Document Control

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CONTENTS

1. Introduction

This document sets out Northern Devon Healthcare NHS Trust's best practice guidelines for the Management of Miscarriage including Medical management.

Miscarriage occurs in 10-20% of clinical pregnancies and accounts for 50000 inpatient admissions to hospitals in the UK annually. The common clinical features include pain and vaginal bleeding.

2. Purpose

Historically, the majority of women who miscarried underwent surgical evacuation of retained products of conception (ERPC). However, in the last 5 years standard management has changed, with more treatment in an outpatient setting and the development of more defined diagnostic techniques and therapeutic interventions. The aim of this guideline is to provide a recognised alternative to surgical management of miscarriage including medical management.

All women will be treated within a safe, acceptable environment allowing individual care to be delivered which is appropriate to the needs of that woman.

The following general principles can be applied in order to improve patient safety and the patient experience, whilst reducing risk.

This is in accordance with best practice guidance issued from The Royal College of Obstetrician and Gynaecologists (RCOG) Green Top guidelines1 and the National Institute for Health and Care Excellence NICE guidelines2,3.

This guideline applies to all staff involved in EPAC (medical and nursing staff and midwives) and all Petter and King George 5th ward nursing staff. Non-compliance with this guideline may be for valid clinical reasons only. Document a reason for non-compliance clearly in the patient's notes.

3. Definitions / Abbreviations

EPAC: Early Pregnancy Assessment Clinic

SMM: Surgical management of miscarriage

TAS/TVS: Trans-abdominal and Trans-vaginal Ultrasound scan.

POC: products of conception

4. Contact Numbers

Contact	Internal extension
Pharmacy	2395
Petter Ward	2332 & 2722
KGV ward	2720

5. Diagnosis

Diagnosis is confirmed through clinical assessment

a. Full History and general examination
b. Speculum examination is required in cases of heavy or recurrent bleeding to exclude products of conception protruding from the cervix and if there is suspicion of infection
c. Ultrasound Trans-abdominal scan TAS / Trans-vaginal scan TVS

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.

6. Counselling

Miscarriage is a significant negative life event for many women affecting both their physical and emotional welfare.

Give thorough counselling to all women to support making an informed choice about their care and management as this is associated with positive quality of life outcomes. Adequate explanation supplemented with written information should be given to assist decision making.

Following a confirmed diagnosis of incomplete or missed miscarriage the options are expectant, medical or surgical methods of miscarriage management. Patient preference is important and should be acknowledged as a determining factor in management decisions.

7. Management

7.1 Expectant Management

Expectant management involves passage of products of conception naturally. A proportion of women prefer conservative management in which natural processes lead to the early pregnancy tissue being expelled spontaneously. It is suitable for missed miscarriages up to 13 weeks of gestation (fetus size). There is no defined time limit for the success of treatment, and there are no signs of infection such as vaginal bleeding, feeling unwell, excessive bleeding, pyrexia or lower abdominal pain. However other options should be considered if no products of conception (POC) are passed after a 2 week 'wait and see' time period,

Expectant management can be offered for 7–14 days as the first-line management strategy for women with a miscarriage and has a success of approximately 70-80%.

Women should take a urine pregnancy test 3 weeks following the passage of products to establish completion of process. If it is positive, an ultrasound scan should be performed[3]. Expectant management requires robust counselling and support for the treatment to succeed. Ensure that women understand the expected size of fetus and placenta to be passed.

Particularly consider other management options if the woman is at increased risk of haemorrhage, she has previous adverse and/or traumatic experience associated with pregnancy, she is at increased risk from the effects of haemorrhage, or there is evidence of infection.

Consider offering and prescribing analgesia such as codeine. Discuss histopathological examination and disposal of pregnancy products in line with trust policy.

7.2 Medical Management

Medical Management of miscarriage is an effective alternative for the management of confirmed miscarriage without any suspicion of molar pregnancy. Patients with missed, delayed or silent miscarriage or early fetal demise as well as those with retained products of conception after incomplete miscarriage should be offered medical management. It involves administration of misoprostol (Cytotec®) to assist passage of POC naturally. Misoprostol, a synthetic E1 prostaglandin analogue, has proven efficacy for the medical management of miscarriage but it is not licensed for this indication. It is however known for its low incidence of side effects and cost effectiveness. It has a success rate of approximately 80%. It has no significant effect on lungs or blood vessels and can be used in stable asthmatics. It causes ripening of the cervix and initiates uterine contractions. The advantage of medical management is that it can be done as an outpatient, it avoids surgical intervention and associated anaesthetic complications and may avoid hospital admission. Misoprostol does not have a UK marketing authorisation for this indication although this use is commonplace in UK clinical practice.

INDICATIONS FOR MEDICAL MANAGEMENT:

- Missed miscarriage up to 23^{+6} weeks
- Incomplete miscarriage

Contraindications of medical management:

- Haemodynamically unstable or Hb <10 g/L
- Suspected ectopic pregnancy or gestational trophoblastic disease
- Evidence of infected retained tissue: will need IV antibiotics for 12 hours followed by SMM
- Haemorrhagic disorders and anticoagulation therapy (aspirin accepted)
- Known allergic reaction to prostaglandins
- Known or suspected heart disease

- Severe asthma

Serious or frequent risks

- With advanced gestation and increased size of gestation sac, pain and bleeding may be more severe.
- Occasionally patients may need to be admitted for stronger pain relief.
- Common side effects include fever, shivering, nausea or diarrhoea.
- Patients may have excessive bleeding requiring blood transfusion.
- It may be required to carry out surgical management.

7.3 Surgical Management

Offer women undergoing a miscarriage a choice of surgical management in a theatre under general anaesthetic. This is a quick and once-only procedure in the presence of moderate to severe vaginal bleeding. However, it includes risks associated with general anaesthesia, possible blood transfusion or uterine perforation.

Consider chlamydia and screening and offer Azithromycin as per section 8.1

Provide oral and written information to all women undergoing surgical management of miscarriage about the treatment options available and what expect during and after the procedure. (RCOG leaflet)

Use of misoprostol prior to surgical management of miscarriage

Practitioners may consider cervical preparation prior to the procedure based on individual patient circumstance. The advantages of prostaglandin administration are well established with significant reduction in dilatation, force, haemorrhage, uterine / cervical trauma and it shortens the length of the procedure. Suggested dose for cervical priming is a single dose of misoprostol 400micrograms 1-3 hours before the procedure (Weeks et al 2007). This can be given vaginally, sublingually or orally.

8. Treatment

8.1 Pre-treatment

Pre-treatment checklist is completed by the specialty doctor in early pregnant assessment clinic.

Check FBC, group and save, Rhesus group

Provide leaflet explaining the procedure and follow up including contact number.

Give one dose of Azithromycin 1g PO for treatment of chlamydia or offer screening if preferred.

Obtain written consent documenting 1% risk of haemorrhage requiring transfusion.

Inform GP and midwife team by telephone. Cancel any antenatal appointments or scans.

8.2 Treatment of missed miscarriage (up to 13 weeks gestation fetus size) of incomplete miscarriage

Prescribe a single dose of misoprostol 800 micrograms (4 tablets) **given vaginally**[3]. Moisten tablets in water as per manufacturer's recommendations to facilitate insertion of drug and ensure patient comfort. Tablets should be inserted high into the vagina to ensure medication is retained and can reach its maximum efficiency.

Oral or sublingual administration is an acceptable alternative if this is the woman's preference. It has more sustained effect if given vaginally or sublingually.

Option for home administration is up to 9 weeks' pregnancy. However, medical management should be offered with caution in remote and rural settings and where geographical barriers exist. Ensure the woman has adequate support. Please liaise with KGV if patient opts for home administration.

From 9+1 weeks up to 13 weeks should be administered as inpatient only.

Misoprostol is stored in the drug cupboard on Petter ward and King George V ward.

All tissue product from miscarriage passed in the hospital should be sent for histopathological examination.

8.3 Prescribing

Offer all women pain relief and anti-emetics. Prescribe as needed:

Misoprostol PV 800micrograms STAT (sublingual or oral acceptable alternatives)

Paracetamol 1g QDS PRN pack 32 x 500mg tablets

Codeine 15 -30 mg QDS PRN x 28 tablets

Ondansetron 4-8 mg TDS x 30

Azithromycin 1g STAT

And possibly:

Ibuprofen 400mg TDS PRN pack 24 tablets (this can be purchased)

If treatment will occur at home prescribe medication on an outpatient prescription, which can then be taken to the hospital pharmacy on Monday to Friday by the patient. The patient will not have to pay for this medication but please mark the script 'EPAC patient therefore exempt from payment'.

8.4 Patient Advice

Give the following advice:

- 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. Offer all women pain relief and anti-emetics.
- Treatment can be managed as an out-patient procedure or at home and can be administered by the SHO or the patient. To administer the tablets vaginally, moisten the tablets in water to facilitate digital insertion.
- The patient is advised to ring EPAC 24 hours after the first dose to discuss if they need the second dose of Misoprostol. (Contact KGV during the weekend.)
- Advise women that if bleeding has not started within 24 hours of treatment, care will be individualised by EPAC. This may include **a repeat dose of 800 micrograms of misoprostol** or surgical management.
- Bleeding and pain may resolve within 7 – 14 days of medical management but can continue for up to 3 weeks. Heavy bleeding is usually just for a few days.
- Ensure there is an opportunity to discuss any concerns and offer further advice about indication for follow-up. Women are informed that they can access 24-hour telephone advice and emergency admission if required from Petter ward from Monday to Friday 08:30 – 18:30 (EPAC nurse Tel: 01271322720) and all other times from KGV Tel: 01271 322720.

8.5 Monitoring and Follow Up

Advise the woman to take a urine pregnancy test 3 weeks after medical management of miscarriage unless they experience worsening symptoms, in which case advise them to return for individualised care. If the urine pregnancy test is positive return for a review to ensure that there is no molar or ectopic pregnancy[2].

NICE has written information for the public explaining the guidance on ectopic pregnancy and miscarriage. (CG154)[2].

8.6 Delayed Miscarriage 13^{+1} up to 23^{+6} Weeks (size of fetus)

Inpatient management only

Dosage and route of administration:

From 13^{+1}-17 weeks:

Misoprostol 200 micrograms vaginally 6 hourly (maximum x4 doses)

From 17^{+1}-23^{+1} weeks:

Misoprostol 100 micrograms vaginally 6 hourly (maximum x4 doses)

If delivery has not occurred after 4 doses a repeat course can be considered 24 hours after the last dose of misoprostol was administered.

Misoprostol is routinely used for medical management of second trimester loss in women with **prior caesarean section** without dose alteration as the risk of uterine scar dehiscence is low and has been reported as less than 0.4%.3

Retained placenta can occur in up to 25% of cases, speculum examination is required and if placenta cannot be removed, commence an infusion of syntocinon 40 units in 500ml of 0.9% sodium chloride at a rate of 125ml/hour via Baxter infusion pump. If not successful arrange for surgical removal in theatre.

9. Discharge Letter is Complete

10. Anti D Immunoglobulin

Rhesus Anti D prophylaxis **is not** required in cases of complete miscarriage, medical management of miscarriage, and threatened miscarriage without uterine instrumentation in a pregnancy of less than 12 weeks.

However, Anti-D immunoglobulin injection 250 international units (50 micrograms) is administered to all non-sensitised patients with a Rhesus negative blood group:

- whose pregnancy was more than 12 weeks, to prevent rhesus isoimmunisation, which may affect subsequent pregnancy outcomes.
- Ectopic pregnancy
- All women who have a surgical management of miscarriage
- Miscarriage with heavy bleeding as per the RCOG guideline for Anti D

Kleihauer test is **NOT** required

NB: **Pregnancies of >18weeks, refer to labour ward guidelines**

11. Failsafe Measures

If a woman fails to comply with the follow up after receiving medical management or expectant management, she will be contacted by the nurse from the EPAC and her GP and Consultant informed.

12. Education and Training

All current staff will be made aware of this guideline during discussion at staff meetings. All new staff will be made aware of this guideline during induction into the Department.

Responsibility for education and training lies with the Lead Clinician for Obs & Gynae and the Lead of the EPAC. It will be provided through formal study days and informal training on the ward. Competencies will be assessed and written confirmation issued.

13. Consultation, Approval, Review and Archiving Processes

The author consulted with all relevant stakeholders. Please refer to the Document Control Report.

Final approval was given by the Lead Clinician for the EPAC.

The guidelines will be reviewed every 3 years. The author will be responsible for ensuring the guidelines are reviewed and revisions approved by the Lead Clinician for EPAC in accordance with the Document Control Report.

All versions of these guidelines will be archived in electronic format by the author within the Obs & Gynae. Team policy archive.

Any revisions to the final document will be recorded on the Document Control Report.

To obtain a copy of the archived guidelines, contact should be made with the EPAC Team/ author.

14. Monitoring Compliance and Effectiveness

Monitoring of implementation, effectiveness and compliance with these guidelines will be the responsibility of the Lead Clinician for Obs & Gynae and EPAC group. Where non-compliance is found, it must have been documented in the patient's medical notes.

Audits will include:

Adherence to the guideline

Any untoward incidents or complaints

15. References

1. RCOG The management of early pregnancy loss. Green Top Guidelines No.25 2006

2. National Institute for Health and Care Excellence (NICE) Clinical Guidelines 154 Ectopic pregnancy and miscarriage in early pregnancy. December 2012 – This includes an information leaflet which can be provided to patients.

3. NICE pathway for medical management of incomplete or missed miscarriage (April 2015)

4. Weeks A & Faundes A. Misoprostol dosages for reproductive health. Int J. Gynecol Obstet 2007 99: 5156-9

16. Associated Documentation

- Appendix-A: Check list for management of miscarriage
- Appendix-B: Flow chart for management of miscarriage
- Appendix-C: Medical management of miscarriage. Information for women up to 13 weeks of pregnancy. Patient Information Leaflet

Appendix A

Check list for Management of Miscarriage (Should be completed by the medical team)

Patient details Date:

Confirm Diagnosis by TAS /TVS	
Explain diagnosis and treatment options. Explain success rate and potential complications. Discuss conservative, medical & surgical management	
Check FBC, G&S , Rh type	
Consider chlamydia screening and offer Azithromycin 1 gram oral STAT.	
Provide written information leaflet and details of the miscarriage association.	
Obtain written consent. Consent form to state 'Medical management of miscarriage with misoprostol'.	
Advise bleeding may continue for up to 3 weeks	
Provide contact numbers for 24 hour telephone advice	
Exclude contraindications to use Misoprostol. Explain 'off label' use of misoprostol.	
Prescribe paracetamol, codeine, NSAIDs, antiemetic & azithromycin if required.	
Advise women that they can bring pregnancy tissue for histological examination if they wish and about sensitive disposal	
Advise women to ring EPAC 24 hours after first dose of Misoprostol	
Prescribe anti D 250 IU for Rh –ve women where indicated	
Complete discharge letter	

Completed by: signature:

Appendix B

Medical Management of Miscarriage Patient Information Leaflet

Other formats

If you need this information in another format such as audio tape or computer disk, Braille, large print, high contrast, British Sign Language or translated into another language, please telephone the PALS desk on 01271 314090.

We are sorry that your scan has shown that your pregnancy has ended and a diagnosis of a delayed miscarriage has been made. Sadly, about one in four women lose their baby in early pregnancy. It may be that you have had very few or no symptoms at all, such as bleeding or pain, but this is not unusual in this type of miscarriage and you will have been given verbal information on how it works and what to expect. This written information is for you to take home, please keep it somewhere safe, as you may want to look at it over the next few weeks.

How does the treatment work?

The medication you will have is called Misoprostol; four tablets will be placed into the vagina. Misoprostol relaxes the neck of the womb and causes the muscles of the womb to contract. The pregnancy should come away in the bleeding that follows. If you do not wish to insert the tablets into the vagina, you can put them under your tongue. This method is equally effective but you are more likely to have side effects.

Is the treatment safe?

Misoprostol has been extensively studied and is very commonly used for the treatment of miscarriage but the use of misoprostol for this indication is off-license (the dug company did not originally market it for this purpose) It has proved to have a very good safety record. Each type of treatment for a miscarriage has some risk or side effect. Up to 95% of women will successfully miscarry using this method, but a small number of women will have problems with heavy bleeding, incomplete miscarriage or infection, if this does happen then a simple surgical procedure may be necessary. The risk of developing an infection is approximately 2%, if you develop a fever or offensive smelling discharge, then please contact the Early Pregnancy Assessment Clinic (EPAC).

Length of time for treatment

The medical management treatment happens in two stages:

- The first stage of the treatment takes approximately one hour and can possibly be arranged/planned for straight after your scan or at a time more suitable for you. You

will have a choice as to whether you wish to have this treatment at home or in hospital, depending on your scan findings and medical history.

- The second stage of the treatment is a repeat pregnancy test, three weeks after your treatment. If the test result is positive you must contact the unit to arrange a follow up scan to check the treatment has been effective. If the pregnancy test is negative you must contact the unit with the result, but won't need any further follow up.

First phase of treatment (if you opt to come to the hospital)

If you are returning to the hospital for your treatment you should return to Petter Ward/KGV.

It is important that you return to the hospital for your appointment even if you think you may already have miscarried, if this is the case, please inform the nurse on arrival.

- On admission a doctor or clinical nurse specialist will take your blood pressure, take a medical history from you and get your consent for the treatment.
- Blood tests will be taken to determine your blood group and iron level, if you are a negative blood group you will require an anti-d, which you will be given more information about, if needed.
- Your treatment will then continue; you will have four tablets inserted into your vagina by either a nurse or a doctor. Afterwards, you may have some period type pains and some vaginal bleeding. If you require pain relief, please ask the nurse looking after you, who will administer some simple pain relief tablets, but stronger pain relief in the form of an injection can be given if needed.
- If you feel sick at any point we can give you an injection to help.
- You will be asked to use a bedpan each time you go to the toilet so that any pregnancy loss can be monitored by the nursing staff.
- You can eat and drink normally while you are on the ward, unless advised otherwise.
- You can bring someone with you, who can stay throughout the day.
- You will need to stay on the ward for approximately eight hours after having the first tablets, after this the doctor will decide if you are fit to be discharged. At this stage you may or may not have miscarried. If you have not miscarried then you can still go home, but the bleeding and pain may carry on. If you are worried, you can contact the ward at any time. If you have persistent heavy bleeding whilst on the ward, you may need to stay overnight.

There are different reactions to the tablets, these include:

- Diarrhoea
- Sickness
- Headache

- Dizziness
- Hot flushes/chills

These are usually nothing to worry about, but if you develop any please inform the nurse.

First phase of treatment (if you opt to stay at home)

If you have opted to have your treatment at home, you will need to attend the hospital to collect your medication and be seen by one of our clinical nurse specialists or doctors.

- At this appointment a clinical nurse specialist or doctor will take a medical history from you and get your consent for the treatment.

- Blood tests will be taken to determine your blood group and iron level, if you are a negative blood group, you will require an anti-d, which you will be given more information about, if needed.

- In addition to the misoprostol tablets, you will need pain relief such as paracetamol and ibuprofen. We will provide you with a prescription for codeine pain relief, antisickness medication and azithromycin to treat possible chlamydia infection on discharge. You will then collect the medication from the hospital pharmacy department and you can commence treatment as soon as it is convenient for you.

- On your day of treatment we would advise that you stay at home for the day and arrange for someone to be with you. It is advisable to commence the treatment in the morning at a time that suits you.

- You should commence the treatment by administering the Misoprostol tablets, as high as possible into the vagina.

- We advise that you rest on the bed for 45 minutes following the insertion of the tablets, to allow time for them to be absorbed. After this time, you can move around as normal.

- You then need to wait for the bleeding and menstrual type pains to occur. It is difficult to say when the pain will start and finish, or how much pain you will feel, as everyone's experience of pain is different. You know what is tolerable for you, but if you have taken the pain relief that we provided and your pain is still not controlled, you can call the EPAC for advice. Most women miscarry within 48 hours of undergoing treatment; however it is important to understand that not everyone does. It can take up to a week to occur.

- The amount of bleeding also varies but it is likely that you will experience heavy bleeding. The bleeding might be more than with a normal period and you may pass clots. These can be as big as the palm of your hand. We would advise that you use sanitary towels and not tampons as they can increase the risk of infection. If the bleeding becomes excessive and you are unable to leave the toilet or are soaking through pads every 30 minutes, for over an hour, please contact the EPAC or come into us.

- Please contact the EPAC clinic 24 hours after the first dose of misoprostol so we can find out how you are. During your treatment, if you have any queries or concerns, please do not hesitate to contact the EPAC and speak to one of our nurses.

What happens to the pregnancy tissue?

During the miscarriage you will pass pregnancy tissue that may not be recognisable; however, you may see a small sac or foetus. If you are in hospital you will use bedpans for the nurse to be able to monitor the bleeding. If you are at home you can use the toilet as you would with a heavy period. If you prefer, you can bring the pregnancy tissue into the EPAC unit, in a clean dry container, which we can provide if you require. It would then be sent to the pathology lab for examination and we can also sensitively bury this for you according to the hospital's policy. If you would like more information about this, please speak to a nurse.

Following the treatment

You may bleed for up to three weeks after the treatment and you may have period type pains. You will have been given suitable painkillers by the hospital, take them as prescribed.

You need to have a pregnancy test 3 weeks after the passage of products.
We ask that you do confirm your pregnancy test results to us. This is also a good time to ask questions and get further support if needed.

If your periods are regular and normally occur once a month, you will usually expect your period within six weeks, although, you may find that it is heavier than usual. Your periods will then return to their normal pattern, but it may take a few cycles for this to happen.

Returning to work varies from person to person and the type of work that you do, as well as how you feel physically and emotionally. You may have feelings of anxiety, distress, sadness and loss. These are all common after a miscarriage and for many women these feelings can pass quite quickly, but for some, these feelings are more prolonged and may be difficult for you to cope with. If you want to talk to someone, please contact your GP to discuss counselling or contact the Miscarriage Association.

For any other problems relating to the treatment or for further advice and support, please contact the ***Early Pregnancy Assessment Clinic*** on ***01271 322722 or KGV Ward on 01271 322720.***

Sources of Advice and Support

- The Miscarriage Association, 01924 200799 www.miscarriageassociation.org.uk
- The Birth Trauma Association, support@birthtraumaassociation.org.uk, www.birthtraumaassociation.org.uk

You can also go to NHS Choices (www.nhs.uk) for more information.

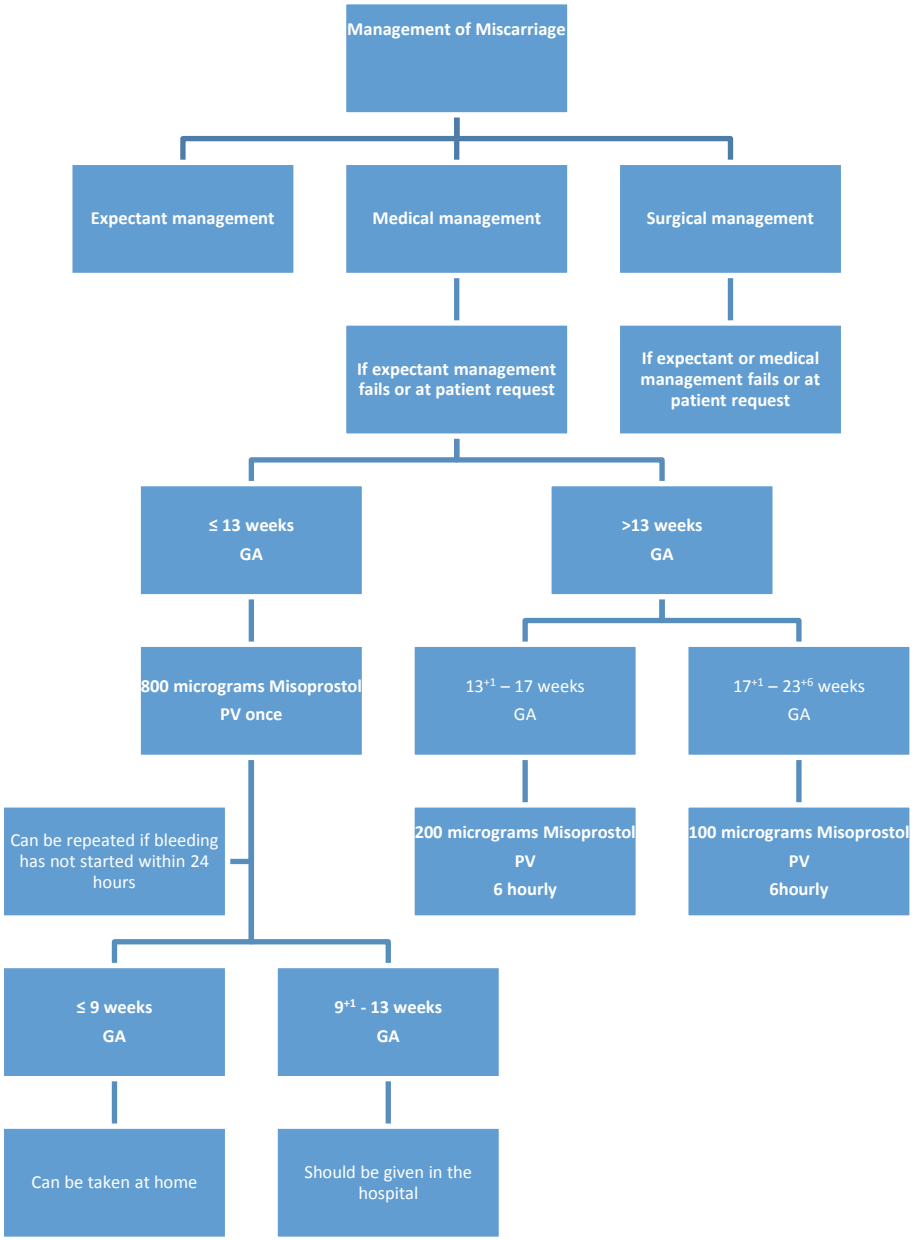
Other NICE Guidance

Routine antenatal care for healthy pregnant women. NICE clinical guideline 62 (2008). See /guidance/cg62/informationforpublic

Source: https://www.nice.org.uk/guidance/cg154/ifp/chapter/About-this-information

The Trust operates a smoke free policy.

Appendix C


Management of Miscarriage
Expectant management
Medical management
Surgical management
If expectant management fails or at patient request
If expectant or medical management fails or at patient request
≤ 13 weeks GA
>13 weeks GA
800 micrograms Misoprostol PV once
13+1 – 17 weeks GA
17+1 – 23+6 weeks GA
Can be repeated if bleeding has not started within 24 hours
200 micrograms Misoprostol PV 6 hourly
100 micrograms Misoprostol PV 6hourly
≤ 9 weeks GA
9+1 - 13 weeks GA
Can be taken at home
Should be given in the hospital