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Diagnosis and Management of First Trimester Miscarriage (<13weeks)

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AUTHORSHIP, RESPONSIBILITY AND REVIEW

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Table of Contents

BACKGROUND	3
Guideline Definition	3
Purpose	3
Scope.....	3
Roles and Responsibilities	3
Training Requirements	3
Monitoring of Compliance	3
Complaints.....	3
MISCARRIAGE AND MANAGEMENT	4
Related Guidelines	4
Definition and Background	4
Safety Net Advice and Urgent Referral	4
Viable Intrauterine Pregnancy (threatened miscarriage).....	5
Pregnancy of Uncertain Viability.....	5
Complete Miscarriage	6
Incomplete Miscarriage	7
Missed Miscarriage	8
Medical Management of Miscarriage.....	9
PRE-OPERATIVE SURGICAL CONSIDERATIONS.....	9
Cervical Preparation	9
Prevention of Post-Operative PID and Endometritis with SMM.....	10
POST-OPERATIVE SURGICAL CONSIDERATIONS	10
Anti-D Immunoglobulin	10
Products of Conception Histology and Cytogenetics	10
Post SMM Admin	10
Follow Up	10
OTHER CONSIDERATIONS.....	10
Serum Progesterone.....	10
What Should We Tell Patients With Retained POC After Two-Weeks?	11
References	11
APPENDICES AND FLOWCHARTS	12
Management of Miscarriage Flowchart.....	13
Table of Different Miscarriage Treatment Options	14

BACKGROUND

Guideline Definition

Clinical guidelines are systemically developed statements that assist clinicians and patients in making decisions about appropriate treatments for specific conditions.

They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.

Purpose

To assist all medical and nursing staff in the general management of miscarriage. In particular, expectant, medical and surgical management.

Many complaints come from poor communication and contradictory advice.

The guideline aims to minimise this by standardising the information, advice and treatment that we provide to those couples who suffer early pregnancy loss.

Scope

For all staff, medical, nursing and clerical, to provide uniformity in the management of patients diagnosed with a first trimester miscarriage.

Roles and Responsibilities

In seeking further advice on any uncertainties contained in this document, or if you feel that there is new or more updated advice it is your responsibility to contact the guideline author or Approval Group manager so that any amendments can be made.

The guideline Approval Group is responsible for disseminating this guideline to all appropriate staff.

The guideline author or a named alternative is responsible for updating the guideline along with any amendments that they become aware of or are highlighted to them.

All health professionals are responsible to ensure that the guideline is utilised effectively, and to ensure that they are competent and compassionate in the implementation of it.

Training Requirements

There is no mandatory training associated with this guideline.

Monitoring of Compliance

- By audit and review of complaints relating to miscarriage diagnosis and management.
- The Governance Department will collate any complaints and distribute to the relevant individuals for comments, and share any learning points.
- The Service Lead will oversee any governance issues, make relevant recommendations to the directorate, and advise the Clinical Director or the directorate of any matters that require implementation.
- The Health Board reserves the right, without notice, to amend any monitoring requirements in order to meet any statutory obligations or the needs of the organisation

Complaints

All complaints should try to be resolved with the patient during any contact to avoid escalation. There concerns should be listened to and documented. If it is not possible to address any concerns at the time, or if the complaint is of a serious nature, the patient's complaint should be discussed with the consultant in charge for the day, or the patient should be given details of how to raise a formal complaint via the local governance department.

MISCARRIAGE AND MANAGEMENT

Related Guidelines

- Medical Management of Miscarriage
- Diagnosis and Management of PUL and Ectopic Pregnancy including Methotrexate Therapy

Definition and Background

First trimester miscarriage relates to the loss of a pregnancy within the first 13 weeks from conception and requires ultrasound scan to reach an informed diagnosis.

Miscarriage occurs in 10–20% of pregnancies and can lead to significant psychological distress. Poor communication is a recurring cause of complaint from women experiencing miscarriage. All patients must be counselled sensitively, with empathy and patience. The correct terminology should be used when counselling and for documentation. The following topics must be covered during counselling, and should be documented in the notes:

- Information on diagnosis and follow-up including oral and written information about what to expect throughout the process and advice on pain relief.
- Miscarriage information leaflet given to the patient
- The patient and partner/companion have no further questions
- When and how to seek help if symptoms worsen or change, and providing a 24 hour contact number(s).
- Advice when conception can next be attempted. There is usually no reason to wait more than one cycle

The Early Pregnancy and Gynaecology Assessment Unit (EPGAU) has experienced nurses who can provide additional counselling if necessary.

Safety Net Advice and Urgent Referral

It is important to provide contact details of the EPGAU, its opening time, and any other emergency contact details so as to allow women to be able to seek advice should they be worried.

Advise all women to seek advice or medical assistance should they have:

- Heavy bleeding sufficient to soak a sanitary towel every 20 minutes or they are feeling faint or unwell
- Passage of large clots that they are concerned about (e.g. clots that cover a large area of their palm)
- Prolonged heavy bleeding for >3 days that is not subsiding
- Persistent bleeding more than 21 days, or persistent bleeding of any duration sufficient to cause fainting or fatigue
- Pain not controlled with simple analgesia
- Prolonged or severe side effects
- Any issue for which they are concerned or worried about

KEY MESSAGE:

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

Viable Intrauterine Pregnancy (threatened miscarriage)

If the ultrasound shows a viable intrauterine pregnancy:

- Advise and reassure the patient that despite bleeding 90% of pregnancies at 8 weeks will not miscarry, and 75% of all pregnancies are likely to continue especially if the bleeding has occurred around the time of her expected period.
- Discharge from EPGAU with safety net advice (see above)
- NICE (Nov 2021) recommends progesterone to lower the risk of miscarriage in women who experience bleeding in early pregnancy and those who have experienced at least one miscarriage. Progesterone may not prevent every miscarriage.
 - **Women who have previously had a miscarriage, and have their current pregnancy confirmed by scan to be still viable, will be offered 400mg of progesterone to be taken twice daily. This may be given by the rectal or vaginal route.**
 - **Women may find the rectal route more preferable, as it is associated with the absence of vaginal discharge from the effect of the pessary dissolving.**

KEY MESSAGE:

- **If the patient has had a previous miscarriage, and presents with a viable threatened miscarriage CONFIRMED BY SCAN, prescribe 400mg BD micronized PROGESTERONE PR/PV until 16 weeks (15+6)**
- **The brand name for progesterone to be used is CYCLOGEST PESSARIES**
- **Explain to women that progesterone may not prevent every miscarriage.**

Pregnancy of Uncertain Viability

This is diagnosed on a single primary ultrasound scan when the ultrasound scan has shown:

- Empty intrauterine gestation sac <25mm and
 - with a fetal pole seen ≤ 7 mm and no fetal heart beat seen
 - without a fetal pole

In order to determine whether these pregnancies will ultimately prove to be viable it is necessary to allow sufficient time to pass for further development to occur. A repeat scan in 7-14 days is indicated, and is best judged by a senior sonographer as to timing, **However, when the MSD ≤ 10 mm, and not believed to be a pseudo-sac, the rescan should be delayed for a minimum of 14 days.** Safety net advice must be given (see above).

Given that these pregnancies are often judged by mean gestation sac diameter (MSD), by the time a fetus is 7mm in size or the sac 25mm in diameter, the pregnancy would be large enough to confirm viability (see Appendices: *Management of Miscarriage Flowchart* below)

Importance of the Yolk Sac

- YS may be visible earliest when MSD is 8mm
- YS must be seen when MSD is 13mm or more
- YS if not seen when MSD is >20 suggests diagnosis of 'blighted ovum'
- YS if seen is direct evidence of a true GS and confirms intrauterine pregnancy (i.e. not a pseudosac), but does not confirm viability

Complete Miscarriage

A strong history (passing clots, central cramping pain) is suggestive, but is not enough to confirm the diagnosis of complete miscarriage.

Complete miscarriage is likely especially when a previous intrauterine pregnancy has been observed AND when the ultrasound shows either:

- a) An empty uterine cavity, or
- b) RPOC <15mm (retained products [RPOC] are unlikely to be found on histology when <15mm)

Diagnostic accuracy of complete miscarriage is further increased clinically when:

- products of conception seen by the attending gynaecologist (and later confirmed by histology), or
- serum β HCG on presentation and 48 hours later is shown to be falling significantly.

KEY MESSAGE:

- A fall in β HCG of >50% in 48 hours usually confirms complete miscarriage
- A 48 hour rise in β HCG, or a fall of <50% indicates a pregnancy of unknown location (PUL) or possible ectopic pregnancy

Once complete miscarriage has been confidently diagnosed:

- Discharge patient from EPGAU
- Provide safety net advice (see above)
- Advise patient to perform a home urine pregnancy test after 3 weeks and if negative she can be reassured that there are no further concerns.

Incomplete Miscarriage

This should be suspected when:

- Ultrasound findings confirm RPOC 15 - 50mm with no visible intrauterine sac +/- open cervical internal os +/- visible POC noted by an experienced clinician

KEY MESSAGE:

- **First line treatment option is expectant (conservative) management because 80% of cases resolve within 3 days**
- **Highly vascular RPOC are less likely to resolve with conservative management despite being 15-50mm**

Follow up arrangements are dependent on whether the woman continues to bleed or not over the next 2 weeks or has additional adverse symptoms (see safety net advice on page4).

Conservative Management

- **STILL BLEEDING AT 2 WEEKS** – organise repeat ultrasound next available date
 - if the RPOC show significant resolution further expectant management should be considered or the woman should be given the option of surgical evacuation (ERPC). (See *OTHER CONSIDERATIONS* section)
- **STOPPED BLEEDING AT 2 WEEKS** - perform a home urine pregnancy test at 3 weeks
 - if negative discharge the woman
 - If positive organise repeat scan within 7 days

Medical Management of Miscarriage

KEY MESSAGE:

- **Medical management should not be routinely offered for incomplete miscarriage in the first trimester, as there is no advantage over expectant management (no difference in time to resolution)**

This does not mean it is contraindicated. Some women will have a strong preference for medical management. Under these circumstances discuss with the consultant on call for possible medical management.

Second trimester miscarriage (>13 weeks by scan) management is described in a separate document.

Surgical Management of Miscarriage (SMM)

The overall (significant) complication rate for surgical evacuation of the uterus is approximately 6%. Women who are obese, who have significant pre-existing medical conditions or who have had previous surgery must be made aware that the quoted risks for serious or frequent complications may be increased.

Bleeding requiring blood transfusion	0-3 per 1000 (0 - 0.3%)
Infection	40 per 1000 (4%)
Retained placental tissue (RPOC)	3 – 18 per 1000 (0.3 – 1.8%)
Intra-uterine adhesions	160-185 per 1000 (16 – 18.5%) {19% for any management type}
Perforation	1 per 1000 (0.1%)
Cervical trauma	<<1 per 1000 (<<0.1%)

Due to the higher risks of complications associated, SMM (aka ERPC) should be a second-line treatment and should be offered rather than recommended unless:

- Conservative/Medical management has failed
- It is the woman's preference

Missed Miscarriage

This is diagnosed on USS when there is an absence of miscarriage symptoms and either:

- a) an empty gestational sac of mean gestational sac diameter ≥ 25 mm, or
- b) embryo with a crown-rump length ≥ 7 mm and no heartbeat

The diagnosis should be confirmed by a second trained sonographer/doctor ideally on the same day.

Where measurements for empty gestational sacs and embryos are below the cut-off values, if the sac is empty or no embryo heartbeat is visible on an ultrasound scan after a further 7-14 days, these are definitive criteria for miscarriage. *{If the mean gestational sac diameter is <10 mm, repeat scanning should be performed more than 14 days later}*

KEY MESSAGE:

The international consensus view on the categorical diagnosis of missed miscarriage is either:

- a) **the absence of an embryo with a heartbeat ≥ 14 days after a scan showing an empty gestational sac, or**
- b) **absence of an embryo heartbeat ≥ 11 days after a scan showing a gestational sac and yolk sac**

There are three management options, all of which must be discussed with every woman:

1. **Expectant management** should be **recommended** because it avoids surgical/ anaesthetic risks, but women should be warned that symptoms may start unpredictably, with 90% starting within 3 weeks of diagnosis.
2. **Medical management** should be offered because it avoids surgical/anaesthetic risks. The woman should be advised that, compared to expectant management, she is:
 - a) less likely to present as an emergency
 - b) less likely to require SMM(ERPC) (20% v 30%)
 - c) more likely to bleed sooner and more predictably
 - d) as likely to bleed for the same duration of time
3. **Surgical Management** of Miscarriage (SMM) should be offered because it usually provides certain resolution.

Medical Management of Miscarriage

For detailed advice refer to the guideline Medical Management of Miscarriage

Do not offer mifepristone as a treatment for missed or incomplete miscarriage.

Offer vaginal or oral misoprostol, depending on the woman's preference, for the medical treatment of missed or incomplete miscarriage. **Vaginal is preferred as it is thought to be more effective.**

<p>MISSED OR INCOMPLETE MISCARRIAGE</p>
<p>single dose of 800 micrograms of misoprostol PO or PV</p>

For those selected women undergoing ambulatory treatment at home, the EPGAU should contact the woman to determine if bleeding has not started 24 hours after treatment to provide further advice. This is preferred to asking the woman to call in to ensure that women do not slip through the safety net.

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, or up to three weeks after POC are passed, unless they experience worsening symptoms (see safety net advice page 4), in which case advise them to return to the EPGAU for further advice.

Advise women with a positive urine pregnancy test after 3 weeks to return for a review in the EPGAU in order to exclude molar or ectopic pregnancy.

Refer to the guideline on Medical Management of Miscarriage for more in depth guidance.

PRE-OPERATIVE SURGICAL CONSIDERATIONS

Cervical Preparation

The risk of significant trauma to the cervix may be reduced by cervical preparation. Pre-op cervical preparation results in reduced dilatation force, haemorrhage and uterine/cervical trauma.

Who Should Have It?

This should be considered for nulliparous women who have not had any significant vaginal bleeding prior to the procedure. The risk of significant trauma to the cervix is extremely low (much less than 1 in 1000 women; uncommon). Pre-op cervical preparation is indicated for missed and most incomplete miscarriages (closed internal os on bimanual examination).

<p>DOSE: Misoprostol 600µg PV (400µg for women with previous caesarean section) 1-2 hours pre-op</p>

Who Should Not Have It?

It is not indicated in patients with incomplete miscarriage and an open internal cervical os.

Prevention of Post-Operative PID and Endometritis with SMM

All women at high risk of post-operative infection (usually women under the age of 25) should be screened for *Neisseria gonorrhoea* (GC) and *Chlamydia trachomatis* (CT). These can be taken at the time of surgery if there has not been an opportunity to take them before. These investigations require pre-op consent, and may be added to the consent form.

The microbiology form should request *CT & GC NAAT + MC&S*

POST-OPERATIVE SURGICAL CONSIDERATIONS

Anti-D Immunoglobulin

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

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

- receive solely medical management for an ectopic pregnancy or miscarriage **LESS THAN 13 weeks 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.

Products of Conception Histology and Cytogenetics

Ensure that POC are seen and documented at evacuation.

Send an adequate sample to histology to confirm intrauterine pregnancy and exclude molar pregnancy. If unsure, or if minimal sample is obtained, the surgeon should empty the suction trap and send the entire sample.

It is the surgeon's responsibility to chase the histology result of all POC samples. This is essential if minimal or no sample is obtained (risk of ectopic pregnancy), or there is a risk of molar pregnancy.

If this miscarriage is the third consecutive miscarriage, offer for the POC to be sent for cytogenetics, if this has not already been done in the past. You must add '*testing for cytogenetics*' to the consent form. If POC are being sent for cytogenetics, they must **not** be sent in formalin and some POC must still be sent for histology.

Post SMM Admin

Provide a contact number for queries relating to potential post-op complications.

Complete the electronic discharge letter.

GP should provide routine follow-up care.

Follow Up

After an early pregnancy loss, offer the woman the option of a follow-up appointment with a healthcare professional of her choice.

OTHER CONSIDERATIONS

Serum Progesterone

Serum progesterone measurement is a predictive tool, with low values associated with miscarriage and ectopic pregnancy and higher levels with a viable pregnancy. In women with pain or bleeding when ultrasound is inconclusive, a low serum progesterone level of 10-19 mmol/L is highly predictive of a nonviable pregnancy.

NICE states: *“for women with a pregnancy of unknown location, when using serial serum hCG measurements, do not use serum progesterone measurements as an adjunct to diagnose either viable intrauterine pregnancy or ectopic pregnancy”*. This would suggest that if the location of the pregnancy is known, there may be a role in determining viability using serum progesterone. A meta-analysis published in the BMJ in 2015 found that a single progesterone measurement for women in early pregnancy presenting with bleeding or pain and inconclusive ultrasound assessments can rule out a viable pregnancy. Their data showed that in women with pain or bleeding when an ultrasound investigation proves to be inconclusive, a low concentration of progesterone in these women ruled out a viable pregnancy in 99.2% of women. **This data does not extrapolate to PUL and ectopic exclusion.**

Suboptimal rise in β -hCG (<66%) after 48 hours indicates that miscarriage or ectopic pregnancy is a possibility. However, a rise in suboptimal β -hCG may occur even in viable pregnancies in up to 19% of cases. Therefore, in very limited and specific circumstances a serum progesterone may be of value but the accuracy of the progesterone test and the interpretation of the measured concentrations are uncertain. It is not a routine test.

What Should We Tell Patients With Retained POC After Two-Weeks?

Although NICE strongly advocate expectant management, Cochrane evidence states: moderate-certainty evidence shows that, compared with expectant management, surgical evacuation reduced the number of women with early pregnancy loss who retained products of conception **at two weeks** (on average, 102 vs 406 per 1000 women) and at six to eight weeks (on average, 33 vs 84 per 1000 women), as well as the number of women who went on to additional or unplanned surgical evacuation (on average, 55 vs 402 per 1000 women). High-certainty evidence shows that surgical evacuation also reduces the requirement for blood transfusion, although event rates were low in both groups (0% vs 14%). Evidence suggests that women experienced less pain with surgical evacuation than with expectant management, with 177 versus 445 per 1000 women requiring additional analgesia. Researchers found no clear differences between groups in localized infection, complications, or subsequent fertility (live births), but some of these analyses were underpowered to detect differences. COMMENT: Therefore, if POC shows significant vascular attachment, SMM may be a better option compared to expectant management.

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APPENDICES AND FLOWCHARTS

Management of Miscarriage Flowchart

It is always a good suggestion to consider that every woman is presumed to have an ectopic pregnancy.

PRESUMED DIAGNOSIS	Viable intrauterine pregnancy (threatened miscarriage)	Pregnancy of uncertain viability	Complete Miscarriage		Incomplete Miscarriage			Missed Miscarriage	
Diagnostic criteria on ultrasound scan	Fetal heart seen on scan	Empty sac <25mm CRL<7mm No FH	RPOC <15mm or Empty uterus		RPOC 15-50mm will often resolve without intervention			Empty sac >25mm CRL>7mm No FH	
					RPOC>50mm or significant bleeding consider medical or surgical management			Offer 2nd confirmatory USS by another sonographer	
Management Option (all options require safety net advice to be given to the woman – see above)	Discharge See back if further concerns	Rescan 7-14 days N.B. If MSD<10 mm then rescan after ≥14 days	Exclude PUL or ectopic if prior intra uterine pregnancy has not been seen	Discharge if prior intra uterine pregnancy has been seen	Expectant		Medical		Surgical Where RPOC are large, >50mm, or USS dates the pregnancy at >10 weeks in a missed miscarriage SMM/ERPC surgery is preferable due to risk of more severe pain or bleeding
			Refer to ectopic pregnancy guideline Serial hCG testing is should be started initially every 48 hours (see Key Message below)	Always consider possible heterotopic pregnancy, infection, bleeding do home preg test in 3 weeks and if negative discharge See back if further concerns	If RPOC not passed Do home preg test in 3 weeks and if negative discharge	RPOC passed Do home preg test 3 weeks after last RPOC passed and if negative discharge	If RPOC not passed do home preg test in 3 weeks and if negative discharge	RPOC passed do home preg test 3 weeks after last RPOC passed and if negative discharge	
					If pregnancy test still positive or if any significant bleeding or pain then return to hospital for further scan and plan of care				

Days Pregnant by D1 LMP	Weeks Pregnant by D1 LMP	Gestational Sac (MSD) mm	CRL mm	hCG level (U/L)	USS main features
32	4.6	3		1710 (1050-2800)	
34	4.9	5		3100 (1940-4980)	
36	5.1	6		5340 (3400-8450)	GS visible
38	5.4	8		8700 (5680-13660)	YS visible
40	5.7	10	2	13730 (9050-21040)	
42	6.0	12	3.5	16870 (11230-25640)	
44	6.3	14	5	24560 (16650-36750)	FH visible
46	6.6	16	7	34100 (25530-50210)	
48	6.9	18	9	45120 (31700-65380)	
	7.1	19			
	7.3	20			
	7.4	21			
	7.5	22			
	7.6	23			
	7.8	24			

Always refer to the main text of this guideline when using these summary flowcharts

Table of Different Miscarriage Treatment Options

Expectant (conservative)	Medical	Surgical (SMM/ERPC)
There is no difference in infection rates (1-3%) between any of the modes of management for miscarriage		
The primary advantage of allowing the miscarriage to resolve 'naturally' is the avoidance of surgical and anaesthetic risks.	Medical management is likely to be most useful when used for women with missed miscarriage.	SMM, previously known as ERPC, should be an option offered (rather than recommended) to women with incomplete or missed miscarriage.
Approximately 30% (20% for medical management) of women will require surgical evacuation following expectant management of miscarriage.	Approximately 20% (30% for expectant management) of women will require surgical evacuation following medical management of miscarriage.	The only advantages over expectant management: a) Predictable start and end point b) No follow up required
Expectant management is by far the most cost effective mode of management.	Medical management is less likely to be successful after failed expectant management.	Where infection is suspected, delaying surgical intervention for 12-24 hours is recommended to allow local policy intravenous antibiotic administration.
Advise patients that SMM is preferable to expectant management after 10 weeks gestation (ultrasound dates rather than menstrual dates) or a tissue diameter >50mm, as pain and bleeding may be severe.	It is preferable to SMM for second trimester miscarriage.	Indications for SMM: <ul style="list-style-type: none"> • Patient preference • Persistent excessive bleeding/pain • Haemodynamically unstable • US tissue diameter of > 50mm (increased risk of excessive bleeding) • US dates >10 weeks' gestation (increased risk of excessive bleeding) • Evidence of infected retained tissue (proceed after 6-24h IV antibiotics) • Suspected gestational trophoblastic disease • Failed medical/ surgical management
Well-informed patients experience less anxiety and are less likely to be readmitted.	The doctor must document that the patient consents to the use of misoprostol, which is unlicensed for medical management of miscarriage. This is because it is sold for a different indication (gastric ulcers).	Book as an elective day case on a future list (unless emergency indication). VTE assessment MRSA swabs, FBC, Rhesus group & save
Advice on analgesia at home and what to expect during the miscarriage process aid this. It is helpful to give a broad indication of the likely degree of pain and blood loss (strong pain, heavy blood loss, passage of fetal remains).	Explain that off-label treatments are fairly common (most medicines administered to children are off-label) in medicine.	In addition to SMM consent, patients should also consent to: <ul style="list-style-type: none"> • Laboratory analysis to confirm the diagnosis and exclude molar pregnancy • Mortuary blessing and cremation. Patients have the right to keep their products of conception (refer to sensitive disposal of early pregnancy remains pathway) • Swabs for Chlamydia and gonorrhoea when indicated
Time to completion of the miscarriage process is unpredictable.	Explain that misoprostol is effective and safe in selected patients and is recommended by NICE.	<ul style="list-style-type: none"> • Haemorrhage (<3%) • Infection (2-3%) - no increase over expectant /medical management. • Incomplete evacuation requiring possible further ERPC <1% • Uterine perf (<1%), cervical tears • Bowel / bladder trauma (<1%) • Intrauterine adhesions (<5%) • No additional risk to fertility
Expectant management may be continued for as long as the patient is willing provided there are no signs of infection or excessive blood-loss. Routine follow-up for missed miscarriage 2-3 weeks later.	Routine follow-up for missed miscarriage 2-3 weeks later.	Pre-op cervical preparation is indicated for missed and most incomplete miscarriages (closed internal os on bimanual examination).