

# Quality Standards

## Early Pregnancy Complications and Loss

Care for Adults in All Settings

DRAFT

**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 health care professionals, 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. While it is not mandatory to use or collect data when using a quality standard to improve care, measurement is key to quality improvement.

For more information on quality standards, contact [qualitystandards@hqontario.ca](mailto: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 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 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.<sup>1</sup>

The emotional and psychological impacts of early pregnancy loss can be serious. For some people, the emotional distress can result in clinical depression, post-traumatic stress disorder, and/or anxiety.<sup>1</sup> Ontario families experiencing early pregnancy loss have reported a lack of kindness and respect from health care professionals, that they felt less supported, and that they experienced more stigma at the time of their loss, compared with people whose loss occurred later in the pregnancy.<sup>2</sup> 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.<sup>2</sup>

There were an estimated 47,776 emergency department (ED) visits for early pregnancy complications or loss in Ontario in 2017/18 (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.<sup>3</sup> 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. In a 2017 survey of Ontario EDs with an annual census of more than 30,000 ED visits, 34 of the 63 EDs reported that they did not have access to early pregnancy clinic services for people who presented to the ED with early pregnancy complications and were safe

to discharge home.<sup>4</sup> Over half of EDs without access to an early pregnancy clinic agreed that patients returned to the ED frequently because there was no adequate follow-up available.<sup>4</sup>

## 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 be welcomed at all related 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 acknowledge and work toward addressing the historical and present-day impacts of colonization in the context of the lives of Indigenous Peoples throughout Canada. This work involves being sensitive to the impacts of intergenerational and present-day traumas and the physical, mental, emotional, and social harms experienced by Indigenous people, families, and communities. This quality standard uses existing clinical practice guideline sources developed by groups that may not include culturally relevant care or acknowledge traditional Indigenous beliefs, practices, and models of care.

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.

## Patient Guide

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

Clinicians and health services planners can make patient guides available in all settings where people receive care.

## 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:

- Number of emergency department visits 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

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

### *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 overall success of the standard and the quality of care patients are receiving; these indicators cannot be measured provincially using currently available data sources:

- Average time that people with early intrauterine pregnancy loss who need a dilatation and curettage (D&C) procedure wait for a D&C
- Average wait time from first presentation to a health care professional of early pregnancy complications or loss, to 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 receive

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

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 transvaginal ultrasound and serum beta-hCG measurement.

### **Quality Statement 2: Early Pregnancy Assessment Services**

People experiencing early pregnancy complications and loss have access to early pregnancy assessment services.

### **Quality Statement 3: Pregnancy of Unknown Location**

People with a pregnancy of unknown location (not visible in the uterus or adnexa, on ultrasound) receive two serial serum beta-hCG measurements taken 48 hours apart. They are followed until a final diagnosis is made or until beta-hCG returns to zero.

### **Quality Statement 4: 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 or other relevant care providers.

### **Quality Statement 5: Management Options for 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 6: Management Options for Tubal Ectopic Pregnancy**

People with a confirmed tubal ectopic pregnancy receive information on all potential management options (expectant, medical, and surgical) 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 7: Compassionate Care**

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, no matter where they receive their care.

### **Quality Statement 8: Psychosocial and Peer Supports**

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



## Quality Statement 1: Comprehensive Assessment

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

### Background

If the person is known to be pregnant, a transvaginal ultrasound is recommended to determine the location of the pregnancy and other markers of growth and viability.<sup>5,6</sup> A single beta-hCG measurement cannot diagnose viability in a pregnancy but may be needed as a baseline for assessing future values and to determine next steps in care for pregnancy of unknown location (quality statement 3) or for an ectopic pregnancy (quality statement 6).<sup>5</sup> Beta-hCG results may also help with the interpretation of a transvaginal ultrasound.

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.<sup>1</sup> Signs and symptoms of ectopic pregnancy can resemble other conditions or miscarriage.<sup>1,5</sup> 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.

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 Care Excellence, 2019<sup>1</sup> | Society of Obstetricians and Gynaecologists of Canada, 2016<sup>5</sup>

### 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 histories, including history of pregnancy loss or ectopic pregnancy, and use of assisted reproductive technology
- Consider a manual pelvic and/or speculum exam if their pregnancy status is unknown or ultrasound is not available
- Who their partner, family member, friend, or other support person is (if none is present, offer to contact them)
- Emotional or psychological distress

Tests to consider based on the clinical situation:

- Urine beta-hCG (if pregnancy status is unknown)
- Blood group
- Hemoglobin
- Rhesus status (Rh)

**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 with transabdominal ultrasound alone. Having the result of a beta-hCG test may help with the interpretation of transvaginal ultrasound.

**What This Quality Statement Means**

**For Patients**

Your health care provider should:

- Ask you about your symptoms and medical history
- Offer you a blood test and a procedure known as a trans-vaginal ultrasound

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 offering a transvaginal ultrasound and a serum beta-hCG.

## **For Health Services**

Ensure all health care professionals have access to pregnancy tests if they care for people who may be pregnant. Provide training and education for health care professionals on early pregnancy assessment and compassionate care. Ensure people with early pregnancy complications have access to transvaginal ultrasound and serum beta-hCG 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: Early Pregnancy Assessment Services

People experiencing early pregnancy complications and loss have access to early pregnancy assessment services.

### Background

Early pregnancy assessment services are recommended to provide patient-centred, high-quality care for people experiencing early pregnancy complications and loss.<sup>1</sup> 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 a previous early pregnancy loss or ectopic pregnancy. The urgency of referral depends on the clinical situation.<sup>1</sup>

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, health care professionals should refer people to the nearest accessible facility that offers specialist clinical assessment and ultrasound scanning with access to specialist gynecology support.<sup>1</sup>

Early pregnancy assessment services offer a care pathway outside of the emergency department and provide continuity of care, timely follow-up, and a single point of contact for patients and families. This requires the promotion of partnerships between interdisciplinary teams and health care professionals in the emergency department, diagnostic imaging, and primary care.

**Source:** National Institute for Health and Care Excellence, 2019<sup>1</sup>

### Definition Used Within This Quality Statement

#### Early pregnancy assessment services

Health care services that have expertise in diagnosing and caring for people with pain or bleeding in early pregnancy. They offer transvaginal ultrasound and assessment of serum beta-hCG to provide diagnoses and inform management options. They offer information and support to patients and families, and opportunities for shared decision-making. Early pregnancy assessment services are staffed with health care and support professionals with training and competency in providing compassionate care (see quality statement 7). Ideally, early pregnancy assessment services are available 7 days a week.

### What This Quality Statement Means

#### For Patients

Health care professionals (such as a family doctor, nurse, midwife, or emergency department doctor) with training and experience in care during early pregnancy complications and/or loss should be available in your area.

#### For Clinicians

Be aware of early pregnancy assessment services available in your region. Refer people to existing services and ensure that relevant health information is shared with other care providers, patients, and families.

**For Health Services**

Ensure services and systems are organized to make early pregnancy assessment services available regionally.

**Quality Indicators**

*Structural Indicator*

**Availability of early pregnancy assessment services that are available 7 days a week**

- Data source: local data collection

## Quality Statement 3: Pregnancy of Unknown Location

People with a pregnancy of unknown location (not visible in the uterus or adnexa, on ultrasound) receive two serial serum beta-hCG measurements taken 48 hours apart. They are followed until a final diagnosis is made or until beta-hCG returns to zero.

### 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 are intrauterine pregnancies, not ectopic. But until a location is confirmed, a pregnancy of unknown location should be considered as potentially ectopic.<sup>5</sup>

Recommended management consists of two serial measurements of serum beta-hCG taken 48 hours apart. Whether beta-hCG is rising, falling, or has plateaued determines the next steps in care and the potential need for further ultrasounds or beta-hCG measurements.

Patients should receive clear information on why they will need multiple follow-up appointments and where to go for repeat ultrasounds and bloodwork, if needed. If no intrauterine or ectopic pregnancy is diagnosed, people should be followed up until the beta-hCG level returns to zero. People with a 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. Potential barriers to follow-up, including language or ability to attend follow-up appointments, should be considered and addressed.

For additional guidance on pregnancy of unknown location, see the [recommended care pathway](#) developed by the National Institute for Health and Care Excellence (NICE).

**Sources:** National Institute for Health and Care Excellence, 2019<sup>1</sup> | Society of Obstetricians and Gynaecologists of Canada, 2016<sup>5</sup>

### 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.<sup>1</sup>

### What This Quality Statement Means

#### For Patients

If you have a positive pregnancy test, but the pregnancy cannot be seen in an ultrasound picture, your health care providers should:

- Repeat ultrasounds and bloodwork until your pregnancy is located or a pregnancy test is negative
- Tell you what to do if your symptoms get worse
- Tell you how to get emergency care

### **For Clinicians**

For people with pregnancy of unknown location, repeat ultrasounds 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 assessment and follow-up care for 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

### *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: local data collection

## Quality Statement 4: 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 or other relevant care providers.

### Background

Findings on transvaginal ultrasound may help health care professionals and their patients develop management strategies that are individually targeted.<sup>5</sup> Ideally, transvaginal ultrasounds should be performed and reviewed by someone with training in, and experience with, diagnosing early pregnancy loss and 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.<sup>5</sup> People diagnosed with a complete miscarriage should be advised to return for care if they have new or worsening symptoms.<sup>5</sup>

Early pregnancy loss can be diagnosed—and no further ultrasound is required—when ultrasound confirms either<sup>5</sup>:

- 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.<sup>5</sup>

A diagnosis of early pregnancy loss should be communicated to the person as quickly as possible, ideally by the person who ordered the testing, in a private place. 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. Health care professionals should provide a “sick note” to the person and/or their partner, if needed.

**Source:** Society of Obstetricians and Gynaecologists of Canada, 2016<sup>5</sup>

### 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
- Let you know who will contact you with a diagnosis and how long it should take
- Encourage you to have a support person with you at appointments

### For Clinicians

Refer people experiencing early pregnancy complications to ultrasound services with experience 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, including when and how they should expect to hear results and if they can access results themselves (i.e., online). Encourage patients to bring a support person to appointments. Share test results with other health care professionals involved in the person's care.

### For Health Services

Create clear processes for ultrasound results and diagnoses of intrauterine early pregnancy loss to be shared with relevant health care professionals, patients, and families as soon as possible. Ensure policies support the presence of support people during care and appointments. Offer training to health care professionals on ultrasound diagnosis of early pregnancy loss and ectopic pregnancy.

## Quality Indicators

### Process Indicator

#### **Average wait time from first presentation to a health care professional for intrauterine early pregnancy loss or complications, to a diagnosis via ultrasound of intrauterine early pregnancy loss**

- Description: average number of days from first presentation to a health care professional of intrauterine early pregnancy loss or complications, to a diagnosis via 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
- Note: this indicator measures a sub-set of one of the overall measures of success

## Quality Statement 5: Management Options for 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 the management option that is right for them. Discussion should cover the possible benefits and harms of each approach, including the potential need for medical or surgical management after expectant management, or surgical management after treatment with medication. The time commitment and number of follow-up appointments for each option should also be discussed.

There are three management options: expectant, medical, and surgical management.

**Expectant management:** A “watchful waiting” management approach in which the early pregnancy loss is not actively treated. The goal in expectant management is for the products of conception to expel from the uterus without intervention. This process may take days or weeks to complete. Sometimes expectant management will not be successful, and medication or surgery will be necessary.

**Medical management:** The use of medication (misoprostol) to dilate the cervix and assist with expulsion of the products of conception from the uterus. People taking misoprostol for medical management should also receive information on expected changes in bleeding, how to manage pain and nausea, and who to contact if bleeding does not start within 24 hours.<sup>1</sup> They should be offered medication for pain and nausea. Notes on recommended dosing for misoprostol<sup>1</sup> are as follows:

- 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
- Some health care providers prescribe a second dose to be taken at 24 hours if bleeding has not started
- Buccal administration (tablets placed in the cheek for 30 minutes) has a similar pharmacokinetic profile to the vaginal route and is a promising route of administration, but further data on efficacy are needed for early pregnancy loss indications<sup>7</sup>

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.<sup>8</sup> (Mifepristone is a drug that blocks the production of progesterone, a hormone needed to maintain the lining of the uterus during pregnancy.) Mifepristone and misoprostol combined (brand name Mifegymiso) is prescribed as 200 mg mifepristone given first, followed by misoprostol 24 hours later. Currently, mifepristone in addition to misoprostol is not available at

all pharmacies or hospitals in Ontario. This should be taken into consideration in the shared-decision making process.

Other medications to manage pain and nausea should be provided. Plans for follow-up after medical management of 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.

**Surgical management:** This approach involves vacuum uterine aspiration or dilatation and curettage (D&C) to surgically remove the products of conception from the uterus.

**Source:** National Institute for Health and Care Excellence, 2019<sup>1</sup>

## 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.

### Information

People should receive written, standardized information on<sup>1,6</sup>:

- How to access and take prescribed medications
- 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
- Postoperative care (for people undergoing surgery)
- Resuming sexual activity, trying to conceive again, and potential impacts on fertility
- How to access psychosocial and peer supports (see quality statement 8)

## What This Quality Statement Means

### For Patients

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
- Offer you written information on what to expect, plans for follow-up care, and how to access support services for pregnancy loss

### For Clinicians

Discuss all management options for intrauterine early pregnancy loss with people and their families. Provide them with information on the benefits and harms of each option. Routinely

provide medication for pain and nausea, as appropriate. Clearly explain and provide written information on follow-up care and other available supports for early pregnancy loss.

### **For Health Services**

Ensure resources are available for people experiencing intrauterine early pregnancy loss to be offered their choice of management option. Provide written resources for people and families experiencing intrauterine early pregnancy loss. Ensure resources are available to allow timely access to operating room time for D&C procedures for early pregnancy loss.

## **Quality Indicators**

### *Process Indicators*

#### **Average wait time to a D&C procedure for people with an intrauterine early pregnancy loss who needed a D&C**

- Description: average number of days from the diagnosis of intrauterine pregnancy loss to a D&C procedure for people who needed a D&C
- 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 within 7 days of their initial visit**

- 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 within 7 days of their initial visit
- Data sources: 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 6: Management Options for Tubal Ectopic Pregnancy

People with a confirmed tubal ectopic pregnancy receive information on all potential management options (expectant, medical, and surgical) 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 as a potential diagnosis when pain and bleeding are present in early pregnancy. Ectopic pregnancy can lead to serious outcomes such as bleeding requiring a blood transfusion and can be fatal if left untreated. Ideally, transvaginal ultrasounds should be performed and reviewed by someone with training in, and experience with, diagnosing ectopic pregnancies. Close follow-up care should be provided by or in consultation with a gynecologist. Ectopic pregnancies may be classified initially as pregnancy of unknown location, as some are too small to be seen as an adnexal mass during the first ultrasound.<sup>6</sup>

Transvaginal ultrasound is the recommended diagnostic tool for ectopic pregnancy.<sup>6</sup> Improvements in ultrasound technology have made earlier diagnosis of ectopic pregnancy possible, which has made expectant management an option for some people.<sup>1</sup> 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.<sup>6</sup>

People with ectopic pregnancy should have access to all appropriate management options. If local facilities do not provide all options, then clear referral pathways and protocols for follow-up should exist.<sup>6</sup> 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 dependent on case selection, with higher success associated with lower initial serum beta-hCG levels.<sup>6</sup> 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**, to end the pregnancy, a single intramuscular dose of 50 mg/m<sup>2</sup> (use body surface area to create a patient-specific dose) of methotrexate can be offered to people with a tubal ectopic pregnancy 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.<sup>6</sup> The largest single study of methotrexate for tubal ectopic pregnancy had a success rate of 91%.<sup>6</sup>

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.<sup>6</sup>

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.

For additional guidance on the management of tubal ectopic pregnancy, see the [recommended care pathway](#) developed by the National Institute for Health and Care Excellence (NICE).

**Sources:** National Institute for Health and Care Excellence, 2019<sup>1</sup> | Royal College of Obstetricians and Gynaecologists, 2016<sup>6</sup> | Society of Obstetricians and Gynaecologists of Canada, 2016<sup>5</sup>

## 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

Your health care provider should:

- Discuss options for managing your ectopic pregnancy so you can choose the one that is best for you and your family
- Offer you information on what to expect during treatment and what to do if your symptoms change or get worse
- Continue to monitor your health

### **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 the level reaches zero.

### **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

#### **Average wait time from the first presentation to a health care professional of tubal ectopic pregnancy, to a diagnosis of tubal ectopic pregnancy by a health care professional with expertise in ultrasound assessment**

- Description: average number of days from the first presentation to a health care professional of tubal ectopic pregnancy, to 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 within 7 days of their initial visit**

- 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 within 7 days of their initial visit
- Data sources: 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: Discharge Abstract Database (DAD), NACRS

## Quality Statement 7: Compassionate Care

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, no matter where they receive their care.

### Background

Early pregnancy loss carries psychological, physical, and social significances that vary 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 that 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. Care should take into account health equity, including culture, language, age, race, and other social factors.

For additional guidance on compassionate care in the emergency department, see the [recommendations](#) developed by the Provincial Council for Maternal and Child Health (PCMCH).<sup>9</sup>

Further [educational opportunities and resources for health care and service professionals](#) are available through PAIL network.

**Source:** National Institute for Health and Care Excellence, 2019<sup>1</sup>

### What This Quality Statement Means

#### For Patients

You and your family should be treated with dignity and respect at all times.

#### 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.

## Quality Indicators

### *Outcome Indicator*

**Percentage of people experiencing early pregnancy complications and/or loss (and their families) who report 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 being treated with dignity and respect by their health care professionals
- Data source: local data collection

## Quality Statement 8: Psychosocial and Peer Supports

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

### Background

People experiencing early pregnancy loss and their family members can benefit from psychosocial support during and/or after the need for acute medical attention. Psychosocial issues may go undetected or untreated when pain and bleeding are the 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.

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,<sup>10</sup> 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.<sup>2</sup>

Ongoing support may be beneficial and should be tailored to a family's changing needs. 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, and online, and can be open to bereaved parents and any other adult family members impacted by the loss.<sup>10</sup>

#### 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

Your health care providers should offer you information on emotional and peer supports. They should offer you a referral to a peer support program if you want one.

### **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 local peer support programs and groups for early pregnancy loss and how they can refer patients. Ensure patient resources and information are available in hospitals and all settings where people receive care for early pregnancy loss.

## **Quality Indicators**

### *Process Indicator*

#### **Percentage of people experiencing an early pregnancy loss (and their families) who are offered information about psychosocial and peer support services and organizations**

- Denominator: total number of people who experience an early pregnancy loss (and their families)
- Numerator: number of people in the denominator who are offered information about psychosocial and peer support services and organizations
- 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](http://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

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