

**Pain and bleeding in early pregnancy:
assessment and initial management of
ectopic pregnancy and miscarriage
in the first trimester**

NICE guideline

Draft for consultation, June 2012

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

Introduction	3
Woman-centred care	4
Key priorities for implementation.....	5
Guidance	7
1.1 Psychological support.....	7
1.2 Early pregnancy assessment units	7
1.3 Signs and symptoms of ectopic pregnancy.....	8
1.4 Diagnosis of viable intrauterine pregnancy and ectopic pregnancy ..	10
1.5 Management of miscarriage	15
1.6 Management of ectopic pregnancy.....	18
1.7 Anti-D rhesus prophylaxis	21
2 Notes on the scope of the guidance	22
3 Implementation	22
4 Research recommendations	22
5 Other versions of this guideline.....	26
6 Related NICE guidance	27
7 Updating the guideline	27
Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team	29

Introduction

Pain and bleeding in early pregnancy has an adverse effect on the quality of life of many women. Approximately 20% of pregnancies miscarry, and miscarriages can cause considerable distress. Early pregnancy loss accounts for over 50,000 admissions in the UK annually. The rate of ectopic pregnancy is 11 per 1000 pregnancies, with a maternal mortality of 0.2 per 1000 estimated ectopic pregnancies. About two thirds of these deaths are associated with substandard care. Women who do not access medical help readily (such as women who are recent migrants, asylum seekers, refugees, or women who have difficulty reading or speaking English) are particularly vulnerable. Improvement in the diagnosis and management of early pregnancy loss is thus of vital importance, in order to reduce the incidence of the associated psychological morbidity and avoid the unnecessary deaths of women with ectopic pregnancies.

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.

Woman-centred care

This guideline offers best practice advice on the care of women with pain and bleeding in early pregnancy.

Treatment and care should take into account women's needs and preferences. Women with pain and bleeding in early pregnancy should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If women do not have the capacity to make decisions, healthcare professionals should follow the [Department of Health's advice on consent](#) and the [code of practice that accompanies the Mental Capacity Act](#). In Wales, healthcare professionals should follow [advice on consent from the Welsh Government](#).

Good communication between healthcare professionals and women is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information women are given about it, should be culturally appropriate. It should also be accessible to women with additional needs such as physical, sensory or learning disabilities, and to women who do not speak or read English.

If the woman agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

Early pregnancy assessment units

- A dedicated early pregnancy assessment service should be available at least during Monday to Friday for women with pain and/or bleeding in early pregnancy, where scanning can be carried out and decisions about management made. [1.2.1]

Signs and symptoms of ectopic pregnancy

- All healthcare professionals involved in the care of women of reproductive age should have access to pregnancy tests. [1.3.2]

Ultrasound for determining a viable intrauterine pregnancy

- Offer women with pain and/or bleeding a transvaginal ultrasound scan to identify the location of the pregnancy and whether there is a fetal pole and heartbeat. [1.4.2]

Human chorionic gonadotrophin measurements in women with pregnancy of unknown location

- Assume women with a pregnancy of unknown location have an ectopic pregnancy until the location is determined. [1.4.20]

Management of miscarriage

- Use expectant management for 7–14 days as the first-line management strategy following confirmed diagnosis of a non-viable pregnancy. [1.5.4]

Setting for surgical management of miscarriage

- Where clinically appropriate, offer women a choice of:
 - manual vacuum aspiration under local anaesthetic in an out-patient or clinic setting
 - evacuation in a theatre under general anaesthetic. [1.5.21]

Performing laparoscopy

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

[1.6.9]

Salpingectomy and salpingotomy

- Offer a salpingectomy to women undergoing surgery for an ectopic pregnancy, unless they have other risk factors for infertility. [1.6.13]

Guidance

The following guidance is based on the best available evidence. The [full guideline](#) [\[hyperlink to be added for final publication\]](#) gives details of the methods and the evidence used to develop the guidance.

1.1 Psychological support

- 1.1.1 Treat all women with pain or bleeding in early pregnancy 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.¹
- 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 sensitive communications and breaking bad news
- 1.1.3 After an early pregnancy loss, offer the woman the option of a follow-up appointment with a healthcare professional in either primary or secondary care according to the woman's preference.

1.2 Early pregnancy assessment units

- 1.2.1 A dedicated early pregnancy assessment service should be available at least during Monday to Friday for women with pain and/or bleeding in early pregnancy, where scanning can be carried out and decisions about management made.

¹ For further guidance about providing information, see NICE clinical guideline 138 – Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (2012).

- 1.2.2 Dedicated early pregnancy assessment services should accept self-referrals from women who have had a previous ectopic or molar pregnancy. All other women with pain and/or bleeding should be assessed by a healthcare professional before referral to an early pregnancy assessment service.
- 1.2.3 Ensure that a system is in place to enable women referred to their local dedicated early pregnancy assessment service to attend it within 24 hours if the clinical situation warrants it. If the service is not available at weekends, and the clinical symptoms warrant further investigation, refer women to the nearest accessible facility that offers specialist clinical assessment and ultrasound scanning.

1.3 *Signs and symptoms of ectopic pregnancy*

- 1.3.1 When assessing women of reproductive age, be aware that they may be pregnant, and think about offering a pregnancy test even when symptoms are non-specific.
- 1.3.2 All healthcare professionals involved in the care of women of reproductive age should have access to pregnancy tests.
- 1.3.3 Exclude the possibility of ectopic pregnancy, even in the absence of risk factors (such as previous ectopic pregnancy), because about a third of women with an ectopic pregnancy will have no known risk factors.

Symptoms and signs

- 1.3.4 Be aware that atypical presentation for ectopic pregnancy is common.
- 1.3.5 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.

1.3.6 Be aware that ectopic pregnancy can present with a variety of signs. 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.

1.3.7 If a woman has a positive pregnancy test the threshold for considering an ectopic pregnancy should be low because 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.

- 1.3.8 Refer women with a positive pregnancy test and continuing or worsening symptoms and signs that could suggest ectopic pregnancy to a dedicated early pregnancy assessment service for further evaluation.
- 1.3.9 If a woman needs to be referred to a dedicated early pregnancy assessment service, explain the reasons for the referral and what she can expect when she arrives there.

Signs

- 1.3.10 Refer immediately women with a positive pregnancy test and pain and abdominal tenderness on examination to a dedicated early pregnancy assessment service for further investigation.
- 1.3.11 If there is no abdominal tenderness or signs of intra-abdominal bleeding, but there is still a suspicion of an ectopic pregnancy, consider a vaginal examination to assess for cervical excitation or pelvic tenderness. If either of these is present, together with a positive pregnancy test, refer the woman immediately to a dedicated early pregnancy assessment service.

1.4 *Diagnosis of viable intrauterine pregnancy and ectopic pregnancy*

Ultrasound

Determining viability of an intrauterine pregnancy

- 1.4.1 Use expectant management for:
- women with a pregnancy of less than 6 weeks' gestation who are bleeding but not in pain
 - women with a pregnancy of 6 weeks' gestation or more who have minimal blood loss (spotting) and who are not in pain.

Advise these women to take a urine pregnancy test after a week and to return if their symptoms worsen. Refer all other women to a dedicated early pregnancy assessment service.

- 1.4.2 Offer women with pain and/or bleeding a transvaginal ultrasound scan to identify the location of the pregnancy and whether there is a fetal pole and heartbeat.
- 1.4.3 If a transvaginal ultrasound scan is unacceptable to the woman offer a transabdominal ultrasound scan and explain the limitations of this method of scanning.
- 1.4.4 Inform women that the diagnosis of miscarriage using one ultrasound scan cannot be guaranteed to be 100% accurate and there is a small chance that the diagnosis may be incorrect, particularly at very early gestational ages.
- 1.4.5 If the crown rump length is 6.0 mm or less with a transvaginal ultrasound scan (or 10.0 mm or less with a transabdominal ultrasound scan) and there is no visible fetal heartbeat, perform a second scan a minimum of 7 days after the first before making a diagnosis.
- 1.4.6 If the crown rump length is more than 6.0 mm with a transvaginal ultrasound scan (or 10.0 mm with a transabdominal ultrasound scan), and there is no visible fetal 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.
- 1.4.7 Do not measure the mean gestational sac diameter if there is a fetal heartbeat.
- 1.4.8 Measure the mean gestational sac diameter if the fetal pole is not visible.

DRAFT FOR CONSULTATION

- 1.4.9 If the mean gestational sac diameter is 25.0 mm or less with no fetal pole, offer the woman a second scan, to be performed a minimum of 14 days after the first. Further scans may be needed before a diagnosis can be made.
- 1.4.10 If the mean gestational sac diameter is greater than 25.0 mm with no 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.
- 1.4.11 Do not use gestational age alone to determine whether a fetal heartbeat should be visible.
- 1.4.12 Inform women that the date of their last menstrual period may not give an accurate representation of gestational age because of variability in the menstrual cycle.
- 1.4.13 Inform women what to expect while waiting for a repeat scan and that waiting for a repeat scan has no detrimental effects on the outcome of the pregnancy.
- 1.4.14 Give women specific verbal and written information on when and how to seek help if symptoms worsen or new symptoms develop.
- 1.4.15 Give women a 24-hour contact telephone number so that they can speak to someone who understands their needs and can advise on appropriate care.
- 1.4.16 Provide women who have a confirmed miscarriage with written and verbal information about where to access support and counselling services (including links to useful websites).

Diagnosing ectopic pregnancy

- 1.4.17 Offer a transvaginal ultrasound scan to diagnose or exclude an ectopic pregnancy.

- 1.4.18 Consider a transabdominal ultrasound scan for women with an enlarged uterus or other pelvic pathology, such as fibroids or an ovarian cyst.
- 1.4.19 All ultrasound scans should be performed or reviewed by someone with training in and experience of diagnosing ectopic pregnancies.

Human chorionic gonadotrophin measurements in women with pregnancy of unknown location

- 1.4.20 Assume women with a pregnancy of unknown location have an ectopic pregnancy until the location is determined.
- 1.4.21 In women with a pregnancy of unknown location, place more importance on clinical symptoms than on human chorionic gonadotrophin (hCG) results, and review the woman's condition if any of her symptoms change, regardless of previous results and assessments.
- 1.4.22 Use hCG measurements only for determining trophoblastic proliferation, to help decide ongoing monitoring.
- 1.4.23 Do not use hCG measurements to determine the location of the pregnancy.
- 1.4.24 Regardless of 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.
- 1.4.25 Take two serum hCG measurements 48 hours apart to determine subsequent management of a pregnancy of unknown location. Take further measurement only after review by a senior healthcare professional.

1.4.26 Inform a woman with an increase in serum hCG concentration greater than 63% that she is likely to have a viable intrauterine pregnancy. Offer her a transvaginal ultrasound scan between 7 and 14 days of the serum hCG test to confirm this:

- If a viable intrauterine pregnancy is confirmed, offer her routine antenatal care.
- If a viable intrauterine pregnancy is not confirmed, refer her for urgent clinical review by a gynaecologist.

1.4.27 For a woman with a decrease in serum hCG concentration greater than 50%:

- inform her that the pregnancy is unlikely to continue but that this is not confirmed
- provide her with written and verbal information about where she can access support and counselling services
- ask her to take a urine pregnancy test 14 days after the serum hCG test, and explain that:
 - if the test is negative, no further action is necessary
 - if the test is positive, she should return for urgent clinical review by a gynaecologist.

1.4.28 For a woman with a change in serum hCG concentration between a 50% decline and 63% rise inclusive:

- refer her for urgent clinical review by a gynaecologist and individualised management
- refer her for a repeat scan between 7 and 14 days
- ask her to report worsening symptoms without delay.

- 1.4.29 For women with a pregnancy of unknown location, do not use progesterone measurements together with hCG measurement as a diagnostic test for either viable intrauterine pregnancy or ectopic pregnancy.

1.5 *Management of miscarriage*

Progesterone for threatened miscarriage

- 1.5.1 Consider progesterone/progestogen for women with a threatened miscarriage (that is, vaginal bleeding and a confirmed intrauterine pregnancy with a fetal heartbeat).²
- 1.5.2 Inform women that although there is some evidence that progesterone/progestogen can prevent a miscarriage, this evidence is not strong.²
- 1.5.3 Advise a woman with threatened miscarriage that:
- if her bleeding gets worse, or persists beyond 14 days, she should return for further assessment
 - if the bleeding stops, she should book for, or return to, routine antenatal care.

² At the time of publication (June 2012), progesterone/progestogen did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

Expectant management

1.5.4 Use expectant management for 7–14 days as the first-line management strategy following confirmed diagnosis of a non-viable pregnancy.

1.5.5 Explain expectant management and that most women will need no further treatment. Also provide written and verbal information about further treatment options.

1.5.6 Give all women verbal and written information about:

- what to expect throughout the process, including the likely duration and severity of bleeding, advice on pain relief and where and when to get help in an emergency
- what to expect in the recovery period, such as how long they should wait before resuming sexual activity and trying to conceive.

Ensure that sufficient time is available to discuss these issues with women. Arrange an additional appointment if necessary.

1.5.7 Inform women where to access support and counselling services. Provide them with leaflets that include helpline numbers for support organisations.

1.5.8 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 such as previous miscarriage or antepartum haemorrhage, or
- she is at increased risk from the effects of haemorrhage.

1.5.9 If the resolution of bleeding and pain indicate that the miscarriage has completed during 7–14 days of expectant management, advise

the woman to take a urine pregnancy test after 3 weeks, and to return if it is positive for individualised management.

1.5.10 Offer a repeat scan if after the period of expectant management the bleeding and pain:

- have not started (suggesting that the process of miscarriage has not begun) **or**
- are persisting and/or increasing (suggesting incomplete miscarriage).

Discuss all treatment options with the woman to allow her to make an informed choice.

1.5.11 Review the condition of a woman who opts for continued expectant management at a minimum of 14 days after the first follow-up appointment.

Medical management

1.5.12 Offer vaginal misoprostol for the medical treatment of missed or incomplete miscarriage. Oral administration is an acceptable alternative if this is the woman's preference.³

1.5.13 For women with a missed miscarriage, use a single dose of 800 micrograms of misoprostol.³

1.5.14 If bleeding has not started 24 hours after treatment, there should be a clinical review to determine individualised care.

1.5.15 For women with an incomplete miscarriage, use a single dose of 600 micrograms of misoprostol. (800 micrograms can be used as an alternative to allow alignment of treatment protocols for missed and incomplete miscarriage.)³

³ Although this use is common in UK clinical practice, at the time of publication (June 2012), misoprostol did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

- 1.5.16 Do not offer mifepristone as a treatment for missed or incomplete miscarriage.
- 1.5.17 Offer all women receiving medical management of miscarriage pain relief and anti-emetics as required.
- 1.5.18 Inform women 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.
- 1.5.19 Advise women to take a urine pregnancy test 3 weeks after medical management unless they experience worsening symptoms, in which case advise them to return to the healthcare professional responsible for providing their medical management.
- 1.5.20 For women with a positive pregnancy test, a follow-up process should be in place to ensure that there is no molar or ectopic pregnancy.

Surgical management

- 1.5.21 Where clinically appropriate, offer women a choice of:
- manual vacuum aspiration under local anaesthetic in an out-patient or clinic setting
 - evacuation in a theatre under general anaesthetic.
- 1.5.22 Provide written and verbal information to all women undergoing surgical management about the treatment options available and what to expect during and after the procedure.

1.6 *Management of ectopic pregnancy*

Surgical versus medical management

- 1.6.1 Give women relevant information in a variety of formats throughout their care. This information should include:

- information about post-operative care (for women undergoing surgery)
- information about resuming normal activity
- reference to the emotional impact of the loss of a baby
- reference to potential future complications and what to do next time the woman becomes pregnant
- advice about how long to wait before trying to conceive
- what follow-up support is available from within the hospital and details of patient support groups provided
- how the woman can contact a healthcare professional for post-operative advice if needed, and who this will be
- how to find further information – for example, on returning to work.

1.6.2 Inform women who have had an ectopic pregnancy that they can self-refer to an early pregnancy assessment service in future pregnancies if they have any early concerns.

1.6.3 Give all women verbal and written information about:

- what to expect throughout the course of their treatment and recovery, especially the likely duration and severity of pain and/or of bleeding
- where and when to get help in an emergency.

1.6.4 Do not offer methotrexate to women who have been diagnosed with an ectopic pregnancy unless they can return for follow-up.

1.6.5 Offer systemic methotrexate⁴ as a first-line treatment to women who have all of the following:

- no significant pain

⁴ Although this use is common in UK clinical practice, at the time of publication (June 2012), methotrexate did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

- an unruptured ectopic pregnancy smaller than 3.5 cm with no visible heartbeat
- an hCG level less than 5000 IU/l.

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

1.6.6 Offer surgery as a first-line treatment to women with any of the following:

- an ectopic pregnancy that is 3.5 cm or larger
- an ectopic pregnancy with a fetal heartbeat visible on ultrasound
- an ectopic pregnancy and an hCG level of 5000 IU/l or more.

1.6.7 Exercise additional consideration with women who have an hCG level greater than 1500 IU/l who choose medical treatment. Be aware that:

- their chance for needing further intervention is increased
- they may need to be urgently admitted if their condition deteriorates.

1.6.8 For women who have had methotrexate, take two serum hCG measurements in the first week (day 4 and 7) following treatment and then one hCG measurement per week until a negative result is obtained.

Performing laparoscopy

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

1.6.10 Surgeons providing care to women with ectopic pregnancy should be competent to perform laparoscopic surgery.

1.6.11 Out-of-hours surgery should only be carried out as an emergency if a woman is haemodynamically unstable or collapsed.

1.6.12 Commissioners and managers should ensure that equipment for laparoscopic surgery is available.

Salpingectomy and salpingotomy

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

1.6.14 Consider salpingotomy as an alternative to salpingectomy for women with factors prognostic of infertility such as contralateral tube damage.

1.6.15 Inform women having a salpingotomy that up to one in five women may need further treatment. This treatment may include methotrexate administration and/or a salpingectomy.

1.6.16 For women who have had a salpingotomy, take one serum hCG measurement at 7 days after surgery, then one hCG measurement per week until a negative result is obtained.

1.6.17 Advise women who have had a salpingectomy that they should take a urine pregnancy test after 3 weeks.

1.7 *Anti-D rhesus prophylaxis*

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

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

- receive solely medical management for an ectopic pregnancy or miscarriage
- have a threatened miscarriage
- have a complete miscarriage
- have a pregnancy of unknown location.

- 1.7.3 Do not use a Kleihauer test for quantifying fetomaternal haemorrhage.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a **scope [add hyperlink]** that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations.

There is more information about [how NICE clinical guidelines are developed](#) on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' is [available](#).

3 Implementation

NICE has developed [tools to help organisations implement this guidance](#).

Note: these details will apply when the guideline is published.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 *Early pregnancy assessment units*

A national evaluation of early pregnancy assessment unit service provision should be undertaken with statistical analysis to identify factors affecting outcomes.

Why this is important

Pain and bleeding in early pregnancy: NICE guideline DRAFT (June 2012)

The first report of an early pregnancy assessment unit in England was published over 20 years ago, and prompted the rapid development of centres for the management of problems in early pregnancy. Today there are an estimated 150 early pregnancy assessment units in England and Wales (Association of early pregnancy units, 2012). However, there is considerable variation between centres in access to services and levels of care provided. In addition, there has been very little good quality research on the effectiveness of early pregnancy assessment units in improving physical and emotional health.

A national audit of early pregnancy assessment units would help to make up for this lack of information. Such an audit should be along the lines of the National Caesarean Section Sentinel Audit, a cross-sectional national survey of service configuration and outcomes. Data recorded would include service location, opening hours, and the healthcare professionals involved. Outcomes would include time of attendance, length of stay, admission rates, time to treatment and patient experience. Obtaining some of this information would require units to undertake more formal follow-up of patients than they may do currently, for the duration of the audit. The evaluation should be structured to allow for comparisons between different models of care.

Comparative outcome data collected would be used to conduct an analysis of the cost effectiveness of early pregnancy assessment units.

4.2 *Ultrasound for determining a viable intrauterine pregnancy*

How does the timing and frequency of ultrasound examination affect diagnosis and outcomes of early pregnancy complications, including patient experience and cost effectiveness?

Why this is important

The rationale behind the frequency of ultrasound to improve diagnosis and outcomes of early pregnancy complications addresses the problems associated with pregnancy of unknown location and intrauterine pregnancy of uncertain viability. There is no evidence base for timing of scans, and number

Pain and bleeding in early pregnancy: NICE guideline DRAFT (June 2012)

of scans is organised by individual units according to capacity and demand. Some experts choose to wait 5 days between scans while others will wait 10 to 14. These decisions are driven by resource availability as well as clinical considerations. Discussions among experts have failed to provide clear consensus, but all are agreed that by 14 days a diagnosis will be clear. To establish the most appropriate time for scans, the efficacy of scans taken after 14 days could be compared with scans taken after 7 days for diagnosis of ectopic pregnancy or viability.

4.3 *Progesterone/progestogen for threatened miscarriage*

Is progesterone/progestogen effective in treating threatened miscarriage?

Why this is important

Approximately 20% of pregnancies miscarry in the first trimester and many women will experience some bleeding and/or pain in early pregnancy that does not cause miscarriage. In many countries, women with bleeding and/or pain will be treated with progesterone or progestogens to try and decrease the risk of miscarriage. The evidence for the effectiveness of this treatment has been inconclusive, but data from a meta-analysis of several small studies suggest that progestogens are better than placebo. However, there are theoretical risks to prescribing any treatment in pregnancy and for many practitioners this will be a major change in practice. The lack of strong evidence makes this a priority area for research.

A multicentre randomised controlled trial of at least 800 women treated with either progesterone/progestogen or placebo should be conducted. The population would be women with pain and bleeding and a spontaneous, confirmed, viable, singleton, intrauterine pregnancy between 6–12 weeks' gestation. Progesterone/progestogen or placebo would be administered from when bleeding starts until the end of the 13th week. Pregnancy proceeding beyond the end of the first trimester might be the primary outcome. Ideally, live birth would be measured, but, this will make the trial much more expensive, and a majority of pregnancies that are going to miscarry will do so

in the first trimester. However, pregnancy outcome should be a secondary outcome, along with gestation at birth and presence of congenital abnormalities.

4.4 *Management of miscarriage*

In women with confirmed miscarriage, does the type of intervention (expectant, medical and surgical) impact on women's experience, including psychological and emotional outcomes?

Why this is important

The management of miscarriage in the UK has changed in many ways over the past two decades, particularly in the shift from inpatient to outpatient or day case care and the introduction of medical and expectant management as alternatives to surgery.

Despite these changes there is a lack of research into the effects of these different approaches from the patient's perspective, in particular their psychological and emotional impact. Miscarriage is distressing for most women, and the type of management itself might affect women's need for counselling, with a resulting cost to the NHS. Because of this it is an important area for research.

The deficiency in the literature could be addressed by a comparative study of women having the different treatments (expectant, medical or surgical) and in a variety of clinical settings (for example, early pregnancy assessment unit, gynaecological ward, or gynaecological emergency unit). The data collected could be both quantitative (using validated psychological health questionnaires) and qualitative (focusing particularly on women's experience of the particular type and setting of care).

4.5 *Surgical compared with medical management of ectopic pregnancy*

In women with ectopic pregnancy, does the type of intervention (laparoscopy or medical management) impact on patient experience, including psychological and emotional outcomes?

Why this is important

Currently there is no evidence exploring the psychological impact of the different treatments for ectopic pregnancy. However, the emotional impact of the condition can be significant, in some circumstances leading to post-traumatic stress disorder. A qualitative comparative study should be undertaken to assess how this impact can be reduced. This would help to maximise women's emotional recovery in the short and long term, enable women and clinicians to decide the optimum treatment method and identify what support is needed for women during and after the process. It could also reduce the cost to the NHS of providing long-term counselling for affected women.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Pain and bleeding in early pregnancy: assessment and initial management of ectopic pregnancy and miscarriage in the first trimester' [\[add hyperlink for final publication\]](#) contains details of the methods and evidence used to develop the guideline. It is published by the [National Collaborating Centre for Women's and Children's Health. **Note: these details will apply to the published full guideline.**

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a [NICE pathway](#). **Note: these details will apply when the guideline is published.**

5.3 'Understanding NICE guidance'

A summary for patients and carers (['Understanding NICE guidance'](#)) is available.

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N[XXXX]). **Note: these details will apply when the guideline is published.**

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about pain and bleeding in early pregnancy.

6 Related NICE guidance

Published

- [Patient experience in adult NHS services improving the experience of care for people using adult NHS services](#). NICE clinical guideline 138 (2012)
- [Venous thromboembolism – reducing the risk](#). NICE clinical guideline 92 (2010).
- [Hypertension in pregnancy](#). NICE clinical guideline 107 (2010).
- [Pregnancy and complex social factors](#). NICE clinical guideline 110 (2010).
- [Antenatal care](#). NICE clinical guideline 62 (2008).
- [Diabetes in pregnancy](#). NICE clinical guideline 63 (2008).
- [Routine antenatal anti-D prophylaxis for women who are rhesus D negative](#). NICE technology appraisal guidance 156 (2008).
- [Surgical site infection](#). NICE clinical guideline 74 (2008).
- [Antenatal and postnatal mental health](#). NICE clinical guideline 45 (2007).
- [Fertility](#). NICE clinical guideline 11 (2004).

Under development

NICE is developing the following guidance (details available from [the NICE website](#)):

- Fertility (update). NICE clinical guideline. Publication date to be confirmed.
- Diabetes in pregnancy (update). NICE clinical guideline. Publication date to be confirmed.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we

DRAFT FOR CONSULTATION

may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

Guideline Development Group

Mary Ann Lumsden (Chair)

Professor of Gynaecology and Medical Education and Honorary Consultant Gynaecologist, Reproductive and Maternal Medicine, School of Medicine, University of Glasgow

Fiona Blake

Consultant psychiatrist, Cambridgeshire and Peterborough NHS Foundation Trust

Nicola Davies

General practitioner, Bute House Medical Centre, Luton

Karen Easton

Consultant nurse, Gloucestershire Hospitals NHS Foundation Trust

Roy Farquharson

Consultant obstetrician and gynaecologist, Liverpool Women's Hospital

Joanne Fletcher

Consultant nurse, Sheffield Teaching Hospitals NHS Trust

Liz Jones

Lay member (stood down July 2011)

Julie Orford

Lay member (joined July 2011)

Caroline Overton

Consultant obstetrician and gynaecologist, St Michael's University Hospital, Bristol

Shammi Ramlakhan

DRAFT FOR CONSULTATION

Consultant in emergency medicine, Sheffield Teaching Hospitals NHS
Foundation Trust

Helen Wilkinson

Lay member

***National Collaborating Centre for Women's and Children's
Health***

Lauren Bardisa-Ezcurra

Research fellow (until April 2011)

Zosia Beckles

Information scientist

Rupert Franklin

Project manager

Maryam Gholitabar

Research associate

Paul Jacklin

Senior health economist

David James

Clinical co-director (women's health)

Emma Newbatt

Research associate

Roz Ullman

Senior research fellow and clinical lead (midwifery)

NICE project team

To be completed by NICE

[Name; style = NICE normal single spacing + bold]

Associate Director/Programme Director/Centre for Clinical Practice Director

[Delete as appropriate]

Pain and bleeding in early pregnancy: NICE guideline DRAFT (June 2012)

DRAFT FOR CONSULTATION

[Name; style = NICE normal single spacing + bold]

Guideline Commissioning Manager

[Name; style = NICE normal single spacing + bold]

Guideline Coordinator

[Name; style = NICE normal single spacing + bold]

Technical Lead

[Name; style = NICE normal single spacing + bold]

Health Economist

[Name; style = NICE normal single spacing + bold]

Editor