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Quality standards and indicators

Briefing paper

Quality standard topic: Pain and bleeding in early pregnancy

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Contents

1 Introduction 2

2 Overview 2

3 Summary of suggestions 6

4 Suggested improvement areas 8

Appendix 1: Providing women with information and emotional support 33

Appendix 2: Initial clinical assessment 34

Appendix 3: Initial ultrasound scan 35

Appendix 4: Pregnancy of unknown location 36

Appendix 5: Intrauterine pregnancy 37

Appendix 6: Management of miscarriage 38

Appendix 7: Medical management of miscarriage 39

Appendix 8: Ectopic pregnancy 40

Appendix 10: Glossary 44

Appendix 11: Suggestions from stakeholder engagement exercise 45

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for pain and bleeding in early pregnancy. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development source(s) referenced in this briefing paper is:

- Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. NICE clinical guideline 154 (2012).

2 Overview

2.1 Focus of quality standard

This quality standard will cover the care of women who experience pain or bleeding in their first trimester (up to 13 completed weeks of pregnancy), including the diagnosis and initial management of ectopic pregnancy and miscarriage.

2.2 Definition[1]

Early pregnancy is pregnancy within the first trimester that is, up to 13 completed weeks of pregnancy. During this time pain and bleeding is relatively common and may be harmless. However during the first trimester of pregnancy, bleeding and/or pain can be a sign of ectopic pregnancy or miscarriage.

An ectopic pregnancy is when the pregnancy is growing outside the womb (uterus), usually in the fallopian tube. The fertilised egg cannot develop properly outside the womb and has to be removed. Common signs and symptoms of an ectopic pregnancy can include pain or tenderness (or both) in the abdomen or pelvis, 1 or

[1] Section 2.2 adapted from NHS choices Vaginal bleeding in pregnancy (April 2013)

more missed periods and vaginal bleeding. Other symptoms can include a fast heartbeat (over 100 beats a minute), dizziness or fainting.

When a pregnancy ends before the 24th week of pregnancy, it is called a miscarriage. Most miscarriages occur during the first trimester of pregnancy and most cannot be prevented.

2.3 Incidence and prevalence

Many women experience pain and bleeding in the early stages of pregnancy. This does not always mean there is a problem and in most cases it is nothing to worry about. However, pain and bleeding can also be a sign of problems with the pregnancy such as an ectopic pregnancy or miscarriage. Some women don't have pain or bleeding, but have other symptoms which may indicate an ectopic pregnancy.

The rate of ectopic pregnancy is 11 per 1000 pregnancies and therefore relatively common and is associated with maternal death (a maternal mortality of 0.2 per 1000 estimated ectopic pregnancies)[2]. It is thought that as much as two-thirds of these maternal deaths are associated with substandard care. Women who do not access medical help readily (such as women who are recent migrants, asylum seekers or refugees, or women who have difficulty reading or speaking English) are particularly vulnerable.

Miscarriage can cause considerable distress. Between 15 and 20% of clinically confirmed pregnancies spontaneously end before the 13th week. It is estimated that there are approximately 168,000 miscarriages per year in England, with 143,000 of these occurring in the first trimester. Early pregnancy loss accounts for over 50,000 admissions in the UK annually (The Health and Social Care Information Centre, 2012).

Both ectopic pregnancy and miscarriage are associated with an increased risk of prevalence with increasing mother age[3].

2.4 Management

Women with pain and bleeding in early pregnancy will often seek guidance and help from their GPs or from services within secondary care. These services can include accident and emergency department or dedicated early pregnancy assessment units (EPAUs). An initial clinical assessment will include taking clinical history, a physical examination and urine pregnancy test (unless very recent pregnancy test result

[2] Cantwell et al. (2011) Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom. BJOG: An International Journal of Obstetrics and Gynaecology; 111: 1-203
[3] Health and Social Care Information Centre (2012) NHS Maternity Statistics – England, April 2011 to March 2012: Summary report

reported by the woman). If a pregnancy is confirmed a health practitioner will refer for further investigation at an early pregnancy assessment service or use expectant management. It is very important to make an accurate diagnosis of an ectopic pregnancy because if left untreated it can rupture and cause serious complications.

Accessibility of EPAUs varies from region to region, with wide variation in service provision in terms of staffing structure, opening hours and acceptability of self-referral.

Ectopic pregnancy is often managed surgically by laparoscopy and/or laparotomy but in some cases women are treated medically including drug treatment such as methotrexate. Very occasionally no active treatment is needed. There is variation in practice in the way ectopic pregnancy is managed in women with the same ultrasound and biochemical characteristics.

Management of miscarriage may be expectant (no intervention and awaiting natural passage of pregnancy tissue), medical (the use of drugs to expel tissue from the uterus), or surgical (the removal of tissue from the uterus), and in many cases women are given a choice of treatments.

Early pregnancy complications can be very upsetting and ectopic pregnancy and miscarriage have an adverse effect on the quality of life of many women. Women should be treated at all times with dignity and respect and healthcare professionals will be aware that problems in early pregnancy can cause great distress for women and their partners. This includes taking into account individual circumstances when giving support and information.

NICE clinical guideline 154 recognises the vital importance of improving the diagnosis and management of early pregnancy loss. This is in order to reduce the incidence of the associated psychological morbidity and avoid the unnecessary deaths of women with ectopic pregnancies.

See appendices 1–8 for the associated care pathway and algorithms from NICE clinical guideline 154.

2.5 National Outcome Frameworks

Table 1 shows the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2014/15

Domain	Overarching indicators and improvement areas
4 Ensuring that people have a positive experience of care	***Overarching indicator*** 4a Patient experience of primary care 4b Patient experience of hospital care ***Improvement areas*** **Improving women and their families' experience of maternity services** 4.5 Women's experience of maternity services
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	***Overarching indicator*** 5a Patient safety incident reported 5b Safety incident involving severe harm or death 5c Hospital deaths attributable to problems in care

3 Summary of suggestions

3.1 Responses

In total 4 stakeholders responded to the 2-week engagement exercise 07/11/13 – 21/11/13.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 2 for further consideration by the Committee.

Full details on the suggestions provided are given in appendix 11 for information.

Table 2 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Identification/Awareness • Initial identification and awareness • Pregnancy tests	NHSE, RCN,SCM
Access • Access to early pregnancy assessment • Availability of 7 day service and referral within 24 hours • Access to ultrasound services	IPULA, SCM
Diagnosis (use of ultrasound) • Diagnosis of miscarriage • Pregnancy of unknown location (PUL) • Repeat ultrasound 7-14 days • Standardisation of staff training	IPULA, RCN, SCM
Management of miscarriage • Full range of treatment options • Time to evacuation of retained products of conception (ERPC) services	IPULA , RCN, SCM
Management of ectopic pregnancies • Full range of treatment options • Use of methotrexate	IPULA, NHSE ,SCM
Staff training • Medical terminology and language to patients and families • Sensitive communication**/**breaking bad news	RCN
Information • Providing information to help inform choice, next steps and what is involved in stages. • 24 hour help line	SCM, RCN
Psychological impact • The psychological impact of early pregnancy events • Follow-up for women who have experienced miscarriage • Availability of psychological services	IPULA, RCN

IPULA, Imperial College Healthcare NHS Trust
NHSE, NHS England
RCN, Royal College of Nurses
SCM, Specialist Committee Member

4 Suggested improvement areas

4.1 Identification/Awareness

4.1.1 Summary of suggestions

Initial identification and awareness

Stakeholders highlighted that many women with pain and bleeding in early pregnancy will initially seek advice from sources outside of secondary specialist care services. Stakeholders mentioned that some healthcare professionals within primary care may not always suspect pregnancy as the underlying cause of pain and bleeding and as a result diagnosis of miscarriage or ectopic pregnancy may be missed. This is due to the fact that there can be limited specialist knowledge amongst some healthcare professionals within primary care services.

Pregnancy tests

Stakeholders suggested that all healthcare professionals should have access to pregnancy tests. Many women when presenting with pain and bleeding may be unaware they are pregnant. The diagnoses associated with pain and bleeding in early pregnancy cannot be made without the confirmation of pregnancy, usually via the result of a urinary pregnancy test. While many secondary care services will have access to pregnancy tests, healthcare professionals within primary care may not.

4.1.2 Selected recommendations from development source

Table 3 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 3 to help inform the Committee's discussion.

Table 3 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Initial identification and awareness	**Symptoms and signs of ectopic pregnancy and initial assessment** NICE CG154 Recommendation 1.3.2, 1.3.3, 1.3.4 and 1.3.5 (KPI)
Pregnancy tests	**Symptoms and signs of ectopic pregnancy and initial assessment** NICE CG154 Recommendation 1.3.6 (KPI)

Initial identification and awareness

NICE CG154 – Recommendation 1.3.2

Be aware that atypical presentation for ectopic pregnancy is common.

NICE CG154 – Recommendation 1.3.3

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

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

NICE CG154 – Recommendation 1.3.4

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

- more common signs:
  - pelvic tenderness
  - adnexal tenderness

  - abdominal tenderness

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

NICE CG154 – Recommendation 1.3.5 (key priority for implementation)

During clinical assessment of women of reproductive age, be aware that:

- they may be pregnant, and think about offering a pregnancy test even when symptoms are non-specific **and**
- the symptoms and signs of ectopic pregnancy can resemble the common symptoms and signs of other conditions – for example, gastrointestinal conditions or urinary tract infection

Pregnancy tests

NICE CG154 – Recommendation 1.3.6 (key priority for implementation)

All healthcare professionals involved in the care of women of reproductive age should have access to pregnancy tests.

4.1.3 Current UK practice

Initial identification and awareness

NHS England patient safety division published evidence from the National Reporting and Learning System (NRLS) in missed diagnosis and delayed treatment for ectopic pregnancies.

A total of 59 incidents relating to cases of missed diagnosis of ectopic pregnancy were reported during the period, with 30 of these reported as severe harm. This report focuses on emergency departments including other settings, although no breakdown was given.

The NICE Guideline Development Group (GDG) for clinical guideline 154 highlighted that ectopic pregnancy is a relatively common and potentially life-threatening complication of pregnancy. However, despite this, the GDG noted that morbidity and mortality attributable to failure to consider the diagnosis, and therefore missed or delayed diagnosis, continues to be problematic. This is often due to misconceptions and ignorance of symptoms and signs of an ectopic pregnancy.

Pregnancy tests

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience, with particular reference to the fact that not all primary care practices have pregnancy testing kits.

4.2 Access to early pregnancy assessment services

4.2.1 Summary of suggestions

Access to early pregnancy assessment

Stakeholders highlighted a general issue in that there is varied access to early pregnancy assessment services. Assessment is preferable at specialist early pregnancy assessment services (such as early pregnancy assessment units) as staff are appropriately trained and have expertise in assessing and managing women with pain and bleeding in early pregnancy.

Availability of 7 day service and referral within 24 hours

Stakeholders highlighted that pain and bleeding in early pregnancy can occur at any time and therefore it is important women have rapid access to assessment services. As a result early pregnancy assessment should be made available 7 days a week with women seen within 24 hours of an appropriate referral being made.

Access to ultrasound services

Stakeholders noted the importance in the use of ultrasound for the accurate diagnosis of pain and bleeding in early pregnancy. There is varied provision of ultrasound services and it is vital to improve the pathway for women and ensuring they obtain early diagnosis.

4.2.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Access to early pregnancy assessment	**Early pregnancy assessment services** NICE CG154 Recommendations 1.2.3 and 1.2.4
Availability of 7 day service and referral within 24 hours	**Early pregnancy assessment services** NICE CG154 Recommendation 1.2.1 (KPI)
Access to ultrasound services	**Early pregnancy assessment services** NICE CG154 Recommendation 1.2.2

Access to early pregnancy assessment

NICE CG154 – Recommendation 1.2.3

Early pregnancy assessment services should accept self-referrals from women who have had recurrent miscarriage or a previous ectopic or molar pregnancy. All other women with pain and/or bleeding should be assessed by a healthcare professional (such as a GP, accident and emergency [A&E] doctor, midwife or nurse) before referral to an early pregnancy assessment service.

NICE CG154 – Recommendation 1.2.4

Ensure that a system is in place to enable women referred to their local early pregnancy assessment service to attend within 24 hours if the clinical situation warrants this. If the service is not available, and the clinical symptoms warrant further assessment, refer women to the nearest accessible facility that offers specialist clinical assessment and ultrasound scanning (such as a gynaecology ward or A&E service with access to specialist gynaecology support).

Availability of 7 day service and referral within 24 hours

NICE CG154 – Recommendation 1.2.1 (key priority for implementation)

Regional services should be organised so that an early pregnancy assessment service is available 7 days a week for women with early pregnancy complications, where scanning can be carried out and decisions about management made.

Access to ultrasound

NICE CG154 – Recommendation 1.2.2

An early pregnancy assessment service should:

- be a dedicated service provided by healthcare professionals competent to diagnose and care for women with pain and/or bleeding in early pregnancy and
- offer ultrasound and assessment of serum human chorionic gonadotrophin (hCG) levels **and**
- be staffed by healthcare professionals with training in sensitive communication and breaking bad news.

4.2.3 Current UK practice

Access to early pregnancy assessment

The NICE costing report for NICE clinical guideline 154 estimated that there were more than 250 early pregnancy assessment units across the UK. They will often be found in gynaecology units, outpatient clinics or dedicated early pregnancy assessment units. [NICE CG154, Ectopic pregnancy and miscarriage: costing report].

Availability of 7 day service and referral within 24 hours

The NICE costing report for NICE clinical guideline 154 reported that opening times of these early pregnancy assessment units vary from unit to unit. This includes some units offering consultations on weekdays during the daytime only, while some will offer an evening and weekend service; the ability for women to self-refer also varies between units [NICE CG154, Ectopic pregnancy and miscarriage: costing report].

Access to ultrasound services

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience, with particular reference to variation in the availability of this service.

4.3 Diagnosis (use of ultrasound)

4.3.1 Summary of suggestions

Diagnosis of miscarriage

Stakeholders stated that the use of ultrasound in accordance with NICE guidance is not routine. In accordance with NICE clinical guideline 154 when diagnosing miscarriage transvaginal ultrasounds scans must be offered. If this is not the case miscarriage can be misdiagnosed which has the potential to lead to inadvertent termination of a wanted pregnancy, this should become a never event[4].

Pregnancy of unknown location (PUL)

Stakeholders highlighted the importance in recognition of pregnancies of unknown location (PUL). PUL should be risk stratified and cared for by an early pregnancy assessment service. According to stakeholders 10 – 40% of PULs will be ectopic pregnancies, and they should be identified as such as soon as possible in order to initiate treatment.

Repeat ultrasound 7-14 days

Stakeholders noted that in order to improve diagnosis of both miscarriage and ectopic pregnancies, the use of ultrasound for diagnosis should always be repeated, between 7 and 14 days (in accordance with NICE guidance). This will also prevent misdiagnosis.

Standardisation of staff training

Stakeholders highlighted that staff using sonographic assessment are trained to varying levels (ranging from masters degrees to in-house training). This should be standardised to ensure there is a set standard of care when performing ultrasound for diagnosis.

4.3.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

[4] Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. National patient safety resources

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Diagnosis of miscarriage	**Using ultrasound for diagnosis** NICE CG154 Recommendations 1.4.1 (KPI) and 1.4.4 to 1.4.6
Pregnancy of unknown location	**Human chorionic gonadotrophin measurements in women with pregnancy of unknown location** NICE CG154 Recommendation 1.4.18
Repeat ultrasound 7-14 days	**Using ultrasound for diagnosis** NICE CG154 Recommendation 1.4.7 to 1.4.11
Standardisation of staff training	**Using ultrasound for diagnosis** NICE CG154 Recommendation 1.4.17

Diagnosis of miscarriage

NICE CG154 – Recommendation 1.4.1 (key priority for implementation)

Offer women who attend an early pregnancy assessment service (or out-of-hours gynaecology service if the early pregnancy assessment service is not available) a transvaginal ultrasound scan to identify the location of the pregnancy and whether there is a fetal pole and heartbeat.

NICE CG154 – Recommendation 1.4.4

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

NICE CG154 – Recommendation 1.4.5

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

NICE CG154 – Recommendation 1.4.6

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

Pregnancy of unknown location (PUL)

NICE CG154 – Recommendation 1.4.18

Be aware that women with a pregnancy of unknown location could have an ectopic pregnancy until the location is determined.

Repeat ultrasound 7-14 days

NICE CG154 – Recommendation 1.4.7

If the crown–rump length is 7.0 mm or more with a transvaginal ultrasound scan and there is no visible heartbeat: seek a second opinion on the viability of the pregnancy and/or perform a second scan a minimum of 7 days after the first before making a diagnosis.

NICE CG154 – Recommendation 1.4.8

If there is no visible heartbeat when the crown–rump length is measured using a transabdominal ultrasound scan: record the size of the crown–rump length and perform a second scan a minimum of 14 days after the first before making a diagnosis.

NICE CG154 – Recommendation 1.4.9

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

NICE CG154 – Recommendation 1.4.10

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

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

NICE CG154 – Recommendation 1.4.11

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

- record the size of the mean gestational sac diameter and

- perform a second scan a minimum of 14 days after the first before making a diagnosis.

Standardisation of staff training

NICE CG154 – Recommendation 1.4.17

All ultrasound scans should be performed and reviewed by someone with training in, and experience of, diagnosing ectopic pregnancies.

4.3.3 Current UK practice

Diagnosis of miscarriage

Recent press coverage of a complaint by Ms D against Cardiff and Vale University local health board highlighted a serious incident in which NICE guidance in the diagnosis of miscarriage was not being followed, with particular reference to the use of transabdomindal ultrasound being used instead of transvaginal ultrasound, full report by public services ombudsman for Wales. While this report was conducted as the result of an individual case, the report also highlighted that this may not be an isolated incident and there may be more similar incidents within this health board's directorate as a result of not following guidelines.

Pregnancy of unknown location (PUL)

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

Repeat ultrasound 7 – 14 days

Recent press coverage of a complaint by Ms D against Cardiff and Vale University local health board highlighted that the repeated use of ultrasound was not widely used at the local health board investigated, full report by public services ombudsman for Wales. While this report was conducted as the result of an individual case, the report also highlighted that this may not be an isolated incident and there may be more similar incidents within this health board's directorate as a result of not following guidelines.

Standardisation of staff training

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

4.4 Management of miscarriage

4.4.1 Summary of suggestions

Full range of treatment options

Stakeholders stated that women diagnosed with a miscarriage should be offered a full range of management options. This included the use of expectant management as a valid treatment option which can be offered as an alternative to medical or surgical interventions. This was dependent on the patient preference and clinical need. The availability of these options is vital to enable patient choice and empowerment, which are important factors in a woman's recovery.

Time to evacuation of retained products of conception (ERPC) services

Stakeholders highlighted that there is currently no standard waiting time to access ERPC services. This can impact on the distress women may feel, and improved access will improve the care pathway of women with miscarriage.

4.4.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Full range of treatment options	**Management of miscarriage** NICE CG154 Recommendations 1.5.2 (KPI) to 1.5.4
Time to ERPC services	**Management of miscarriage** NICE CG154 Recommendation 1.5.18 (KPI) and 1.5.19 **
** Recommendations 1.5.18 and 15.19, while referring to surgical management of miscarriage do not offer any timescales, which stakeholders highlighted as the quality improvement area.	

Full range of treatment options

NICE CG154 – Recommendation 1.5.2 (key priority for implementation)

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

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

NICE CG154 – Recommendation 1.5.3

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

NICE CG154 – Recommendation 1.5.4

Explain what expectant management involves and that most women will need no further treatment. Also provide women with oral and written information about further treatment options.

Time to ERPC services

NICE CG154 – Recommendation 1.5.18 (key priority for implementation)

Where clinically appropriate, offer women undergoing a miscarriage a choice of:

- manual vacuum aspiration under local anaesthetic in an outpatient or clinic setting **or**
- surgical management in a theatre under general anaesthetic.

NICE CG154 – Recommendation 1.5.19

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

4.4.3 Current UK practice

Full range of treatment options

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience with particular reference to patient feedback.

Time to ERPC services

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

One stakeholder provided anecdotal evidence that waiting times can be up to 7 days.

4.5 Management of ectopic pregnancy

4.5.1 Summary of suggestions

Full range of treatment options

Stakeholders stated that women who experience an ectopic pregnancy should be offered a full range of management options. This included the use of expectant management as viable alternative to medical and surgical management in certain circumstances. This was dependent on the women's preference and clinical need. The availability of these options is vital to enable choice and empowerment, which are important factors in a woman's recovery.

Use of Methotrexate

Stakeholders highlighted that where Methotrexate is used to in the management of ectopic pregnancy, women have all the information they need to support safety issues associated with this medication. While oral Methotrexate is a safe and effective medication if taken at the right dose, incorrect dosage may lead to serious harm.

4.5.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Full range of treatment options	**Management of ectopic pregnancy** NICE CG154 Recommendations 1.6.2 and 1.6.5*
Use of Methotrexate	**Management of ectopic pregnancy** NICE CG154 Recommendation 1.6.3**
***** There are currently no recommendations with the clinical guideline on use of expectant management for ectopic pregnancy. **The guideline does not have any recommendations around the dosage provided	

Full range of treatment options

NICE CG154 – Recommendation 1.6.2

Give all women with an ectopic pregnancy oral and written information about:

- how they can contact a healthcare professional for post-operative advice if needed, and who this will be **and**

- where and when to get help in an emergency.

NICE CG154 – Recommendation 1.6.5

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

- no significant pain

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

- no intrauterine pregnancy (as confirmed on an ultrasound scan).

Advise women who choose methotrexate that their chance of needing further intervention is increased and they may need to be urgently admitted if their condition deteriorates.

Use of Methotrexate

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

- no significant pain

- an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat

- a serum hCG level less than 1500 IU/litre

- no intrauterine pregnancy (as confirmed on an ultrasound scan).

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

4.5.3 Current UK practice

Full range of treatment options

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

Use of Methotrexate

As part of the stakeholder engagement exercise for this quality standard, NHS England patient safety division highlighted published evidence from the National Reporting and Learning System (NRLS) relating to improving compliance with oral methotrexate.

In 2006 the then Patient Safety Agency published a safety alert, highlighting reports of patient safety incidents involving oral methotrexate (between July 2004 and June 2006 165 patient safety incidents were reported). While this report was based mainly on the use of methotrexate in rheumatoid arthritis, NHS England felt that dosage issues would be still be relevant in this context.

In a recent report of provisional never events data summary for Q1 and Q2 2013/14 published by NHS England, Patient Safety Domain Team, a total of 7 'never events' relating to inappropriate administration of daily oral methotrexate are reported.

4.6 Staff training

4.6.1 Summary of suggestions

Medical terminology and language to women and their families

Stakeholders indicated the need for all healthcare professionals to be able to use appropriate medical terminology in relation to pain and bleeding in early pregnancy. A document may be required to identify current terminology that encompasses the spectrums of possible outcome. This will aid those healthcare professionals who have limited or no midwifery, obstetrics or gynaecology experience to ensure that a minimum of distress and misunderstanding is experienced by women.

Sensitive communication/breaking bad news

Stakeholders highlighted that there is currently no standard training for staff in communication to patients. Improvement in communication is required due to the sensitive nature of the information provided to women with pain and bleeding in early pregnancy as well as the skills required in breaking bad news.

4.6.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 8 to help inform the Committee's discussion.

Table 8 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Medical terminology and language to women and their families	**None**
Sensitive communication/breaking bad news	**Support and information giving** NICE CG154 Recommendation 1.1.1 and 1.1.2

Sensitive communication/breaking bad news

NICE CG154 – Recommendation 1.1.1

Treat all women with early pregnancy complications with dignity and respect. Be aware that women will react to complications or the loss of a pregnancy in different ways. Provide all women with information and support in a sensitive manner, taking into account their individual circumstances and emotional response.

NICE CG154 – Recommendation 1.1.2

Healthcare professionals providing care for women with early pregnancy complications in any setting should be aware that early pregnancy complications can cause significant distress for some women and their partners. Healthcare professionals providing care for these women should be given training in how to communicate sensitively and breaking bad news. Nonclinical staff such as receptionists working in settings where early pregnancy care is provided should also be given training on how to communicate sensitively with women who experience early pregnancy complications.

4.6.3 Current UK practice

Medical terminology and language to patients and families

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

Sensitive communication/breaking bad news

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

4.7 Information

4.7.1 Summary of suggestions

Providing information to help inform choice, next steps and what is involved in stages

Stakeholders suggested that providing women with written information helps inform their options regarding initial assessment, diagnosis and management. Stakeholders commented that as little as 10% of information is retained at initial consultation. As a result providing written information will help in recalling information when making important decisions about care. This information should provide details of what to expect at each stage (assessment, diagnosis and management) and what support is available.

24 hour help line

Stakeholders highlighted the importance of a 24 hour help line for women who experience pain and bleeding in early pregnancy. This is not routinely available and will provide information for women, while they do not have access to assessment, diagnosis or management services.

4.7.2 Selected recommendations from development source

Table 9 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 9 to help inform the Committee's discussion.

Table 9 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Providing information to help inform choice, next steps and what is involved in stages	**Support and information giving** NICE CG154 Recommendation 1.1.3 (KPI) **Diagnosis of viable intrauterine pregnancy and of ectopic pregnancy** NICE CG154 Recommendation 1.4.23 **Management of miscarriage** NICE CG154 Recommendation 1.5.19
24 hour help line	**Support and information giving** NICE CG154 Recommendation 1.1.3 (KPI) **Diagnosis of viable intrauterine pregnancy and of ectopic pregnancy** NICE CG154 Recommendation 1.4.15

Providing information to help inform choice, next steps and what is involved in stages

NICE CG154 – Recommendation 1.1.3 (key priority for implementation)

Throughout a woman's care, give her and (with agreement) her partner specific evidence-based information in a variety of formats. This should include (as appropriate):

- When and how to seek help if existing symptoms worsen or new symptoms develop, including a 24-hour contact telephone number.
- What to expect during the time she is waiting for an ultrasound scan.
- What to expect during the course of her care (including expectant management), such as the potential length and extent of pain and/or bleeding, and possible side effects. This information should be tailored to the care she receives.
- Information about post-operative care (for women undergoing surgery).
- What to expect during the recovery period – for example, when it is possible to resume sexual activity and/or try to conceive again, and what to do if she becomes pregnant again. This information should be tailored to the care she receives.
- Information about the likely impact of her treatment on future fertility.
- Where to access support and counselling services, including leaflets, web addresses and helpline numbers for support organisations.

Ensure that sufficient time is available to discuss these issues with women during the course of their care and arrange an additional appointment if more time is needed.

NICE CG154 – Recommendation 1.4.23

Regardless of serum hCG levels, give women with a pregnancy of unknown location written information about what to do if they experience any new or worsening symptoms, including details about how to access emergency care 24 hours a day. Advise women to return if there are new symptoms or if existing symptoms worsen.

NICE CG154 – Recommendation 1.5.19

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

24 hour help line

NICE CG154 – Recommendation 1.1.3 (key priority for implementation)

Throughout a woman's care, give her and (with agreement) her partner specific evidence-based information in a variety of formats. This should include (as appropriate):

- When and how to seek help if existing symptoms worsen or new symptoms develop, including a 24-hour contact telephone number.
- What to expect during the time she is waiting for an ultrasound scan.
- What to expect during the course of her care (including expectant management), such as the potential length and extent of pain and/or bleeding, and possible side effects. This information should be tailored to the care she receives.
- Information about post-operative care (for women undergoing surgery).
- What to expect during the recovery period – for example, when it is possible to resume sexual activity and/or try to conceive again, and what to do if she becomes pregnant again. This information should be tailored to the care she receives.
- Information about the likely impact of her treatment on future fertility.
- Where to access support and counselling services, including leaflets, web addresses and helpline numbers for support organisations.

Ensure that sufficient time is available to discuss these issues with women during the course of their care and arrange an additional appointment if more time is needed.

NICE CG154 – Recommendation 1.4.15

Give women a 24-hour contact telephone number so that they can speak to someone with experience of caring for women with early pregnancy complications who understands their needs and can advise on appropriate care.

4.7.3 Current UK practice

Providing information to help inform choice, next steps and what is involved in stages

The Miscarriage Association produced Communication: the key to helping people through. This highlights the lack of information provided to women through several anecdotal experiences, and how often there is a lack of support provided in this manner. It also outlines the work that the miscarriage association is able to provide in terms of information provision.

24 hour help line

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

4.8 Psychological impact

4.8.1 Summary of suggestions

Awareness of the psychological impact of early pregnancy events

Stakeholders highlighted the need for healthcare practitioners to be aware of the psychological impact of pain and bleeding in early pregnancy. While most healthcare professionals focus on the physical management of miscarriage and ectopic pregnancy, the provision of psychological services is less well developed.

Follow-up for women who have experienced miscarriage

Stakeholders outlined the need to follow-up those women who have experienced a miscarriage in order to help identify those who may be at risk, or who have already developed psychological complications.

Availability of psychological services

Stakeholders noted that there are currently patchy psychological and counselling services for care of women post pregnancy loss. Psychological services are required in order to assess the psychological impact upon these women (if required) and the impact this may have on future pregnancies.

4.8.2 Selected recommendations from development source

Table 10 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 10 to help inform the Committee's discussion.

Table 10 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Awareness of the psychological impact of early pregnancy events	**Support and information giving** NICE CG154 Recommendation 1.1.1
Follow-up for women who have experienced miscarriage	**Support and information giving** NICE CG154 Recommendation 1.1.4
Availability of psychological services for patients	**None**

Awareness of the psychological impact of early pregnancy events

NICE CG154 – Recommendation 1.1.1

Treat all women with early pregnancy complications with dignity and respect. Be aware that women will react to complications or the loss of a pregnancy in different ways. Provide all women with information and support in a sensitive manner, taking into account their individual circumstances and emotional response.

Follow-up for women who have experienced miscarriage

NICE CG154 – Recommendation 1.1.4

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

4.8.3 Current UK practice

Awareness of the psychological impact of early pregnancy events

No current practice data relating to healthcare professionals awareness of the psychological impact of early pregnancy events.

A journal article from the Journal of Psychosomatic Research, Anxiety following miscarriage and the subsequent pregnancy: A review of the literature and future directions, suggests women are at an increased risk for anxiety symptoms immediately following miscarriage and continuing until approximately 4 months post-loss.

Follow-up for women who have experienced miscarriage

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

Availability of psychological services

The Improving Access to Psychological Therapies (IAPT) data set collects national data to encourage improved access to talking therapies for people with common mental health problems. While this does not record if someone will have had a miscarriage or ectopic pregnancy it does provide data on psychological service provision.

Appendix 1: Providing women with information and emotional support

Taken from full clinical guideline 154

1.2 Care pathway

A. Providing women with information and emotional support

Treat all women with early pregnancy complications with dignity and respect. Be aware that women will react to complications or the loss of a pregnancy in different ways. Provide all women with information and support in a sensitive manner, taking into account their individual circumstances and emotional response. (For further guidance about providing information, see Patient experience in adult NHS services [NICE clinical guidance 138, 2012]).

Healthcare professionals providing care for women with early pregnancy complications in any setting should be aware that early pregnancy complications can cause significant distress for some women and their partners. Healthcare professionals providing care for these women should be given training in how to communicate sensitively and breaking bad news. Non-clinical staff such as receptionists working in settings where early pregnancy care is provided should also be given training on how to communicate sensitively with women who experience early pregnancy complications.

Throughout a woman's care, give her and (with agreement) her partner specific, evidence-based information in a variety of formats. This should include (as appropriate):

- When and how to seek help if existing symptoms worsen or new symptoms develop, including a 24-hour contact telephone number.
- What to expect during the time she is waiting for an ultrasound scan.
- What to expect during the course of her care (including expectant management), such as the potential length and extent of pain and/or bleeding, and possible side effects. This information should be tailored to the care she receives.
- Information about the likely impact of her treatment on future fertility.
- Information about post-operative care (for women undergoing surgery).
- What to expect during the recovery period – for example, when it is possible to resume sexual activity and/or try to conceive again, and what to do if she becomes pregnant again. This information should be tailored to the care she receives.
- Where to access support and counselling services, including leaflets, web addresses and helpline numbers for support organisations.

Ensure that sufficient time is available to discuss these issues with women during the course of their care and arrange an additional appointment if more time is needed.

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

Throughout the care pathway, where these symbols appear, refer back to section A and provide women with information about:

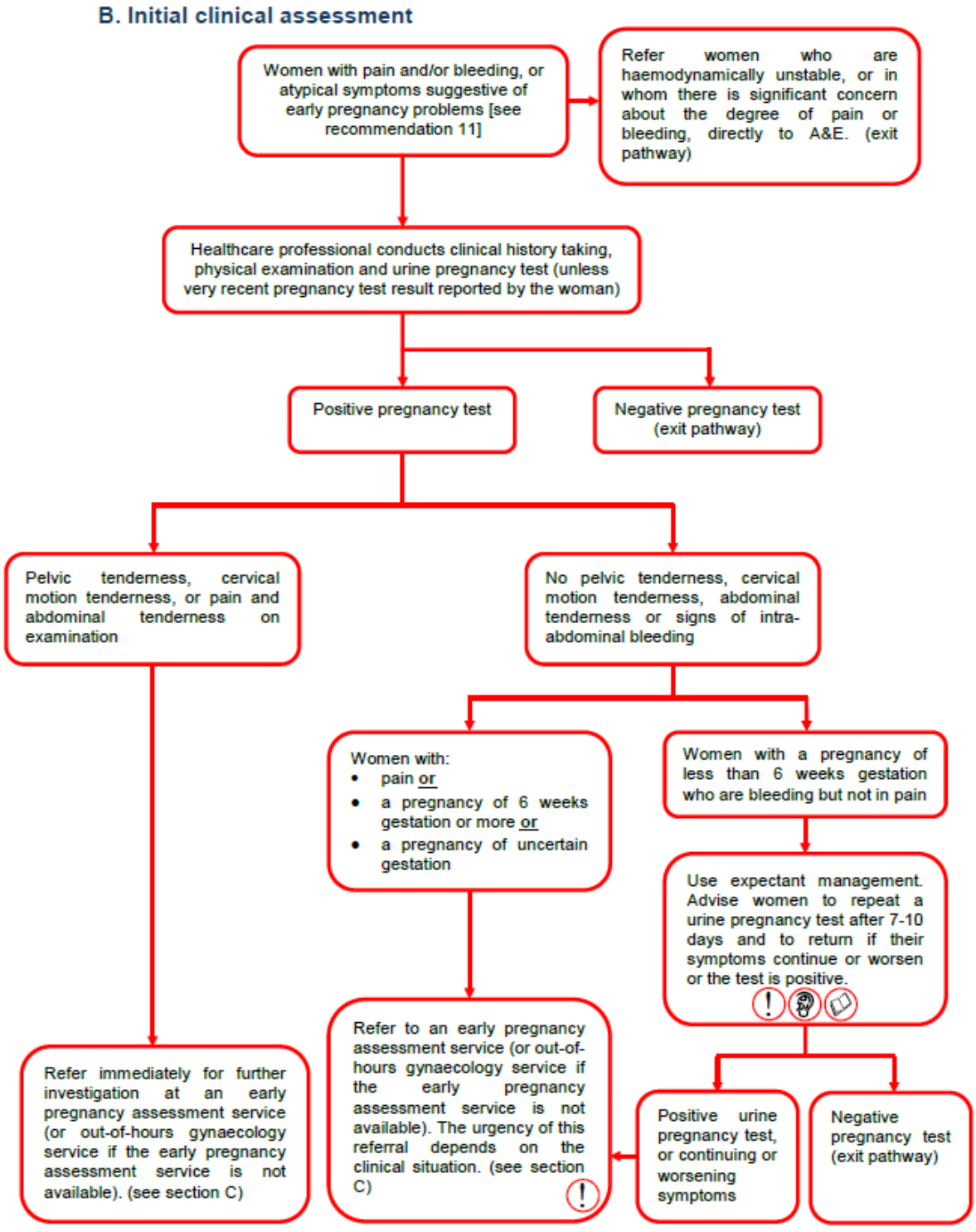
Where to seek help in an emergency

Where to access support and counselling services

The recovery period

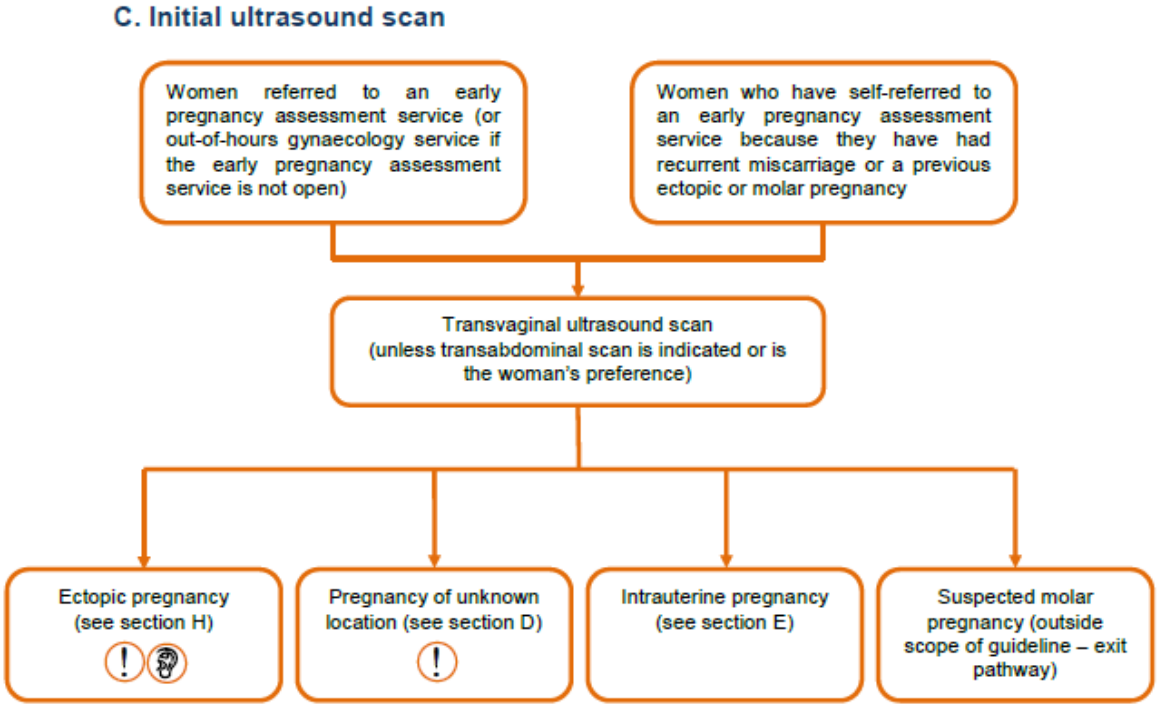
Appendix 2: Initial clinical assessment

Taken from full clinical guideline 154



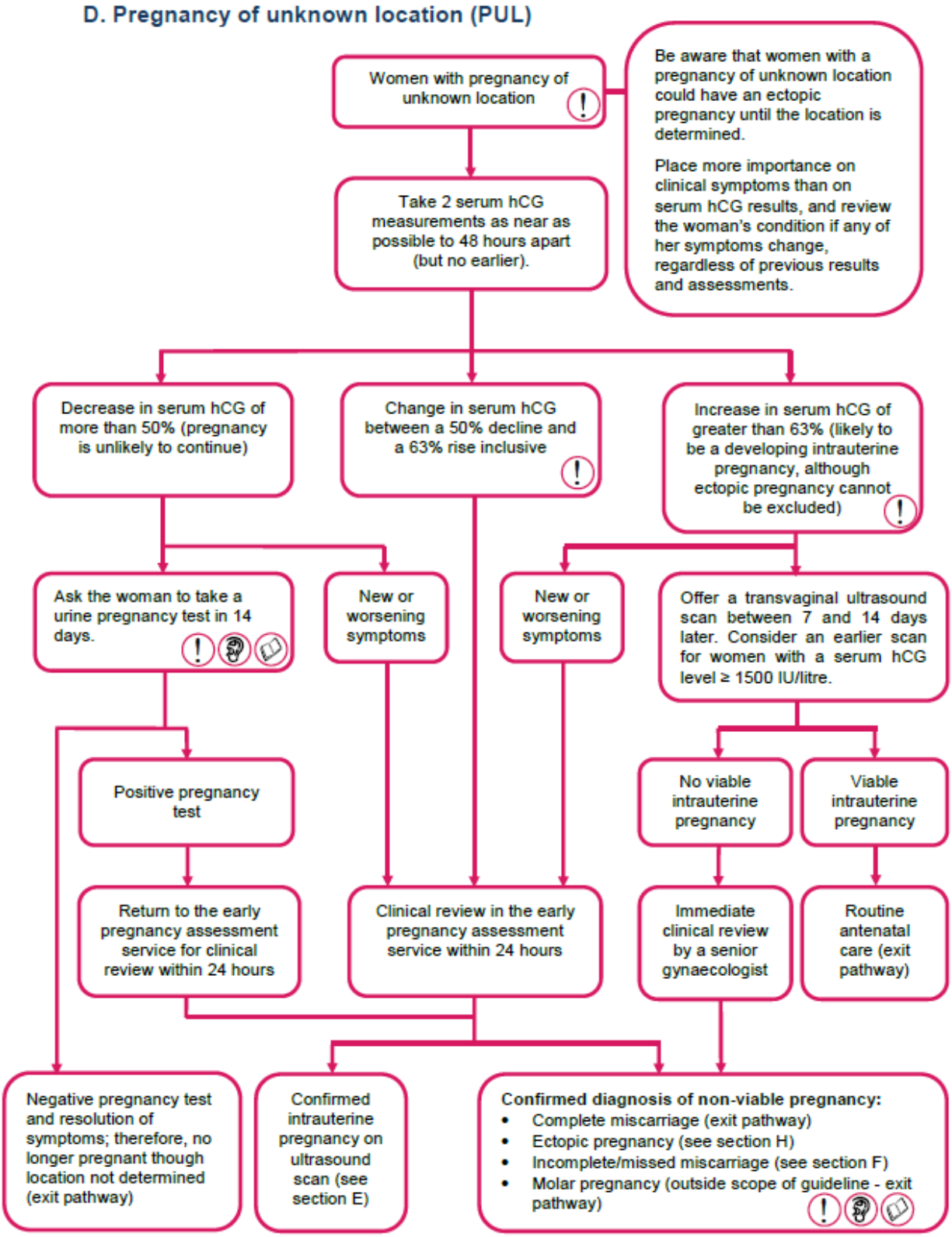
Appendix 3: Initial ultrasound scan

Taken from full clinical guideline 154



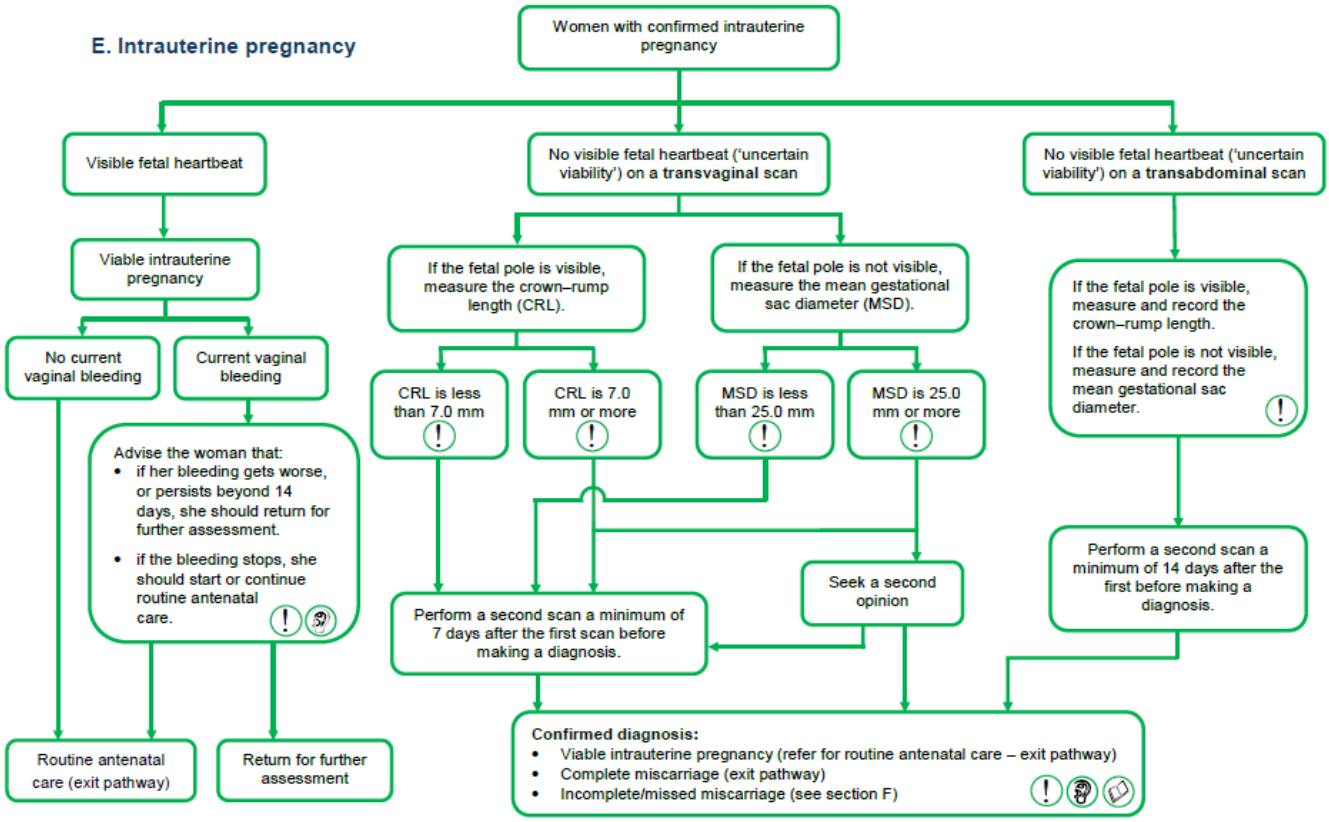
Appendix 4: Pregnancy of unknown location

Taken from full clinical guideline 154



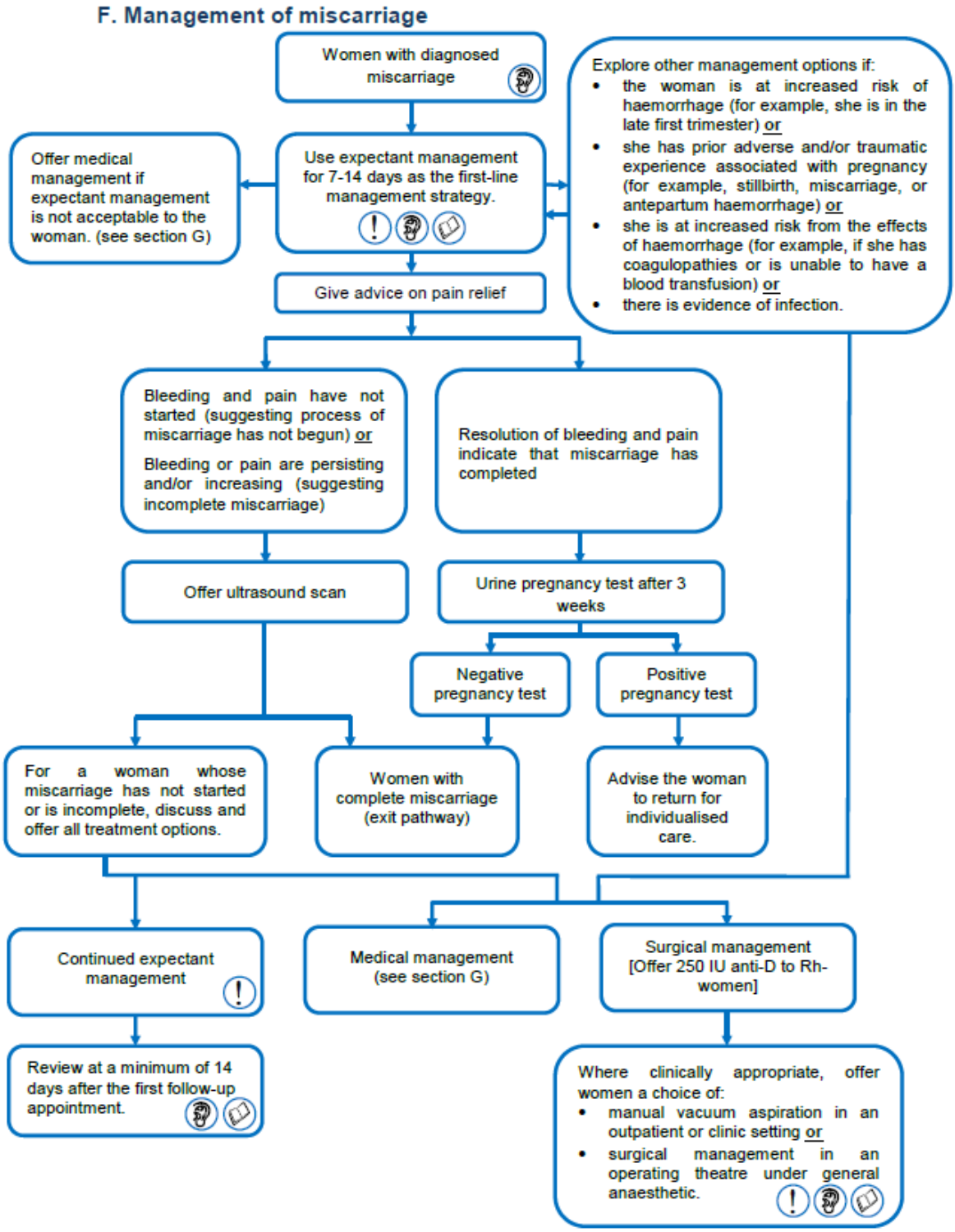
Appendix 5: Intrauterine pregnancy

Taken from full clinical guideline 154



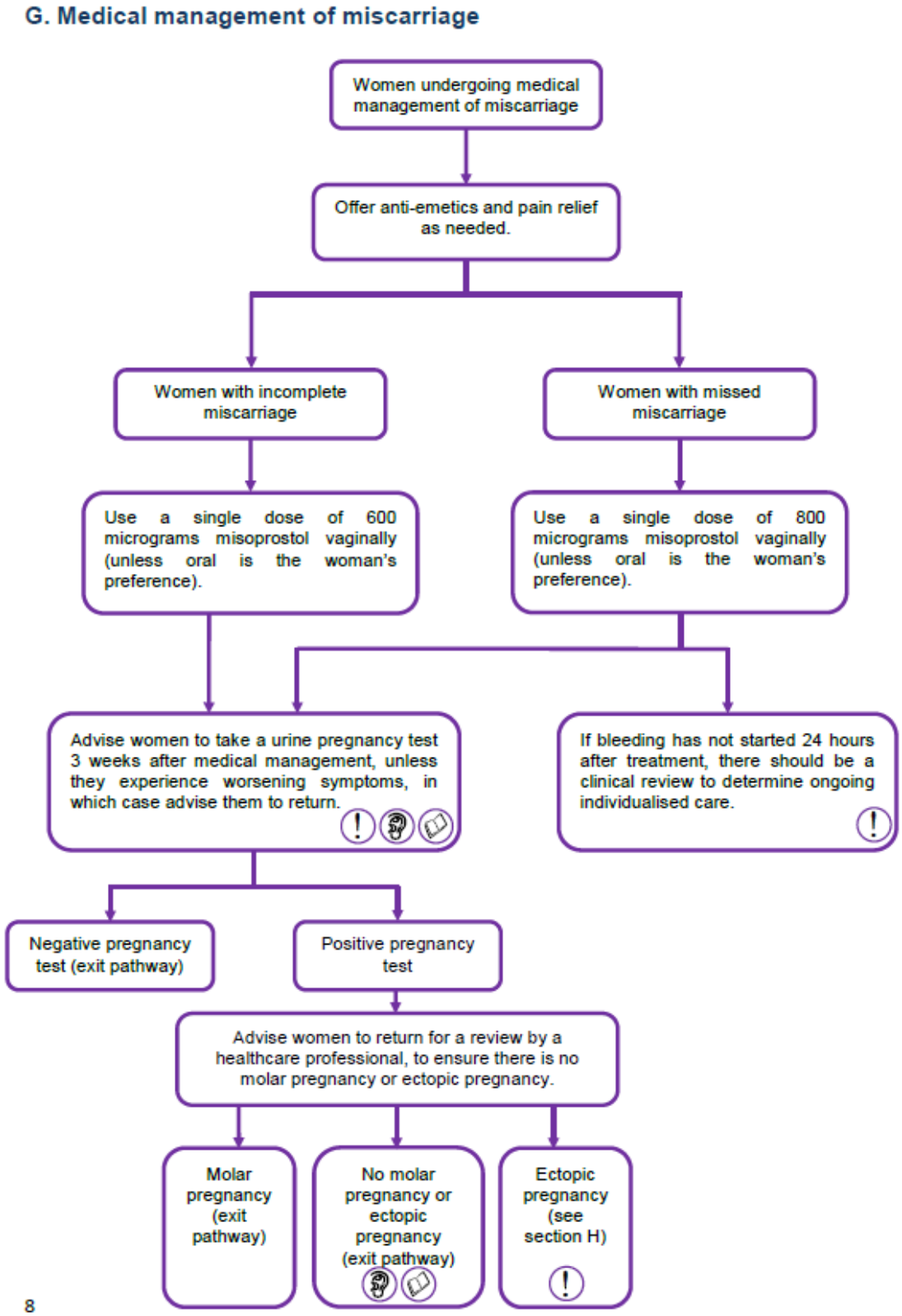
Appendix 6: Management of miscarriage

Taken from full clinical guideline 154



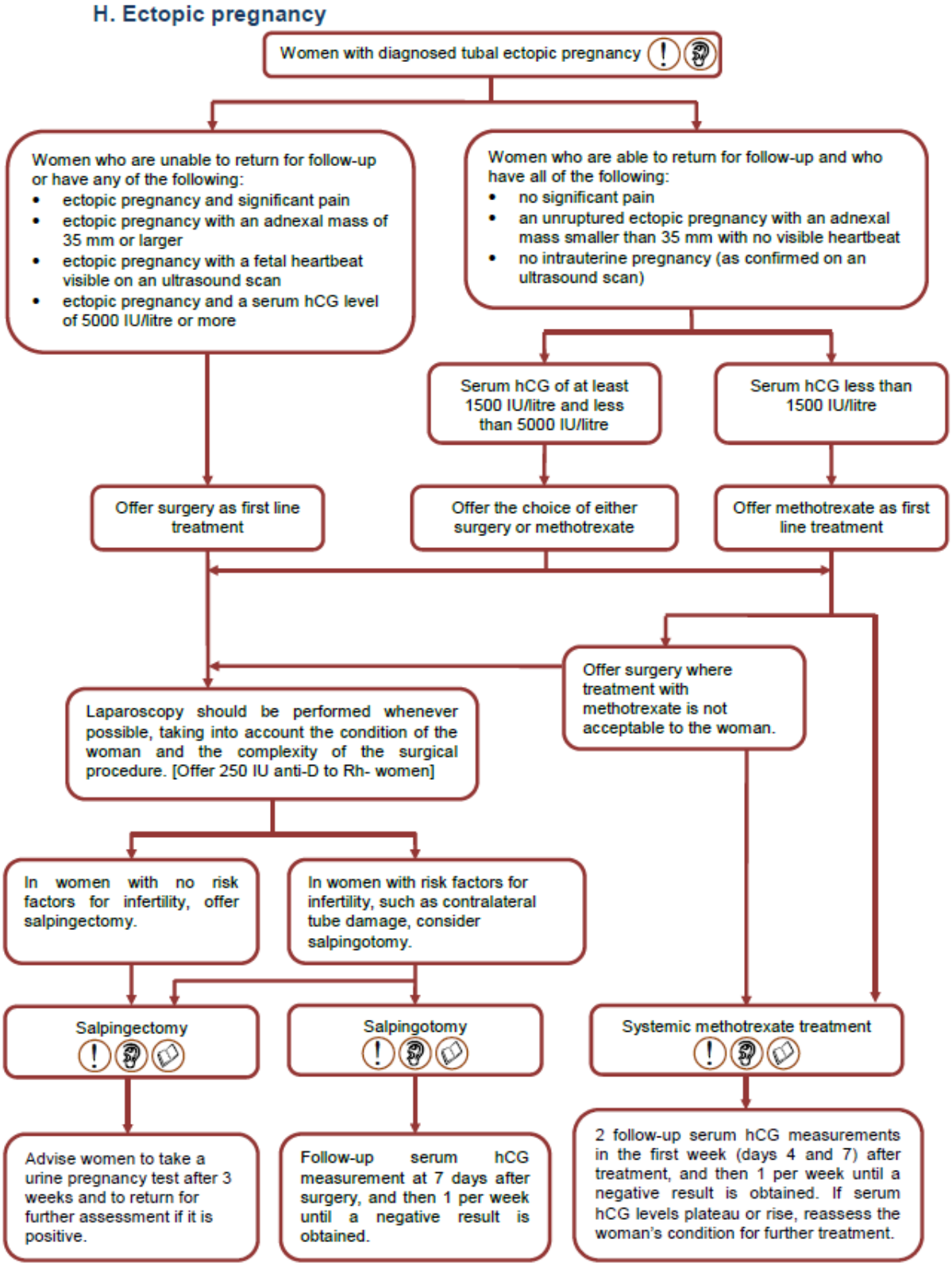
Appendix 7: Medical management of miscarriage

Taken from full clinical guideline 154



Appendix 8: Ectopic pregnancy

Taken from full clinical guideline 154



Appendix 9: Key priorities for implementation (CG154)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Support and information giving

- Throughout a woman's care, give her and (with agreement) her partner specific evidence based information in a variety of formats. This should include (as appropriate):
  - When and how to seek help if existing symptoms worsen or new symptoms develop, including a 24-hour contact telephone number.
  - What to expect during the time she is waiting for an ultrasound scan.
  - What to expect during the course of her care (including expectant management), such as the potential length and extent of pain and/or bleeding, and possible side effects.
  - This information should be tailored to the care she receives.
  - Information about post-operative care (for women undergoing surgery).
  - What to expect during the recovery period – for example, when it is possible to resume sexual activity and/or try to conceive again, and what to do if she becomes pregnant again. This information should be tailored to the care she receives.
  - Information about the likely impact of her treatment on future fertility.
  - Where to access support and counselling services, including leaflets, web addresses and helpline numbers for support organisations.

Ensure that sufficient time is available to discuss these issues with women during the course of their care and arrange an additional appointment if more time is needed.

Early pregnancy assessment services

- Regional services should be organised so that an early pregnancy assessment service is available 7 days a week for women with early pregnancy complications, where scanning can be carried out and decisions about management made.

Symptoms and signs of ectopic pregnancy and initial assessment

- During clinical assessment of women of reproductive age, be aware that:
  - they may be pregnant, and think about offering a pregnancy test even when symptoms are non-specific and
  - the symptoms and signs of ectopic pregnancy can resemble the common symptoms and signs of other conditions – for example, gastrointestinal conditions or urinary tract infection.
- All healthcare professionals involved in the care of women of reproductive age should have access to pregnancy tests.

Using ultrasound for diagnosis

- Offer women who attend an early pregnancy assessment service (or out-of-hours gynaecology service if the early pregnancy assessment service is not available) a transvaginal ultrasound scan to identify the location of the pregnancy and whether there is a fetal pole and heartbeat.

Human chorionic gonadotrophin measurements in women with pregnancy of unknown location

- Be aware that women with a pregnancy of unknown location could have an ectopic pregnancy until the location is determined.

Expectant management

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

- the woman is at increased risk of haemorrhage (for example, she is in the late first trimester) **or**

- she has previous adverse and/or traumatic experience associated with pregnancy (for example, stillbirth, miscarriage or antepartum haemorrhage) **or**

- she is at increased risk from the effects of haemorrhage (for example, if she has coagulopathies or is unable to have a blood transfusion) **or**

- there is evidence of infection.

Surgical Management

- Where clinically appropriate, offer women undergoing a miscarriage a choice of:

  - manual vacuum aspiration under local anaesthetic in an outpatient or clinic setting or

  - surgical management in a theatre under general anaesthetic.

Performing laparoscopy

- When surgical treatment is indicated for women with an ectopic pregnancy, it should be performed laparoscopically whenever possible, taking into account the condition of the woman and the complexity of the surgical procedure.

Salpingectomy and salpingotomy

- Offer a salpingectomy to women undergoing surgery for an ectopic pregnancy unless they have other risk factors for infertility.

Appendix 10: Glossary

Early pregnancy Pregnancy in the first trimester – that is, up to 13 completed weeks of pregnancy.

Expectant management A management approach in which treatment is not administered, with the aim of seeing whether the condition will resolve naturally.

Pregnancy of unknown location A descriptive term used to classify a pregnancy when a woman has a positive pregnancy test but no pregnancy can be seen on an ultrasound scan.

Appendix 11: Suggestions from stakeholder engagement exercise

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
001	IPULA	Women with symptoms in early pregnancy should have access to an Early Pregnancy Assessment Unit.	The recommendation that women with symptoms should see another healthcare professional before accessing EPAU will impede access and will not offer additional useful information in the same way as ultrasonography. Access should not be restricted on basis on gestational age or symptoms as this could lead to women with EP being missed.	An assessment prior to referral to EPAU will not yield additional useful information and is an inefficient use of resources and clinicians time. It may also lead to unnecessary repetition of intimate examinations, which would not provide useful information. Ultrasound is the definitive way of assessing viability and location of pregnancy. Therefore, women presenting with symptoms in early pregnancy at any gestation should have direct access to an EPAU within 24 hours of presentation.	The optimal timing of an ultrasound scan to assess the location and viability of an early pregnancy. Bottomley C et al. Human Reproduction. 2009, Aug;24(8):1811-7 Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination. Savitz DA et al. Am J Obstet Gynecol. 2002 Dec;187(6):1660-6.
002	IPULA	Management and diagnosis of PUL	Pregnancy of unknown location is a diagnosis made on ultrasound. These pregnancies should be risk stratified and cared for by an EPAU with dedicated and trained staff. Inability to locate a pregnancy on transvaginal ultrasound should result in quantitive measurement of hCG and progesterone and repeat hCG 48hrs later to determine management approach.	10-40% percentage of PUL's will be ectopic pregnancies. It is important to note that using the approach suggested in this guidance may lead to 20% of ectopic pregnancies being misclassified as low risk and therefore not being referred for further ultrasound or appropriate follow up, which may be dangerous.	Early Pregnancy failure: beware of the pitfalls of modern management. Barnhart KT. Fert Steril. 2012 Nov;98(5):1061-5.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
003	IPULA	Management of miscarriage	Expectant management is a valid treatment option that should be offered as an alternative to medical or surgical depending on patient preference and other factors but not as the only first line option. Given the absence of significantly increased risk of the interventional options, there is no indication to restrict patient choice.	This is key as a woman's choice of how her pregnancy loss is managed should not be rationed. For some women, expectant management may be psychological distressing and therefore inappropriate. Offering options and considering the patient as an individual is essential.	Management of miscarriage: expectant, medical or surgical? Results of randomised control trial (Miscarriage treatment Trial, MIST) Trinder J et al. BMJ 2006;332:1235
004	IPULA	Management of Ectopic Pregnancy	NICE has recommended the first line approach to management of EP is methotrexate. However, there has yet to be evidence-based consensus on the optimal management of unruptured ectopic pregnancy. An expectant approach with monitoring of hCG levels may be an option for some patients, and is not dangerous. In addition, operative management may be more suitable for a patient in specific circumstances.	It is important to consider alternatives in the management of EP, particularly as methotrexate has associated morbidity. It may therefore be unnecessary and avoidable. In addition, methotrexate may be given in error to pregnancies which are in fact located within the uterus. This would result in miscarriage of potentially wanted pregnancy or potential serious abnormalities in the baby if it survives. It is essential therefore that management is individualised to the patient, her history, symptoms, scan findings and hormone tests. Quality ultrasound and interpretation of results must be carried out within an EPAU.	Rationalizing the management of pregnancies of unknown location: temporal and external validation of a risk predication model on 1962 pregnancies. B Van Calster et al. Hum. Reprod. (2013) doi: 10.1093/humrep/des440 Methotrexate or expectant management in women with an ectopic pregnancy or pregnancy of unknown location and low serum hCG concentrations? A randomized comparison. Van Mello NM et al.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					Human Reproduction. 2013 Jan;28(1):60-7. doi: 10.1093/humrep/des373
005	IPULA	Diagnosis of miscarriage	NICE guidance in accordance with latest data has issued appropriately conservative criteria for the diagnosis of miscarriage. Adherence with this is crucial to prevent misdiagnosis of miscarriage. Guidance must be clearer as to who should be offered repeat ultrasound scans and when the diagnosis of miscarriage can be made confidently on a single scan. In addition, units must ensure transvaginal scans in these cases are performed.	The misdiagnosis miscarriage and thus inadvertent termination of a wanted pregnancy must never happen. Care must be taken in this diagnosis and caution exercised. It is recognised that inter-observer variation and differences in growth rates of pregnancies may explain the differences seen. This must be taken into account when performing ultrasound scans in women and prior to diagnosis being made.	Limitations of current definitions of miscarriage using mean gestational sac diameter and crown–rump length measurements: a multicenter observational study Abdallah Y et al. Ultrasound in Obstetrics & Gynecology Volume 38, Issue 5, pages 497–502, November 2011
006	IPULA	Audit	EPAU units must ensure continuous audit is carried out. In particular, important markers of this include the percentage of women scanned who are diagnosed with pregnancy of unknown location and the percentage of these women who go on to be diagnosed with ectopic pregnancy. These can be viewed as markers of the quality of scanning with the unit.	Audit will ensure adherence of local guidance, care is consistent and is of high quality. In addition, this will help identify areas for future research. Audit across units may help identify areas of strengths and weaknesses.	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
007	IPULA	The psychological impact of early pregnancy events	Early pregnancy events, such as ectopic pregnancies or miscarriages, can be traumatic for both the patient and her partner. Consideration must be given to this when caring for such patients. More evidence is required to truly assess the consequences of such events and the impact on patients psychological well being.	While a lot of attention has been devoted to the physical management of miscarriage, the evidence for psychological management of miscarriage is less well developed. Miscarriage is viewed as a traumatic event, distressing all the affected women to a greater or lesser degree. Follow-up of women who have experienced a miscarriage could help to identify at-risk women or those who have already developed psychological complications.	Anxiety following miscarriage and the subsequent pregnancy: A review of the literature and future directions. Geller PA et al. Journal of Psychosomatic Research 2004;56: 35–45.
008	NHS England Patient Safety Division	The QS needs to be framed and promoted in a way that makes clear its relevance outside obstetric services, as patients with pain and bleeding in early pregnancy do not always know they are pregnant, nor is this always suspected by healthcare staff	We have published evidence from the National Reporting and Learning System (NRLS) on significant numbers of cases of missed diagnosis of ectopic pregnancy	See http://www.nrls.npsa.nhs.uk/resources/?EntryId45=65335 for more details on the nature and numbers of missed diagnosis of ectopic pregnancy.	In a separate workstream on identifying pregnancy before any surgery, we noted that some younger patients who were pregnant denied the possibility of pregnancy (especially when asked in front of parents) see http://www.nrls.npsa.nhs.uk/alerts/?entryid45=73838
009	NHS England Patient Safety Division	Where Methotrexate is used to treat ectopic pregnancy, patients have all the information they need to support the safety issues associated with this medication	Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, very occasionally problems with taking the medication can cause serious harm and even death.	We have issued advice on improving compliance with oral methotrexate guidelines – see http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800 Whilst these relate to Methotrexate use mainly in rheumatoid arthritis, the principles of patients being fully	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				informed of side effects to look out for that are relevant to Methotrexate use in other contexts	
010	Nordic Pharma Ltd	The current Guidelines make no clear differentiation between sporadic and recurrent miscarriage.	Nordic suggest that the standards should make provision for the assessment, care and management of patients with recurrent miscarriage (3 or more previous consecutive miscarriages), this affects approximately 1% of couples trying to conceive. (RCOG Green Top Guideline 17, 2011) These Green Top Guidelines recommend that patients with recurrent miscarriage are referred to a specialist clinic. The NICE Quality Standards should clearly differentiate sporadic miscarriage from recurrent miscarriage as the investigation and management of these patients will differ.	It is shown in the NICE guidance on Ectopic Pregnancy and Miscarriage (No. 154) that women with recurrent miscarriage may self refer to the early pregnancy assessment services. The way the guidance is currently written means these patients could be assessed and treated as if it was a sporadic miscarriage rather than recurrent and missing out on potentially useful treatment. The quality standards should incorporate wording to ensure that patients with recurrent miscarriage who do self refer to an early pregnancy assessment centre are identified and treated differently from those presenting with sporadic miscarriage. It is important because there is evidence to suggest that whilst some treatments, e.g. progesterone, have no demonstrable effect on reducing rates of sporadic miscarriage but there is evidence to show they can be effective in preventing recurrent miscarriage.	There are treatments available to help prevent recurrent miscarriage, the most recent work on progesterone and recurrent miscarriage has been the recent Cochrane review, published in October 2013. It is suggested by this recent Cochrane Review of progestogens for preventing miscarriage that whilst there's no evidence to support the use of progesterone for sporadic miscarriage there is evidence for use of progesterone to prevent recurrent miscarriage. The review goes on to say that treatment for these women may be warranted given the reduced rates of miscarriage in the treatment group and the finding of no statistically significant difference

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					between treatment and control groups in rates of adverse effects suffered by either mother or baby in the available evidence. Link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003511.pub3/abstract A recent non randomised trial looked at the effect of progesterone in reducing miscarriage in approximately 200 patients with a history of recurrent miscarriage (Hussain et al J Hum Reprod Sci 2012). They did not have a control group so compared their 9 year cohort of patients against historical data that showed subsequent miscarriage rates of 45% (95% CI 40–50) and 54% (95% CI 44–64) in women with previous three and four miscarriages, respectively.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					Hussain et al found their use of progesterone demonstrated a reduction in the subsequent miscarriage rate in women with previous three miscarriages (35% vs. 45%) but the confidence limits overlapped (hence not likely to be statistically significant), while for women with previous four miscarriages, there was a further reduction in miscarriage rates (30% vs. 54%) with no confidence limit overlap (suggesting statistical significance). They acknowledge the limitations of this data (e.g. no control group) but it does contribute further evidence to support the use of progesterone in women with recurrent miscarriage. Link to Hussain et al: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC360483

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					0/ It is recognized that large quality trials have been lacking in this area. This is being addressed with a large RCT of progesterone supplementation versus placebo in over 800 patients with recurrent miscarriage (PROMISE trial) has taken place in in 40 centres in the UK and the Netherlands. The trial recruitment was expected to close at the end of October 2013. According to the trial's website, recruitment has closed and the trial report is due in October 2014. This large placebo controlled trial will provide good evidence on the use of progesterone in miscarriage prevention in patients with a history of recurrent miscarriage. Link to PROMISE study homepage:

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					http://www.medscinet.net/promise/default.aspx
011	Royal College of Nurses	Improved and equal access to ultrasound	The diagnosis of pregnancy loss often depends on this diagnostic where there is patchy provision throughout the UK	Improve the pathway for women and obtain an earlier diagnosis	
012	Royal College of Nurses	Improved access to counselling services post pregnancy loss.	There is patchy and unequal psychological and counselling services	Improve the psychological care of women post pregnancy loss	
013	Royal College of Nurses	Staff in early pregnancy service should have formal training in communication and breaking bad news.	There is currently no standard training in communication for staff working in early pregnancy units.	Improve communication in a sensitive way with women who are experiencing pregnancy loss	
014	Royal College of Nurses	Consistent care and support for supporting women experiencing early pregnancy problems such as pain and bleeding	Many Women (with their supporting partners), may well initially seek advice/ help / intervention from sources outside of secondary care. Some primary Care / telephone triage personnel may have limited information or no clinical experience of early pregnancy and women may present at an Emergency Department or Walk-in Centres. (Nurses/ medical staff who are no longer actively working in midwifery / Obstetric / Gynaecology will still retain	Whilst the guidelines may address health professionals working in clinical settings providing women's health care, a wider perspective will ensure limited delay in referral to the appropriate department.	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			knowledge of the subject however it cannot be expected that every Health Care professional will have had that clinical experience)		
015	Royal College of Nurses	Appropriate use medical terminology	To avoid distress and misunderstanding for the Woman (and supporting partner / family)	To ensure that all clinicians in whatever setting are conversant with the appropriate terminology to be used. A handy document to identify current terminology that encompasses the spectrums of possible outcomes including a accepted universal definition with a section for explanatory notes for those health care professionals with limited or no midwifery / obstetrics/ gynaecology experience (example miscarriage, inevitable miscarriage etc)	
016	Royal College of Nurses	Provision of Service 1)Utilisation of the Early Pregnancy Units 2)Service provision has limited hours 3)Geographical or Social isolation	Clinical and economic benefits to the provider, referral agency (Emergency Department / GP etc), and Woman To support a woman who have limited or no access to transport	Improvement of service, efficiency of care, avoiding hospital admission limited stay in hospital. Clinical management pathways (written) Defined lines of communication/ governance and accountability for clinical practice national / local protocols / guidance , for referral to an appropriate clinical setting & Clinician, when a woman seeks information or presents and either an Emergency dept / Walk in Centre	

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				Twenty four hour communication link with information where to access the relevant department supporting an out of hours service and where to access transport.	
017	Royal College of Nurses	Infection Control	Appropriate infection control measure, when invasive ultra sounds probes is in use, or other equipment that require sterilisation / disinfecting procedures	Adherence to appropriate standardised infection control measures /policy / protocol. Standard for audit	
018	Royal College of Nurses	Access to laboratory services	To prevent delay in access to results. To ensure that out of hours facility is available The woman does not have to return or seek the results from another source for example GP	Interdepartmental communication The results are communicated to and communicated by the appropriate staff The woman is provided with results without delay Information is communicated on discharge avoid unnecessary repetition of investigations	
019	Royal College of Nurses	Discharge / follow documentation	To avoid unnecessary duplication of investigations Follow up criteria recorded Guidance for the woman / supporting partner / other healthcare professionals/out of hours departments are aware care and to whom to refer.	To provide clearly defined pathways of care / regimens / follow up plans / discharge information For staff in out of hours settings to be aware of previous care . All patient information leaflets / referral / discharge / follow up documents have a time limitation review	
020	Royal College of Nurses	Psychological support	Provision of such is variable However in the economic climate	Allowing the woman the choice of attending a counselling session with or without her	

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			of Health / Social care provision at this time. It may not be possible to mandate National Certification for staff. Support for the Woman and supporting partner is important and Local protocols / guidance for Education of staff – in house should be a recommendation for breaking " bad news"	supporting partner. Referral to an outside agency as appropriate (with the woman's consent) Communicating the woman's decision to the GP	
021	Royal College of Nurses	Audit	Reviewing standard of care provision	Systematically capture patient views to improve standard of care. For example using patient satisfaction questionnaires Complications of interventions? including failure rates Number of visits to the unit? including information visits to reach definitive diagnosis Standards of documentation and when reviewed.	
022	Royal College of Nurses	Improved access to ERPC provision	There is no standard time to wait for an EPRC which can impact on the distress women feel.	To improve the pathway of care of women with miscarriage and to enable a quick resolution to the miscarriage if a surgical option is needed	Currently women can wait for a long time to have an EPRC, there is anecdotal evidence that this can be up to 7 days. Women on priority table are also often starved and cancelled repeatedly as ERPC is not seen as a priority.

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023	SCM1	Throughout a woman's care she should be provided with evidence-based information.	This is vital to her journey and her recovery. It is known that following a consultation as little as 10% of information is retained by the patient. The woman (and her partner) may then need to recall information in order to make important decisions about her care.	Although many early pregnancy services do provide good information, this is certainly not true of all services across England and Wales.	NICE guidelines Patient feedback to the Miscarriage Association. AEPU have some date but there is no good quality collection of data
024	SCM1	An early pregnancy assessment service should be available regionally 7 days a week for the assessment of problems in early pregnancy. This is a NICE recommendation.	It is important both for safety (in the case of an undiagnosed ectopic pregnancy) and also for the emotional wellbeing of women and their partners living with uncertainty.	There are a minority of regions currently offering a 7 day service. These units also need to provide excellent senior support to prevent mis-diagnosis.	NICE guidelines
025	SCM1	An ultrasound scan should always be repeated after 7-14 days.	To prevent mis-diagnosis of viable pregnancies and ectopic pregnancies/pregnancies of unknown location.	To prevent inadvertent termination of viable pregnacies. This has received much media coverage recently.	NICE guidelines http://onlinelibrary.wiley.com/doi/10.1002/uog.10109/full
026	SCM1	Explore other management options in special circumstances, such as a previous traumatic miscarriage	Patient choice and empowerment are so important to a woman's recovery, particularly when her emotions have been built on a previous traumatic experiences, such as previous miscarriages, haemorrhage, or long periods of uncertainty	It is important gynaecologists do not use the NICE guidelines as an excuse to remove patient choice and individualised care plans.	NICE guidelines Patients feedback

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027	SCM1	Be aware that ectopic pregnancy can present with a variety of signs and symptoms. All healthcare professionals should have access to pregnancy tests	Whilst emergency units will have pregnancy tests, doctors and nurses in primary care may not. Women with ectopic pregnancies may be unaware that they are pregnant and the diagnosis cannot be suspected nor made without the result of a urinary pregnancy test	Because it could save lives by providing an earlier diagnosis.	NICE guidelines As a GP I know that not all Practices have pregnancy testing kits.
028	SCM2	Access to EP assessment services 7 days a week	Pain and Bleeding in early pregnancy can occur at any time so it is vitally important women have access to assessment services and also know where to go when this service is not available.	Some women can have a long wait for a scan after a bleed. This can cause a huge amount of distress and worry. More consideration of the psychological aspect and having quicker access to scanning services would be extremely beneficial, particularly if the woman is very anxious (i.e previous miscarriage, has had difficulty conceiving). Fast and accurate diagnosis of ectopic pregnancy in particular is also very important as this can quickly turn into a life threatening situation.	CG154 Ectopic pregnancy and miscarriage: NICE guideline
029	SCM2	Give women a choice of management options	Expectant management may not be suitable for all women due to their personal home situation, previous adverse/traumatic experience or because they are at risk of haemorrhage.	Taking away choice could put some women at risk if they are sent away and go on to haemorrhage. This could have a serious impact on their psychological well-being as well as their physical health, especially during the latter part of the trimester when haemorrhage is more likely to occur. Some women can be very frightened due to previous trauma so it is imperative they are	CG154 Ectopic pregnancy and miscarriage: NICE guideline

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				treated as individuals and their psychological state taken into account when discussing management options.	
030	SCM2	Ensure women are kept fully informed and given detailed information throughout the process	Information about what to expect during each stage and how to seek help should they need it is important as women will often have many unanswered questions and not know who to turn to for help.	Women are often in a very distressed state when accessing early pregnancy assessment services for pain and bleeding so it is vital they are given information at each stage of the process in a variety of formats. Some may feel in need of further counselling support services so it is important they know how to access this type of support.	CG154 Ectopic pregnancy and miscarriage: NICE guideline
031	SCM3	Staff undertaking sonographic assessment in early pregnancy should be qualified to do so	Sonographic assessment is a key component of the assessment of women in early pregnancy with pain and/ or bleeding (NICE 2012 Ectopic pregnancy and miscarriage). To date there are varying degrees of training and assessment (ranging from Masters level qualification to in-house training) which could contribute to incorrect sonographic assessment and diagnosis	NICE 2012 key recommendation is to use ultrasound for diagnosis. To ensure women receive the best possible care and assessment they should be scanned by appropriately trained staff with robust protocols for management	Recent misdiagnosis of miscarriage in Cardiff Recent papers (Pexsters et al 2011, Abdallah et al 2011, Abdallah et al 2011. VanCalster et al 2013, Doubilet and Benson 2013) all indicate the requirement for staff training and robust protocols for management
032	SCM3	Appropriate management options are offered to all women who experience a miscarriage	Women diagnosed with a miscarriage should be offered a full range of management options	NICE 2012 key recommendation for research to review women's experiences of different types of miscarriage	NICE 2012 recommend expectant management as first line management. New research (Peterson et al 2013) & audits

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					presented at this years AEPU conference Leeds indicate that out patient management of miscarriage is safe and effective and may be a viable alternative

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033	SCM3	Written information regarding methods of management/ ongoing assessment is provided to all women with pain and bleeding in pregnancy or those with a diagnosed miscarriage	Providing women with written information helps inform their options regarding assessment and management	NICE 2012 key recommendation. It is vital that women are given appropriate information and the time to digest that information prior to commencing miscarriage management	
034	SCM3	Access to 24 hour early pregnancy assessment	Women should have access to 24 hour early pregnancy assessment in the form of scanning and Bhcg assessment 24 hour help line	NICE 2012 key recommendation. Staff work in established EPAUs are trained appropriately and have expertise in assessing and managing women with pain and bleeding in pregnancy	Approx 220 maternity units in the UK but only 150 known EPAU (AEPU & UKEPPS data 2012)
035	SCM3	Ectopic pregnancy management	Women should have access to appropriately trained staff who can offer all methods of management for ectopic pregnancy (expectant, medical, surgical) dependent upon sonographic assessment, Bhcg level and patient symptoms	NICE 2012 recommendation	Recent audits and case studies presented at AEPU conference in Leeds November 2013 would suggest that expectant management of tubal ectopic pregnancy can be a viable alternative in certain circumstance to that of medical and surgical management
036	Royal College of Paediatrics and Child Health	No comments to make			