Quality Standards

Early Pregnancy Complications and Loss

Care for Adults in All Settings

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Health Quality Ontario

Let's make our health system healthier

Sunnybrook
PREGNANCY AND INFANT LOSS NETWORK

Summary

This quality standard addresses care for people experiencing complications, such as pain and vaginal bleeding, and/or the loss of their pregnancy in the first 13 weeks. It applies to all health care settings and includes diagnosis, follow-up, and management of physical and emotional aspects of care for early pregnancy complications or loss.

This standard includes pregnancy of unknown location (where a person has a positive pregnancy test but no pregnancy is visible in an ultrasound), tubal ectopic pregnancy (a potentially dangerous condition in which the embryo implants in a fallopian tube), and intrauterine pregnancy loss (missed, complete, or incomplete miscarriage).

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About Quality Standards

Health Quality Ontario, in collaboration with clinical experts, patients, residents, and caregivers across the province, is developing quality standards for Ontario.

Quality standards are concise sets of statements that will:

- Help patients, residents, families, and caregivers know what to ask for in their care
- Help health care professionals know what care they should be offering, based on evidence and expert consensus
- Help health care organizations measure, assess, and improve their performance in caring for patients

The statements in this quality standard do not override the responsibility of health care professionals to make decisions with patients, after considering each patient's unique circumstances.

How to Use Quality Standards

Quality standards inform clinicians and organizations about what high-quality health care looks like for aspects of care that have been deemed a priority for quality improvement in the province. They are based on the best available evidence.

Tools and resources to support clinicians and organizations in their quality improvement efforts accompany each quality standard. One of these resources is an inventory of indicator definitions to help clinicians and organizations assess the quality of care they are delivering, and to identify gaps in care and areas for improvement. These indicator definitions can be used to assess processes, structures, and outcomes. It is not mandatory to use or collect data when using a quality standard to improve care. The indicator definitions are provided to support quality improvement efforts; clinicians and organizations may choose indicators to measure based on local priorities and local data availability.

For more information on how to use quality standards, contact qualitystandards@hqontario.ca.

About This Quality Standard

Scope of This Quality Standard

This quality standard addresses care for people experiencing early pregnancy complications (such as pain and/or vaginal bleeding) and/or loss in the first trimester of pregnancy. This standard applies to all settings and includes diagnosis, follow-up, management, and psychosocial aspects of care for early pregnancy complications and loss up to 13 completed weeks of pregnancy. The standard includes:

- Pregnancy of unknown location (a temporary diagnosis meaning a person has a positive pregnancy test but no pregnancy is visible on ultrasound)
- Tubal ectopic pregnancy (a pregnancy in which the embryo implants in a fallopian tube)
- Intrauterine pregnancy loss (missed, complete, or incomplete miscarriage)

This standard does not address other types of ectopic pregnancy, termination of pregnancy (therapeutic abortion), or molar pregnancy (gestational trophoblastic disease, a rare pregnancy-related condition in which the cells that form the placenta develop abnormally).

A Note on Terminology

Language used to talk about early pregnancy complications and loss should be led by the person and family. Health care professionals should avoid using terms such as “missed abortion” and should ask people and families what terminology they prefer when referring to the pregnancy (e.g., whether they prefer “baby” or “fetus”).

Why This Quality Standard Is Needed

Early pregnancy complications and loss affect many people in Ontario. It is estimated that approximately 20% of pregnancies end in miscarriage, and nearly 80% of miscarriages occur in the first trimester.[1]

The emotional and psychological impacts of early pregnancy loss can be serious. For some people, the emotional distress can result in adverse effects such as clinical depression, post-traumatic stress disorder, and/or anxiety.[1] Ontario families experiencing early pregnancy loss have reported a lack of kindness and respect from health care professionals, felt less supported, and experienced more stigma at the time of their loss, compared with people whose loss occurred later in the pregnancy.[3] They were also less likely to be offered a follow-up appointment and get the support they needed, highlighting the need for significant system improvement.[3]

More than 28,000 emergency department (ED) visits were for early pregnancy complications or loss in Ontario in 2014/15 (IntelliHealth Ontario). An estimated 6% to 13% of patients presenting to the ED with vaginal bleeding or abdominal pain in early pregnancy have an ectopic pregnancy.[2] Ectopic pregnancy is a potentially life-threatening event, and there is a need to standardize care for pregnant people and their families, as well as to ensure people are offered their choice of management options. Currently, early pregnancy clinics offering assessment, diagnosis, and management of early pregnancy complications and loss outside of the ED setting are available in some communities in Ontario, but the services offered and hours of operation vary.

Principles Underpinning This Quality Standard

This quality standard is underpinned by the principles of respect and equity.

People experiencing early pregnancy complications and/or loss should receive services that are respectful of their rights and dignity and that promote shared decision-making. High-quality care for early pregnancy complications and loss is family-centred. Family or friends who can offer support should be encouraged to attend and welcomed at all appointments.

People experiencing early pregnancy complications and/or loss should be provided services that are respectful of their gender, sexual orientation, socioeconomic status, housing, age, background (including self-identified cultural, linguistic, ethnic, and religious backgrounds), and disability. Equitable access to the health system also includes access to culturally safe care.

Language, a basic tool for communication, is an essential part of safe care and needs to be considered throughout a person's health care journey. For example, in predominantly English-speaking settings, services should be actively offered in French and other languages.

Health care professionals should be aware of the historical context of the lives of Indigenous peoples throughout Canada and be sensitive to the impacts of intergenerational trauma and the physical, mental, emotional, and social harms experienced by Indigenous people, families, and communities.

A high-quality health system is one that provides good access, experience, and outcomes for everyone in Ontario, no matter where they live, what they have, or who they are.

How Success Can Be Measured

The Early Pregnancy Complications and Loss Quality Standard Advisory Committee identified a small number of overarching goals for this quality standard. These have been mapped to indicators that providers may want to monitor to assess quality of care provincially and locally.

How Success Can Be Measured Provincially

In this section, we list indicators that can be used to monitor the overall success of the standard provincially, given currently available data:

- Rate of emergency department use by people with early pregnancy complications and/or loss
- Percentage of people with early pregnancy complications and/or loss who have repeat emergency department visits within 30 days of the initial visit for early pregnancy complications or loss
- Percentage of people with a tubal ectopic pregnancy that ruptures within 30 days after an emergency department visit for tubal ectopic pregnancy
- Percentage of people with early pregnancy complications and/or loss who receive a blood transfusion
- Maternal mortality due to tubal ectopic pregnancy per 100,000 live births

If additional data sources are developed, other indicators could be added.

In addition to the overall measures of success, each quality statement within the standard is accompanied by one or more indicators. These indicators are intended to guide the measurement of quality improvement efforts related to the implementation of the statement.

How Success Can Be Measured Locally

Providers may want to monitor their own quality improvement efforts and assess the quality of care they provide to people experiencing early pregnancy complications or loss. It may be possible to do this using their own clinical records, or they might need to collect additional data. We recommend the following indicators to measure the quality of care patients are receiving; these indicators cannot be measured provincially using currently available data sources:

- Average time people with early pregnancy loss who need a dilatation and curettage (D&C) wait for a D&C. Note: This indicator includes only intrauterine early pregnancy loss
- Median wait time from (1) first presentation to a health care professional of early pregnancy complications or loss, to (2) a diagnosis via transvaginal ultrasound of early pregnancy complications or loss
- Percentage of people with early pregnancy complications or loss who are satisfied with the care they received

To assess the equitable delivery of care, the statement-specific indicators and the overall indicators can be stratified by patient socioeconomic and demographic characteristics, such as income, education, language, and age.

Quality Statements in Brief

Quality Statement 1: Comprehensive Assessment
People with signs or symptoms of early pregnancy complications receive a comprehensive assessment that includes a serum beta-hCG measurement and transvaginal ultrasound.

Quality Statement 2: Pregnancy of Unknown Location
People with a pregnancy of unknown location (not visible in the uterus or adnexa, on ultrasound) receive repeat transvaginal ultrasound assessments and serial serum beta-hCG measurements until a final diagnosis is made.

Quality Statement 3: Diagnosis of Intrauterine Early Pregnancy Loss
Pregnant people who experience intrauterine early pregnancy loss receive this diagnosis as quickly as possible based on transvaginal ultrasound. While waiting to learn whether or not the pregnancy is viable, they receive information on who to contact, where to go, and how long it should take to receive a diagnosis. A diagnosis of early pregnancy loss is also communicated to the person's primary care provider.

Quality Statement 4: Management of Intrauterine Early Pregnancy Loss
People with intrauterine early pregnancy loss receive information on all potential management options (expectant, medical, and surgical) and are supported in making an informed decision on the most appropriate management approach for them, based on their diagnosis, clinical situation, values, and preferences.

Quality Statement 5: Management of Tubal Ectopic Pregnancy
People with a confirmed tubal ectopic pregnancy receive information on all potential management options and are supported to make an informed decision about their care. They have access to their preferred management option. Health care professionals closely monitor signs and symptoms and arrange appropriate access to follow-up care.

Quality Statement 6: Compassionate Care and Psychosocial Supports
People and families experiencing early pregnancy complications and/or loss are treated with dignity and respect, and receive support in a sensitive manner, taking into account their individual circumstances and emotional responses. They are offered psychosocial supports.

Quality Statement 7: Peer Support
People who experience an early pregnancy loss and their families are offered information about peer support services and organizations.

Quality Statement 8: Early Pregnancy Assessment Services
People experiencing early pregnancy complications and loss have access to early pregnancy assessment services that are available 7 days a week. People referred to early pregnancy assessment services are seen within 24 hours when clinically indicated.

Quality Statement 1: Comprehensive Assessment

People with signs or symptoms of early pregnancy complications receive a comprehensive assessment that includes a serum beta-hCG measurement and transvaginal ultrasound.

Background

If a person presents with signs or symptoms of early pregnancy complications but their pregnancy status is unknown, health care professionals should offer a urine or serum pregnancy test (beta-hCG measurement). People presenting to primary care who are hemodynamically unstable, or where there is significant concern about the degree of pain or bleeding, should be referred directly to the emergency department.[1] Signs and symptoms of ectopic pregnancy can resemble other conditions or miscarriage.[1,4] If conditions requiring immediate or emergency management or care are ruled out, such as ruptured ectopic pregnancy, excessive vaginal bleeding, severe pain, or hemodynamic instability, the assessment does not need to be completed at one visit or by the same health care professional.

If pregnancy status is known, a transvaginal ultrasound is recommended to determine the location of the pregnancy and other markers of growth and viability.[4,5] A single beta-hCG measurement cannot diagnose viability in a pregnancy but is needed as a baseline for assessing future values.[4] Beta-hCG results may also help with interpretation of a transvaginal ultrasound.

After comprehensive assessment, pregnancy will fall into one of the following categories:

- Intrauterine pregnancy, developing normally
- Intrauterine pregnancy, not developing normally
- Pregnancy of unknown location
- Ectopic pregnancy
- Early pregnancy loss, including complete, incomplete, or missed miscarriage

This categorization determines the appropriate next steps, management options, and follow-up care to offer.

Sources: National Institute for Health and Clinical Excellence, 2012[1] | Society of Obstetricians and Gynaecologists of Canada, 2016[4]

Definitions Used Within This Quality Statement

Signs and symptoms of early pregnancy complications
These can include abdominal pain, pelvic pain, pelvic tenderness, adnexal tenderness, abdominal tenderness, vaginal bleeding with or without clots, and/or clinically abnormal fetal heart rate or growth detected by ultrasound, up to 13 completed weeks' gestation.

Comprehensive assessment
A comprehensive assessment of early pregnancy complications includes history taking and testing.

History taking:

- Last normal menstrual period
- Vaginal bleeding (amount and characteristics)
- Pain or cramping (severity and location)
- Obstetric, medical, and surgical history, including history of pregnancy loss or ectopic pregnancy, use of assisted reproductive technology
- Consider manual pelvic and/or speculum exam, if pregnancy status is unknown or ultrasound is not available
- Partner, family member, friend or other support person (if none present, offer to contact them)
- Emotional or psychological distress

Tests (in addition to transvaginal ultrasound and serum beta-hCG):

- Urine pregnancy test, if pregnancy status unknown
- Rhesus status

Beta-human chorionic gonadotropin (beta-hCG)
Beta-hCG is a hormone that increases rapidly during early pregnancy. It can be detected by a blood test about 11 days after conception and by a urine test about 12 to 14 days after conception. Pregnancy tests measure the presence and/or amount of beta-hCG in the blood or urine.

Transvaginal ultrasound
A transvaginal ultrasound is done by inserting an ultrasound probe into the vagina. A transvaginal ultrasound should include a transabdominal ultrasound. This is recommended for the evaluation of early pregnancy complications or loss because of greater accuracy compared to transabdominal ultrasound alone. Having the result of a beta-hCG test helps with the interpretation of transvaginal ultrasound.

What This Quality Statement Means

For Patients
If you have pain or bleeding during the first 13 weeks of pregnancy, your health care professionals should ask you about your symptoms and medical history. They should offer you a blood test and a transvaginal ultrasound (an ultrasound using a probe inserted into your vagina). These steps will help them assess your pregnancy and offer the next steps in your care.

For Clinicians
When a person presents with signs and/or symptoms of early pregnancy complications or loss, complete a comprehensive assessment that includes serum beta-hCG and a transvaginal ultrasound. Ensure the health care professional interpreting this and any further ultrasounds has access to previous test results (ultrasound and beta-hCG).

For Health Services
Ensure all health care professionals have access to pregnancy tests if they care for people who may be pregnant. Ensure people with early pregnancy complications have access to

transvaginal ultrasound and serum beta-hCG tests, and that radiologists with expertise in early pregnancy ultrasound are available to interpret the tests.

Quality Indicators

Process Indicator

Percentage of people with signs or symptoms of early pregnancy complications or loss who receive a comprehensive assessment that includes:

  - **serum beta-hCG measurement**
  - **transvaginal ultrasound**

- Denominator: total number of people with signs or symptoms of early pregnancy complications or loss
- Numerator: number of people in the denominator who receive a comprehensive assessment including
  - serum beta-hCG measurement
  - transvaginal ultrasound
- Data source: local data collection

Quality Statement 2: Pregnancy of Unknown Location

People with a pregnancy of unknown location (not visible in the uterus or adnexa, on ultrasound) receive repeat transvaginal ultrasound assessments and serial serum beta-hCG measurements until a final diagnosis is made.

Background

"Pregnancy of unknown location" describes a temporary state until a final diagnosis of developing intrauterine pregnancy, ectopic pregnancy, or miscarriage can be made. Most pregnancies of unknown location will be intrauterine pregnancies, not ectopic. But until location is confirmed, a pregnancy of unknown location should be considered as potentially ectopic.[4]

Recommended management is serial measurements of serum beta-hCG taken 48 hours apart (to determine whether it is rising, falling, or has plateaued) and repeat transvaginal ultrasounds.[4]

Patients should receive clear information on why they will need three to five follow-up appointments and where to go for repeat ultrasounds and bloodwork. If no intrauterine or ectopic pregnancy is diagnosed, people should be followed up until beta-hCG returns to zero. People with pregnancy of unknown location should receive counselling and clear written information on when and where to return for follow-up care, and what to do if they experience any new or worsening symptoms, including how to access emergency care.

Sources: National Institute for Health and Clinical Excellence, 2012[1] | Society of Obstetrician and Gynaecologists of Canada, 2016[4]

Definitions Used Within This Quality Statement

Adnexa
The structures that connect to the uterus, such as the fallopian tubes and ovaries.

Pregnancy of unknown location
A pregnancy in which a person has a positive pregnancy test but, on an ultrasound scan, no pregnancy is visible in the uterus or adnexa.[1]

What This Quality Statement Means

For Patients
If you have a positive pregnancy test, but the pregnancy cannot be seen in an ultrasound picture, repeat transvaginal ultrasounds and bloodwork should be performed until your pregnancy is located or a pregnancy test is negative (your beta-hCG, a pregnancy hormone, returns to zero). Your health care providers should offer you information on what to do if your symptoms get worse and how to access emergency care.

For Clinicians
For people with pregnancy of unknown location, repeat ultrasound and serum beta-hCG testing until the pregnancy is located or the beta-hCG level returns to zero. Establish and follow clear guidelines and protocols for follow-up of pregnancy of unknown location.

For Health Services
Create and maintain systems for follow-up care for people with pregnancy of unknown location. Develop and disseminate information to patients and families on how to access follow-up and emergency care.

Quality Indicators

Process Indicators

Percentage of people with a pregnancy of unknown location who receive a transvaginal ultrasound assessment

- Denominator: total number of people with a pregnancy of unknown location
- Numerator: number of people in the denominator who receive a transvaginal ultrasound assessment
- Data sources: local data collection, National Ambulatory Care Reporting System (NACRS), Ontario Health Insurance Plan Claims Database (OHIP)

Percentage of people with a pregnancy of unknown location who receive serial serum beta-HCG measurements 48 hours apart until a diagnosis is confirmed or until levels return to zero

- Denominator: total number of people with a pregnancy of unknown location
- Numerator: number of people in the denominator who receive serial serum beta-HCG measurements 48 hours apart until a diagnosis is confirmed or until levels return to zero
- Data source: local data collection

Percentage of people with pregnancy of unknown location who have a follow-up appointment with a health care professional

- Denominator: total number of people with a pregnancy of unknown location
- Numerator: number of people in the denominator who have a follow-up appointment with a health care professional
- Data sources: NACRS, OHIP, local data collection

Outcome Indicator

Percentage of people with a pregnancy of unknown location who have a subsequent ruptured ectopic pregnancy

- Denominator: total number of people with a pregnancy of unknown location
- Numerator: number of people in the denominator who have a subsequent ruptured ectopic pregnancy
- Data sources: NACRS, OHIP, local data collection

Quality Statement 3: Diagnosis of Intrauterine Early Pregnancy Loss

Pregnant people who experience intrauterine early pregnancy loss receive this diagnosis as quickly as possible based on transvaginal ultrasound. While waiting to learn whether or not the pregnancy is viable, they receive information on who to contact, where to go, and how long it should take to receive a diagnosis. A diagnosis of early pregnancy loss is also communicated to the person's primary care provider.

Background

Findings on transvaginal ultrasound may help health care professionals and their patients develop management strategies that are individually targeted.[4] Ideally, transvaginal ultrasounds should be interpreted by a health care professional with expertise in early pregnancy loss.

If no previous ultrasound has confirmed an intrauterine pregnancy, clinicians should always consider the possibility of ectopic pregnancy. If ultrasound confirms an intrauterine pregnancy and the person is clinically stable or asymptomatic, a follow-up ultrasound should be booked for 7 to 10 days later.[4]

Early pregnancy loss can be diagnosed—and no further ultrasound is required—when ultrasound confirms either[4]:

- An embryonic pregnancy: no embryo and an intrauterine gestational sac of at least 25 mm mean diameter; or
- Embryonic demise: an intrauterine gestational sac, an embryonic crown-rump length of at least 7 mm, and no fetal cardiac activity

If there is no fetal cardiac activity and the crown rump length is less than 7 mm, follow-up should include a repeat ultrasound in 7 to 10 days and/or serial beta-hCG measurement. Beta-hCG levels not rising appropriately confirms a diagnosis of early pregnancy loss.[4] People diagnosed with a complete miscarriage should be advised to return for care if they have new or worsening symptoms.[4]

A diagnosis of early pregnancy loss should be communicated to the person as quickly as possible, ideally by the person who ordered the testing or by the radiologist if the results are available immediately. Receiving a diagnosis outside of the emergency department setting is preferable. When early pregnancy loss occurs, health care professionals should consider offering ultrasound pictures or the opportunity for people and families experiencing loss to take their own pictures.

Source: Society of Obstetricians and Gynaecologists of Canada, 2016[4]

Definitions Used Within This Quality Statement

Intrauterine pregnancy
A pregnancy seen in the uterus on ultrasound.

Intrauterine early pregnancy loss
Loss of a confirmed intrauterine pregnancy of up to 13 completed weeks' gestation. This includes complete, missed, or incomplete miscarriage.

What This Quality Statement Means

For Patients
Your health care providers should diagnose your early pregnancy loss as quickly as possible. They should give you information about who will contact you with a diagnosis and how long it should take. They should encourage you to have a support person with you at appointments.

For Clinicians
Refer people experiencing early pregnancy complications to ultrasound services with expertise in diagnosing early pregnancy loss. Provide diagnoses of early pregnancy loss as soon as possible. Give people and families information about receiving results of tests or diagnoses: when they should expect to hear and if they can access results themselves (i.e., online). Encourage patients to bring a support person to appointments.

For Health Services
Create clear processes for ultrasound results and diagnoses of intrauterine early pregnancy loss to be shared with primary care providers or most responsible health care professionals, patients, and families. Ensure policies support the presence of support people during care and appointments. Ensure results of ultrasounds performed in the community are communicated to the patient's health care professionals as soon as possible.

Quality Indicators

Process Indicator

Median wait time from (1) first presentation to a health care professional of intrauterine early pregnancy loss, to (2) a diagnosis via transvaginal ultrasound of intrauterine early pregnancy loss

- Description: median number of days from (1) first presentation to a health care professional of intrauterine early pregnancy loss, to (2) a diagnosis via transvaginal ultrasound of intrauterine early pregnancy loss
- Data source: local data collection

Outcome Indicators

Percentage of people with an intrauterine early pregnancy loss who are satisfied with the wait time to receive the diagnosis

- Denominator: total number of people with an intrauterine early pregnancy loss
- Numerator: number of people in the denominator who are satisfied with the wait time to receive the diagnosis
- Data source: local data collection

Percentage of people with an intrauterine early pregnancy loss who have repeat unplanned emergency department visits within 30 days of the initial visit for intrauterine early pregnancy loss

- Denominator: total number of people with an intrauterine early pregnancy loss

- Numerator: number of people in the denominator who have repeat unplanned emergency department visits within 30 days of the initial visit for intrauterine early pregnancy loss
- Data source: NACRS

Quality Statement 4: Management of Intrauterine Early Pregnancy Loss

People with intrauterine early pregnancy loss receive information on all potential management options (expectant, medical, and surgical) and are supported in making an informed decision on the most appropriate management approach for them, based on their diagnosis, clinical situation, values, and preferences.

Background

When diagnosis of an intrauterine early pregnancy loss is confirmed, health care professionals should engage in shared decision-making with the person and their family to assist them in choosing a management option. Discussion should cover the benefits and harms of each approach, including the potential need for medical or surgical management after expectant management.

People taking misoprostol for medical management should also receive information on expected changes in bleeding, how to manage pain or nausea, and who to contact if bleeding does not start within 24 hours.[1] They should be offered medication for pain and nausea. (Misoprostol is a drug that opens the cervix and causes uterine contractions.) Recommended dosing for misoprostol[1]:

- 800 mcg vaginally for a missed miscarriage
- 600 mcg vaginally for an incomplete miscarriage
- 800 mcg can be used for both missed and incomplete miscarriages to allow alignment of treatment protocols
- Oral administration is an acceptable alternative to vaginal administration if this is the person's preference

Recent evidence from a randomized controlled trial supports pre-treatment with mifepristone, versus misoprostol alone, for people with a confirmed early pregnancy loss to increase the likelihood of completely expelling the gestational sac and avoiding surgical management.[6] (Mifepristone is a drug that blocks the production of progesterone, a hormone needed to maintain the lining of the uterus during pregnancy.) Currently, mifepristone in addition to misoprostol is not available at all hospitals in Ontario.

Plans for follow-up after early pregnancy loss should be clearly explained to patients and their families when they are discharged from the emergency department, early pregnancy clinic, gynecologist, or primary care clinic.

Source: National Institute for Health and Clinical Excellence, 2012[1]

Definitions Used Within This Quality Statement

Intrauterine early pregnancy loss
Loss of a confirmed intrauterine pregnancy of up to 13 completed weeks' gestation. This includes complete, missed, or incomplete miscarriage.

Expectant management
A "watchful waiting" management approach in which the early pregnancy loss is not actively treated, with the goal of waiting for the products of conception to expel from the uterus without intervention. This process may take days or weeks to begin and complete.

Information
People should receive written, standardized information on[1,5]:

- When and how to get help if symptoms get worse or new symptoms develop, including how to access emergency care
- What to expect and when to follow up; for example, how to manage any ongoing symptoms if bleeding or pain increases or continues longer than expected
- What is normal for each management option: timelines, side effects, recovery, bleeding, and pain; this information should be tailored to the clinical situation and management option chosen
- Success rates associated with each management option, and what would happen if the management option were not successful
- Information about postoperative care (for people undergoing surgery)
- Information on resuming sexual activity, trying to conceive again, and potential impacts on fertility
- How to access psychosocial and peer supports (see Quality Statement 6 and Quality Statement 7)

Medical management
Use of medication (misoprostol) to dilate the cervix and assist with expulsion of the products of conception from the uterus.

Surgical management
Vacuum uterine aspiration or dilatation and curettage (D&C) to surgically remove the products of conception from the uterus.

What This Quality Statement Means

For Patients
You and your health care provider should discuss your options for managing your early pregnancy loss so you can choose the one that is best for you and your family. Your health care provider should offer you written information on what to expect, plans for follow-up care, and how to access support services for pregnancy loss. The patient guide on early pregnancy complications and loss can help you have conversations with your health care provider. Inside you will find questions you may want to ask as you work together to make a plan for your care.

For Clinicians
Discuss all management options for intrauterine early pregnancy loss. Provide people and their families with information on the benefits and harms of each option. Clearly explain and provide written information on follow-up care and other available supports for early pregnancy loss. Share the patient guide on early pregnancy complications and loss to help your patients have conversations with you about their care.

For Health Services
Ensure people experiencing intrauterine early pregnancy loss are offered their choice of management option. Provide written resources for people and families experiencing intrauterine early pregnancy loss.

Quality Indicators

Process Indicators

Percentage of people with an intrauterine early pregnancy loss who receive information on all potential management options (expectant, medical, surgical)

- Denominator: total number of people with intrauterine early pregnancy loss
- Numerator: number of people in the denominator who receive information on all potential management options (expectant, medical, surgical)
- Data source: local data collection

Percentage of people with an intrauterine early pregnancy loss who have a follow-up appointment with a health care professional

- Denominator: total number of people with an intrauterine early pregnancy loss
- Numerator: number of people in the denominator who have a follow-up appointment with a health care professional
- Data sources: NACRS, OHIP, local data collection

Outcome Indicator

Percentage of people with an intrauterine early pregnancy loss who report being involved in developing their care plan

- Denominator: total number of people with an intrauterine early pregnancy loss
- Numerator: number of people in the denominator who report being involved in developing their care plan
- Data source: local data collection
    - An example of a validated survey question that can be used to inform your local data collection is available in the Health Care Experience Survey (Ministry of Health and Long-Term Care): “When you see your provider or someone else in their office, how often do they involve you as much as you want to be in decisions about your care and treatment?” (Response options: “Always, Often, Sometimes, Rarely, Never, Volunteers it depends on who they see and/or what they are there for, Volunteers no decisions required on care or treatment/not applicable, Don’t know, Refused”)

Quality Statement 5: Management of Tubal Ectopic Pregnancy

People with a confirmed tubal ectopic pregnancy receive information on all potential management options and are supported to make an informed decision about their care. They have access to their preferred management option. Health care professionals closely monitor signs and symptoms and arrange appropriate access to follow-up care.

Background

Ectopic pregnancy should always be considered when pain and bleeding are present in early pregnancy. Ectopic pregnancy can lead to serious outcomes, such as bleeding requiring a blood transfusion, or can be fatal if left untreated. It requires an ultrasound assessment by an experienced radiologist and close follow-up care by or in consultation with a gynecologist. Ectopic pregnancies may be first classified as pregnancy of unknown location, as some are too small to be seen as an adnexal mass during the first ultrasound.[5]

Transvaginal ultrasound is the recommended diagnostic tool for ectopic pregnancy.[5] Improvements in ultrasound technology have made earlier diagnosis of ectopic pregnancy possible, which has made expectant management an option for some people.[1] The initial serum beta-hCG level at the time of ultrasound diagnosis is useful in deciding on appropriate management options. For all treatment options, serial beta-hCG measurements should be followed until they return to zero. If levels fail to fall as expected, there is a risk of delayed ectopic rupture.[5]

People with ectopic pregnancy should have access to all appropriate management options. If local facilities do not provide all options, then clear referral pathways should exist.[5] For all management options, people should receive written information on what to expect and what to do if they experience any new or worsening symptoms, including how to access emergency care.

Expectant management is an option for pregnant people who are clinically stable with an ultrasound diagnosis of tubal ectopic pregnancy and a decreasing beta-hCG level initially less than 1,500 mIU/mL. Reported success rates for expectant management vary considerably and are very dependent on case selection, with higher success associated with lower initial serum beta-hCG levels.[5] If expectant management is chosen, close follow-up and awareness of any changes in signs or symptoms are essential to ensure patient safety.

For **medical management**, a single intramuscular dose of 50 mg/m^2 of methotrexate (to end the pregnancy) can be offered to people with a tubal ectopic pregnancy and who:

- Are hemodynamically stable
- Have minimal pain
- Have serum beta-hCG levels up to 5,000 mIU/mL (beta-hCG > 5,000 mIU/mL is not an absolute contraindication but is associated with a higher risk of rupture)
- Are willing and able to attend follow-up care appointments

Methotrexate should not be given unless tubal ectopic pregnancy is confirmed and a viable intrauterine pregnancy has been excluded.[5] The largest single study of methotrexate for tubal ectopic pregnancy had a success rate of 91%.[5]

Two follow-up beta-hCG measurements should be taken on days 4 and 7 after treatment, and then weekly until they reach zero. If beta-hCG levels plateau or rise, clinicians should reassess the person's condition for further treatment. If beta-hCG does not decrease by 15% or more between days 4 and 7, a repeat transvaginal ultrasound should be considered to exclude ectopic fetal cardiac activity and significant hemoperitoneum (blood in the abdomen). Then a second dose of methotrexate can be considered.

When **surgery** is necessary, a laparoscopic approach is recommended. (Laparoscopic surgery uses a tube with a camera inserted into the abdominal wall to allow the surgeon to see the uterus and fallopian tubes.) When there is a healthy contralateral fallopian tube, salpingectomy (removal of the fallopian tube) is preferred to salpingostomy (incision into the fallopian tube) in people with no infertility concerns or no previous ectopic pregnancy.[5]

This quality statement applies only to tubal ectopic pregnancy. Other types of ectopic pregnancy (e.g., Caesarean scar, ovarian), although rare, must be ruled out. Other types of ectopic pregnancy require different management approaches and are beyond the scope of this quality standard.

Sources: Royal College of Obstetricians and Gynaecologists, 2016[5] | Society of Obstetrician and Gynaecologists of Canada, 2016[4]

Definitions Used Within This Quality Statement

Tubal ectopic pregnancy
A pregnancy in which the embryo implants in a fallopian tube, outside the endometrial cavity. This quality statement does not apply to any other type of ectopic pregnancy.

What This Quality Statement Means

For Patients
If you are diagnosed with an ectopic pregnancy (where the pregnancy implants in your fallopian tube, which can be life-threatening), discuss your options for managing it with your doctor and choose the one that is best for you. Your health care provider should offer you information on what to expect during treatment and what to do if your symptoms worsen or you have new ones. They should continue to perform blood tests until your beta-hCG hormone level returns to zero.

The patient guide on early pregnancy complications and loss can help you have conversations with your health care provider. Inside you will find questions you may want to ask as you work together to make a plan for your care.

For Clinicians
Offer people with tubal ectopic pregnancy their choice of management options and discuss the benefits and harms of each approach. Discuss the estimated success rate for each option, based on the person's beta-hCG levels, and the chance of treatment failure. Arrange follow-up beta-hCG tests until they reach zero.

Share the patient guide on early pregnancy complications and loss to help your patients have conversations with you about their care.

For Health Services
Ensure that all management options for ectopic pregnancy are available. Create processes and protocols to ensure people treated for ectopic pregnancy have serum beta-hCG tests until the level is zero.

Quality Indicators

Process Indicators

Percentage of people with a tubal ectopic pregnancy who receive information on all potential management options (expectant, medical, surgical)

- Denominator: total number of people with a tubal ectopic pregnancy
- Numerator: number of people in the denominator who receive information on all potential management options (expectant, medical, surgical)
- Data source: local data collection

Median wait time from (1) first presentation to a health care professional of tubal ectopic pregnancy, to (2) a diagnosis of tubal ectopic pregnancy by a health care professional with expertise in ultrasound assessment

- Description: median number of days from (1) first presentation to a health care professional of tubal ectopic pregnancy, to (2) a diagnosis of tubal ectopic pregnancy by a health care professional with expertise in ultrasound assessment
- Data source: local data collection

Percentage of people with a tubal ectopic pregnancy who receive follow-up care by or in consultation with a gynecologist

- Denominator: total number of people with a tubal ectopic pregnancy
- Numerator: number of people in the denominator who receive follow-up care by or in consultation with a gynecologist
- Data sources: NACRS, OHIP, local data collection

Outcome Indicators

Percentage of people with a tubal ectopic pregnancy treated with methotrexate who have a subsequent tubal ectopic rupture

- Denominator: total number of people with a tubal ectopic pregnancy treated with methotrexate
- Numerator: number of people in the denominator who have a subsequent tubal ectopic rupture
- Data source: local data collection

Percentage of people with a ruptured tubal ectopic pregnancy who receive a blood transfusion

- Denominator: total number of people with a ruptured tubal ectopic pregnancy
- Numerator: number of people in the denominator who receive a blood transfusion
- Data sources: NACRS, OHIP

Maternal mortality due to tubal ectopic pregnancy per 100,000 live births

- Denominator: total number of people with a tubal ectopic pregnancy
- Numerator: number of people in the denominator who die of tubal ectopic pregnancy per 100,000 live births
- Data sources: Canadian Mortality Database (CMD), Registered Persons Database (RPDB)

Quality Statement 6: Compassionate Care and Psychosocial Supports

People and families experiencing early pregnancy complications and/or loss are treated with dignity and respect, and receive support in a sensitive manner, taking into account their individual circumstances and emotional responses. They are offered psychosocial supports.

Background

Early pregnancy loss carries considerable psychological, physical, and social significance that varies by person. Early pregnancy complications can be distressing and cause concern about the health and viability of the pregnancy and of future pregnancies, even if the complications do not end in a loss. Throughout all episodes of care, pregnant people and their families should be given clear, evidence-based information about the potential benefits, harms, and limitations of treatment options so they can make decisions that are right for them.

All health care and support professionals who are or will likely be working with people and families experiencing early pregnancy complications and/or loss should receive specialized training in compassionate care and bereavement care.

People and family members experiencing early pregnancy complications and loss can benefit from psychosocial support (including peer support; see Quality Statement 7) during and/or after the need for acute medical attention. Psychosocial issues may go undetected or untreated when pain and bleeding are the initial focus of treatment, but clinicians should also regularly assess psychosocial well-being. A psychosocial assessment can facilitate the identification of any supports a person or their family may need. Supports and information offered should be culturally appropriate and culturally sensitive.

For more information about compassionate care in the emergency department, please see the 2017 report by the Provincial Council for Maternal and Child Health, Early Pregnancy Loss in the Emergency Department: Recommendations for the Provision of Compassionate Care.[7]

Source: National Institute for Health and Clinical Excellence, 2012[1]

Definitions Used Within This Quality Statement

Psychosocial support
Care related to a person's state of mental, emotional, social, cultural, and spiritual well-being. Psychosocial supports can be provided by a wide variety of health care professionals, peer support leaders, or others in the community.

What This Quality Statement Means

For Patients
You and your family should be treated with dignity and respect at all times. Health care professionals should consider your emotional and physical needs when giving you support and information. They should discuss options for mental and emotional supports with you and your family.

For Clinicians
Treat all patients and families with dignity and respect and provide compassionate care and information that is supportive of physical and emotional needs. Give appropriate information on the person's condition, how they can access care if needed, and what to expect physically and emotionally during complications and/or loss in early pregnancy. Ensure that sufficient time is available to discuss these issues during each visit, and arrange an additional appointment if more time is needed.

For Health Services
Provide education and training in the provision of compassionate care to all health care and support professionals providing care to people experiencing early pregnancy complications or loss. Ensure health facilities and teams offer or refer people to psychosocial supports.

Quality Indicators

Outcome Indicator

Percentage of people experiencing early pregnancy complications and/or loss (and their families) who report not being treated with dignity and respect by their health care professionals

- Denominator: total number of people who experience early pregnancy complications and/or loss (and their families)
- Numerator: number of people in the denominator who report not being treated with dignity and respect by their health care professionals
- Data source: local data collection

Quality Statement 7: Peer Support

People who experience an early pregnancy loss and their families are offered information about peer support services and organizations.

Background

While people may seek support and reassurance from health care professionals, these interactions may not always meet their needs. For many families, it is important to feel a connection to others who have experienced a similar loss and to talk about their loss in a safe space,[8] and peer support may be more appropriate. But relatively few families in Ontario experiencing early pregnancy losses are offered and attend a peer support appointment.[3]

Ongoing support may be beneficial and should be tailored to the family's changing needs. Peer support is an evidence-based practice, and referrals can be offered at the time of diagnosis, at follow-up appointments, or later by a primary care provider.

Source: Advisory committee consensus

Definitions Used Within This Quality Statement

Peer support
Peer support is emotional and practical support between people who share a common experience. It involves having a facilitated discussion in which the family is offered emotional and social support for normal grief responses to their loss. Peer support is provided by a person who has lived experience of early pregnancy loss and has completed training to gain the necessary knowledge and skills to companion a bereaved family through their grief. Peer support can be provided in a variety of formats including in-person, on the phone, or online, and can be open to bereaved parents and any other adult family members impacted by the loss.[8]

What This Quality Statement Means

For Patients
Your health care providers should offer you information on—and a referral to—peer support groups for early pregnancy loss.

For Clinicians
Be familiar with peer support groups and programs for early pregnancy loss in your community. Offer information on peer support resources, and a referral if the patient wants one.

For Health Services
Ensure that clinicians are aware of peer support programs and groups locally and how they can refer patients.

Quality Indicators

Process Indicator

Percentage of people experiencing an early pregnancy loss (and their families) who receive a referral for peer support

- Denominator: total number of people who experience an early pregnancy loss (and their families)
- Numerator: number of people in the denominator who receive a referral for peer support
- Data source: local data collection

Quality Statement 8: Early Pregnancy Assessment Services

People experiencing early pregnancy complications and loss have access to early pregnancy assessment services that are available 7 days a week. People referred to early pregnancy assessment services are seen within 24 hours when clinically indicated.

Background

Early pregnancy assessment services are recommended to provide patient-centred, high-quality care for people experiencing early pregnancy complications and loss.[1] The emergency department is not a patient-centred setting for this care, due to long wait times, a lack of privacy, and sometimes a lack of staff with specialized training and competency in caring for these patients. People with early pregnancy complications should be assessed by a health care professional before being referred to early pregnancy assessment services. Self-referrals may be available to people who have experienced recurrent early pregnancy loss or an ectopic pregnancy.

Early pregnancy assessment services can be adapted to the location and context where care is offered, and may be organized, staffed, and located in various ways to best support local community needs. This could include the use of e-referrals or e-consults to increase access to specialist care. If the service is not available, and clinical symptoms warrant further assessment, refer people to the nearest accessible facility that offers specialist clinical assessment and ultrasound scanning with access to specialist gynecology support.[1]

Source: National Institute for Health and Clinical Excellence, 2012[1]

Definitions Used Within This Quality Statement

Early pregnancy assessment services
Health care services that have expertise in diagnosing and caring for people with pain and/or bleeding in early pregnancy. They offer transvaginal ultrasound and assessment of serum beta-hCG to provide diagnosis and inform management options. Early pregnancy assessment services are staffed with health care and support professionals with training and competency in providing compassionate care (see Quality Statement 6). Ideally, early pregnancy assessment services are available 7 days a week.

What This Quality Statement Means

For Patients
A health care professional (family doctor, nurse, midwife, or emergency department doctor) should assess you. If you are referred to early pregnancy assessment services, the appointment should take place within 24 hours, if appropriate.

For Clinicians
See people referred to early pregnancy assessment services within 24 hours when clinically indicated.

For Health Services
Ensure services and systems are organized to make early pregnancy assessment services available regionally 7 days a week.

Quality Indicators

Structural Indicator

Availability of early pregnancy assessment services that are available 7 days a week and see patients within 24 hours of referral when clinically indicated

- Data source: local data collection

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About Health Quality Ontario

Health Quality Ontario is the provincial lead on the quality of health care. We help nurses, doctors and other health care professionals working hard on the frontlines be more effective in what they do – by providing objective advice and data, and by supporting them and government in improving health care for the people of Ontario.

We focus on making health care more effective, efficient and affordable through a legislative mandate of:

- Reporting to the public, organizations, government and health care providers on how the health system is performing,
- Finding the best evidence of what works, and
- Translating this evidence into clinical standards; recommendations to health care professionals and funders; and tools that health care providers can easily put into practice to make improvements.

For more information about Health Quality Ontario: www.hqontario.ca

About Pregnancy and Infant Loss (PAIL) Network

Pregnancy and Infant Loss (PAIL) Network is a provincial program mandated to provide peer-based support to families who experience the loss of a pregnancy or infant and education to health care providers who care for them. Our support programs are led by trained volunteers who have experienced pregnancy or infant loss first-hand. We are a barrier-free, inclusive organization. We can provide interpreters in several languages, at a family's request.

We know that there is no time limit on grief. For this reason, families can access our services *at any time* for as long as they need.

The experience of pregnancy or infant loss can be devastating for all involved. PAIL Network helps health care providers to make a positive difference at this time of loss by knowing what to say and what not to say, and by providing compassionate, sensitive, and skilled care.

For more information about PAIL Network: https://pailnetwork.sunnybrook.ca/

Quality Standards

Looking for more information?

Visit our website at **hqontario.ca** and contact us at **qualitystandards@hqontario.ca** if you have any questions or feedback about this guide.

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