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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 1,000 pregnancies between 2006 and 2008, with a maternal mortality rate of 0.2 per 1,000 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 measurable 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:


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

<table>
<thead>
<tr>
<th>Domain</th>
<th>Overarching indicators and improvement areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Preventing people from dying prematurely</td>
<td>Overarching indicator</td>
</tr>
<tr>
<td>1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare* (PHOF 4.3)</td>
<td></td>
</tr>
<tr>
<td>i Adults</td>
<td></td>
</tr>
<tr>
<td>4 Ensuring that people have a positive experience of care</td>
<td>Overarching indicators</td>
</tr>
<tr>
<td>4a Patient experience of primary care</td>
<td></td>
</tr>
<tr>
<td>4b Patient experience of hospital care</td>
<td></td>
</tr>
<tr>
<td>Improvement area</td>
<td></td>
</tr>
<tr>
<td>Improving women and their families' experience of maternity services</td>
<td></td>
</tr>
<tr>
<td>4.5 Women's experience of maternity services</td>
<td></td>
</tr>
</tbody>
</table>
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

*Indicator complementary with Public Health Outcomes Framework (PHOF)*

### Table 2 Public Health Outcomes Framework for England 2013–2016

<table>
<thead>
<tr>
<th>Domain</th>
<th>Objectives and indicators</th>
</tr>
</thead>
</table>
| 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) |

*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 different audiences

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.

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: diagnosis and initial management (2019) NICE guideline NG126, 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’s guideline on ectopic pregnancy and miscarriage, 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’s guideline on ectopic pregnancy and miscarriage, 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’s guideline on ectopic pregnancy and miscarriage, 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 to identify miscarriage or tubal ectopic pregnancy

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.

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.

**What the quality statement means for different audiences**

**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.

**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: diagnosis and initial management** (2019) NICE guideline NG126, 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’s guideline on ectopic pregnancy and miscarriage, 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's guideline on ectopic pregnancy and miscarriage, 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’s guideline on ectopic pregnancy and miscarriage, 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.
What the quality statement means for different audiences

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.

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: diagnosis and initial management (2019) NICE guideline NG126, 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's guideline on ectopic pregnancy and miscarriage, recommendation 1.3.9]
Second assessment

Confirming a diagnosis of miscarriage with a second assessment is outlined in NICE's guideline on ectopic pregnancy and miscarriage, 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.

See NICE’s how to use quality standards 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.
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: diagnosis and initial management (2019) NICE guideline NG126

Policy context

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


Definitions and data sources for the quality measures

Related NICE quality standards

Published

- Diabetes in pregnancy (2016) NICE quality standard 109
- Multiple pregnancy (2013) NICE quality standard 46
- Antenatal care (2012 updated 2016) NICE quality standard 22
- Patient experience in adult NHS services (2012) NICE quality standard 15

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:

- 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:

Mr Lee Beresford
Director of strategy and system development, NHS Wakefield Clinical Commissioning Group

Dr Gita Bhutani
Professional lead, Psychological Services, Lancashire Care NHS Foundation Trust

Mrs Jennifer Bostock
Lay member

Dr Helen Bromley
Locum consultant in public health, Cheshire West and Chester Council

Dr Hasan Chowhan
GP, NHS North East Essex Clinical Commissioning Group

Mr Phillip Dick
Psychiatric liaison team manager, West London Mental Health Trust

Ms Phyllis Dunn
Clinical lead nurse, University Hospital of North Staffordshire

Dr Nourieh Hoveyda
Consultant in public health medicine, London Borough of Richmond Upon Thames

Dr Ian Manifold
Consultant oncologist, Quality Measurement Expert, National Cancer Action Team

Dr Colette Marshall
Consultant vascular surgeon, University Hospitals Coventry and Warwickshire

Mr Gavin Maxwell
Lay member

Mrs Juliette Millard
UK nursing and health professions adviser, Leonard Cheshire Disability

Ms Robyn Noonan
Lead commissioner adults, Oxfordshire County Council

Ms JoAnne Panitzke-Jones
Quality assurance and improvement lead, South Devon and Torbay Clinical Commissioning Group

Dr Bee Wee (Chair)
Consultant and senior clinical lecturer in palliative medicine, Oxford University Hospitals NHS Trust and Oxford University

Ms Karen Whitehead
Strategic lead health, Families and Partnerships, Bury Council

Ms Alyson Whitmarsh
Programme head for clinical audit, Health and Social Care Information Centre

Ms Jane Worsley
Chief operating officer, Advanced Childcare Limited

Dr Arnold Zermansky
GP, Leeds

The following specialist members joined the committee to develop this quality standard:

Dr Nicola Davies
GP, Honeypot Medical Centre, Harrow Clinical Commissioning Group

Mrs Joanne Fletcher
Consultant nurse gynaecology, Sheffield Teaching Hospitals NHS Foundation Trust
Professor Mary Ann Lumsden (written contributions only)
Consultant gynaecologist, International Lead and Deputy Dean of Graduate School, University of Glasgow

Miss Julie Orford
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Consultant in emergency medicine, Sheffield Teaching Hospitals NHS Foundation Trust

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Lead technical analyst

Ms Esther Clifford
Project manager

Mr Lee Berry
Coordinator
Update information

Minor changes since publication

April 2019: References and source guidance sections have been updated throughout to align this quality standard with the updated NICE guideline on ectopic pregnancy and miscarriage. The heading for statement 2 has been amended for clarity.
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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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made
aware of and encouraged to use the quality standard.

- Miscarriage Association
- Royal College of General Practitioners (RCGP)
- Royal College of Nursing (RCN)
- Royal College of Obstetricians and Gynaecologists