

Miscarriage or early pregnancy loss-diagnosis and management

(Version 5)

Guideline Readership

This guideline applies to all women diagnosed with miscarriage in early pregnancy (up to 13 completed weeks) within the Heart of England Foundation Trust and to attending clinicians, sonographers and nursing staff on Gynaecology ward and early pregnancy unit.

All care is tailored to individual patient needs, with an in-depth discussion of the intended risks and benefits for any intervention offered to woman with early pregnancy loss.

Guideline Objectives

The objective of this guideline is to enable all clinicians to recognise the different types of miscarriages and to follow a recognised management pathway so that all women with actual or suspected miscarriage receive, an appropriate and individualised care.

Other Guidance

Ectopic pregnancy and miscarriage: diagnosis and initial management. NICE guidance Dec 2012

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Guideline Author: Dr Rajmohan, Dr Cheema

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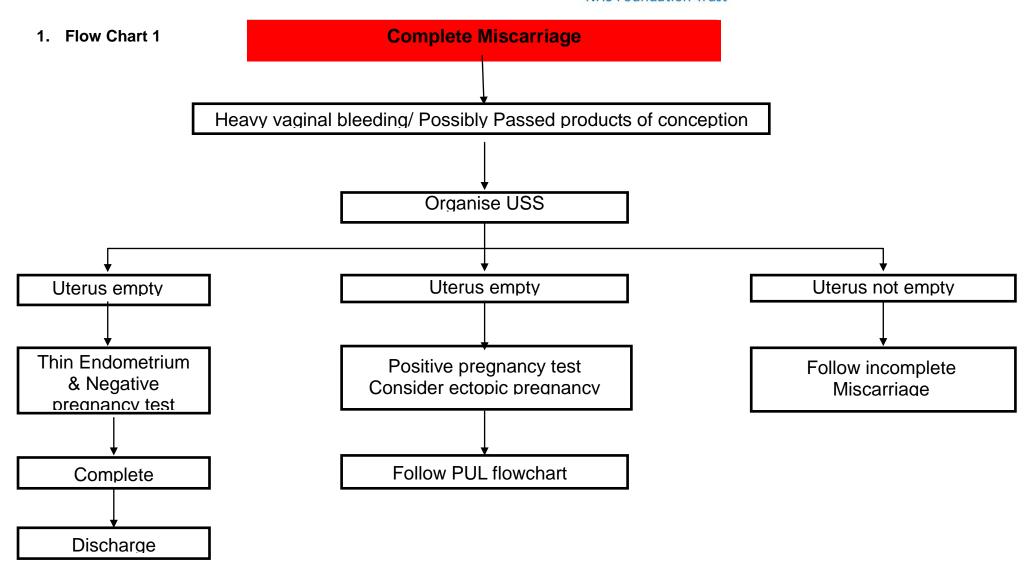
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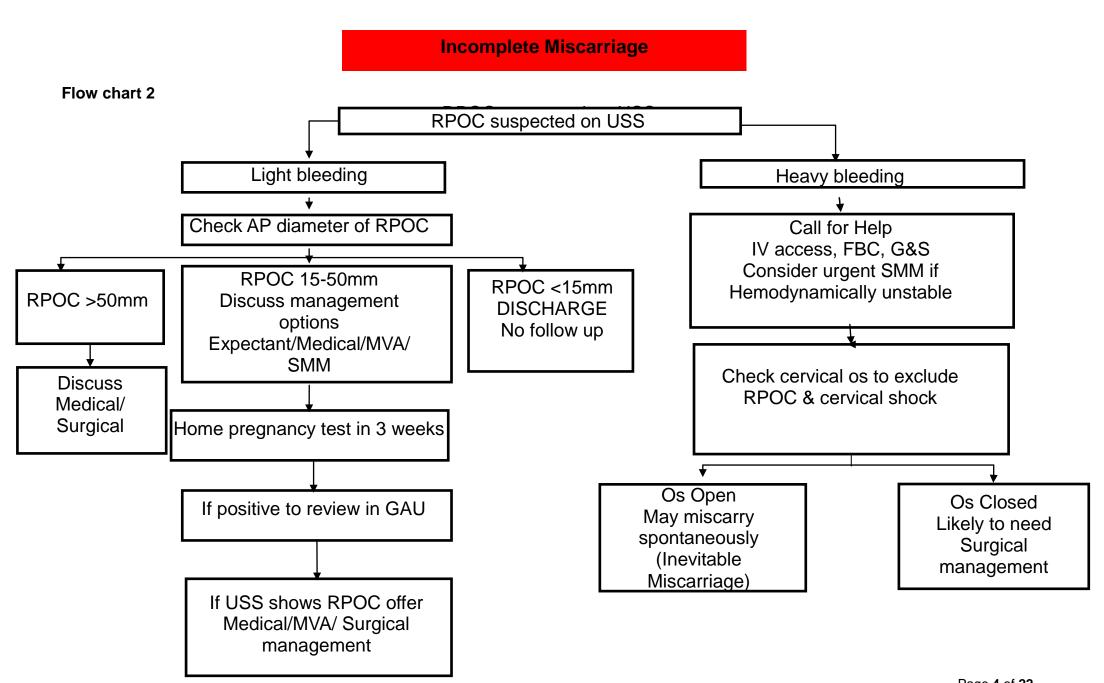
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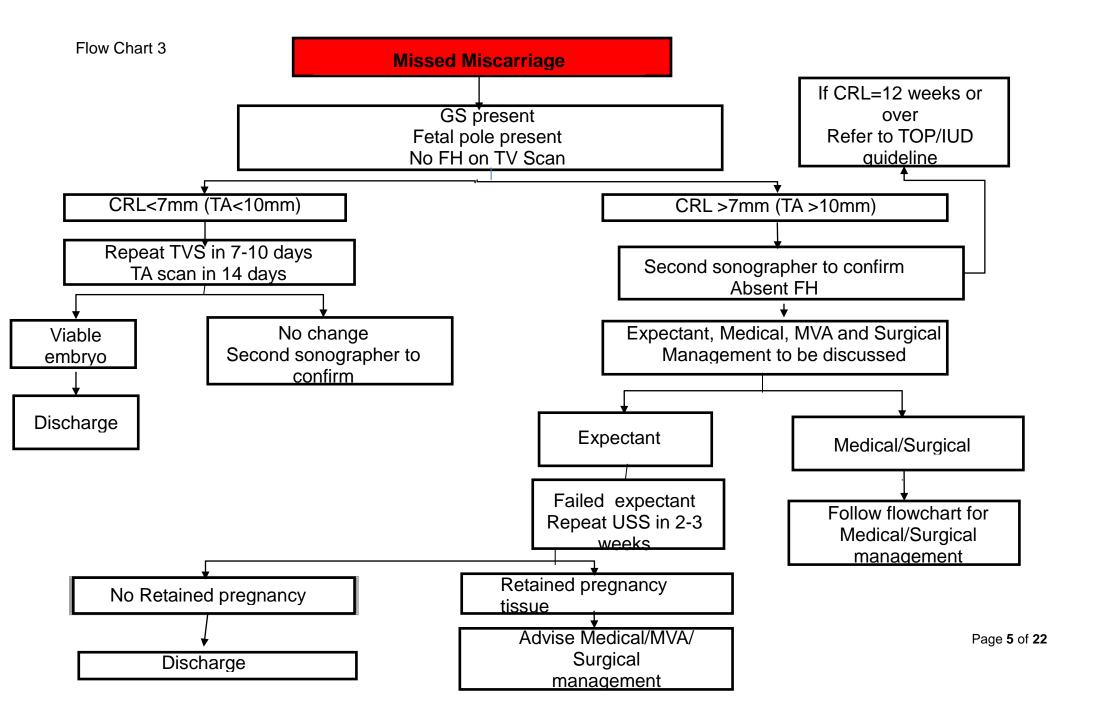


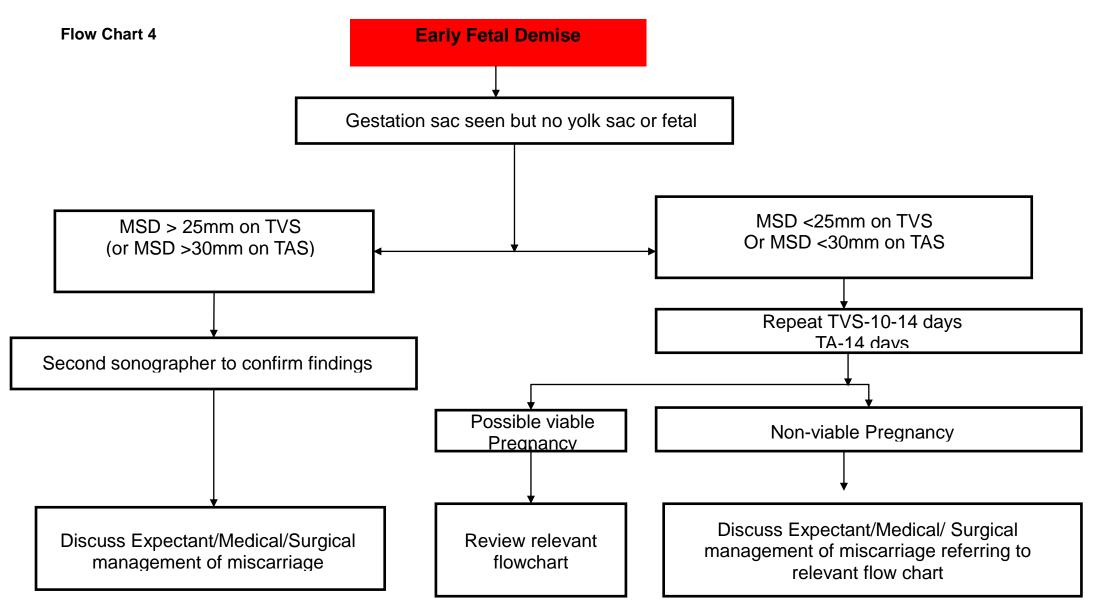


NB: Consider the possibility of an ectopic pregnancy when no previous evidence of intrauterine pregnancy. Perform pregnancy test.



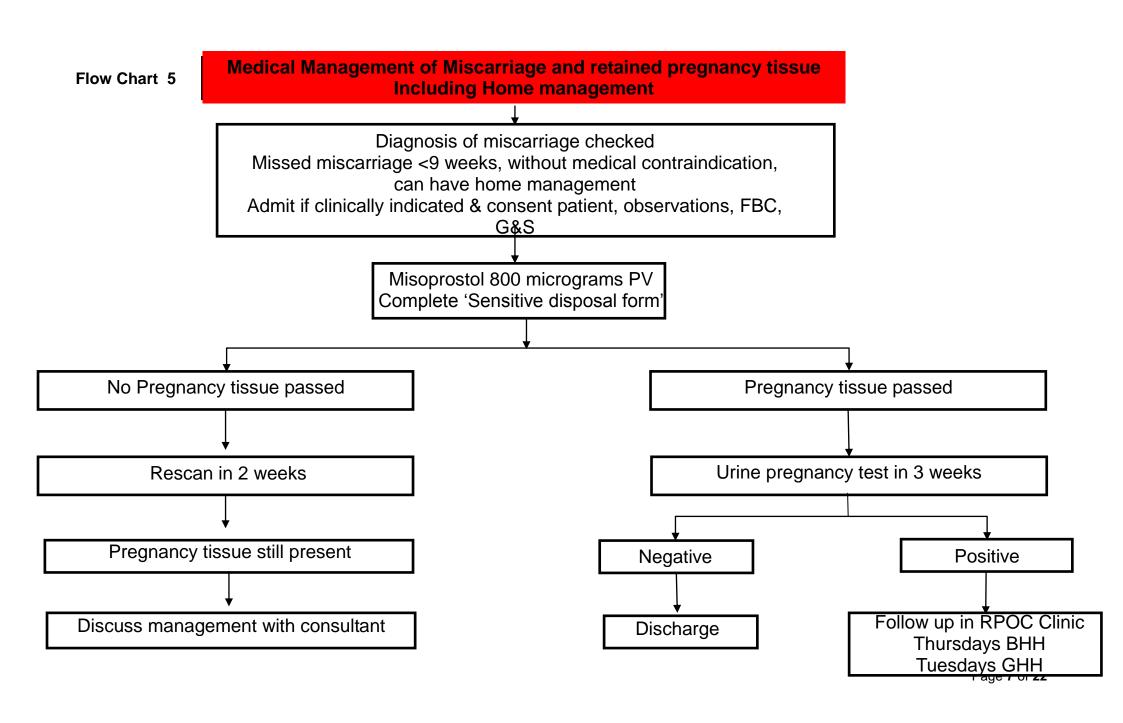
NB: No need for anti-D prophylaxis to women <12 weeks pregnant and who have complete, threatened or medical management for miscarriage

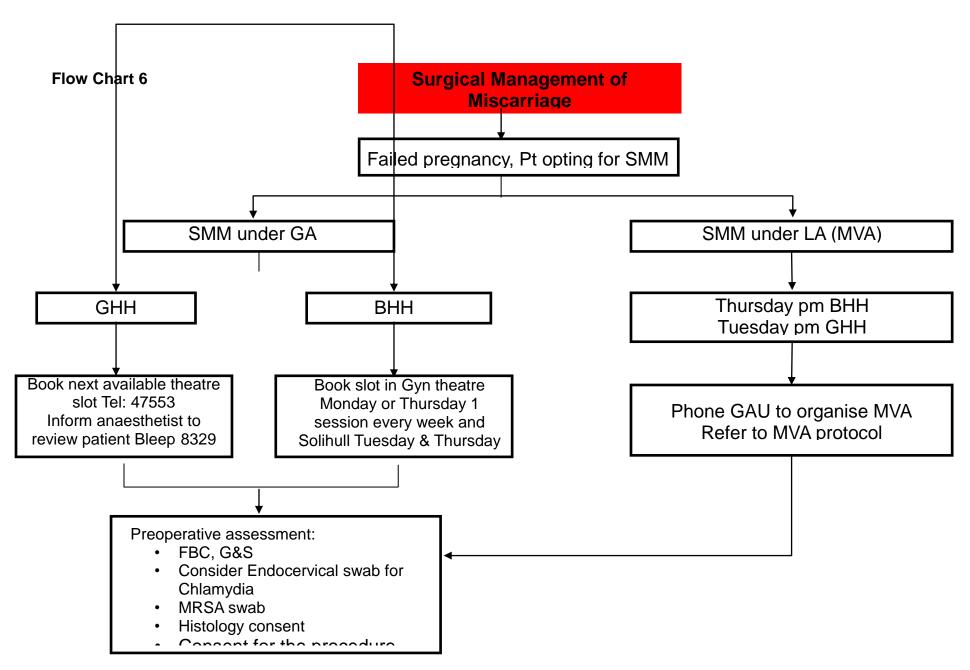




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NB: If referral is only for pain and a yolk sac seen, no further follow-up is required and patient discharged with routine





NB: Offer anti-D rhesus prophylaxis (atleast 250IU) within 72 hours of having SMM to all non-sensitised rhesus regative



2. Executive Summary & Overview

Miscarriage is common and is thought to occur in 10-20% of clinical pregnancies. 1 it accounts for 50000 inpatient admissions in the United Kingdom annually 2 and can have both medical and psychological consequences.

Most miscarriages are thought to be related to chromosomal abnormalities (50%), but other causes should be considered especially in cases of recurrent miscarriage. Regardless of the cause, protocols of management should be followed.

3. Body of Guideline

Types of Miscarriage

Threatened Miscarriage

Clinical definition- There are symptoms of bleeding and or pain in ongoing pregnancy. No products of conception have been passed The cervix is closed on examination.

This describes the presence of vaginal bleeding in early pregnancy when the pregnancy has been found to still be viable. About 25% of all pregnancies threaten to miscarry⁴.

Demonstration of fetal heart activity is generally associated with a successful pregnancy rate of 85-97%⁵, depending on the period of gestation and the woman should be reassured of this.

Further ultrasound scans are not routinely needed unless there are further clinical concerns.

A dating scan at 12 weeks will pick up the small proportion of women who go on to have a missed miscarriage.

Complete Miscarriage

Clinical definition-The products of conception have totally passed, the cervix is closed on examination and there is no bleeding and cramping.

A complete miscarriage is defined as cessation of vaginal bleeding and an endometrial thickness <15mm with no evidence of retained products of conception on TVS⁵.

A woman with complete miscarriage, where intrauterine pregnancy had previously been confirmed on a scan, does not require any further follow up unless further clinical concerns. See flow chart 1 for management guide

Remember – always consider the possibility of an ectopic pregnancy where an empty uterus is found on ultrasound scan.

Incomplete Miscarriage

Clinical definition-Some products of conception have passed but some still remain in the uterine cavity. The cervical os is open and the patient still has cramps and bleeding.

Incomplete miscarriage is defined as vaginal bleeding with the presence of heterogeneous (not uniform in density), irregular tissues (with or without a gestational sac) consistent with retained products of conception 15-50mm on TVS⁵.

See flow chart 2 for management guide.

92% of women will complete their miscarriage spontaneously without surgical intervention within 2 weeks. Any woman who presents with an incomplete miscarriage with haemodynamic compromise, heavy vaginal bleeding, or signs of infection should be managed surgically without delay⁵.

Missed Miscarriage

Clinical definition-No products of conception have been passed. There may be spotting or some pain, but there may be no symptoms.

The term "embryonic failure" or missed miscarriage is used to describe a pregnancy where the embryo stops developing and no heart pulsations can be seen.

The diagnosis of a missed miscarriage may only be made on the basis of the crown rump length (CRL) of at least 7 mm on transvaginal scan (CRL>10mm if only transabdominal scan performed) with no cardiac activity⁶ as about one-third of embryos with a crown rump length of less than 5 mm have no demonstrable cardiac activity.

Use the phrase 'pregnancy of uncertain viability 'for a gestation sac less than 25mm with a yolk sac or CRL less than 7mm with NO heart beat.

Women should be informed that diagnosis of miscarriage using one ultrasound scan cannot be guaranteed to be 100 % and there is small chance that the diagnosis may be incorrect, particularly at very early gestational ages⁷.

A small or irregular gestational sac, discrepancies between the crown rump length and gestation by LMP, and an abnormal pattern of embryonic heart rate are predictors of a poor pregnancy outcome. Thus a repeat diagnostic transvaginal scan with an interval of 7-10 days is frequently necessary before a definitive diagnosis of a non-viable pregnancy can be made. Always consider the possibility that conception occurred later than expected – especially if contraceptive pill recently stopped or if patient has irregular cycle.

If CRL = 12 weeks gestation or over, refer to IUD guideline for management See flow chart 3 for management guide

Early fetal demise (Empty sac)

Early fetal demise is defined as a failed pregnancy where the gestation sac develops but there is no identifiable fetal parts i.e. no yolk sac or fetal pole (empty sac). This can also be referred as an anembryonic pregnancy

Transvaginal ultrasound diagnosis classically requires a gestational sac with: mean sac diameter > 25mm without a yolk sac, or an embryo⁷.

To avoid an error in missing an early yolk sac, the diagnosis of early fetal demise should be made using: MSD of at least 25mm on TVS (30mm on TAS) and absence of fetal parts OR absent normal growth of the gestation sac and absence of fetal parts after 10-14 days. See flow chart 4 for management guide

Management

A clinical assessment should be carried out in all patients who are symptomatic. This will include an abdominal and pelvic assessment to assess severity of bleeding, products of conception and the status of the cervical os. Management should take into account patient choice and the clinical situation. In emergency situations, when patient is bleeding heavily, Surgical management under general anaesthetic is most appropriate. In non-emergency situation advise woman of following management options with pros and cons of each.

Management option	Advantages	Disadvantages
Expectant	safe, 'natural' (avoid hospital admission / intervention), autonomy	Need for follow up, may take few weeks, discomfort, need for further intervention,
Medical	Safe, avoid surgery and anaesthetic	Discomfort, side effects of diarrhoea, may need surgical intervention for failure or heavy bleeding
Surgical (including MVA under local)	Safe, quick, low risk of further intervention	Risks of anaesthetic, surgical risk of damage to cervix, uterus, intrauterine synechiae, perforation, failure less than 5%

Expectant Management of Miscarriage

A successful outcome without surgical intervention is expected in 81% of cases of miscarriage regardless of cause. However, different types of miscarriage carry different rates of spontaneous resolution (incomplete miscarriage 91%, missed miscarriage 76%, early fetal demise 66%)⁸

Overall, 70% of women complete their miscarriage within 14 days of diagnosis, and again this varies depending on the type of miscarriage: incomplete miscarriage 84%, missed and embryonic miscarriage 52%. The duration may be as long as 8 weeks. Ultrasonography can be used to advise patients on the likelihood that their miscarriage will complete spontaneously within a given time.

NICE guideline (2012) recommends 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 if⁷

- The women is at increased risk of haemorrhage (for example late first trimester)
- Previous adverse or traumatic experience (still birth, haemorrhage)
- At increased risk from the effects of haemorrhage (coagulopathies or unable to have transfusion)
- Evidence of infection

Expectant management of incomplete miscarriage has excellent success rate and evidence suggests that it is associated with lower rates of infection than surgical management⁸. This is the preferred treatment option in haemodynamically stable women with small volume RPOC (antero-posterior endometrial thickness 15-50mm) on scan, and should be offered and encouraged to all women who present with an incomplete miscarriage. It has been demonstrated to be safe and without serious morbidity.

Those who choose to be managed conservatively where bleeding is light should repeat a urine pregnancy test in 21 days (refer to relevant guideline). They should contact the hospital for review if urine pregnancy test remains positive after 3 weeks or if they continue to have bleeding for more than 2 weeks⁵. Depending on the symptoms and clinical assessment, FBC and G&S may be required in some cases.

Medical Management

Medical management of miscarriage is an accepted and safe alternative to surgical management, and utilizes prostaglandins (Misoprostol) and or anti-progesterone agents (Mifepristone) Do not offer Mifepristone for missed or incomplete miscarriage.

Medical management should be offered to women with confirmed diagnosis of miscarriage if expectant management is not acceptable to the women. The medical management, if successful, avoids the need for general anaesthesia and surgical instrumentation. Morbidity in those treated medically was lower (1.7% versus 6.6%) than in those requiring surgery. However, women should be advised that medical management may fail and the need for surgery remains a possibility.

The efficacy of medical management is greatest in pregnancies of ≤9 weeks on ultrasound scan, or with a mean sac diameter of less than 24mm. A success rate of 92-94% can be expected in such cases¹¹.

There is no statistical difference in efficacy between surgical and medical evacuation at this gestation or sac size. However, subsequent intrauterine/pelvic infection is significantly greater in the surgical group. The preferred prostaglandin, Misoprostol, is most effective if administered vaginally, however, oral administration is an option (95% versus 87%)¹².

The diagnosis of miscarriage must be confirmed and the decision of treatment must be made by a ST2 or above or a Consultant.

Medical management can be undertaken successfully on an outpatient basis. This approach should be considered and offered to all suitable patients.

Suitability for outpatient medical management

- Confirmed diagnosis of miscarriage by USS
- Pregnancy less than 9 week gestation by USS
- Incomplete miscarriage with RPOC <50mm

- Healthy patients with stable vital signs
- Not bleeding heavily
- Patient must be reliable and compliant
- Patient must be aware of advantages and disadvantages including risk of heavy bleeding and possible need for surgery
- Availability of adult company at home following misoprostol administration

Contraindications

Absolute

- Overt signs of infection or clinical signs of infected RPOC
- Anticoagulant therapy
- Anaemia (Hb <10 g/dl)
- Non-compliant and non-consenting patient
- Molar pregnancy
- Severe intolerable pain

Relative (See Flowchart 5 showing medical management of miscarriage)

- Inflammatory bowel disease
- Cardiovascular disease

Treatment regimen - Day 1 Misoprostol 800 micrograms vaginal (oral administration is an acceptable alternative if woman declines PV)

If no pregnancy tissue passed:

- Follow up in EPAU or GAU with pelvic USS (preferably TVS) in two weeks.
- If the scan shows empty uterus or RPOC <15mm, to consider as complete expulsion and discharge
- If scan shows RPOC 15-50 mm, to discuss further management options (expectant, medical or surgical RPOC). To encourage SMM especially if bleeding.
- Follow up in 2 weeks for all women who have retained products >15mm and choose to continue with expectant or medical management.
- Pregnancy tissue passed (consider USS if in doubt) & Offer pelvic scan to confirm complete expulsion

Women with previous caesarean section or myomectomy having medical management for missed miscarriage for pregnancies <14 weeks gestation do not require any reduction in misoprostol dosages, however, such patients may need a period of observation in the hospital following misoprostol administration. In a case where pregnancy is above 14 week gestation and a woman has had multiple previous uterine surgeries or a complicated previous uterine surgery, a consultant's advice should be taken with regard to the management plan.

For outpatient management of miscarriage

- 1. All eligible women should receive explanation of the procedure, the risks and benefits of outpatient medical management and should be provided with the information leaflet.
- 2. Once a woman has agreed for the outpatient medical management, the ST2-ST7 or EPAU/GAU nurse should commence the checklist and complete the following:
- a. Clerking
- b. Clarification of the procedure and documentation
- c. Consent
- d. Samples for FBC and G&S
- e. Prescribe misoprostol, analgesics, (optional antiemetic, Loperamide)
- f. Follow up dates should be arranged with EPAU/GAU
- 3. The checklist should be filed in patient's main records (appendix 1). Name, hospital number and date of first visit of all women having home medical management should be recorded in the EPAU book for follow up and audit purposes.

4. Women should be given the information leaflet (what to expect during and after outpatient medical management for miscarriage). She should be provided the contact number(s) and open access to call the gynaecology ward for advice and support during the procedure. Psychological support and contraceptive advice should be provided to all women who have had a miscarriage.

Follow up

All women having outpatient medical management, with whom a scan shows retained products >15mm and who chose to continue with expectant or medical management, should be offered a follow up appointment in EPAU/GAU 2 weeks after the start of procedure. At this appointment, enquiry should be made about passage of tissue and amount of bleeding PV. If the history suggests complete expulsion of products and/or pregnancy test is negative, women should be discharged. If there is suspicion of incomplete expulsion, women should be offered a pelvic scan (preferable TVS). RPOC >15mm in AP diameter should be classified as incomplete miscarriage and in these cases women should be offered a further management plan, which could either be an expectant management, SMM or a further course of medical management in hospital or at home.

Inpatient medical management of miscarriage

All women who wish for a medical management, but are unsuitable for an outpatient treatment, should be advised to stay in hospital for 24 hours. If no pregnancy tissue is passed within 24 hours, a senior review is needed to discuss further treatment options including a second dose of misoprostol. Women continuing with the expectant or medical management should be offered a follow up appointment in EPAU/GAU 2 weeks after the start of procedure as above.

Surgical Management of miscarriage (SMM)

Surgical management should be reserved for those with heavy bleeding or who are compromised, tissue diameter >50mm, have infected tissue or who change their mind during course of conservative management.⁵ If spontaneous resolution does not occur within a 4 week period of conservative management then these women should be advised to have an SMM to exclude gestational trophoblastic disease, and placed on the theatre list. Fewer than 10% of women who miscarry fall into these categories¹⁴.

See flowchart 6

Depending on the HEFT site, patients are booked preferably onto the daily morning emergency theatre list (0830hrs at Good Hope Hospital) or onto an elective general consultant list after discussion with the relevant consultant, or as a last resort on to the emergency list to be done between other emergency cases.

The diagnosis of miscarriage must be confirmed and the decision of treatment must be made by a ST2 or above or a Consultant.

When infection is suspected, iv antibiotics for 24-48 hours should be considered before surgical procedure.

Consider screening for STIs (Chlamydia) in women less than 24 years of age due to higher prevalence. Alternatively give metronidazole 1g rectally at the time of surgery and Doxycyline 100mg orally for 7 days.

All patients booked for SMM need a pack containing as a minimum:

- Consent form
- Information sheet
- Scan report
- Blood test reports (minimum FBC, G&S)
- Drug chart
- Clerking form
- Early pregnancy loss leaflet
- Counselling services leaflet

The RCOG study group (1997) recommended that all tissue obtained at a surgical evacuation for miscarriage should be sent for histology examination to exclude molar and ectopic pregnancy. (see Flowchart 6)

Referrals from Fetal Medicine Unit (GHH)

All woman referred from the Fetal Medicine Unit (FMU) with an early pregnancy loss >10 weeks gestation should be advised to have surgical management because of the potential for heavy vaginal bleeding following expectant management.

Any referrals can be put directly onto the theatre list (see procedures steps below). If any woman wishes to have a consultation to discuss their early pregnancy loss and/or further management required an appointment should be made via reception.

Where possible, preoperative assessment should be carried out prior to admission to ensure patients are not delayed for early morning lists (GHH), and also to ensure that all requisite paperwork required for surgery is completed.

Fetal medicine should liaise with GAU directly for the date and time of the next available or convenient admission for SMM. A date and time should be given to the patient to attend the EPU the morning of the surgery for clerking and consenting. The patients Name, date of birth (DOB) and diagnosis must be recorded onto the theatre list. A copy of the scan report from FMU must be in the patient notes. On arrival to EPU on the morning of treatment the women will follow the Day Surgery unit SMM list guidelines. Patients should be given an appointment to return to the emergency gynae unit (EGU) prior to the theatre list.

On the day of surgery, they will have a consultation with a member or the EPU team. If they have had any increased bleeding since their last scan, a rescan may be necessary to ensure that surgery is still necessary. If surgery is still required, they will see the EGU nurse who will admit them, assess their suitability for surgery, and check that the woman's 'SMM Pack' is available and up-to-date for surgery to commence. The doctor undertaking the operation should see, the consent and patient prior to surgery to familiarise themselves with the case and the suitability for operation.11

Women likely to have a closed Os should be counselled for the need for Misoprostol 800 micrograms to be inserted into the posterior vaginal fornix 2 hours prior to surgery to aid cervical dilatation. The patient should be advised to remain seated after insertion to ensure the tablets are absorbed effectively.

Outpatient surgical management of Miscarriage (manual vacuum aspiration [MVA] under local anaesthesia)

Vacuum aspiration is an appropriate method of surgical abortion and services should be available to provide surgical abortion without resort to general anesthesia.16 A number of women will be suitable for outpatient surgical management i.e. manual vacuum aspiration (MVA) under local anesthesia. This service is currently being offered at the Heartlands site via GAU. See flow chart 6 Inclusion criteria.

- Incomplete miscarriage RPOC <50mm
- Failed medical management
- Missed miscarriage ≤ 10weeks
- Haemodynamically stable
- No signs of clinical infection- fever/offensive discharge/ generalized lower abdominal pain.

At the time of decision

- Take consent
- Send bloods for FBC, G&S
- Prescribe Misoprostol 800 micrograms PV and Ibuprofen 400 mg PO on the drug chart (codeine if asthmatic) or Paracetamol 1gm or diclofenac 100mg PR
- Provide patient information leaflets- MVA
- Early pregnancy loss
- Counselling service
 - Arrange for procedure after discussing with relevant gynaecology consultants.

Provide patient with details of admission (day, date, time and contact details of ward).

Post procedure patient recovers in the recovery area for 1-2 hrs. MEoWS chart will need to be completed as for routine post op.

Anti-D rhesus prophylaxis

Blood Group should be checked and offer anti-D rhesus prophylaxis (at least 250IU within 72 hours of the event) to all rhesus negative women who have a surgical procedure to manage a miscarriage.

Do not offer anti-D rhesus prophylaxis to women who are less than 12 weeks pregnant and:

- · have received solely medical management of miscarriage or
- · have a threatened miscarriage or have a complete miscarriage or
- have a pregnancy of unknown location (PUL) refer to relevant guideline

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

General management after a miscarriage

All suspected pregnancy tissue should be sent in formalin for histological examination.

Cytogenetics studies should be offered to all women who have had 3 or more consecutive miscarriages. The tissue for cytogenetics should be sent in Sodium Chloride 0.9%.

The 'Sensitive disposal of pregnancy tissue' form must be completed for all tissue samples sent for histological and or cytological examination.

The leaflets 'After a Miscarriage' and 'We are sorry you have had a Miscarriage' should be given to the patient along with verbal advice about what to expect.

Women should be informed about the miscarriage association support group, which is run once a month at the Heartlands hospital.

4. Reason for Development of the Guideline

The guideline provides information to all clinicians as to the appropriate management and care for women presenting with suspected or actual miscarriage.

5. Methodology

Development of all guidelines adheres to a process of examining the best available evidence relevant to the topic, incorporating guidance and recommendations from national and international reports.

Finalised guidelines will ultimately be approved and ratified by the directorate locally

6. Implementation in HEFT & Community – Communications

Following approval the guideline will be disseminated and available for reference to all members of the multidisciplinary team via the Trust and Obstetric intranet site; also paper copies will be stored in a marked folder within a designated clinical area

7. Monitoring & Suggested Quality Standards

Adherence and efficiency of the clinical guideline will be monitored through regular clinical audit. Following clinical audit of a guideline an addendum to change in clinical practice may be necessary. Any change to a clinical guideline requires that it must be ratified by the directorate locally.

Review dates for guidelines will be set at a period of three years; however this set period can be overridden in light of new clinical evidence.

All unused/previous guidelines will be logged and archived electronically, and in paper format within the trust.

8. References

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Meta Data

Guideline Author:	Dr Rajmohan , Dr Cheema	
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Approved by:	The individual or Committee approving the Guideline	
Date of CGG Ratification:	The date that the Guideline was ratified by the Clinical Guideline Group	
Date of Launch:	The date on which the Guideline will be implemented / 'go-live'	
Review Date:	A date by which the guideline must be reviewed and amendments made	
Key Words	Include key words which can be used as search criteria for a document management system or intranet site. Do not include commonly used words such as "Guideline" "Patient" etc	
Related Policies / Topic /	In this section list or provide hyperlinks to known documentation either	
Driver	internal or external that have been recognised as drivers for the ratification of the Guideline	

Revision History

Version No	Date of Issue	Author	Reason for Issue
1	November 2010	J. Rutter & P. Pradhan	Trust merger, updated version but not published
2	November 2013	J. Rutter – CNS specialist N. Aslam – Specialist Registrar P. Gupta – Cons. O&G	Full review
3	January 2014	M. Wyldes – Cons. O&G P. Gupta – Cons. O&G	p.11-12 Inclusion management of Molar pregnancy
4	December 2014	R. Small – Specialist midwife J. Rees – CNS Gynaecology	page 8 flow chart 5 & page 14 -medical management of miscarriage and retained pregnancy tissue, changed to offer pelvic scan to confirm complete expulsion Page 6 flowchart 3 & page 11 - Management inclusion: If CRL = 12 weeks gestation or over, refer to TOP/ IUD guideline for management
5	March 2018	Rajmohan Palaniaapan- D Cheema- Cons O&G	Reformatted to new trust guideline template Change in terminology- early fetal demise instead of anembryonic pregnancy. Change in recommendations for TA scan from 10- 14 days. Addition of clinical definition for types of miscarriage Management options table with summary of pros and cons Addition of surgical management if infection is suspected. Molar pregnancy excluded as now a separate guideline

Clinical Director: Signed:

Name: Pratima Gupta

Date: 16 March 2018

11. Appendices Appendix 1 - Checklist - <u>Outpatient management for miscarriage</u>

Date checklist commenced	
Name	
PID	
DOB	
Address	
Contact telephone no	
·	

Date when diagnosis confirmed by USS		
Gestational age less than 9 weeks	Yes	No
Clerking completed	Yes	No
Indication and contraindications checked and documented	Yes	No
Consent form completed and signed	Yes	No
Samples sent for FBC and G&S	Yes	No
Prescription chart completed	Yes	No
TTOs signed (misoprostol, analgesics, antiemetic, Loperamide)	Yes	No
Patient details recorded in the result follow up book for Blood group	Yes	No
Patient details recorded in the EPAU book for follow up	Yes	No
Information leaflets given (home management, support leaflets)	Yes	No
Patient satisfaction questionnaire given	Yes	No
Emergency contact number given	Yes	No
Treatment Date and time of 1st misoprostol administration	not needed	l
Date and time of 2nd misoprostol administration	not needed	I

Date and time of next follow up appointment
Contact telephone
1st Follow up (2 weeks after start of treatment)
Date of Follow up scan DNA
Outcome Complete expulsion – no further follow up required Incomplete expulsion – ERPOC arranged Incomplete expulsion – further medical management Incomplete expulsion – expectant management to be followed 2nd Follow up arranged Yes No
2nd Follow up
Date of Follow up scan DNA
Outcome Complete expulsion – no further follow up required Incomplete expulsion – ERPOC arranged Incomplete expulsion – further medical management Incomplete expulsion – expectant management to be followed
Please record below if any further follow up visits required Date:// Purpose:

Appendix 2 - Checklist. Outpatient surgical management of miscarriage (MVA) under local anaesthesia

PID: Patient label:			Date of procedure://
MVA Nurse: Patient understands the proce Consent taken	edure	Yes No . Yes No . Yes No . Yes No . Yes No . Yes No	
State allergy(ies) if applicable	:		
Observation before procedure	BP Sats		
Observation after the procedu 15 Min	ire BP Sats		
30 Min	BP Sats		•
Swabs pre count checked Swabs post count check POC sent & consent taken Minimal PV loss Discharge letter & information TTO's Yes No Nurse's/Doctor's signature:	_	No No No No No	number of swabs used: number of swabs used:Printed:

Patient can be discharged after 1 hour, please give GAU telephone number if patient requires any advice following procedure and repeat pregnancy test is not required.



