks of pregnancy*
- Previous ectopic or molar pregnancy (self-referral from this group is acceptable)
- Recurrent miscarriage (more than 3 confirmed miscarriages)
- Pre-existing medical condition known to increase the risk of miscarriage
- * Women less than 6 weeks pregnant with PV bleeding but no pain or other symptom should NOT be referred to EPAU. They should be advised to continue with expectant management and to perform urine pregnancy test after a week and return if it is positive. A negative test means that the pregnancy has miscarried. Also advise women to seek medical advice if her symptoms continue or worsen.

2.1 Assessment

All women attending EPAU for the first time this pregnancy should have a comprehensive history taken by a gynae nurse or doctor and recorded on the EPAU history and assessment proforma on the computer. History includes details of the last menstrual period (LMP), cycle length, date of positive pregnancy test and estimated gestation as prompted by the proforma. Any relevant medical history, medications, obstetric history and allergies should also be

recorded. The woman should be asked about her smoking status, alcohol intake and any drug misuse.

Women should be informed that the date of their LMP may not give an accurate representation of gestational age due to the variability in menstrual cycles.

2.2 Information and Advice

- Clear, concise documentation should be filled in the appropriate place in the records
- Women should be informed what to expect while waiting for a repeat scan and should be given 24 hour telephone contact numbers so advice can be sought when needed
- Up to date, appropriate written information should be given to the woman
- If a miscarriage is diagnosed, the woman should be informed regarding listening and support service available and/ or counselling.

2.3 Investigations

A chlamydia test should be offered to all women who attend EPAU under the age of 25 years, in line with current screening policy. In addition all women who have a pregnancy loss should be offered chlamydia screening

3.0 Ultrasound Scan Diagnostic Criteria

NB: All scans must be transvaginal (unless unacceptable to the woman)

- All ultrasound scans should be performed and reviewed by someone with training in and experienced with diagnosing ectopic pregnancies
- Verbal consent should be obtained by the person performing the scan
- If a TV scan is declined by the woman, it should be documented and TA scan should be performed. The limitations of such should be clearly explained to the woman.
- TA scans should be considered when women have an enlarged uterus or other pelvic pathology such as fibroids or an ovarian cyst.
- Inform women that the diagnosis of miscarriage using one 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.
- An attempt to identify fetal heartbeat should be made. If there is no visible heartbeat but there
 is a visible fetal pole, the CRL should be measured. Only measure gestational sac diameter if
 fetal pole is not visible.
- When diagnosing complete miscarriage on scan, in the absence if a previous scan confirming

an intrauterine pregnancy, always be aware of the possibility of an ectopic pregnancy

 In all cases where a decision is being made on whether a pregnancy is non-viable, the scan must be checked by a second sonographer and/or a second scan should be performed a minimum of 7 days after the first scan before making a diagnosis

Type of scan	Fetal Pole CRL For determining viability	Mean GS measurement For determining viability (only measure MGSD id there is no visible fetal pole)
TV/TA	Greater than or equal to 7mm	Greater than or equal to 25mm

*on transvaginal scan, if the CRL is less than 7mm and there is no visible fetal heartbeat, or if the MGSD is less than 25mm and there is no visible fetal pole, perform a second scan minimum of 7 days after the first scan before making a diagnosis

Tubal Ectopic Pregnancy

- TV scan is the diagnostic tool of choice for tubal ectopic pregnancy. TV scan has reported sensitivities of 87.0 – 99.0% and specificities of 94.0- 99.9% for the diagnosis of ectopic pregnancy
- Tubal ectopic pregnancies should be positively identified, if possible, by visualising an adnexal mass that moves separate to the ovary
- There is no specific endometrial appearance or thickness to support a diagnosis of tubal ectopic pregnancy
- A small amount of free fluid in pouch of Douglas can be seen in both intrauterine and ectopic pregnancies and hence not diagnostic of ectopic pregnancy

Cervical Ectopic Pregnancy

- Occurs in less than 1% of ectopic pregnancies
- TV scan shows an empty uterus, a barrel shaped cervix, a gestational sac present below the level of the internal cervical os, absence of sliding sign and blood flow around the gestational sac using colour Doppler
- Sliding sign enables cervical ectopic pregnancies to be distinguished from miscarriages that ae
 within the cervical canal

Caesarean Scar Pregnancy

- Prevalence is 1 in 2000 pregnancies
- TV scan shows empty uterus, gestational sac or solid mass of trophoblast located anteriorly at

^{**}on transabdominal scan if the CRL is 7mm or greater and there is no visible fetal heartbeat or if the MGSD is 25mm or greater and there is no visible fetalpole, record the size of the CRL or MGSD respectively and perform a second scan a minimum of 14 days after the first scan before making a diagnosis

the level of the internal os embedded at the site of the previous lower uterine segment caesarean section scar, thin or absent layer of myometrium between the gestational sac and the bladder, evidence of prominent trohpblastic/placental circulation on Doppler examination and empty endocervical canal.

Interstitial Ectopic Pregnancy

- Pregnancy implants in the interstitial part of the fallopian tube, reported incidence varies between 1.0-6.3% of ectopic pregnancies
- TV scan shows empty uterine cavity, products of conception/gestational sac located laterally in the interstitial (intramural) part of the tube and surrounded by less than 5mm of myometrium in all imaging planes and the presence of the 'interstitial line sign'
- Interstitial line sign is a thin echogenic line extending from the central uterine cavity echo to the periphery of the interstitial sac
- 3D TV scan may be useful, ,supplemented by MRI if required

Cornual Ectopic Pregnancy

- One in 76000 pregnancies
- TV scan visualisation of a single interstitial portion of fallopian tube in the main uterine body, gestational sac/products of conception seen mobile and separate from the uterus and completely surrounded by myometrium, and a vascular pedicle adjoining the gestational sac to the unicornuate uterus

Ovarian Ectopic Pregnancy

- No specific agreed criteria for ultrasound diagnosis of ovarian pregnancy
- TV scan shows an empty uterine cavity, wide echogenic ring with an internal echoic area on the ovary

Abdominal Ectopic Pregnancy/ Hetrotopic Pregnancy

Rare, 1in12000 pregnancies

4.0 Medical Management of Miscarriage

All women should be offered expectant management as first line treatment for missed/incomplete miscarriage unless this is contraindicated (NICE 2012 Ectopic pregnancy & Miscarriage).

For women undergoing medical management the use of mifepristone is no longer recommended (NICE 2012 Ectopic Pregnancy & Miscarriage).

Aim for Medical management of Miscarriage as out-patient provided there are no contraindicated and the following criteria are met. Criteria for out-patient medical management:

- No contraindications
- Ultrasound diagnosis must be transvaginal

- Haemodynamically stable and not bleeding heavily
- Singleton pregnancy
- Gestation up to 13 completed weeks confirmed on scan
- In cases of incomplete miscarriage retained products of conception (RPOC) must be ≤ 50mm diameter
- Patient understands the procedure and need for compliance with follow-up arrangements
- Continuous support at home from an adult for at least 24-48 hours
- Must not be geographically isolated
- Must have access to transport in case admission to hospital is required#

Contra-indications to medical management

- Pyrexia
- Infection
- Anaemia (hb <95g/l)
- Haemoglobinopathies
- Anticoagulant therapy
- Long term steroid therapy
- Adrenal insufficiency
- Porphyria
- Jehovah's witness
- Allergy to misoprostol or other prostaglandins
- Heavy smoker over 35 yrs of age

Examination and Disposal of Products of Conception

- Options for disposal discussed with parents by midwife / nurse / doctor
- Sensitive disposal consent form completed & signed
- Any material which needs to be sent for histopathological examination must be accompanied by relevant request form and the pot must be labelled with the woman's details.
- Refer to policy on 'Disposal of Products of conception

References

National Institute of Health and Clinical Excellence (NICE) (2012) Pain & Bleeding in Early Pregnancy

National Institute of Health and Clinical Excellence (NICE) (2012) Ectopic pregnancy and Miscarriage

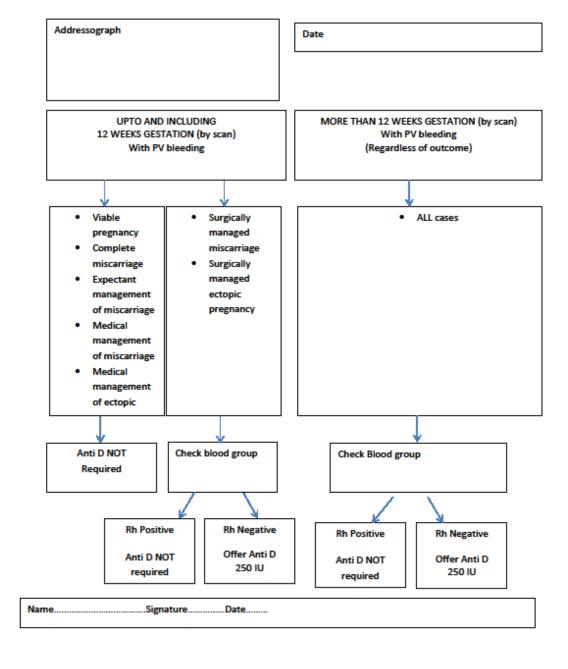
Diagnosis and Management of Ectopic Pregnancy, Green-top Guideline No. 21; Joint with the Association of Early Pregnancy Units November 2016

Appendix 1

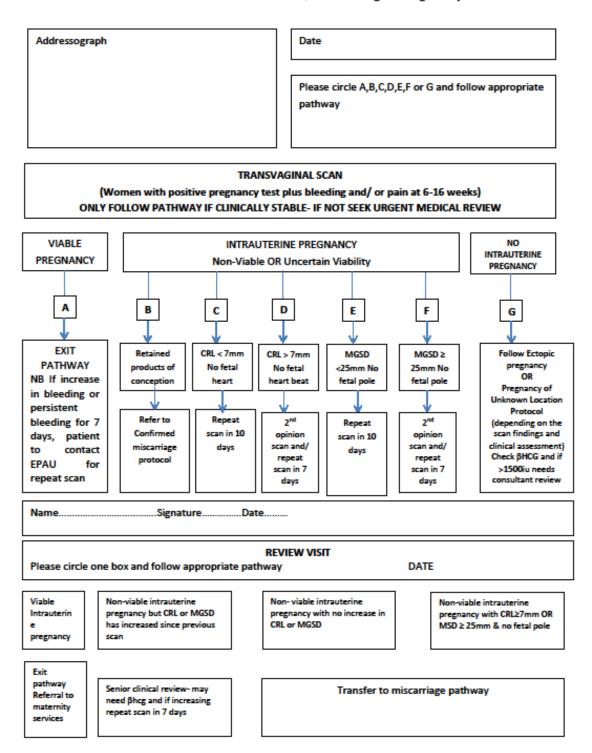
Internal Professional Standards for Patient Referrals

- Patients accepted by the specialty (or known to the specialty pre ED attendance) should be reviewed by the gynaecology team within 60 minutes of triage in ED
- Patients should not be discharged without direct clinical review by the middle grade specialty doctor
- If it is not possible to review the patient by the middle grade specialty doctor within 30 minutes of the initial gynaecology review the service consultant (08.30 to 1700) should be informed by the gynaecology team and between 1700 and 08.30 the on call consultant should be informed and asked to review the patient.
- Patients in whom an intrauterine pregnancy has not been previously confirmed and an EPAU appointment cannot be arranged within 24 hours should be offered admission
- The above patients who have previously been seen in ED and attend for a second time should be reviewed at consultant level or immediate admission arranged for subsequent review as an inpatient.

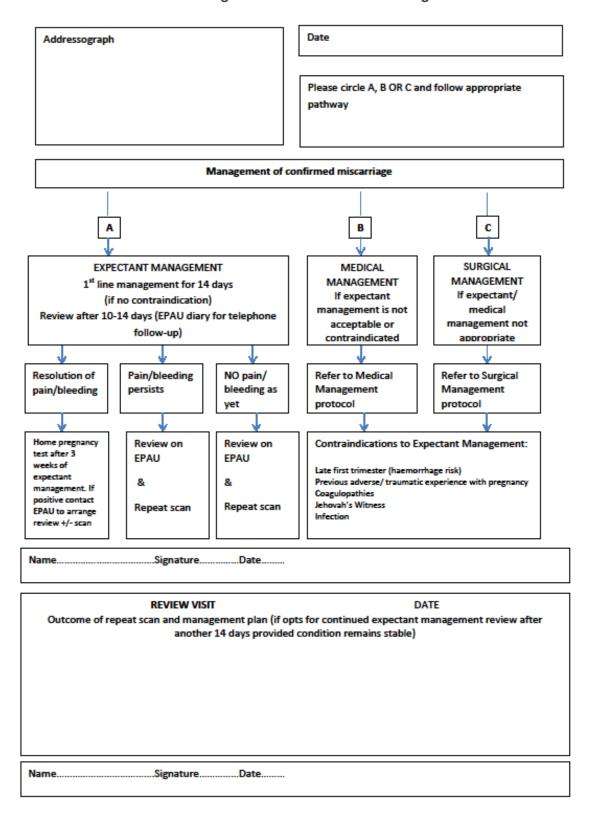
Anti D Administration



Assessment of Pain and/or Bleeding in Pregnancy



Management of Confirmed Miscarriage



Management of Ectopic Pregnancy

Addressograph	Date		
	Please circle A,B OR C pathway	and follow appropriate	
PATIENT WITH CONFIRMED ECTOPIC PR	GNANCY OR HIGHLY SUSPICIOUS OF E	ECTOPIC PREGNANCY	
Ţ		1	
HAEMODYNAMICALLY UNSTABLE	HAEMODYNAM	MICALLY STABLE	
Urgent Surgical management Large bore cannula FBC, G&S (if not done already), U&E, clotting? Crossmatch 4 units of blood Inform gynae reg/cons Inform anaesthetist Consent for surgery Consent for histology and disposal of tissue VTE Transfer to theatre Aim for laparoscopic	Medical Management A good candidate for methotrexate is one with: No significant pain Unruptured ectopic adnexal mass (<4cms) No visible FH βHCG: 1500iu/L — 3000iu/L (up to 5000iu/L may be acceptable) NO intrauterine pregnancy on TV Scan Willingness to return for follow up	Unable to return for follow up Medical management	
 surgery Salpingectomy is the surgery of choice 	No contraindications to MTX (sensitivity, pre-		
(salpingotomy if necessary) Complete surgical notes	Refer to Medical Management of Ectopic Pregnancy Protocol with Methotrexate Refer Surgical Management of Ectopic Pregnancy Protocol		

Non-Surgical Management of Ectopic Pregnancy

Expectant Management

Remember an ectopic usually needs treatment. Some ectopic pregnancies can be managed conservatively (and often have been in hindsight). It can only be done after discussion with the consultant on call. Expectant management is only suitable for small ectopic pregnancies with a tubal mass of less than 2 cms, the absence of recognisable fetal parts/identifiable extra uterine gestation sac on ultrasound scan, a serum β -HCG level <1000 IU/I, absence of free fluid and the absence of clinical symptoms.

Methotrexate

The use of laparoscopy for the diagnosis of ectopic pregnancy is often the main reason for the use of surgical interventions. In stable patients who fulfil the criteria below Methotrexate treatment is as effective as surgery. This should be discussed with a consultant first.

The ideal patient for methotrexate has minimal symptoms, no fetal heart activity, no blood in the POD an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat (NICE 2012), no intrauterine pregnancy (as confirmed on an ultrasound scan), is compliant with follow up and has a serum BHCG level of <3000. Á level up to 5000 may be acceptable, but the need for further doses of methotrexate, adverse quality of life data and likelihood of surgical intervention increases with increasing serum β -HCG levels at presentation and make it a less attractive option.

Side effects of methotrexate are occasional conjunctivitis, stomatitis and GI upset. Nearly 75% will experience abdominal pain following treatment, usually on day 6 or 7 and sometimes it is difficult to distinguish the 'separation pain' due to tubal abortion from pain due to tubal rupture. Women should be advised to avoid sexual intercourse during treatment and to use reliable contraception for 3 months following treatment because of the teratogenic risk.

The dose of methotrexate is 50 mg/m² and it is administered IM

Serum β -HCG level is checked on day 4 and day 7. A 15% fall in level is expected between day 4 and day 7. If this fall is smaller than 15% a second dose of methotrexate should be given. If the decrease is larger than 15% a weekly β -HCG level should be done until the level is less than 50 iu/l.

15% of women will need more than 1 dose of methotrexate and 7% will experience tubal rupture during follow-up

Methotrexate can also be used for the treatment of persistent trophoblast after surgical treatment of ectopic pregnancy and for pregnancies of unknown location if the serum β -HCG is less than 1500 and levels have reached a plateau. All women should receive the information leaflet and be counselled prior to starting methotrexate treatment.

Methotrexate administration should be a carefully considered intervention for suspected or confirmed ectopic pregnancy where there are no contraindications and viable intrauterine pregnancy has been excluded (see guidance). Adhering in particular to a BHCG of <3500 iu and a mass of less than 3.5cm in a stable patient is important. If there is perceived urgency to administer the methotrexate (unacceptable pain in particular) then the patient should be admitted and urgent laparoscopy considered.

Methotrexate (MTX) is prescribed using an order set which calculates the dose; it can be prescribed at any time of the day or night by any Medic working in the gynaecology team. However it can only be administered Monday-Friday 8.30-4.30pm:

- Methotrexate is only available from the pharmacy chemo unit, where they keep a range of different doses in ready-made syringes
- The chemo unit is **only open 8.30-4.30 Monday Friday.** It is not easily accessible outside of these hours
- Nursing staff from the Chemotherapy Day Case Unit administer the dose. It is usually given in
 the Day Case Unit towards the end of their working afternoon. There is *no* nursing staff available
 to administer the methotrexate outside of these hours

If a time delay of 2- 4 days (weekends / Bank Holidays) is too long, then the patient should either be taken to theatre for laparoscopy or transferred to Derby.

Methotrexate dose is 50mg/m² dose banded based on body surface area. To calculate the body surface area take the following measurements of the patient:

Weight in Kgs

- Height in cms
- BNF online can be used to calculate the patients BSA

Dosages are as follows:

Addressograph

- BSA 1.5-1.7m2 80mg
- BSA >1.7m2 <1.9m2 90mg
- BSA 1.9m2 and above 100mg

Medical Management of Ectopic Pregnancy - Results Sheet

			BLOOD	RESULTS				
	DATE	βHCG (IU/L)	FBC	U&E's	CREATININE	LFT's	G&S	Name & signature
Administration of Methotrexate (Day 0)								
Day 4								
Day 7								
Day 14								
Day 21								
Day 28								
Day 35								
Day 42								

1

Medical Management of Ectopic Pregnancy

Addressograph	Date
	(Please tick all boxes)
Ensure patient meets ALL criteria for medical Ensure patient has been counselled Obtain written consent Check baseline OBS are normal and docume Pulse	al management (see pathway) ent
NameDate	
REVIEW VISIT ON DAY 4 • Assess medical condition & if any concerns of Take blood for βHCG and record level on resonance of the Arrange to review on Day 7 Name	sults sheet
 Assess medical condition & if any concerns α Take blood for βHCG, FBC, U&E's, Creatining 	
If βHCG has increased or fallen by <15%, discuss wit consultant and reassess the woman's condition for further treatment	clinically stable, continue to repeat weekly until is 15iu/L. Senior medical review if <15% fall in βHCG at any time.
NameDate	1

Surgical Management of Ectopic Pregnancy

Addressograph	Date
	All surgical managements are performed under general anaesthetic
	(Please tick ALL boxes)
Insert wide bore cannula (If UNSTABLE, in If UNSTABLE Cross match at least 4 units Inform senior medical staff (Immediately Inform Anaesthetist If UNSTABLE, speak to theatre co-ordinately Inform Anaesthetist If STABLE, book patient onto the theatre Contact Bed Manager Ensure patient has been counselled and polyobain written consent Obtain written consent for histology and Prescribe Anti-D if required-Refer to Anti-Advise patient regarding fasting and admit	nsert two wide bore cannulas) of blood y if UNSTABLE) for to arrange transfer to theatre urgently list provide written information disposal of tissue i-D flowchart
NameSignature	Date

1

Medical Management of Miscarriage

Addressograph		Date			
Medical Management of confirm	ed Miscarriage				
(Missed or Incomplete)			(Please tick all boxes)		
	411				
		utpatient medical manage to outpatient medical mai			
	as been counselled	o outpatient medical mai	nagement		
Obtain written co					
Check baseline O	BS are normal and do	cument			
Pulse	BP	. Temp			
		ct patient & admit for in p	_		
l .	_	se of MISOPROSTOL 800 r OL 800 micrograms for 2	_		
		take home (advise avoid			
_	minister Anti-D if requ	•	ance of rearing sy		
			mation & contact numbers		
Check advice give	en re: disposal of any f	etal tissue			
Post size of Poin	/blooding	Daile (Line diese	No original desired		
	/bleeding	Pain/bleeding persists beyond 3	No pain/bleeding		
1 1	sening	1	after 24 hours		
bleeding		weeks			
	<u></u>				
Home pregnancy Con	tact EPAU /	Contact EPAU	Contact EPAU to		
	ae registrar	Contact Li Ao	arrange review. Either		
	rrange	Repeat scan &	repeat misoprostol or		
	ENT review	review	continue expectant. If		
arrange repeat			neither acceptable		
scan & review			review by consultant		
NameSignat	NameDate				
REVIEW	REVIEW VISIT DATE				
Outcome of repeat scan and management plan:					
NameSignato	ureDate				
•					

Pregnancy of Unknown Location

Addressograph		Date				
			Please circle A,B OR C and follow appropriate pathway			
NB Signs and	Symptoms along with	clinical examinati	REMENTS 48 HOUR on are equally impo on or any of her syn	ortant along with β	hcg with a view	
	A V	B		c		
βHCG INCREASE (likely to be vial BUT Ectopic car out)	ble intrauterine,	βHCG CHANGE BETWEEN 50% DECREASE AND 63% INCREASE (Ectopic likely)			BHCG DECREASE >50% (likely to be failing pregnancy)	
		? ECTOPIC Urgent senior re	eview	Repeat home urine pregnantest in 14 days Make a note in the diary for telephone follow-up		
NameSignatureDate						
REVIEW VISIT Please circle one box and follow appropriate pathway DATE						
Viable intrauterine pregnancy	Non-Viable intrauterine pregnancy	NO intrauterine pregnancy		Positive	Negative	
EXIT pathway, referral to maternity services	Refer to 'Bleeding in pregnancy' pathway	? ECTOPIC Urgent senior review		? ECTOPIC Urgent senior review	EXIT pathway	
NameSignatureDate						

Surgical Management of Miscarriage

Addressograph	Date
	All surgical managements of miscarriage are performed under general anaesthetic
Surgical Management of Miscarriage (Missed or In	ncomplete)
	Please tick all boxes
No contraindications to surgical managen Counselling offered and written informati Written consent Histology and disposal consent Baseline OBS Pulse	ion given
Take blood for FBC, G&S	•
 Prescribe Misoprostol 400 micrograms ?? antibiotics 	
Prescribe Anti-D as required (refer to anti	i d flowchart)
 Book onto theatre list Advise patient regarding fasting and admi 	ission arrangements
Allow patient to go home if appropriate v	vith written information and contact numbers
•	

.....Date......Date.....