NICE National Institute for Health and Care Excellence

Ectopic pregnancy and miscarriage

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NICE quality standard 69

guidance.nice.org.uk/qs69

Contents

Introduction

This quality standard covers the diagnosis and initial management of ectopic pregnancy and miscarriage in women in their first trimester (up to 13 completed weeks of pregnancy). For more information see the topic overview.

Why this quality standard is needed

An ectopic pregnancy occurs when a fertilised egg is located outside the womb (uterus), usually in the fallopian tube. The fertilised egg cannot develop properly outside the womb and may need to be removed. Common signs and symptoms of an ectopic pregnancy can include pain or tenderness (or both) in the abdomen or pelvis, often following 1 or more missed periods and accompanied by light vaginal bleeding. Sometimes women with ectopic pregnancy have non-specific symptoms such as diarrhoea and it may go unrecognised.

The Centre for Maternal and Child Enquiries report Saving mothers' lives: reviewing maternal deaths to make motherhood safer 2006–2008 states that the rate of ectopic pregnancy in the UK was 11 per 1000 pregnancies between 2006 and 2008, with a maternal mortality rate of 0.2 per 1000 estimated ectopic pregnancies. As many as two-thirds of these maternal deaths may have been associated with inadequate care. Women who cannot access medical help quickly (such as women who are recent migrants, asylum seekers or refugees, or women who have difficulty reading or speaking English) are particularly vulnerable.

When a pregnancy spontaneously ends before the 24th week of pregnancy, it is called a miscarriage. Most miscarriages occur in the first trimester of pregnancy and most cannot be prevented. Between 15% and 20% of clinically confirmed pregnancies spontaneously end before the 13th week.

The quality standard is expected to contribute to improvements in the following outcomes:

- maternal mortality rates
- women's experiences of maternity services
- safety incidents involving severe harm.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measureable quality improvements within a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcome frameworks published by the Department of Health:

- NHS Outcomes Framework 2014/15.
- Improving outcomes and supporting transparency: a public health outcomes framework for England 2013–2016, Part 1 and Part 1A.

Tables 1 and 2 show 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
1 Preventing people from dying prematurely	***Overarching indicator*** 1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare* (PHOF 4.3) i Adults
4 Ensuring that people have a positive experience of care	***Overarching indicators*** 4a Patient experience of primary care 4b Patient experience of hospital care ***Improvement area*** **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 indicators*** 5a Patient safety incident reported 5b Safety incident involving severe harm or death 5c Hospital deaths attributable to problems in care
Alignment across the health and social care system * Indicator complementary with Public Health Outcomes Framework (PHOF)	

Table 2 Public Health Outcomes Framework for England 2013–2016

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	***Objective*** Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities ***Indicator*** 4.3 Mortality rate from causes considered preventable* (NHSOF 1a)
Alignment across the health and social care system * Indicator complementary with NHS Outcomes Framework (NHSOF)	

Coordinated services

The quality standard for ectopic pregnancy and miscarriage specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole ectopic pregnancy and miscarriage care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to women experiencing ectopic pregnancy or miscarriage.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social

care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality ectopic pregnancy and miscarriage service are listed in Related quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating women experiencing an ectopic pregnancy or miscarriage should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting women experiencing an ectopic pregnancy or miscarriage. If appropriate, and with the woman's consent, healthcare professionals should involve family members and carers in the woman's care, but the decision-making process about investigations, treatment and care should preserve the woman's autonomy.

List of quality statements

Statement 1. Women referred to early pregnancy assessment services are seen by the service at least within 24 hours of referral.

Statement 2. Women who are referred with suspected ectopic pregnancy or miscarriage are offered a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Statement 3. Women with a suspected miscarriage who have had an initial transvaginal ultrasound scan are offered a second assessment to confirm the diagnosis.

Quality statement 1: Timely referral to early pregnancy assessment services

Quality statement

Women referred to early pregnancy assessment services are seen by the service at least within 24 hours of referral.

Rationale

Women with a suspected ectopic pregnancy or miscarriage should be referred to an early pregnancy assessment service for diagnosis and management based on an initial clinical assessment. Women should always be seen within 24 hours of referral. However, depending on the clinical assessment, some women may need to be seen immediately to avoid adverse incidents, such as the rupture of a fallopian tube in an ectopic pregnancy. In addition, some women should be referred directly to an accident and emergency department, for example if they are haemodynamically unstable. It is important that appropriate measures are put in place to ensure the safety of the woman.

Quality measures

Structure

Evidence of local arrangements to ensure that women referred to early pregnancy assessment services are seen by the service at least within 24 hours of referral.

Data source: Local data collection.

Process

Proportion of women referred to early pregnancy assessment services who are seen by the service at least within 24 hours of referral.

Numerator – the number in the denominator who are seen in early pregnancy assessment services at least within 24 hours of referral.

Denominator – the number of women referred to early pregnancy assessment.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (secondary care services) ensure that a system is in place to enable women referred to early pregnancy assessment services to be seen by the service at least within 24 hours of referral.

Healthcare professionals (such as consultant obstetricians, gynaecologists and ultrasonographers) see women in an early pregnancy assessment service at least within 24 hours of referral.

Commissioners (clinical commissioning groups for secondary care) ensure that early pregnancy assessment services are able to see women at least within 24 hours of referral. They may also work with NHS England area teams to raise awareness and ensure clear that protocols and referral pathways are in place.

What the quality statement means for patients, service users and carers

Women who are referred to a hospital early pregnancy assessment service are seen within 24 hours of referral. They may be referred by a healthcare professional (for example, their GP, midwife or nurse, or an emergency department doctor) or, if they have had an ectopic pregnancy in the past, or 3 or more miscarriages, they should be able to book an appointment themselves.

Source guidance

- Ectopic pregnancy and miscarriage (NICE clinical guideline 154), recommendation 1.2.4.

Definitions of terms used in this quality statement

Early pregnancy assessment services

An early pregnancy assessment service can be located in a dedicated early pregnancy assessment unit or within a hospital gynaecology ward. All early pregnancy assessment services 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 transvaginal 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. [Adapted from NICE clinical guideline 154, recommendation 1.2.2]

Referral

Women can be referred by a healthcare professional (such as a GP, emergency department doctor, midwife or nurse) who has made a clinical decision about whether the woman should be seen immediately or within 24 hours of the referral. [NICE clinical guideline 154, recommendations 1.2.3 and 1.3.11]

Women who have had recurrent miscarriage (the loss of 3 or more pregnancies before 24 weeks of gestation) or a previous ectopic pregnancy can self-refer to an early pregnancy assessment service. [NICE clinical guideline 154, recommendation 1.2.3]

Equality and diversity considerations

Appropriate care may depend on the ability of a woman to access services quickly, which may be difficult for some groups of women, such as women who are recent migrants, asylum seekers, refugees, or women who have difficulty reading or speaking English. It is important to ensure that services are easily accessible to women from these groups.

Quality statement 2: Ultrasound assessment

Quality statement

Women who are referred with suspected ectopic pregnancy or miscarriage are offered a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Rationale

An initial ultrasound scan should be performed to diagnose an ectopic pregnancy or assess for miscarriage. A transvaginal ultrasound scan provides the best quality imaging and is more effective than a transabdominal scan because it can offer clearer pictures of the womb, ovaries and surrounding areas. However, a single transvaginal ultrasound scan may not always accurately diagnose miscarriage.

Quality measures

Structure

Evidence of local arrangements to ensure that women who are referred with suspected ectopic pregnancy or miscarriage are offered a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Data source: Local data collection.

Process

a) Proportion of women who are referred with a suspected ectopic pregnancy and who receive a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Numerator – the number in the denominator who receive a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Denominator – the number of women who are referred with a suspected ectopic pregnancy.

Data source: Local data collection. Data can be collected using the NICE Ectopic pregnancy and miscarriage: ultrasound for determining viable intrauterine pregnancy clinical audit tool, audit standard 2.

b) Proportion of women who are referred with a suspected miscarriage and who receive a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Numerator – the number in the denominator who receive a transvaginal ultrasound scan to identify the location and viability of the pregnancy.

Denominator – the number of women who are referred with a suspected miscarriage.

Data source: Local data collection. Data can be collected using the NICE Ectopic pregnancy and miscarriage: ultrasound for determining viable intrauterine pregnancy clinical audit tool, audit standard 2.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (secondary care services) ensure that protocols and equipment are in place for transvaginal ultrasound scans to be offered to women with a suspected ectopic pregnancy or miscarriage to identify the location and viability of the pregnancy.

Healthcare professionals (such as consultant obstetricians, gynaecologists and ultrasonographers) offer women with a suspected ectopic pregnancy or miscarriage a transvaginal ultrasound scan to identify the location of the pregnancy and viability of the pregnancy.

Commissioners (clinical commissioning groups for secondary care) ensure that protocols and equipment are in place to offer transvaginal ultrasound for the diagnosis of ectopic pregnancy and miscarriage, and ensure that they monitor the provision of transvaginal ultrasound by relevant service providers.

What the quality statement means for patients, service users and carers

Women with a suspected ectopic pregnancy (when a fertilised egg is outside the womb) or a suspected miscarriage are offered a scan called a transvaginal ultrasound scan (where a small probe is inserted into the vagina) to check whether the pregnancy is in the womb and if it is continuing.

Source guidance

- Ectopic pregnancy and miscarriage (NICE clinical guideline 154), recommendation 1.4.1.

Definitions of terms used in this quality statement

Suspected ectopic pregnancy

The symptoms and signs of ectopic pregnancy are outlined in NICE clinical guideline 154, recommendations 1.3.3 and 1.3.4.

Suspected miscarriage

Women with bleeding or other symptoms and signs of early pregnancy complications who have:

- pain **or**
- a pregnancy of 6 weeks' gestation or more **or**
- a pregnancy of uncertain gestation. [NICE clinical guideline 154, recommendation 1.3.9]

Transvaginal ultrasound scan

In a transvaginal ultrasound scan, a small probe is inserted into the vagina to check whether the pregnancy is in the womb and if it is continuing. The use of transvaginal ultrasound scanning is outlined in NICE clinical guideline 154, recommendations 1.4.5–1.4.7, 1.4.9 and 1.4.10.

Equality and diversity considerations

When offering a transvaginal ultrasound scan, healthcare professionals should provide information about the scan that is sensitive to the woman's religious, ethnic or cultural needs and takes into account whether the woman has learning disabilities, or difficulties in communication or reading. Women provided with information should have access to an interpreter or advocate if needed.

If a transvaginal ultrasound scan is unacceptable to the woman, healthcare professionals should offer a transabdominal ultrasound scan and explain the limitations of this method.

All women should have the option to be examined by a female member of staff if requested. This may be particularly important for women from certain cultural or religious groups.

Quality statement 3: Confirming a diagnosis of miscarriage

Quality statement

Women with a suspected miscarriage who have had an initial transvaginal ultrasound scan are offered a second assessment to confirm the diagnosis.

Rationale

A single transvaginal ultrasound scan may not always accurately diagnose miscarriage, and so a second assessment should be offered to confirm the diagnosis in women with suspected miscarriage. Treatment for miscarriage should not start until the site and viability of the pregnancy have been confirmed by a second assessment.

Quality measures

Structure

Evidence of local arrangements to ensure that women with a suspected miscarriage who have had an initial transvaginal ultrasound scan are offered a second assessment to confirm the diagnosis.

Data source: Local data collection.

Process

Proportion of women with a suspected miscarriage who have had an initial transvaginal ultrasound scan and are offered a second assessment to confirm the diagnosis.

Numerator – the number in the denominator who receive a second assessment to confirm the diagnosis.

Denominator – the number of women with a suspected miscarriage who have had an initial transvaginal ultrasound scan.

Data source: Local data collection. Data can be collected using the NICE Ectopic pregnancy and miscarriage: ultrasound for determining viable intrauterine pregnancy clinical audit tool, audit standards 3b, 3c, 4b and 4c.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (secondary care services) ensure that procedures and protocols are in place for women with a suspected miscarriage who have had an initial transvaginal ultrasound scan to be offered a second assessment to confirm the diagnosis.

Healthcare professionals (such as consultant obstetricians, gynaecologists and ultrasonographers) offer women with a suspected miscarriage who have had an initial transvaginal ultrasound scan a second assessment to confirm the diagnosis.

Commissioners (clinical commissioning groups for secondary care) ensure that they monitor service providers to make sure they are offering second assessments to women with a suspected miscarriage who have had an initial transvaginal ultrasound scan to confirm the diagnosis.

What the quality statement means for patients, service users and carers

Women with a suspected miscarriage who have had a transvaginal ultrasound scan (where a small probe is inserted into the vagina) are offered a second assessment to confirm the diagnosis. This may involve a second opinion from another healthcare professional and/or a second scan 1 or 2 weeks after the first.

Source guidance

- Ectopic pregnancy and miscarriage (NICE clinical guideline 154), recommendations 1.4.6, 1.4.7, 1.4.9 and 1.4.10.

Definitions of terms used in this quality statement

Suspected miscarriage

Women with bleeding or other symptoms and signs of early pregnancy complications who have:

- pain **or**
- a pregnancy of 6 weeks' gestation or more **or**
- a pregnancy of uncertain gestation. [NICE clinical guideline 154, recommendation 1.3.9]

Second assessment

Confirming a diagnosis of miscarriage with a second assessment is outlined in NICE clinical guideline 154, recommendations 1.4.6, 1.4.7, 1.4.9 and 1.4.10. This includes seeking a second opinion on the viability of the pregnancy and/or offering a repeat transvaginal ultrasound scan at either a minimum of 7 days or a minimum of 14 days after the initial scan to confirm diagnosis (depending on the clinical situation).

Equality and diversity considerations

When offering a repeat transvaginal ultrasound scan, healthcare professionals should provide information about the scan that is sensitive to the woman's religious, ethnic or cultural needs and takes into account whether the woman has learning disabilities, or difficulties in communication or reading. Women provided with information should have access to an interpreter or advocate if needed.

If a transvaginal ultrasound scan is unacceptable to the woman, healthcare professionals should offer a transabdominal ultrasound scan and explain the limitations of this method.

All women should have the option to be examined by a female member of staff if requested. This may be particularly important for women from certain cultural or religious groups.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its Indicators for Quality Improvement Programme. If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's What makes up a NICE quality standard? for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in Development sources.

Information for commissioners

NICE has produced support for commissioning that considers the commissioning implications and potential resource impact of this quality standard. This is available on the NICE website.

Information for the public

NICE has produced information for the public about this quality standard. Patients, service users and carers can use it to find out about the quality of care they should expect to receive; as a basis for asking questions about their care, and to help make choices between providers of social care services.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments are available.

Good communication between healthcare professionals and women experiencing ectopic pregnancy or miscarriage is essential. Treatment, care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Women experiencing ectopic pregnancy or miscarriage should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards process guide on the NICE website.

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- Ectopic pregnancy and miscarriage. NICE clinical guideline 154 (2012).

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Ectopic pregnancy and miscarriage: ultrasound for determining viable intrauterine pregnancy. NICE clinical audit tool (2012).
- NHS maternity statistics 2011–12 summary report. The Health and Social Care Information Centre, Hospital Episode Statistics (2012).

Definitions and data sources for the quality measures

- The Health and Social Care Information Centre, Hospital Episode Statistics (2012) NHS maternity statistics 2011–12.

Related NICE quality standards

Published

- Multiple pregnancy. NICE quality standard 46 (2013).
- Antenatal care. NICE quality standard 22 (2012).
- Patient experience in adult NHS services. NICE quality standard 15 (2012).

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Diabetes in pregnancy.
- Provision of termination of pregnancy services.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 1. Membership of this committee is as follows:

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About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the quality standards process guide.

This quality standard has been incorporated into the NICE pathway for ectopic pregnancy and miscarriage.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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