HIV SCREENING FOR PREGNANT WOMEN

U. S. Department of Health and Human Services
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Contents

HIV SCREENING FOR PREGNANT WOMEN

Measure Description ................................................................................................................ 2

Part 1: Introduction .................................................................................................................. 2

Performance Measurement: HIV Screening for Pregnant Women ......................................... 4

Measure Description .............................................................................................................. 5

Part 2: Characteristics for Success: HIV Screening for Pregnant Women ............................. 7

Part 3: Implementation of HRSA CCM: HIV Screening for Pregnant Women ................. 14

Critical Pathway for HIV Screening for Pregnant Women ...................................................... 15

Factors That Impact the Critical Pathway ............................................................................... 17

Data Infrastructure: HIV Screening for Pregnant Women ...................................................... 20

Data Infrastructure to Monitor the Performance Measure—An Overview ............................. 21

Implementation: HIV Screening for Pregnant Women ............................................................ 21

Part 4: Improvement Strategies: HIV Screening for Pregnant Women ............................. 29

What Changes Can an Organization Make? ........................................................................... 29

How Can an Organization Make Those Changes? ................................................................ 38

How Can an Organization Know That Changes Caused Improvement? ............................... 41

Part 5: Holding the Gains and Spreading the Improvement ................................................. 42

Holding the Gains .................................................................................................................. 42

Spreading Improvement ........................................................................................................ 42

Part 6: Supporting Information .............................................................................................. 43

Case Study ............................................................................................................................ 43

References ............................................................................................................................. 43

Additional Resources ........................................................................................................... 46
HRSA CCM: HIV SCREENING FOR PREGNANT WOMEN

The goals of this module are to provide a detailed overview of the HRSA’s Core Clinical Measure, HIV Screening for Pregnant Women, outline the intended use for this measure, and highlight the benefits of implementing this measure into an organization’s quality improvement (QI) program.

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Part 1: Introduction

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) are leading causes of illness and death in the United States and only 40 percent of the United States population has been tested. (1) One of the major ways in which children become HIV-infected is via perinatal transmission from the infected mother to her fetus. By targeting pregnant women for screening, this mode of transmission can be reduced through monitoring and treatment of HIV-infected pregnant women. Without antiretroviral therapy, approximately 25 percent of pregnant women infected with HIV in the United States will transmit the virus to their child. (2) Appropriate health care management of women with HIV during pregnancy and delivery, as well as care for infants promptly after delivery, can reduce the rate of HIV transmission to less than two percent. (2) Regularly testing pregnant women for HIV and providing pregnancy appropriate antiretroviral drugs, if they are infected, has dramatically reduced the number of children born with HIV. Recommendations for HIV Testing for Pregnant Women in Health Care Settings can be found on the Center for Disease Control and Prevention (CDC) Web site.

Perinatal HIV transmission accounts for nearly all pediatric AIDS cases. In Figure 1.1, the graph shows that the number of perinatally-acquired AIDS cases decreased dramatically recommendations for perinatal treatment and prenatal HIV testing were introduced. Data also indicates that perinatal HIV transmission can be prevented when appropriate antiretroviral medications are given during pregnancy, labor and delivery, and after birth. The risk of transmission can be reduced to less than 2 percent compared to approximately 25 percent when no interventions are given. (3)
HIV Screening for Pregnant Women

On a national level, HIV/AIDS surveillance and other studies continue to demonstrate that perinatal HIV prevention efforts are making a difference. Between 1991 and 2004, the number of new perinatally-acquired HIV cases in the United States declined more than 80 percent from an estimated 1,650 (4) to an estimated 96 to 186 cases. (5) Between 1992 and 2005, perinatally-acquired AIDS cases declined 93 percent in the United States from 855 to 57 cases. (6) It is, therefore, vital that an HIV infection in a mother is identified during the early stages of pregnancy to provide an opportunity to reduce the risk of transmission to her baby. Early screening even prior to conception is ideal, but in practice, screening at any time is better than none. Although this measure focuses on early screening it is important to emphasize that intervention to reduce mother-to-child transmission can be successful even during labor and in the immediate postpartum period.

Offering HIV screening for pregnant women is the standard of care in the United States. The CDC recommends that all pregnant women in the United States be tested for HIV infection. Health care providers should recommend HIV testing to all of their pregnant patients, pointing out the substantial benefit of knowledge of HIV status for the health of women and their infants. HIV screening should be a routine part of prenatal care for all women. (7) Universal HIV testing with patient notification and opt-out options should, however, be in accordance with current State laws. (8,9) HIV Testing for Mothers and Newborns is a resource for current laws for HIV screening by State.

Since 1994, the availability of increasingly effective antiretroviral drugs for both the prevention of perinatal HIV transmission and maternal treatment has resulted in a greater emphasis on prenatal HIV testing and substantial increases in prenatal testing rates. In 2000, preliminary data indicated that 766 of 824 HIV-infected women (93 percent) in 25 States knew their HIV status before delivery (CDC, unpublished data, 2002). However, about 100 to 200 infants in the United

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Figure 1.1: HIV Screening and Antiretroviral Drugs for Pregnant Women Reduces Perinatally-Acquired AIDS Cases

Adapted from [http://www.cdc.gov/hiv/topics/perinatal/index.htm](http://www.cdc.gov/hiv/topics/perinatal/index.htm)
States are infected with HIV annually. Many of these infections involve women who were not tested early enough in pregnancy or who did not receive prevention services. (1) The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women. States and Canadian provinces have implemented three different prenatal HIV-testing approaches. To assess their effectiveness, CDC reviewed prenatal HIV-antibody testing rates associated with these approaches. Medical record data suggests that the opt-in voluntary testing approach is associated with lower testing rates than either the opt-out voluntary testing approach or the mandatory newborn HIV-testing approach.

According to the United States Preventive Services Task Force (USPSTF), clinicians should screen all pregnant women for HIV. The task force categorizes this as A Recommendation, which indicates that there is good evidence to support the practice. It cites evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women, and there is fair evidence that introduction of universal prenatal counseling and voluntary testing increase the proportion of HIV-infected women who are diagnosed and treated before delivery. (7)

Monitoring the percentage of pregnant women screened for HIV during the first or second prenatal care visit assists an organization in its efforts to improve care and provide optimal outcomes for mothers and babies.

Performance Measurement: HIV Screening for Pregnant Women

Measuring performance allows an organization to document how well care is currently provided and lay the foundation for improvement. The HRSA Core Clinical Measures (CCMs) are a set of performance measures, designed for use by HRSA programs as an integral part of quality improvement programs, to improve care for the safety-net population. More information about the purpose and development of these measures can be found in the HRSA Core Clinical Measures module.

The HRSA HIV Screening for Pregnant Women measure is designed to measure screening of pregnant patients for HIV. The goal for improvement for HIV Screening for Pregnant Women is to minimize perinatal transmission of HIV infection through early diagnosis and treatment of HIV-infected pregnant women. (10) The ultimate goal is to decrease the number of children perinatally infected with HIV.

Consider the characteristics of a good performance measure and the IOM framework, Envisioning the National Healthcare Quality Report:

- **Relevance**: Does the performance measure relate to a frequently-occurring condition or have a great impact on patients at an organization’s facility?
- **Measurability**: Can the performance measure realistically and efficiently be quantified given the facility’s finite resources?
- **Accuracy**: Is the performance measure based on accepted guidelines or developed through formal group decision-making methods?
**Feasibility**: Can the performance rate associated with the performance measure realistically be improved given the limitations of the clinical services and patient population?

To ensure that a performance measure has these characteristics, it is often based on, or aligned with, an organization’s existing and proven measures.

The HRSA CCMs were developed in alignment with national clinical practice guidelines and other performance measures that went through a national consensus process. The HIV Screening for Pregnant Women measure aligns with measures endorsed by the National Quality Forum (NQF) and is supported by recommendations and guidelines by National Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics, American College of Obstetricians and Gynecologists (ACOG), and U.S. Preventive Services Task Force (USPSTF) sponsored by the Agency for Healthcare Research and Quality (AHRQ). Similar measures also exist in the national measure set for Healthy People 2010 as shown in Figure 1.2 and will likely be retained in Healthy People 2020. Measures are also available as part of the Advancing HIV Prevention Program (AHP) from the CDC, Strategy 4: Further Decrease Mother-to-Child HIV Transmission. The AHP initiative represents a multi-agency collaboration within the Department of Health and Human Services (DHHS). Strategy 4 states that treatment of pregnant women and their infants can substantially reduce the number of babies born with HIV infection. (11)

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**Reduce the number of new cases of perinatally-acquired HIV/AIDS diagnosed each year and perinatally-acquired AIDS. (11)**

a. (Developmental) Number of new cases of perinatally-acquired HIV/AIDS

b. Number of new cases of perinatally-acquired AIDS

**Data Source**: HIV/AIDS Surveillance System, CDC, NCHHSTP

**Status**: Retained Healthy People 2010 Objective 13-17

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**HRSA Core Clinical Measure**: HIV Screening for Pregnant Women

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As with all performance measures, paying close attention to specifications, such as, inclusions, exclusions, and clarifications are required to ensure that an organization collects and reports data consistently. This consistency allows an organization using the measure to compare itself with others. Detailed specifications for the measure, with descriptions of inclusion and exclusion criteria, are found in the section, **Part 3: Data Infrastructure: HIV Screening for Pregnant Women**

**Improvement Experience: HIV Screening for Pregnant Women**

As mentioned previously, the **HIV Screening for Pregnant Women** measure was chosen to align with existing measures. The data demonstrating the experience with these measures is discussed briefly in this section.

In 2002, the CDC reviewed the HIV-testing rates for pregnant women for the period of 1998 to 2001. (13) A variety of data sources were used to determine rates, including interviews with patients, large-scale research studies, and regional databases. The CDC study found that HIV-testing rates for pregnant women varied widely and that a relatively high proportion of women of child-bearing age were unaware that treatment is available to reduce the risk of perinatal transmission. (14) Additionally, the CDC found that rates varied with different approaches to testing. Locations that used the *opt-out* approach presented HIV screening as part of the routine prenatal testing panel and informed the woman that she had the right to refuse HIV testing. Locations that used the *opt-in* approach provided HIV pre-test counseling and required specific consent from the patient. Mandatory newborn testing, which tested newborns whose mothers’ HIV status was unknown at the time of birth, was also reviewed. The *opt-out* approach resulted in higher screening rates of 71 to 98 percent than the *opt-in* approach, which resulted in screening rates of 25 to 83 percent, or mandatory newborn testing. In addition, it was found that locations that transitioned from the *opt-in* to the *opt-out* approach saw an increase in screening rates and the likelihood that HIV testing was offered to pregnant patients. A limitation of the study was noted to be the lack of a standardized national database. (13)

As depicted in **Figure 1.3**, a study of HIV testing showed 69 percent of the 748 women who had a completed pregnancy during the 12 months before participating in the 2002 National Survey of Family Growth reported that they had been tested during prenatal care. This percentage is consistent with the range of values found in a number of State and local studies, including follow-back surveys of recent mothers and chart review studies, and was applied to the 5.5 million pregnancies completed in the past year in the same 2002 study. (17, 18)
A large U.S. survey found that overall prenatal testing rates increased from 41 percent in 1995 (when recommendations for universal prenatal HIV counseling and testing were issued) to 60 percent in 1998 (prior to the revision recommending the opt-out approach). Other studies have found higher screening rates when the provider endorses testing and when testing is offered routinely to all pregnant patients. (19)

A lack of data related to prenatal HIV testing has proven to be a problem in defining national goals. Healthy People 2010 Objective 25-17 is defined as: *Increase the proportion of pregnant females screened for sexually transmitted diseases (including HIV infection and bacterial vaginosis) during prenatal health care visits, according to recognized standards*. This objective was deleted at the Healthy People 2010 Midcourse Review because a national data source was unavailable.

Indirect data, however, supports the impact of the dramatic increase in perinatal HIV screening. According to 2004 data, HIV counseling and testing of pregnant women and the use of appropriate antiretroviral therapy on HIV-infected women during pregnancy have saved lives and resources. The number of children diagnosed with AIDS, who had been perinatally exposed to HIV, declined from 122 in the year 2000 to 47 in 2004. Additionally, it was reported that perinatal transmission of HIV peaked in 1991 and has continued to decline. This decline is attributed primarily to practices that have increased the identification of HIV-positive women during pregnancy, allowing for appropriate interventions to be implemented. (13)

**Part 2: Characteristics for Success: HIV Screening for Pregnant Women**

Organizations successful in improving HIV Screening for Pregnant Women pay close attention to those factors that have an impact on timely prenatal care. Although clinics may differ in specific work flow, documentation, and staffing models, organizations that experienced successful improvement efforts shared these three fundamental characteristics:

1. Clear direction
HIV Screening for Pregnant Women

2. Functional infrastructure for quality improvement
3. Commitment from leadership

1. Clear Direction

Successful organizations found that it is important to define clearly what they are trying to accomplish. Most often in improvement work, leadership defines an aim that guides an organization’s efforts. An aim is a written, measurable, and time-sensitive statement of the accomplishments a team expects to achieve from its improvement efforts. The aim statement contains a general description of the work, the system of focus, and numerical goals. The aim statement includes a very specific indication of what success looks like and may include guidance that further frames the work, including methodologies to be used and budgetary and staffing limitations. Examples of tools used by QI teams to create their aim statements include an Aim Worksheet and Aim Statement Checklist. Additional information, including tools and resources to assist an organization in developing its aim statement, can be found in the Readiness Assessment and Developing Project Aims module. A completed aim statement for the measure, HIV Screening for Pregnant Women, is shown in Example 2.1: Assessing the Aim Statement for Big Valley Health Care Organization (BVHCO) Using the Aim Statement Checklist.

The following hypothetical example provides an aim statement created by a QI team of a fictional center called the Big Valley Health Care Organization, and the checklist the team used to assess its completed aim statement. Using the Aim Statement Checklist to assess the QI team’s aim statement provides reassurance that the team included the necessary components of the aim statement for its improvement project.
Example 2.1: Assessing the Aim Statement for Big Valley Health Care Organization (BVHCO) Using the Aim Statement Checklist

**Aim Statement:** Over the next 12 months, we will redesign the care systems of Big Valley Health Care Organization to improve HIV screening for pregnant women. We will accomplish this so that 90 percent of our prenatal patients will receive HIV testing during their first or second prenatal visit.

**Guidance:**
- No additional staffing will be required as a result of this improvement
- A key focus will be education of staff and patients

*Here is an example of how Big Valley Health Care Organization evaluated its aim statement using the Aim Statement Checklist*

**Aim Statement Checklist for Example 2.1:** (21)

- What is expected to happen?  
  **BVHCO:** Higher percentage of prenatal patients will receive HIV screening at their first or second prenatal visit
- Time period to achieve the aim?  
  **BVHCO:** 12 months
- Which system will be improved?  
  **BVHCO:** Care systems that improve HIV screening in pregnancy
- What is the target population?  
  **BVHCO:** Prenatal patients
- Specific numerical goals?  
  **BVHCO:** 90 percent of the prenatal population
- Guidance, such as, strategies for the effort and limitations?  
  **BVHCO:** As noted, no new staff plus focus on education of patients and families

Other examples of aim statements for **HIV Screening for Pregnant Women** that an organization may consider are:

- Ninety percent of prenatal patients will be offered HIV testing at their initial prenatal intake visits.
- Seventy-five percent of prenatal patients will be tested for HIV prior to their third prenatal care visits.
- One hundred percent of prenatal patients tested for HIV will have a signed consent form in their charts. (Note—a consent form is not required in every State.) CDC recommends opt-out, routine HIV screening of all pregnant women, and newborn testing if mother's HIV status is unknown. Currently, 22 States have opt-out testing of pregnant women, 30 have opt-in, and 10 States have newborn testing. (8)
Evaluating what others achieved provides appropriate context for choosing the numerical portion of an organization’s aim. (21) In some cases, data is available to show average performance for a group of practices that focused on a particular measure. For example, the Indian Health Service (IHS) monitors HIV testing of pregnant women and has seen an increase in screening rates from 54 percent in 2005 to 76 percent in 2009, as shown in Figure 2.1.

![Percentage of IHS AI/AN Prenatal Patients Screened for HIV](image)

**Figure 2.1: Indian Health Service’s HIV Screening Rates from 2005 to 2009 for AI/AN Prenatal Patients**

The IHS goal for 2009 was to maintain the rate at 75 percent, but IHS’ rate surpassed that goal with an increase to 76 percent. IHS has not established a 2010 goal for this measure.

For some measures, it may be possible to find examples of benchmark data, which demonstrates the performance of a best practice. It is important to consider an organization’s particular patient population when making comparisons to others’ achievements. An organization may consider socioeconomic status or race/ethnicity of the population served, organizational size, payer mix, and other criteria in an effort to achieve an accurate comparison. Reviewing what others accomplished may help an organization to understand what is feasible to achieve. The numerical part of the aim should be obtainable, yet high enough to challenge the team to substantially and meaningfully improve. Additional guidance about setting aims can be found in the **Readiness Assessment and Developing Project Aims** module.

Sources to consider when choosing an aim or making performance comparisons for the measure, **HIV Screening for Pregnant Women**, include the IHS measure, *Prenatal HIV Screening*, which is the percentage of IHS pregnant women who are tested for HIV during their pregnancy. The 2009 goal for this measure is 75 percent. (22) Sources of data for additional comparisons vary regionally but may include payers, managed care organization databases, State programs, and State or regional quality improvement programs.

### 2. Functional Infrastructure for Quality Improvement

Successful organizations found that improvement work requires a systematic approach to measuring performance, testing small changes, and tracking the impact of those changes over
HIV Screening for Pregnant Women

time. This section describes four essential components of an infrastructure to support quality improvement efforts, including:

- Quality improvement teams
- Tools and resources
- Organizing improvements
- Building on the efforts of others by using changes that worked

There is considerable variation in how this infrastructure for quality improvement is created and maintained. It is important that each component is addressed in a way that fits an organization.

**Quality Improvement Teams**

Multidisciplinary QI teams are typically tasked to carry out this work. For improvement focused on HIV Screening for Pregnant Women, it is important to include a provider who wants to focus on improving the rate of early prenatal care, i.e., a provider champion for improvement. (23) In addition to the provider champion, other appropriate members of a QI team may include:

- Nurses
- Case managers
- Patient outreach specialist
- Patient navigator
- Scheduling staff
- Information specialist
- Other staff involved in the patient care process, such as, receptionists, administrative staff, medical assistants, and health coaches

It should be noted that patients can add great value to the QI process when prepared to participate in a meaningful way. The reference manual by the National Quality Center (NQC), *A Guide to Consumer Involvement*, has practical ideas to assist an organization on involving patients in its QI process. (24)

There are no wrong answers here. Members of a team bring expert knowledge of the work they do for prenatal patients. Together, the team learns where and how its individual actions intersect and how each can have a positive impact on patients’ HIV testing. The ability to think from a systems perspective and the will to improve early access to prenatal care are the primary prerequisites that contribute to a successful improvement team. A more advanced discussion on forming an improvement team can be found in the Improvement Teams module.
**Tools and Resources**

It is important that a QI team have the tools and resources necessary to achieve its established organizational aim. Some personnel may struggle shifting from the daily work of patient care to their roles on the quality improvement team. Those challenges can be straightforward, such as, coordinating meeting times or developing content for the meetings to support the team’s quality improvement efforts. Successful QI teams learned that organizing meetings efficiently is essential in their improvement efforts. Tools such as **Tips for Effective Meetings** can help a QI team to structure meetings that focus its scheduled time on improvement efforts. Another useful tool includes one that displays data in a way that makes sense to the team members. These types of tools are commonly used by improvement teams to remain focused on the work of improvement. The most important resource needs are uninterrupted time to focus on quality improvement and autonomy to test changes responsibly. Additional team resources and tools can be found in the **Improvement Teams** module.

**Organizing Improvements**

Successful organizations learned that planning an approach to change is essential. Change is, by nature, unsettling for some and presenting a clear direction and methodology can be reassuring and can engender support from staff. Most organizations with quality improvement experience adopted methodologies that help them organize their improvements.

As a QI team approaches improvement of HIV screening for pregnant women, it should use quality models already embraced by its organization. For example, many organizations adopted the **Care Model** to organize their approaches to implementing quality improvement changes. Others successfully embraced the **FOCUS PDSA** approach; both of these models provide a framework for a health care organization to plan and move toward implementing its improvement efforts. There is no single model that is considered correct. Organizational alignment of methodology makes sense from the perspective of efficient training. A consistent quality improvement approach and the sharing of improvement ideas among members of a quality team can facilitate the replication of QI activities across an organization and maximize the impact of the overall QI program.

Just as organizations that are experienced in quality improvement activities adopted quality models that guide their work, many embraced a change methodology. A change methodology guides the actual change process, which involves managing how changes are made as opposed to what changes are made.

For some organizations, all changes are approved by a decision leader and then implemented. Others use a committee structure to evaluate and implement changes. Again, there is no right or wrong methodology, but one change methodology that is helpful in quality improvement is the **Model for Improvement**. The Model for Improvement, developed by Associates in Process Improvement, is a simple, yet powerful, tool for accelerating improvement. The model is not meant to replace a change model that an organization may already be using, but rather to accelerate improvement by making it systematic and stepwise in approach. This
model has been used successfully by health care organizations to improve many different health care processes and outcomes.

The Model for Improvement encourages small, rapid-cycle tests of changes. In improvement, this has a distinct advantage in decreasing the time it takes for changes resulting in improvement to be implemented. This methodology also directly involves the individuals who do the work, as they provide additional practical insights into how to rapidly improve care processes. Advance discussions can be found in the Testing for Improvement module.

**Building on the Efforts of Others by Using Changes that Worked**

One hallmark that successful organizations found beneficial in advancing their quality improvement programs is that everyone across the organization uses the same tools and language to make continuous improvements. A motto of many QI training leaders is "steal shamelessly." This is not the unethical, criminal intent, but instead the sense of “Why reinvent the wheel?” What does it mean to “steal shamelessly”? It means “stealing” or using what has worked in other organizations and “shamelessly” testing and implementing it to create rapid change in one’s own organization.

Specific change ideas that worked for others to successfully improve prenatal care are detailed later in this module in the Changes that Work section. Additionally, an organization that has improvement experience in another measurement area, such as, diabetes, cancer screening, or immunizations, is often able to adapt the successful tools to use with a new measure.

**3. Commitment from Leadership**

For quality improvement efforts to be effective and sustained, leaders must show commitment to them. Typically, leaders may make a commitment to specific target areas for improvement once they consider the overall needs of the organization, requirements of funders, and how the proposed efforts align with the organization’s vision, mission and strategic plan. Leaders that consider quality improvement efforts as an “add-on” may be unable to maintain QI as a priority as other realities compete for the organization’s attention and resources. Successful leaders in quality improvement integrate and align QI activities as part of their daily business operations and are able to message that concept to the rest of the organization.

A quality improvement team needs to have leadership commitment expressed in a tangible way. Often, it is an explicit dedication of resources, which may include team meeting time, data support, and specific planned opportunities that communicate actionable improvement suggestions to an organization’s leadership. The authority of the improvement team and any constraining parameters should be clear. Detailed information highlighting the important role of leadership in a QI project can be found in the Quality Improvement module.

Below is a hypothetical case study that is followed throughout the module and depicts the effort of a fictional QI team as it focuses on improving the number of prenatal patients in its
organization who receive HIV screening. The case story may be read in its entirety by clicking here.

**The Problem:**
Big Valley Health Care Organization is an organization that provides full-scope primary care and inpatient services to an urban population. It has one site that is located near the city’s public hospital. The organization has a large prenatal caseload, five FTE nurse-midwives, and three Ob/Gyn physicians who provide care for their pregnant patients. They have seen growing numbers of HIV-positive patients in recent years and the providers are aware of the consequences of HIV/AIDS infections.

**Part 3: Implementation of HRSA CCM: HIV Screening for Pregnant Women**

Before following the steps in Part 3, an organization should first make a commitment to improve HIV screening for pregnant women and complete the initial steps outlined in the previous section that include:

- Developing an aim statement
- Creating an infrastructure for improvement
- Gaining commitments from leadership

Performance on this measure indicates how effectively all the steps of the processes used to deliver care work together so that prenatal patients will receive HIV screening. Because there are a variety of factors that can have an impact on the success of screening, it helps to visualize how these steps are mapped. The next section defines Critical Pathway and illustrates the application of this concept to implement HIV Screening for Pregnant Women.
The case story continues…

**The Approach:**

Big Valley’s Quality Improvement committee had recently revised its clinical guideline related to prenatal HIV testing. Previously, education regarding HIV testing was provided to prenatal patients at the time of their initial intake, and they were asked to decide whether they wanted to be tested. The new guideline followed the *opt-out* approach, in which HIV screening would be routinely included in prenatal testing unless the patient declined to be tested. A chart audit performed at that time revealed that 65 percent of pregnant women were receiving HIV testing during their first or second prenatal visit.

The QI committee’s initial steps in addressing this finding included:

1. The Prenatal Services Department and QI Committee agreed to include *HIV Screening for Pregnant Women* as a measure for the coming year.
2. Research was done on the evidence supporting the measure and effective improvements adopted in other settings.
3. An improvement team of interested staff members with involvement in prenatal care was appointed under the direction of Patricia Y., the lead nurse-midwife.
4. Time and staff support were allotted to allow the team to meet and proceed with its work. The team was asked to meet every two weeks initially and report monthly to the QI Committee.
5. The team elected to focus improvement efforts initially on the midwife’s patients.

**Critical Pathway for HIV Screening for Pregnant Women**

A critical pathway, also known as a clinical pathway, is a visual depiction of the process steps that result in a particular service or care. The sequence and relationship among the steps are displayed, which reveals a *map* of the care process. Additional information, including tools and resources regarding the mapping of care processes, can be found in the [Redesigning a System of Care to Promote QI](#) module. In an ideal world, the care process is reflective of evidence-based medical guidelines. Evidence-based medicine aims to apply the best available evidence gained from the scientific method for medical decision making. (25) A map of the care process steps that incorporates all of the known evidence and follows respected evidence-based medical guidelines can be considered the *idealized critical pathway*.

While the needs of individual patients should always be considered, clinical guidelines synthesize the best evidence into a pragmatic set of action steps that strive to provide the optimum health care delivery system. It is important to emphasize that clinical evidence and guidelines will evolve as knowledge progresses; therefore, the idealized critical pathway may evolve over time and not meet the needs of every individual.

**Note:** Please consider the following regarding critical pathways:

- There can be more than one way to depict the idealized critical pathway.
- Authorities vary on critical issues that have an impact on important decisions in medicine, and there is latitude within guidelines for variation related to less critical matters.
- It is important that an organization agrees on the guidelines with which to align. References are located in *Part 6: Supporting Information* at the end of this module.
In Figure 3.1, the schematic for **Critical Pathway for HIV Screening for Pregnant Women** incorporates available evidence and represents an idealized critical pathway for HIV screening for pregnant women. The boxes represent typical steps in care delivery. If these steps happen reliably and well, HIV screening for pregnant women will occur.

**Figure 3.1: Critical Pathway for HIV Screening for Pregnant Women**

**Walkthrough of the Idealized Critical Pathway**

The critical pathway for **HIV Screening for Pregnant Women** is not overly complex and integrates well with processes already in place in most prenatal care settings, such as, the intake visit and other routine testing. Strategies or program elements that are critical to successful performance on this measure include:

- The scheduling procedure for new prenatal patients
- Testing discussion that includes the importance of early detection of HIV for mother and baby in pregnancy
- Training about the importance of HIV screening and HIV pre-test counseling skills for staff who perform prenatal intake visits
- Using the opt-out approach to screening with prenatal patients; that is, HIV testing is presented as a part of the basic testing panel for all pregnant patients and is only excluded if she declines to be tested
- Availability of convenient and affordable lab services
• Availability of skilled interpretation services if the patient and staff member do not speak the same language
• Accuracy in filing and documentation of test results

A couple of important notes:
• An organization may adopt additional prenatal guidelines that include important care parameters beyond early access. The Institute for Clinical Systems Improvement, by the National Guidelines Clearinghouse, describes guidelines for comprehensive prenatal care in Routine Prenatal Care, including recommendations for HIV testing at the first visit (six to eight weeks). (26)
• A critical pathway can also be constructed to illustrate how care is currently provided within an organization (the existing pathway). Understanding the gap between an organization’s existing critical pathway (how you provide care now), and the idealized critical pathway (how to provide reliable, evidence-based care aligned with current guidelines), form the basis for improvement efforts.

Factors That Impact the Critical Pathway

In addition to understanding the steps for providing HIV screening for pregnant women, factors that interfere with optimal care should be understood. As there may be several of these factors, a QI team may find it helpful to focus its attention on factors that interfere with ideal outcomes. This becomes especially useful as plans are developed to mitigate these factors.

Factors that have an impact on HIV Screening for Pregnant Women can be organized into those that are patient-related, relative to the care team, and a result of the health system. Overlaps exist in these categorizations, but it is useful to consider factors that have an impact on care processes from each perspective to avoid overlooking important ones.

Patient factors are characteristics that patients possess, or have control over, that have an impact on care. Examples of patient factors are age, race, diet, and lifestyle choices. Examples of how patient factors may influence HIV screening for pregnant women include:
• Age—Women over the age of 25 may be more likely to appreciate the importance of HIV screening.
• Cultural differences—Immigrant women may have practices or beliefs in their native countries that do not view HIV testing as a priority.
• Health literacy—Women unaware of the importance of positive health behaviors are less likely to agree to screening. Ability to read and language proficiency may be barriers to understanding health information.
• Education—Women may not be aware of the availability of the HIV early treatment and the direct correlation with positive outcomes for the baby.

Care team factors are controlled by the care team. These types of factors may include care processes, workflows, how staff follows procedures, and how effectively the team works.
together. Care team factors that may influence HIV screening for pregnant women include the processes and procedures that:

- Staff skilled in scheduling prenatal appointments and rescheduling those appointments
- Provide culturally competent care to address the patient’s cultural norms
- Provide planned care for pregnant women
- Educate staff on counseling patients on the importance of early HIV testing in pregnancy and success of early interventions

**Health system factors** are controlled at the high level of an organization and often involve finance and operational issues. Health system factors that may influence HIV screening for pregnant women include:

- **Cost**—uninsured or underinsured women may have difficulty paying for testing
- **Scheduling systems**—availability of lab testing at the same location and time as prenatal visits
- **Location**—no transportation or an unsafe location may present barriers to keeping clinic or lab appointments
- **Legal factors**—for a resource that outlines State HIV testing laws, refer to the *National HIV/AIDS Clinician Consultation Center: Compendium of State HIV Testing Laws 2009*
These factors, when added to the critical pathway, create another dimension to the map as shown in Figure 3.2:

![Critical Pathway for HIV Screening for Pregnant Women with Potential Factors that Have an Impact on Early HIV Testing](image)

Figure 3.2: Critical Pathway for HIV Screening for Pregnant Women with Potential Factors that Have an Impact on Early HIV Testing

Next, a team may identify specific factors that pertain to the way care is provided for its patients. A team may look at Step 1: Patient presents for prenatal care services, and Step 2: Patient completes intake process which includes discussion and order for routine lab testing of the critical pathway. What factors have an impact on how effectively, timely, and reliably Step 2 follows Step 1? It is tempting to consider the first thoughts that come to mind, but a QI team is best served by systematically thinking through the potential impact of each category. In Example 3.1: A Team’s Brainstorming Session a QI team’s output is illustrated:
Example 3.1: A Team’s Brainstorming Session

The team brainstorms on factors that have an impact on the arrow (or opportunity) between Steps 1 and 2 [link] of the Critical Pathway for HIV Screening for Pregnant Women (from Figure 3.1).

<table>
<thead>
<tr>
<th>Factor Category</th>
<th>Factors Pertinent to our Organization—Steps 1 and 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Some patients are resistant to being seen for nurse visit before seeing a provider</td>
</tr>
<tr>
<td>Care Team</td>
<td>Schedulers do not always schedule prenatal intake visit appropriately (schedule with a provider instead or result in excessive delay)</td>
</tr>
<tr>
<td>Health System</td>
<td>Scheduling system does not always allow for adequate time for intake visit, bilingual staff or interpreter not always available, or no-shows not always rescheduled appropriately</td>
</tr>
</tbody>
</table>

The team continues to look at different parts of the pathway to identify relevant impacts for each part. Once it is able to evaluate where there are potential opportunities for improvement, it can use this information to target its efforts. Additional examples of strategies to improve care for the measure, HIV Screening for Pregnant Women, are described in the Improvement Strategies section of this module.

Once the team visualizes the pathway and identifies opportunities for improved care, the next step is to collect and track data to test and document them. First, a QI team needs to determine how to collect data to support its improvement work. This step is essential for understanding the performance of its current care processes, before improvements are applied, and then monitoring its performance over time.

Data Infrastructure: HIV Screening for Pregnant Women

This section begins to address the important role of data throughout the improvement process. It is important to recognize that different types of data are collected during the improvement project. First, data to calculate and monitor the HIV Screening for Pregnant Women performance measure results is needed. Monitoring a performance measure involves calculating the measure over time and is used to track progress toward a numerical aim. This section provides an overview of what is needed. A detailed and stepwise approach follows to explain the types of infrastructure elements needed to gather data to support improvement. Second, changes an organization is making to improve care processes and their effects must be tracked. Tracking the impact of changes reassures the team that the changes caused their intended effects.
Data Infrastructure to Monitor the Performance Measure—An Overview

There are three major purposes for maintaining a data infrastructure for quality improvement work:

- To know the starting baseline
- To track and monitor performance as changes are implemented
- To perform systematic analysis and interpretation of data in preparation for action

After determining what data is needed for a specific measure, the next step to creating a data infrastructure for monitoring the performance measure is to determine the baseline. A baseline is the calculation of a measure before a quality improvement project is initiated. It is later used as the basis for comparison as changes are made throughout the improvement process. For the HIV Screening for Pregnant Women measure, an organization can determine the percentage of prenatal patients that receive HIV testing as a result of established systems of care. Systems of care reflect the current organizational infrastructure and the patient’s interactions with existing care processes and the care team.

Baseline data is compared to subsequent data calculated similarly to monitor the impact of quality improvement efforts. The details of how to calculate the data must be determined to ensure that the calculation is accurate and reproducible. The difference between how an organization provides care now (baseline) and how it wants to provide care (aim) is the gap that must be closed by the improvement work.

The next step of data infrastructure development involves a process in place to calculate the measure over time as improvements are tested. A QI team’s work is to make changes, and it is prudent to monitor that those changes result in achieving the stated aim. This involves deciding how often to calculate the measure and adhering to the calculation methodology.

Finally, an organization’s data infrastructure must include systematic processes that allow analysis, interpretation, and action on the data collected. Knowledge of performance is insufficient for improvement. It is important for an organization to understand why performance is measured and to predict which changes will improve HIV Screening for Pregnant Women based on an organization’s specific situation. Collecting data related to specific changes and overall progress related to achieving an organization’s specified aim are important to improvement work. The next section describes in more detail how to develop a data infrastructure to support improvement.

Implementation: HIV Screening for Pregnant Women

This section explores each step to create the data infrastructure used to improve performance on the measure, HIV Screening for Pregnant Women. This measure is intended for an organization that provides or assumes primary responsibility for some or all of a patient’s prenatal care services, regardless if it performs the delivery. Since the HIV Screening for Pregnant Women measurement must include all prenatal patients, consideration of the
mechanism for data collection is critical, especially if an organization is not using an electronic database as its source of information for this measure. If data is accessed through chart audits, consistent documentation of HIV screening and reasons for not screening are especially important.

**Note:** If an organization is currently funded by HRSA, some performance measures, including the HRSA CCM set, may be among those that will be reported to HRSA. An organization should consult its program’s Web site for more information and links to Bureau- and Office-required guidelines and measures:

- BCRS
- BPHC
- MCHB
- HAB
- HSB
- BHPt
- ORHP
- OHITQ
- ORO

General information on HRSA grants including searchable guidelines, are available and accessible at the HRSA Grants Web site.

**Grantees are encouraged to contact their project officer with questions regarding program requirements**

1. **Step 1 - Determine and Evaluate the Baseline**

   As previously discussed, a *baseline for improvement* is a calculation that provides a snapshot of the performance of the systems of care for a measure before improvements are applied. The baseline is determined by calculating the measure and collecting the information for the numerator and denominator.

   The following tables depict a calculation guideline for the measure, **HIV Screening for Pregnant Women**. The guideline outlines the calculation for determining baselines and monitoring improvements for **HIV Screening for Pregnant Women**: (27)
Identify the Denominator

The denominator for this measure is all pregnant women who were seen for two or more prenatal visits during the measurement year.

a. Use a one-year date range: the measurement year.

b. Inclusion criteria

- All patients, regardless of age, who were seen for at least two prenatal care visits during the measurement year, are included in the denominator.
- A prenatal care visit is defined as a visit with a prenatal care provider and does not include pregnancy testing, registration, or lab testing.
- In selecting charts for tracking data on this measure, consider ICD-9 codes to include all pregnant women (i.e., women who experienced a spontaneous abortion or stillbirth after their initial visit, women who transferred out of care during pregnancy, etc.). It is important to remember that for the purpose of reporting, this measure must include all pregnant women cared for by an organization.

c. Exclusion criteria

Documentation of medical reason(s) for not screening for HIV during the first or second prenatal visit (e.g., patient has known HIV).

Identify the Numerator

The numerator for this measure is all women from the denominator with documentation (electronic or paper chart) that they were screened for HIV infection during the first or second prenatal visit.

a. Patients included in numerator have:

i. a note with documentation of screening for HIV infection including: enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), Western blot (WB), indirect immunofluorescence assay (IFA), rapid test, during the first or second prenatal visit.

ii. If a patient transfers into care during pregnancy, documentation of prenatal HIV screening done elsewhere for the same pregnancy must be dated within the first or 2nd visit.

iii. Do not include HIV testing from a previous pregnancy or from before the pregnancy.

c. There are no exclusions for the numerator. There is no exclusion for patient refusal.

Calculate the Measure

Divide the numerator by the denominator and multiply by 100 to get the percentage of women who received HIV screening.

Special considerations related to sampling and collecting data for this measure include the following:

- All women who were seen for at least two prenatal care visits during the measurement year are included in the denominator.

- A prenatal care visit is defined as a visit with a prenatal care provider and does not include pregnancy testing, registration, or lab testing.

- Data source is documentation (electronic or paper chart) of HIV infection screening (enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], Western blot [WB], indirect immunofluorescence assay [IFA], and rapid test during the first or second prenatal visit).

- If a woman transferred to an organization’s care, she is counted in the numerator if she had documented HIV screening with the previous provider during the first or second visit, or if HIV testing was performed at her first or second prenatal visit with the new provider.

- If a woman has two pregnancies in the same measurement year, she is counted twice.
HIV Screening for Pregnant Women

- Do not include HIV testing from a previous pregnancy or from before the pregnancy.
- Women previously documented as HIV positive are excluded.

In selecting charts for tracking data on this measure, consider ICD-9 codes to include all pregnant women (i.e., women who experienced a spontaneous abortion or stillbirth after their initial visit, women who transferred out of care during pregnancy, etc.). It is important to remember that for the purpose of reporting, this measure must include all pregnant women cared for by an organization as defined in the Managing Data for Performance Improvement module.

Detailed specifications, including instructions to identify the denominator and numerator for the measure, HIV Screening for Pregnant Women, can be accessed on the HRSA Clinical Quality Performance Measures Web site, or the Physician Consortium for Performance Improvement. Prenatal Care, Physician Performance Measurement Set, September 2007.

Evaluate the baseline. Initially, a team compares its baseline to the performance it hopes to achieve. It is important to remember this gap in performance is defined as the difference between how the care processes work now (baseline) and how an organization wants them to work (aim). An organization may often modify its aim or timeline after analyzing its baseline measurement and considering the patient population and organizational constraints.

As an organization moves forward, the baseline is used to monitor and compare improvements in care over time. While it is important for an organization to stay focused on its aim, it is equally significant to periodically celebrate the interim successes.

2. **Step 2: Create a reliable way to monitor performance over time as improvements are tested.** An organization should:
   a. Standardize its processes and workflows to ensure the team collects and calculates performance data the same way over time. An organization should document exactly how the data is captured so staff turnover does not interfere with the methodology.
   b. Determine the frequency that performance will be calculated. Frequent data collection is often associated with higher levels of improvement. Monthly measurement is recommended if feasible, as it is associated with a higher level of team engagement and success. If it is infeasible, quarterly measurements may be obtained. Less frequent performance measurements are adequate for reporting purposes, but do not adequately support improvement efforts. An advanced discussion can be found in the Managing Data for Performance Improvement module.
   c. Chart and display results. A simple chart audit form as shown in Figure 3.3 is appropriate for manual audits and can be repeated frequently as desired. Results of multiple audits can be presented in a graphic format to demonstrate trends. Refer to the Managing Data for Performance Improvement module for more
information and examples of data displays that have been used to communicate information about improvement efforts to a variety of stakeholders.

Note: Frequent team meetings are not necessarily required for success. Many successful teams meet once a week while others may meet bi-weekly when focusing their improvement efforts on any given measure. These meetings can be short but intently focused on tests, findings and next steps. Successful meetings are based on the output of the team members’ active engagement and being prepared to report on recent improvement findings. More information, including resources and tools supporting developing and implementing effective team meetings can be found in the Improvement Teams module.
### Measure: HIV Screening for Pregnant Women

<table>
<thead>
<tr>
<th>#</th>
<th>Medical Record # and/or Name</th>
<th>Two PN Visits in year?</th>
<th>Date of HIV Test</th>
<th>Excluded</th>
<th>In Compliance: testing in 1st or 2nd PN visit</th>
<th>Notes</th>
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**Figure 3.3: Chart Audit Form for HIV Screening for Pregnant Women Measure**

3. **Step 3:** Create systematic processes that allow an organization to analyze, interpret, and act on the data collected.

Having the data is not enough. Improvement work involves thinking about the data and deciding what to do based on that analysis. A QI team needs to put processes in place – team meetings, scheduled reports, and periodic meetings with senior leaders, to use the data tracked. This section describes how a QI team may accomplish the work of creating actionable plans based on the data collected. In **Example 3.2: QI Team at Big Valley Health Care Organization**, the scenario illustrates how a team may use these concepts to act on its data:

a. **Analyze:** What are the data trends? Tracking performance over time for the measure, **HIV Screening for Pregnant Women**, is critical to successful
improvement, but calculation of performance is not enough. It is important for a team to meet to analyze the data on a regular basis. QI teams that are experienced in looking at data recognize these common patterns:

- Performance is improving
- Performance is decreasing
- Performance is flat
- Performance has no recognizable pattern
- The results bring attention to other issues involved in the process that may not directly reflect on performance

Additional examples of common data patterns are provided with further explanation in the **Managing Data for Performance Improvement** module. It is typical for a team to see little movement in its data over the first several months. If a team has chosen to monitor an associated process measure, such as, the percent of no-show prenatal patients who are rescheduled, performance improvement may be evident more quickly. Regardless, it is important that a QI team review performance progress regularly. A QI team that meets regularly and calculates performance monthly should spend part of one meeting each month reviewing its progress to date.

b. **Interpret: What do these data trends mean?** A QI team needs to then interpret what these data trends mean within the context of its own organization. If performance is increasing, but has not yet reached the numerical aim, perhaps the changes in place are having the desired effect and the aim will be reached over time. If performance is decreasing, what has changed? Are there new care process changes, a failure of registry data input, or a large increase in those patients included in the registry? If performance is flat, did the organization maximize the benefits from changes implemented or was there some regression to the former way of doing things? Improvement trends that have reached a plateau may indicate that an organization needs to think differently about future changes. A few suggestions that an organization may consider when experiencing a plateau in improving HIV Screening for Pregnant Women are listed below:

   i. Consider looking at outliers that may create barriers to patients accessing timely prenatal care, for example, lack of insurance, transportation, or language and cultural differences.

   ii. Consider changes in a different part of the framework to get improvement back on track. If using a critical pathway approach, an organization may look at the steps prior to where the problem seems to be. If a Care Model approach is used and the team worked hard on delivery system design issues, opportunities to better leverage the clinical information systems or engage the community may be considered.

Interpretation of data over time is critical in determining where a team will target its efforts. Additional tools that can assist a team in understanding underlying causes for data trends are beyond the scope of this toolkit but are discussed in detail in a monograph that was published by the NQC, *A Modern Paradigm for Improving Healthcare Quality*. 
c. **Act:** Make decisions based on data. Once a QI team has a better understanding of what the data means, efforts should be targeted to further advance the performance toward the aim. Often the decisions are made at the team level about what to tackle first. Then small tests of change can be accomplished to determine what improvements could be implemented to enhance performance. The practice of using small tests of change actually allows multiple changes to be tested simultaneously.

*Note:* An advanced discussion on how to use the data collected to advance an organization’s improvement, including resources and tools to support improvement, can be found in the Managing Data for Performance Improvement module.

### Example 3.2: QI Team at Big Valley Health Care Organization

The Quality Improvement (QI) Team at Big Valley worked diligently to improve HIV screening for prenatal patients within their first or second prenatal visit increasing its rate from 65 to 80 percent over the last several months. The team focused on staff education and scheduling issues and had streamlined those processes. But during the last three months, the performance remained the same, which was below its aim of 90 percent.

**Analysis:** The team noted improvement initially. Registry input, care processes and patient volumes seemed to be stable but performance was flat for the last four months.

The team leader asked for a list of those patients who did not have HIV screening during the past month—outliers for the measure. Further study of these specific cases found that of the 42 new prenatal patients seen during the month, 33 had received the HIV test (80 percent), 8 had not had any prenatal lab work and 1 had declined the HIV test. Of the 8 who did not have testing, 5 were uninsured and waiting for Medicaid eligibility determination, and 3 did not return for their next scheduled appointment.

**Interpretation:** The team leader interpreted the data to mean that initial changes provided some improvement, but more work was needed. The team leader employed a common strategy to find additional opportunities; i.e., looked at the population not in compliance (the outliers) for a common cause to be addressed. In this case, a common thread was that patients who were uninsured were not receiving testing. The delay between applying for Medicaid and receiving notification of eligibility could be a problem. In addition, a small number of patients were being lost to follow-ups.

This information allowed the team to consider processes that might help to improve the screening rate. The team brainstormed about ideas and suggestions based on its own patient population. It decided to look into a way of streamlining Medicaid eligibility since this had proven to be a problem in other areas of the clinic. The team also decided to refer prenatal no-shows to the prenatal case manager. The improvement team will continue to monitor its performance to determine if these changes are effective for achieving its aim statement goals.

**Act:** The information gathered from the analysis and interpretation of the data allowed the team to focus its next efforts. This enabled the team to focus on PDSAs (Plan-Do-Study-Act) to test changes specific to these areas and monitor its progress.

A QI team leader needs to monitor the pace of the progress over time. If there is insufficient progress to meet the specified aim, reasons should be analyzed and addressed. One organization may choose to accelerate its improvement efforts; another may decide to
extend its initial allotment of time to achieve its aim and consider other constraints within the organization.

**Part 4: Improvement Strategies: HIV Screening for Pregnant Women**

The actual improvement process is composed of three steps that respond to the following questions:

1. What changes can an organization make?
2. How can an organization make those changes?
3. How can an organization know the changes caused an improvement?

**What Changes Can an Organization Make?**

It is important to understand that improvement requires change, but not all change results in improvement. Considering all of the possible changes that can be made to health care systems, considerable effort has been dedicated to creating various quality improvement strategies providing a framework that organizes possible changes into logical categories. Frameworks for change in health care quality improvement are known as *quality models* and have been tested to guide change. In fact, considering that there are limited resources to dedicate to improvement, most organizations adopt one or more quality models to guide their improvement efforts. There is not a right or wrong approach, and there are many areas of overlap in quality models. Experienced quality improvement teams often use multiple strategies to overcome challenges as they progress. Two approaches often used by teams that are working to improve HIV Screening for Pregnant Women are the *Care Model* approach and the *Critical Pathway* approach.

The case story continues...

**The Improvement Journey:**

In undertaking the HIV Screening for Pregnant Women measure, the team chose to use the Care Model as an improvement approach. This involved considering the various aspects of care relevant to the measure (as outlined in the table above). Some of the team members’ concerns were:

1. They observed that they did have good patient education materials in Spanish related to HIV screening.
2. Pregnant women were usually scheduled for an initial visit with the nurse for education and history and at that time were given a lab slip for prenatal testing. They were asked to take that paper across the street to the hospital lab.
3. Rescheduling of pregnant women who did not keep prenatal appointments was not handled consistently.
4. Uninsured patients had difficulty paying for prenatal testing.

They brainstormed some improvement ideas and strategies and decided to begin with the following:

1. They set a goal of a 90 percent prenatal HIV screening rate for Patricia Y.’s patients by the end of 6 months of improvement testing.
2. They would conduct a chart audit of Patricia Y.’s initial prenatal visits for the past month (12 patients) to determine her baseline, detect any problems with documentation, and review charts of those who did not have prenatal HIV screening.
1. **Care Model Approach:** Implementing the changes described in the Care Model is a proven method to improve care delivery. The Care Model, shown in Figure 4.1, is an organizational framework for change and is organized into six domains:

   a. Organization of Health Care  
   b. Clinical Information Systems  
   c. Delivery System Design  
   d. Decision Support  
   e. Community  
   f. Self-Management Support

Changes within these domains can effectively leverage transformation of a current reactive care system to one that better supports care for preventative health measures, such as, **HIV Screening for Pregnant Women** and chronic disease conditions.

---

**Care Model**

![Care Model Diagram](attachment:image.png)

**Figure 4.1: The Care Model**
If an organization does not have general experience with the Care Model, reading about the Care Model before proceeding is recommended. The Care Model recognizes that care for pregnant women is ongoing and requires more proactive care than the health care system often provides. The Care Model is implemented to improve care by working in six domains, defined below, that transform the way care is delivered:

**Community**—To improve the health of the population, a health care organization reaches out to form powerful alliances and partnerships with State programs, local agencies, schools, faith organizations, businesses, and clubs.

**Organization of Health Care**—A health care system can create an environment in which organized efforts to improve the care of people with chronic illness take hold and flourish.

**Self Management**—Effective self management is very different from telling patients what to do. Patients have a central role in determining their care and one that fosters a sense of responsibility for their own health.

**Delivery System Design**—Delivery of patient care requires not only to determine what care is needed, but to clarify roles and tasks to ensure the patient receives the care; all of the clinicians who take care of a patient have centralized, up-to-date information about the patient’s status, and make follow-up a part of their standard procedures.

**Decision Support**—Treatment decisions need to be based on explicit, proven guidelines supported by at least one defining study. A health care organization integrates explicit, proven guidelines into the day-to-day practice of primary care providers in an accessible and easy-to-use manner.

**Clinical Information System**—A registry, that is, an information system that can track individual patients and populations of patients, is a necessity when managing chronic illness or preventive care.

*Definitions above are adapted from the Institute for Healthcare Improvement Web site.*
In Table 4.1: Care Model Key Changes, key changes are presented that have been used successfully to improve prenatal care within the Care Model framework:

### Table 4.1: Care Model Key Changes

<table>
<thead>
<tr>
<th>Community</th>
<th>Organization of Health Care</th>
<th>Self-Management Support</th>
<th>Delivery System Design</th>
<th>Decision Support</th>
<th>Clinical Information Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarify community served by clinical facility and cultural/language needs</td>
<td>Provide opportunity for perinatal staff to meet regularly and participate in continuing education</td>
<td>Appreciate and consider the culture—provide patient with culturally- and literacy-appropriate educational tools and resources for HIV screening</td>
<td>Anticipate and plan the prenatal intake visit to ensure timely screening and follow-up</td>
<td>Provide initial and ongoing education for providers and staff regarding HIV screening</td>
<td>Use clinical information systems to identify prenatal patients</td>
</tr>
<tr>
<td>Develop partnerships with community organizations that promote screening and provide HIV/AIDS treatment</td>
<td>Allocate resources and remove barriers for improving HIV screening and access</td>
<td>Provide appropriate pretest counseling</td>
<td>Include HIV test on prenatal lab forms</td>
<td>Facilitate provider access to clinical guidelines</td>
<td>Establish a registry of prenatal patients</td>
</tr>
<tr>
<td>Increase access to diagnostic screening services, especially for uninsured patients</td>
<td>Integrate prenatal HIV screening and follow-up into performance improvement plans</td>
<td>Create expectation that patient should pursue results and provide feedback to the providers</td>
<td>Design communication and organize follow-up systems to meet patient and provider needs</td>
<td>Develop and implement standing orders for prenatal testing</td>
<td>Generate automatic reminders for screening at initial prenatal intake in EMR</td>
</tr>
<tr>
<td>Look to community agencies to help reduce barriers to the evaluation of abnormal screens</td>
<td>Regularly update Board, senior leadership, staff, and community on process and progress</td>
<td>Develop incentives for timely prenatal testing</td>
<td>Make notification of results a routine part of care</td>
<td>Make performance feedback available to appropriate staff</td>
<td></td>
</tr>
<tr>
<td>Maintain a resource/referral database on support services available to people diagnosed with HIV infection</td>
<td></td>
<td>Repeat testing later in pregnancy for women at risk</td>
<td></td>
<td>Develop a process for using and maintaining the prenatal patient registry</td>
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</tbody>
</table>
This toolkit is meant as a guide to help organize ideas, but is also designed to allow flexibility for creative planning.

**Note:** An organization may choose to adapt and refine a tool to assist improvement for the measure, HIV Screening for Pregnant Women. Testing the measure before fully implementing it offers a way to try something new and modify it before additional resources are spent.

The case story continues....

**The QI Team:**

The review of Patricia Y.’s initial prenatal charts from the previous month revealed that:

1. Seven of the twelve (58 percent) had HIV test results documented in the chart. The other five had documented orders in their charts for prenatal testing without an order for HIV testing, nor did their records indicate that HIV testing was discussed and/or declined.
2. The nurse who did the chart audits also reported that there was a backlog in the Medical Records Department in filing lab reports into patients’ charts. (Big Valley does not use electronic health records.)

A patient satisfaction survey asked about ease of contacting the clinic, scheduling an appointment, and treatment at the time of visits. Questions about the importance of prenatal care and testing were also asked.

The team decided its first improvement test would focus on delivery system design, and it planned to meet with the prenatal case managers to revise the lab ordering procedure for initial prenatal patients by:

1. Pre-printing lab slips with standard prenatal tests including HIV testing already selected.
2. Reviewing points to include in patient education related to HIV and other prenatal testing.
3. Asking for their input on other possible improvements.

The new procedure would be implemented immediately for Patricia Y.’s patients and a chart audit would be repeated one month later.

2. **Critical Pathway Approach:** As with all critical pathways, good performance relies on many different systems and processes working together efficiently. An organization is encouraged to map its own critical pathway for HIV Screening for Pregnant Women or refer to the schematic in Figure 4.2. Often when a QI team maps its pathways, it readily can see how complex each step is. It is common for different team members to do the same step differently. Workflow inefficiencies become clear when an organization visualizes how each step is completed and the interdependencies among the steps. Some teams are overwhelmed by the possibilities of changes that can be made in their systems; others focus only on a specific group of factors.
One way to organize the factors that have an impact on the systems is to consider that some are controlled by the patient, others are primarily controlled by the care team, and still others are inherent in the system of care delivery. All three sets of changes must be considered to improve systems of care. In general, these categories can be defined as follows:

- **Patient changes**—efforts to support self-management efforts, patient engagement, and navigation of the care system
- **Care team changes**—changes in job duties or work flow that assist to retain patients in care and ensure timely evidence-based prenatal care
- **Health system changes**—changes that have an impact on how care is delivered, independent of who does it

A team should use the steps along the critical pathway to target improvements. For this measure, **HIV Screening for Pregnant Women**, influences on performance begin prior to the pregnancy, as indicated by the first step in the critical pathway: **Patient presents for prenatal care services**.

An organization can think through each part of the critical pathway in turn, teasing out what happens and what could be improved. In **Table 4.2**, changes that have worked for other QI teams are matched with the part of the system on which they have the most
impact. These ideas are not meant to be inclusive, but to start a dialogue of what may improve each part of the critical pathway in an organization, and thus improve it overall.

**Changes That Work**

In Table 4.2, a matrix of *sample* changes that work are linked to the critical pathway for HIV Screening for Pregnant Women in Figure 3.1.
### Table 4.2: Sample Changes That Work

<table>
<thead>
<tr>
<th>Area of Critical Pathway</th>
<th>Patient Changes</th>
<th>Care Team Changes</th>
<th>Health System Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient presents for prenatal care services</td>
<td>Create expectation that patient must take responsibility to ensure good prenatal care</td>
<td>Care team understands importance of prenatal education and care</td>
<td>Health system understands importance of HIV screening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adapt and print copies of patient educational brochure, place in waiting areas, and have available where staff offers testing</td>
</tr>
<tr>
<td>Patient completes initial intake process which includes discussion and order for routine lab testing</td>
<td>Education provided on the prevention of HIV testing in pregnancy</td>
<td>Care team is educated on counseling patients on the importance of HIV testing in early pregnancy</td>
<td>Clinical guidelines for HIV screening embedded in health system</td>
</tr>
<tr>
<td></td>
<td>Educational materials provided regarding HIV testing in pregnancy</td>
<td>Care team is knowledgeable about importance of HIV screening and can reinforce with messaging and materials during well-woman exams</td>
<td>Prepare tool for staff to be used when discussing and offering HIV testing to patients</td>
</tr>
<tr>
<td></td>
<td>Patient educational resources regarding early treatment to prevent mother-to-child transmission</td>
<td>Care team is educated on the cultural differences in the acceptance of HIV testing</td>
<td></td>
</tr>
<tr>
<td>Provider orders HIV test</td>
<td>Patient understands process for obtaining testing, costs, and appropriate timing</td>
<td>Determine and provide proper referral form to appropriate testing site</td>
<td>Identify State/local partnerships that an organization can partner with for HIV screening</td>
</tr>
</tbody>
</table>
## HIV Screening for Pregnant Women

<table>
<thead>
<tr>
<th>Area of Critical Pathway</th>
<th>Patient Changes</th>
<th>Care Team Changes</th>
<th>Health System Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient consents to (or opts out of) HIV testing</td>
<td>Patient presents to appropriate location for testing</td>
<td>Care team is knowledgeable to provide patient counseling (pretest)</td>
<td>Build informed consent into organization’s general consent for care</td>
</tr>
</tbody>
</table>
| HIV test performed on patient | Educational materials provided to explain negative test results:  
- Discuss importance of partner testing and discordance  
- Explain importance of HIV prevention and risk-reduction steps  
- Encourage continuous health care attendance and delivery in health and repeat testing if any risk factors | Care team is knowledgeable and able to provide post-test counselling to explain negative test results:  
- Discuss importance of partner testing and discordance  
- Explain importance of HIV prevention and risk-reduction steps  
- Encourage continuous health care attendance and delivery in health | Opportunities for CEU for care team skills in counseling for HIV test results |
| HIV test results documented in chart | Explain positive test result and provide support:  
- Discuss available MTCT services  
- Discuss importance of partner testing and prevention of sexual transmission  
- Provide information on available treatment, care, nutrition, family planning and support services  
- Encourage health care visits and return visit. | Explain positive test result and provide support:  
- Discuss available MTCT services  
- Discuss importance of partner testing and prevention of sexual transmission  
- Provide information on available treatment, care, nutrition, family planning, and support services  
- Encourage health care visits and return visit. | Community partnerships in place for affordable and convenient lab testing for patients |
|                         |                 |                   | Organized protocols for lab receipt and entry into patient chart |
This toolkit is meant as a guide to help organize ideas, but is also designed to allow flexibility for creative planning.

Note: While an organization may choose to adapt and refine a tool to assist improvement for the measure, HIV Screening for Pregnant Women, testing the measure before fully implementing it offers a way to try something new and modify it before additional resources are spent.

How Can an Organization Make Those Changes?

Earlier in this module, examples are provided of changes (Critical Pathway and Care Model) that have led to improved organizational systems of care and better patient health outcomes. Because every change is not necessarily an improvement, changes must be tested and studied to determine whether the change improves the quality of care. This concept is addressed in detail in the Testing for Improvement module.

It is important that these changes be tested in the context of an organization’s staff, current processes, and patients. The goal is that the change results in lasting improvements within an organization.

Organizations commonly use tools to manage change as they work to improve their systems. For a comprehensive discussion of change management, refer to the Testing for Improvement and Redesigning a System of Care to Promote QI modules. Here are a couple of tools that are worth mentioning in the context of this measure:

1. Small tests of change – Model for Improvement and PDSA (Plan-Do-Study-Act)
2. Process mapping

1. Model for Improvement

The Model for Improvement (28) identifies aim, measure, and change strategies by asking three questions:

<table>
<thead>
<tr>
<th>AIM</th>
<th>MEASURE</th>
<th>CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are we trying to accomplish?</td>
<td>How will we know that a change is an improvement?</td>
<td>What changes can we make that will result in improvement?</td>
</tr>
</tbody>
</table>

These questions are followed by the use of learning cycles to plan and test changes in systems and processes. These are referred to as PDSA (Plan-Do-Study-Act) cycles. The PDSA Cycle is a test-and-learning method for discovering effective and efficient ways to change a current process. In Figure 4.3: The PDSA Cycle, the graphic provides a visual of the PDSA process:
An organization focusing its improvement efforts on **HIV Screening for Pregnant Women** benefits from implementing PDSAs to test change processes that have an impact on mother-to-child HIV transmissions. Those organizational processes tested may focus on outreach, operational procedures, or patient education interventions ensuring that patients have timely access to care. A few examples of such processes relating to **HIV Screening for Pregnant Women** are listed below:

- What is the recall system in place if a prenatal patient *no-shows* for a first appointment?
- What is the process for ordering prenatal testing?
- What is the appropriate content for education regarding **HIV Screening for Pregnant Women**?
- Are there institutional barriers to HIV testing, such as, reporting to a new location, need for insurance coverage, or need for written consent?
- Are there cultural, linguistic, and literacy barriers that the organization may need to address?

As an organization plans to test a change, it should specify *who, what, where, and when* so that all staff know their roles clearly. Careful planning results in successful tests of change. Documentation of what happened – the *S* or study part of the PDSA – is also important. This can help a team to understand the impact of changes to a process as unanticipated consequences may occur.
The case story continues...

**PDSA Cycles in Action:**
Printing new lab slips for prenatal testing was the first PDSA cycle undertaken by the team. At the end of the month, a repeat chart audit showed that 13 out of 13 (100 percent) of Patricia Y.’s initial prenatal patients had HIV testing ordered and documented in their charts. Of those 13 patients, 10 also had HIV test results documented, 1 declined HIV testing, and 2 had no prenatal lab results recorded. The team decided to continue with that procedure and tried other improvements.

Other strategies included discussing with the hospital the possibility of having it sponsor a lab drawing station at the clinic, discussing with the Medicaid office possibilities for streamlining the eligibility determination process, and interviewing women who do not have their prenatal testing done promptly.

**Tips for Testing Changes**
- Keep the changes small and continue testing
- Involve care teams that have a strong interest in improving prenatal care
- Study the results after each change. All changes are not improvements; do not continue testing something that does not work!
- If stuck, involve others who do the work even if they are not on the improvement team
- Make sure that overall aims are improving; changes in one part of a complex system sometimes have an adverse effect in another

2. **Process Mapping**

*Process mapping* is another valuable tool that an organization focused on improvement often uses. A process map provides a visual diagram of a sequence of events that result in a particular outcome. Many organizations use this tool to evaluate a current process and again when restructuring a process. The purpose of process mapping is to use diagramming to understand the current process; i.e., how a process currently works within the organization. By looking at the steps, their sequence, who performs each step, and how efficiently the process works, a team can often visualize opportunities for improvement.

Process mapping can be used before or in conjunction with a PDSA cycle. Often, mapping out the current process uncovers unwanted variation. In other words, different staff may perform the process differently, or the process is changed on certain days or by specific providers. By looking at the process map, a team may be able to identify gaps and variation in the process that have an impact on HIV screening for pregnant women.

Process mapping, when used effectively, can identify opportunities for improvement, supporting the testing of changes in the current system of care. Additional information, including tools and resources to assist an organization in adapting process mapping as an improvement strategy within its organization, can be found in the *Redesigning a System of Care to Promote QI* module.

Both of these improvement strategies are illustrated in Example 4.1:
Example 4.1: Illustrations of Improvement Strategies

Improving recall for patients who “no-showed” for their first prenatal visit

At a small clinic in the Southwest, about 40 percent of prenatal patients in the last year were Latina and only 20 percent of them transferred into care from another provider. The improvement team felt that this may be a group that was not receiving good continuity of care, including appropriate prenatal testing. They decided to look at the process of how women transferring into care were enrolled. The current process mapped by the improvement team was:

1. Patient called or presented requesting prenatal appointment
2. First available appointment given (front desk)
3. Routine no-show policy followed; patient called and given next available appointment (front desk)

The improvement team immediately noticed that no attention was paid to securing records of previous prenatal care or to assessing gaps in care during the current pregnancy. These tasks fell to the provider seeing the patient for the first time. The QI team called the prenatal nurse and front desk personnel together to discuss this issue and the impact it might have on the organization’s performance rate on the measure of HIV Screening for Pregnant Women. The proposed solution was to schedule all new prenatal patients with the prenatal nurse who would request past records, perform a history, and provide appropriate education.

Over the next few weeks, the nurse and front desk staff worked together to ensure patients were seen promptly and appropriately. The nurse’s schedule was changed to allow her to accommodate all first prenatal care visits.

The team strategy was successful. By choosing an improvement and then testing the best ways to make it operational in the clinic, the team improved prenatal HIV testing rates an additional eight percent.

How Can an Organization Know That Changes Caused Improvement?

Measures and data are necessary to answer this question. Data is needed to assess and understand the impact of changes designed to meet an organization's specified aim. Measurement is essential in order to be verified or document that changes are leading to improvements and that the improvements are in the areas intended. It is also important to look for unintended consequences of changes that have been made and to be aware that they can be positive or negative. Organizations that have experienced successful improvement efforts found that data, when shared with staff and patients outside the core improvement team, led to the spread of improvement strategies, in turn generating interest, excitement and momentum in the overall adoption of a culture of quality and continued energy for the organization’s quality improvement program.

Measures are collected prior to beginning the improvement process (the baseline) and continue on a regularly scheduled basis throughout the improvement program (trending over time). Once an organization reaches its specified goal, frequency of data collection may be reduced. Additional information regarding frequency of data collection, tracking, and analyzing data can be found in the Managing Data for Performance Improvement module.
Part 5: Holding the Gains and Spreading the Improvement

Holding the Gains

Once an organization has redesigned the process for prenatal patients accessing care in the first trimester, it can be tempting to move on to other issues and stop monitoring the process. Ongoing monitoring ensures that an organization holds the gains over time.

Although an organization may be able to reduce the frequency of monitoring the process, some ongoing assessment of the measure is necessary to ensure an organization continues to meet its intended goal. Processes that work well now may need to change as the environment shifts. For example, if a new immigrant population moves to the community, processes and strategies may need adjustment to engage that population in prenatal HIV screening. Often organizations designate a staff member(s) to be responsible for monitoring these issues, updating protocols/order sets, and revising the frequency of measurement based on the outcomes reported.

Because all systems are dynamic, they change unless efforts are made to ensure that the improvements continue. Organizations often do a few simple things to ensure that successful changes are embedded in the daily work. Examples include:

1. Change the procedure book to reflect the new care process.
2. Include key tasks in the new process as part of the job descriptions.
3. Adjust the expectations for performance to include attention to quality improvement and teamwork to improve care.
4. Re-align hiring procedures to recruit individuals who are flexible and committed to quality improvement.

The case story continues...

Sustaining Improvements:
After 6 months of work on the HIV Screening for Pregnant Women measure, the team achieved a 96 percent HIV screening rate for the last month, but was at 83 percent for the previous six months. It made significant strides in its improvement project and learned how to design trials efficiently, involve relevant staff and patients, and communicate its results. Successful changes included:

1. Printing standard prenatal testing lab slips, which included the order for HIV testing.
2. Training of appropriate prenatal team members in education and documentation related to HIV testing.
3. Acquiring patient education materials in English and Spanish.
4. Placement of a Medicaid eligibility worker in the clinic by the city health department.
5. Hiring a phlebotomist for all clinic patients.

The team planned to continue its efforts in the coming year and would include the patients of all of the nurse-midwives and then all of the prenatal patients by the end of the year.

Spreading Improvement

Spread can be defined differently based on an organization’s defined target population for the improvement effort. An organization often begins an improvement intervention on a smaller
scale, possibly focusing on one site or one provider’s patient panel, and then increases the population of focus (POF) or the number of providers. Spread can mean spreading improvements to another area of an organization. An organization can still focus on prenatal patients accessing care in the first trimester but also include other or all providers that provide prenatal care. Ideally, others can learn from the initial improvement experience and implement the interventions of the improvement team in their own environments. Spread of this kind is often at an accelerated pace as there is experience about changes that work within the organization.

If an organization has a small number of prenatal patients, it may focus its initial improvement efforts on care for its entire prenatal population. Once it has successfully reached its goal for **HIV Screening for Pregnant Women**, it may choose another measure to improve other aspects of prenatal care. Another option is to target a different topic or another population of patients. An organization may evaluate organizational priorities as it did when initially choosing the **HIV Screening for Pregnant Women** measure and begin to plan for its next improvement effort.

Additional information on **Holding the Gains** and **Spreading Improvements**, including specific resources and tools to support an organization’s improvement program, can be found in the **Redesigning a System of Care to Promote QI** module.

**Part 6: Supporting Information**

**Case Story**

To gain insight into how one QI team approached this measure, review a case study highlighting Big Valley’s Quality Improvement Program and its approach to improving **HIV Screening for Pregnant Women**.

**References**


13. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5145a1.htm
23. Adapted from pre-work manual used in HRSA sponsored Health Disparities Collaborative www.healthdisparities.net
27. Adapted from HRSA Clinical Quality Performance Measures (2009)
   http://www.hrsa.gov/quality/coremeasures.htm
Additional Resources

1. The Web site at CDC presents Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
3. AHRQ provides a summary on Physician Performance Measures
4. The Joint Commission presents relevant information on Performance Measurement in Pregnancy-related conditions at their Web site.
   Murray Enkin, Marc J.N.C. Keirse, James Neilson, Caroline Crowther, Lelia Duley, Ellen Hodnett and Justus Hofmeyr.
6. HRSA HIV/AIDS Bureau offers information on performance measures on their Web site.
7. National and State Maternal and Child Health (MCH) Performance Measures and Health Status Indicators
10. NQF-Endorsed™ National Voluntary Consensus Standards for Physician-Focused Ambulatory Care APPENDIX A – NCQA Measure Technical Specifications, April, 2008 V.7
12. Centers for Disease Control - One Test Two Lives
http://www.cdc.gov/hiv/topics/perinatal/1test2lives/ One Test. Two Lives. provides a variety of resources for providers—as well as materials for their patients—to help encourage universal prenatal testing for HIV.
   Publications: A Guide to the Clinical Care of Women with HIV/AIDS, 2005 edition ... See also A Guide to Primary Care for People with HIV/AIDS, 2004 edition. ...
   hab.hrsa.gov/publications/womencare05/ - Cached - Similar -- also Edited by Jean Anderson, MD
14. Target Center - Technical Assistance for the Ryan White Community -
http://www.careacttarget.org/dataacademy/
15. Women, Children & HIV: Resources for prevention and treatment -
16. National Perinatal HIV Consultation and Referral Service (Perinatal Hotline) - 1-888-448-8765