

Cervical Cancer Screening

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Guidance

Executive Summary

Although cervical cancer used to be one of the most common causes of cancer deaths among US individuals with a cervix, incidence and death rates have declined in recent years, thanks largely to the development of effective cancer screening tests and increased vaccination rates. Despite these improvements, issues related to accessibility, variations in professional guidelines, and human and system errors among key care processes can hinder further progress.

This article discusses strategies to reduce the rate of cervical cancer by improving common pitfalls in patient and provider education, testing policies and procedures, patient follow-up, and error reporting.

More Tools for This Topic

- [Leadership Tool](#) for a Learning Organization
- [Make a Plan](#) action planning template

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Full Text

Cervical cancer used to be one of the most common causes of cancer deaths among US individuals with a cervix; however, the incidents and death rates of US cervical cancer cases have declined by over 50% from 1975 to 2017, thanks largely to the development of the Papanicolaou test (or Pap smear or Pap test)—one of the most effective cancer screening tests available.¹ Further reductions in cervical cancer rates can be attributed to the availability of the human papillomavirus (HPV) vaccination; since its availability, cervical cancer rates in women ages 20 to 24 have shown a decline of 11% per year.² Despite these declines, the American Cancer Society (ACS) estimates 13,490 new cervical cancer diagnoses, and 4,200 cervical cancer deaths in 2026.²

The early detection of cervical cancer remains critical to successfully treating the disease. When detected early, the 5-year relative survival rate between 2015 and 2021 was 91% for cervical cancer classified as localized by the National Cancer Institute's SEER (Surveillance, Epidemiology, and End Results) database, compared with 20% for cancers detected at the distant stage.³ However, access to screening may be limited in certain geographic areas or in certain populations. More than half of new cervical cancers diagnosed in the United States are in individuals who were never screened or who had not been screened in the previous 5 years before receiving their diagnosis.⁴ Thus, many experts believe implementing strategies to increase access to cervical cancer screening—and to guide follow-up evaluation and care—is the most important factor in reducing the rate of cervical cancer in the United States.

Current professional guidelines from organizations such as ACS, the American College of Obstetricians and Gynecologists (ACOG), and the US Preventive Services Task Force (USPSTF) include three approaches to cervical cancer screening: HPV testing alone; Pap testing alone; and HPV/Pap cotesting, which checks the same cell sample for both high-risk HPV types and cervical cell changes. In 2025, ACS included a self-collected testing option that can be done every 3 years. This was added due to advances in screening technology, with a goal of improving access to testing. Additional updates to the guidelines include increasing the interval between screenings to three years for most patients who are screened solely with the Pap test and to five years for patients who are tested for cervical cancer using either the HPV test alone or via HPV/Pap cotesting, beginning at age 30. Because there is not yet consensus among the various guidelines, healthcare providers must be ready to answer patient questions and clarify areas where no consensus has been reached. Guidelines from these organizations as well as from The American Society for Colposcopy and Cervical Pathology are summarized below.

Despite the success of cervical cancer screening methods, these tests are still imperfect tools designed to screen populations rather than definitively diagnose the disease in individuals, and human and systems errors can reduce their reliability. Test tracking and follow-up, obtaining an accurate patient history, and proper documentation are also important factors in cervical cancer screening.

Claims and Litigation

When cervical cancer goes undetected, not only can it compromise patient safety, but it can also result in expensive lawsuits, bad press, and unannounced inspections from regulatory agencies for the healthcare facility. In fact, failure to diagnose and delay in diagnosis of cervical cancer are among the most prevalent types of medical malpractice claims encountered in obstetrics and gynecology; additionally, claims alleging a delay in cervical cancer diagnosis are difficult to defend.⁵

Other areas of physician and laboratory negligence in cytology malpractice lawsuits can include the following^{5,6}:

- Failure or delay in ordering diagnostic tests
- Narrow diagnostic focus or failure to establish differential diagnosis
- Improper sampling/scraping or identification (failure to collect and/or find abnormal cells on a slide)

- Failure to address abnormal findings
- Incomplete patient history or failure to follow up with the patient
- Inadequate patient or family education regarding follow-up instructions
- Patient nonadherence with follow-up call or appointment
- Improper Pap smear processing (including identification, staining, and reviewing previous Pap slides)
- Failure to follow up after examining a slide and noting the presence of few abnormal cells, small or cytologically bland cells, or the presence of obscuring factors such as inflammation or blood
- Erroneous interpretation, comments, or recommendations by a cytotechnologist or pathologist
- Inexperienced or overworked cytotechnologists
- Inaccurate prescreening software
- Inadequate training and supervision of cytotechnologists
- Greater volume of Pap smear specimen
- Absence of a quality assurance program

Many cases arise when a false-negative result is found during review of a prior Pap smear from a patient in whom cervical cancer was recently diagnosed or when an unsatisfactory smear is reported as being normal.⁷ These slides may be susceptible to being interpreted differently by various cytotechnologists and pathologists.

Experts retained to review questioned slides in the context of litigation generally have the advantage of knowing that the patient subsequently developed cancer. Plaintiffs in these cases may allege negligence against one or more pathologists or cytotechnologists.⁶

Cervical screenings can be considered "sensitive exams" that may require medical chaperones. For more information, refer to [Providing Chaperones during Sensitive Examinations and Procedures](#).

Disparities in Cervical Cancer Screening

Despite improvements in cervical cancer screening, diagnosis, and treatment, care disparities still exist, and factors such as race, geographic location, and socioeconomic status can affect screening and treatment accessibility as well as mortality. According to the Centers for Disease Control and Prevention (CDC), "In the United States, Hispanic, non-Hispanic American Indian and Alaska Native, and non-Hispanic Black women have higher rates of new cervical cancer than women of other races and nationalities."⁸ Even greater disparities can exist among these populations depending on the geographic area in which they reside and their socioeconomic status.⁹

Although cervical cancer death rates overall have declined steadily over recent decades, ACS found that the cervical cancer death rates for Black women and Native American women are about 55% and 80% higher, respectively, than for White women.² In addition, ACS states that the incidence rate of cervical cancer is 19% higher in Black women than White women; after correcting for hysterectomy (which is more common in Black women), the incidence rate was approximately 40% higher in Black women than White women.¹⁰

These disparities may exist for a number of reasons, including lack of access to cervical cancer screening, insurance issues, lack of follow-up care, and cultural differences (e.g., mistrust of the healthcare system). Community-based efforts that improve access to screening and vaccination can help narrow the gap.¹¹ For more information, refer to [Engage in Efforts to Increase Access to Cervical Cancer Screening](#) in this article.

Treatment disparities may also exist for transgender men, who are at risk for cervical cancer. Such individuals are less likely to be current on cervical cancer screening than cisgender women, and may face challenges obtaining pelvic exams or Pap tests, as well as accessing gender-affirming healthcare.¹² Studies indicate that transgender men have higher rates of abnormal cervical cancer screening results, higher likelihood of not being screened for cervical cancer in their lifetimes, and lower likelihood of receiving regular cervical cancer screening compared to cisgender women.¹³ Cervical cancer screening for transgender men should follow the same schedule as that for cisgender women.¹²

Regulations and Standards

The Clinical Laboratory Improvement Amendments

Numerous mandates are provided in the federal Clinical Laboratory Improvements Amendments (CLIA) regulatory standards for cytology; some of these are discussed in [Review Laboratory Policies and Procedures](#). In addition, the US Centers for Medicare and Medicaid Services (CMS) has issued survey procedures and interpretive guidelines for laboratories and laboratory services addressing cytology standards, which are available on the [CLIA website](#). Risk managers should be aware that CLIA regulations mandate only minimum standards for laboratories and that guidelines from professional organizations may recommend a higher standard. More information can be found on this subject in the guidance article [Clinical Laboratory Improvement Amendments](#).

Accrediting Agencies

Clinical laboratories can choose to be surveyed by CMS, their state-approved CLIA program, or a private accrediting organization. There are currently seven approved private accrediting organizations¹⁴; laboratories issuing CLIA certificates who choose to be surveyed by private accreditors will receive a certificate of accreditation rather than a certificate of compliance. The College of American Pathologists accredits the most (6,433), followed by COLA (6,017) and the Joint Commission (1,961).¹⁵ These accreditors may have more stringent standards than CMS, such as survey and other quality-related requirements for certificate-of-waiver laboratories or point-of-care-testing-related requirements.

For clinical laboratories that have chosen to be surveyed by an accrediting organization, that accreditor is also responsible for investigating all complaints and determining how serious they are. Situations that should be communicated to CMS include the following¹⁶:

- "Immediate jeopardy situations" (within 10 days)
- Newly accredited laboratories using the accreditation organization's program for CLIA compliance, including specialty and subspecialty information (within 30 days)
- Data related to unsuccessful PT [proficiency testing] performance and actions taken (within 30 days)
- Any adverse actions taken by the organization i. e, denial, temporary loss, suspension, or withdrawal of accreditation, limitation of specialty/subspecialty, etc. (within 30 days)
- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited laboratories (within 30 days)"

Complaints of substantial allegations of noncompliance may be investigated on-site or through communications between the survey organization and the laboratory. A substantial allegation of noncompliance has two elements: "harmful or potentially harmful impact on the health and safety of the general public or the individuals served by the laboratory"; and if it "raises doubt as to the laboratory's compliance with one or more CLIA conditions." Complaint investigations for all survey organizations are unannounced.¹⁷

Federal and State Laws

Coverage of cervical cancer screening tests is required under the Patient Protection and Affordable Care Act of 2010. Likewise, Medicaid or public assistance programs in all 50 states and the District of Columbia cover screening for cervical cancer either routinely or on a doctor's recommendation. Medicare Part B beneficiaries are eligible to receive a Pap test, pelvic exam, and a clinical breast exam every two years; women of childbearing age who have had an abnormal Pap test in the previous three years or who are considered high risk for cervical or vaginal cancer are eligible under Medicare to be covered for yearly screening. Part B also covers HPV screening once every five years for individuals ages 30 to 65.¹⁸

In January 2026, the Health Resources and Services Administration (HRSA) issued new guidelines that included a new self-collect option for collecting samples for screening. HRSA stated that insurance plans will be required to cover the full cost of self-collected HPV screenings beginning January 1, 2027.¹⁹

In addition, the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which is managed by CDC, "provides breast and cervical cancer screening to women without health insurance for free or at very little cost." The program "attempts to reach as many women in underserved communities as possible, including older women, women without health insurance and women who are members of racial and ethnic minorities." If cervical cancer is detected during screening in this program, most states can extend Medicaid benefits to these women to cover the costs of treatment.¹⁸

Action Plan

Download the customizable [Make a Plan: Cervical Cancer Screening](#) to track your implementation of these action recommendations.

Educate Providers About Current Cervical Cancer Screening Guidelines

Action Recommendation: Ensure that primary care providers are aware of the different cervical cancer screening methods, what they test for, and when they are appropriate for use.

Action Recommendation: Ensure that primary healthcare providers are aware of current guidelines for cervical cancer screening.

Screening Methods

There are three overall approaches to cervical cancer screening: Pap testing alone; HPV testing alone; and HPV/Pap cotesting. Healthcare providers should be well acquainted with these methods, what they test for, and when they are appropriate to use.

The Pap test. The Pap test enables clinicians to detect cervical intraepithelial neoplasia so it can be removed before it progresses to cervical cancer. The test also enables detection of cervical cancer at an early stage.

During a Pap test, cells are removed by a healthcare provider (typically a doctor or nurse) by inserting a speculum into the vaginal canal, using a cotton swab to remove excess mucus from the cervical opening, and gently scraping a sample of cells from the cervix. Once the cells are removed, they are prepared for examination using one of two methods:

- In a conventional Pap test, the cells are collected and spread directly onto one or more glass slides. This process can result in less consistent cell distribution and the presence of debris (e.g., blood, mucus), which can result in false negatives.²⁰ In addition, not all cells are transferred onto the slides, slides can be broken during transport, and cells can become damaged before they arrive at the lab for analysis.
- In liquid-based cytology, the cells are placed into a vial of liquid solution, which helps filter out blood and other potentially obscuring materials, prevents the cells from drying out, and can protect the cells during transport.²⁰ The cells are then processed in a lab. This method produces a more homogenous sample that rests on a single layer on the slide, making cells more clearly visible than in conventional Pap testing. In addition, because only a representative portion of the sample is used, the residual material in the vial can be used for other ancillary testing, such as HPV testing.²¹

Pap slides are typically analyzed by a computer-based imager or sent to a cytotechnologist and/or pathologist for review. If no abnormal cells are found, a report describing the findings is made and sent to the referring healthcare provider. If an abnormality is identified, the smear is examined by a pathologist for an independent evaluation. The pathologist describes the nature of the abnormal cells using standardized nomenclature (refer to [The Bethesda System](#)), and a report is sent to the referring clinician.

HPV test. The HPV test detects the presence of certain high-risk strains of HPV, a virus that can cause cell changes that can lead to cervical cancer.²² Genital HPV infection is the most common sexually transmitted infection in the United States.²³ Most HPV infections are transient and benign. However, persistent infection with a high-risk type of HPV can lead to the development of high-grade precursors to cancer or cervical cancer if the precursors are not detected through screening and subsequently treated.²⁴ "Two high-risk HPV types, HPV 16 and HPV 18, are responsible for about 70% of cervical cancers worldwide," and the detection of these genotypes using the HPV DNA test can be a good indicator of a person's risk of cervical cancer. The HPV test is generally performed at the same time as a Pap test.²⁵

An HPV at-home self-collection test has recently been approved by the US Food and Drug Administration for use both at home and in a healthcare facility under supervision of a clinician. The test is designed to improve access to cervical cancer screening. Healthcare providers must still order the test and provide the collection device to the patient. Once the specimen is collected, the test must be mailed to the lab for testing.²⁶

HPV/Pap cotesting. HPV/Pap cotesting checks the same cell sample for both high-risk HPV types and cervical cell changes. Many guidelines summarized below recommend cotesting as the preferred method of screening for cervical cancer in patients older than age 30.

Cervical Cancer Screening Guidelines

Healthcare risk managers should take steps to ensure that providers are aware of the latest cervical cancer screening guidelines as well as the facility's policy on how often patients from different populations should be screened. In addition, they should ensure that the medical staff has accepted and approved the guidelines and incorporated them into the facility's policy. Caregivers should also make every attempt to ensure that patients are involved in decisions regarding care plans, particularly patients who are at high risk of cervical cancer and who must therefore be screened more frequently. Refer to the discussion in [Engage in Efforts to Increase Access to Cervical Cancer Screening](#).

ACS, ACOG, and USPSTF have each published and updated cervical cancer screening guidelines throughout the years regarding screening intervals, when to stop screening, the use of new technology, and the routine use of HPV testing as adjunct to cytology screening. Although cervical cancer screening guidelines have become more consistent across professional organizations in recent years, a 2020 update of the ACS cervical cancer screening guidelines differs substantially from other guidelines by recommending HPV testing as the primary method for screening. Other professional organizations are in the process of re-evaluating their guidelines to determine whether they should better align with ACS's guidelines. Healthcare providers must be ready to answer patient questions and clarify areas where there is no consensus among the various cervical cancer screening guidelines.

American Cancer Society. ACS has provided a revised [Guideline for Cervical Cancer Screening](#) in 2025 for the prevention and early detection of cervical cancer. As mentioned, the most

significant change is that HPV testing is now recommended as the primary method for screening; this is different from past guidelines, where cytology every three years was the preferred method for screening and HPV testing was not recommended as a primary method. These guidelines were again updated in 2025 to include the HPV at-home self-collection test as an alternate, approved method of testing.

The following summarizes the [ACS guideline](#)²⁷:

- Cervical cancer screening should begin at age 25:
 - The preferred method is to undergo an FDA-approved HPV test alone every five years.
 - Where access to primary HPV testing is limited or not available, other options include the following:
 - Self-collected HPV testing every three years
 - Cotesting every five years
 - Cytology alone every three years
- For individuals who are older than age 65, who have had regular screening with normal results, HPV testing should be discontinued. Individuals older than 65 without documentation of prior screening should continue screening until criteria for cessation are met. (Adequate negative prior screening is currently defined as two consecutive, negative primary HPV tests, or two negative cotests, or three negative cytology tests in a row, with the most recent test occurring within the past three to five years, depending on the test used.)
- Individuals who have had a total hysterectomy (removal of the uterus and cervix) should stop screening unless the hysterectomy was done as a treatment for cervical cancer or serious precancer. Individuals who have had a hysterectomy without removal of the cervix should continue cervical cancer screening according to the guidelines above.
- Individuals who have had the HPV vaccine should still follow the screening recommendations for their age group.

Individuals who are at high risk for cervical cancer may need to be screened more often, including those with HIV infection, organ transplant, or exposure to the drug diethylstilbestrol (DES). These individuals should consult with their doctor or nurse to determine an appropriate screening interval.²⁷

American College of Obstetricians and Gynecologists. In April 2021, and reaffirmed in April 2025, [ACOG adopted the USPSTF cervical cancer screening guidelines](#), which recommend the following (ACOG "Guidelines")²⁸:

- All relevant individuals should begin cervical cancer screening at age 21.
- Individuals age 21 through 29 should have cytology alone every three years. HPV testing is not recommended for this age group. However, because primary hrHPV testing is approved for use starting at age 25 years, primary hrHPV screening every 5 years can be considered as an alternative to cytology-only screening in average-risk patients aged 25 to 29 years.
- For individuals aged 30 through 65, any of the following options can be chosen:
 - Cytology alone every three years
 - FDA-approved primary hrHPV testing alone every five years
 - Cotesting every five years
- Individuals older than 65, who have no history of moderate or severe abnormal cervical cells or cervical cancer, and who have had either three consecutive negative Pap test results or two consecutive negative cotest results within the past 10 years, with the most recent test being performed within the recommended screening interval for the test used, do not need to be screened for cervical cancer.
- Individuals should not follow the above guidelines if they have any of the following: a history of cervical cancer, an HIV infection, a weakened immune system, or an exposure to DES before birth. These populations may require additional screening.
- Those who have had a hysterectomy with removal of the cervix do not need to be screened as long as there is no prior history of high-grade cervical precancerous lesions or cervical cancer.

In response to the HRSA's women's preventive services initiative guidelines to include self-collected HPV tests, Steven J. Fleischman, MD, MBA, FACOG, president of ACOG, released the following statement²⁹:

"While ACOG recognizes the exciting potential of self-collected high-risk HPV testing to expand cervical cancer screening access, we acknowledge that the appropriate infrastructure must be in place to promptly connect people using at-home testing to follow up testing and treatment when indicated. Increasing screening access without established systems to provide follow-up testing and treatment could delay diagnosis and treatment and prove detrimental to patients.... ACOG supports the new language in HRSA's recommendation that requires no cost-sharing for any additional testing and pathological evaluation needed as a result of the initial findings of a screening."

US Preventive Services Task Force. USPSTF is a federally appointed panel of independent experts. In 2018, USPSTF [updated its cervical cancer guidelines](#); as of this writing, these guidelines are in the process of being updated. The following is a summary of the 2018 guidelines (USPSTF)³⁰:

- All relevant individuals should begin cervical cancer screening at age 21. USPSTF recommends against screening for cervical cancer before age 21.
- Individuals age 21 through 29 should have a Pap test alone every three years. USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with the Pap test, in individuals younger than age 30.
- Individuals aged 30 through 65 should be screened every three years with the Pap test alone, every five years with high-risk HPV (hrHPV) testing alone, or every five years with hrHPV testing in combination with Pap testing (cotesting).
- Individuals older than age 65 who have had adequate prior screening and are not otherwise at high risk for cervical cancer should not be screened. However, further screening may be indicated for women older than 65 who have not been adequately screened. USPSTF estimates that approximately a quarter of women aged 45 to 64 have not been screened for cervical cancer in the preceding three years. In particular, women with limited access to care, women from racial/ethnic minority groups, and women from countries where screening is not available may be less likely to meet criteria for adequate prior screening.
- Individuals who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion or cervical cancer should not be screened for cervical cancer.

USPSTF notes that its recommendations still apply regardless of a person's sexual history or HPV vaccination status. The recommendations do not apply to individuals who have received a diagnosis of high-grade precancerous cervical lesion or cervical cancer, individuals with in utero exposure to DES, or individuals who are immunocompromised, such as those who are HIV positive.³⁰

The American Society for Colposcopy and Cervical Pathology (ASCCP). ASCCP endorses the 2018 USPSTF recommendations, supports the ACS cervical cancer screening guidelines, and the April 2021 ACOG Practice Advisory. The following is a summary of ASCCP's recommendations³¹:

- All relevant individuals should begin cervical cancer screening at age 21. ASCCP does not recommend screening before age 21.
- Individuals ages 21 through 25 should have cytology alone every three years.
- For individuals ages 25 through 29, the preferred method is to undergo an FDA-approved HPV test every five years. It is also acceptable to undergo cotesting every five years or cytology alone every three years.
- Individuals aged 30 through 65 should be screened every three years with cytology alone, every five years with cotesting, or every five years with primary HPV testing.
- Individuals older than 65 who have had adequate prior screenings and are not otherwise at high risk for cervical cancer do not need to be screened.
- Individuals who have had a prior total hysterectomy do not need to be screened unless they have a history of high-grade cervical dysplasia or cervical cancer.

Educate Patients About the Importance of Cervical Cancer Screening

Action Recommendation: Educate patients about the nature of the Pap and HPV tests as screening tools.

Action Recommendation: Provide patients with information about cervical cancer risks and the importance of periodic cervical cancer screening, even if they've been vaccinated.

Action Recommendation: When recommending at-home HPV testing, provide detailed instructions for patients and ensure that patients have someone to contact, if necessary.

Because cervical cancer screening is so effective in reducing the risk of patient mortality from cervical cancer, it is important to educate adult patients on the importance of periodic cervical cancer screening. However, patients should also be informed that the Pap test and the HPV test are not 100% accurate; therefore, a yearly wellness visit should always be scheduled to ensure that the patient is in good health and to detect any warning signs of cervical cancer. In addition, patients should be educated on how to recognize subtle symptoms of gynecological cancers (e.g., abdominal pain/pressure, vaginal bleeding, skin changes, bloating, frequent urination), and on how to contact their healthcare providers to ensure such symptoms are addressed.

It is also important to emphasize to patients that it is still necessary to get screened even if they have had the HPV vaccination.³² While the vaccine protects against many types of HPV, it does not protect against all of them, and no vaccine is 100% effective. In addition, the vaccine does not treat any existing HPV infections present before vaccination.³³

When communicating information about cervical cancer screening, it is important to do so in a way that patients can understand. Language, hearing, or vision barriers should be documented in the patient's medical record, and the organization should address such barriers with multilingual clinicians, interpreters, language lines, translated written materials, or other strategies.

A number of resources are available for patients, including resources from [US Centers for Disease Control and Prevention](#), [the American College of Obstetricians and Gynecologists](#), and [the American Cancer Society](#), that explain how testing is performed, the efficacy of the tests, and why it's important to be screened for cervical cancer. In addition, the [Chronic Care Model](#) can be utilized to promote patient engagement and goal-oriented care.

According to the [National Cervical Cancer Coalition](#), patients should take the following steps to ensure the best and most accurate results from a Pap or HPV test²⁵:

- The test should be scheduled on a day when the patient is not menstruating. If the patient's period begins unexpectedly and will continue on the day of the test, attempts should be made to reschedule the exam for a different day.
- The patient should avoid sexual intercourse in the 48 hours before the test.
- The patient should not douche in the 48 hours before the test.
- The patient should not use tampons or vaginal creams, foams, films, or jellies (such as spermicides or medications inserted into the vagina) for 48 hours before the test.

When recommending self-collection HPV tests, physicians should ensure that patients receive detailed instructions on how to perform the test correctly and should be available to answer any questions. An infographic from NCCC, [HPV Screening with Self Collection](#), can help aid physicians when instructing patients on how to perform the cell collection at home. In addition, patients should be instructed to call the office if they have any questions before or while administering the self-collection; staff should be available to return patient calls in a timely manner.

Engage in Efforts to Increase Access to Cervical Cancer Screening

Action Recommendation: Create opportunities for diagnosis by developing and implementing strategies for primary care providers to identify and offer cervical cancer screening to individuals who have never been screened or whose screening status is uncertain.

The early detection of cervical cancer is critical to successful treatment of the disease. When detected early, the five-year relative survival rate for cervical cancer is 91% at the localized SEER stage, compared to 20% for cancers detected at the distant stage.³ However, access to screening may be limited in certain geographic areas or in certain populations. More than half of new cervical cancers diagnosed in the United States are in individuals who were never screened or who had not been screened in the previous five years before receiving their diagnosis.⁴ Many experts believe that because of this, implementing strategies to increase access to cervical cancer screening—and to guide follow-up evaluation and care—is the most important factor in reducing the rate of cervical cancer in the United States.

Socioeconomic status and financial limitations can play an important role in whether patients are routinely screened for cervical cancer. Studies have shown that patients who are income restricted or uninsured, have limited formal education and limited health literacy, face cultural and language barriers, have fearful misconceptions about cancer, or distrust healthcare providers comprise a population at risk of becoming lost to the system and experience delayed diagnosis of cervical cancer. Additionally, those without insurance are more likely to be diagnosed with late-stage cervical cancer than those who are privately insured.⁹ (For more information, refer to the guidance articles [Culturally and Linguistically Competent Care](#) and [Health Literacy](#).) To help alleviate financial hardships, programs like the NBCCEDP exist, which can help income restricted or uninsured individuals or those in underserved communities secure much needed healthcare appointments and cervical cancer screening. Providers can do their part to help identify underserved women who may have such financial issues and direct them to programs like the NBCCEDP.³⁴ For more information, refer to [Federal and State Laws](#).

Various methods can be employed to increase cervical cancer screening rates. These can include sending reminder cards, sending invitation letters to new patients, utilizing patient portals, launching a promotional campaign to promote cervical cancer screening awareness, using campaigns to remind patients to schedule their screenings, providing face-to-face education on the benefits of cervical cancer screening at a patient's appointment, using a clinical decision support system, and providing opportunities for group education.³⁵ Organizations can also implement

patient navigators and community health workers as trusted community members to provide information, support, and encouragement to patients related to receiving screening tests and improving health literacy. In addition, providing targeted health education sessions and campaigns can help improve community knowledge about cervical cancer and other gynecologic cancer.

Self-administered HPV tests are one tool that has shown to improve screening rates. According to ACS, studies indicate that self-collected vaginal specimens demonstrate similar sensitivity and specificity compared to clinician-collected specimens and can increase patient participation in screening. One systematic review found that, in 40 of 42 studies, self-collected primary HPV testing increased the proportion of participants completing cervical cancer screening. In addition, screening rates were generally greater among individuals who were underscreened or who were from traditionally underscreened populations. As a result, ACS found that self-collection can be an avenue to improve cervical cancer screening access, equity, and adherence.³⁶

Healthcare organizations should also promote cervical cancer screening to transgender men, and to improve the patient experience for such individuals by promoting a more supportive setting. Such efforts may include using gender-affirming language, interviewing the patient prior to disrobing, investigating methods to make the pelvic exam less uncomfortable for this population, and asking the patient to change from the waist down only.¹² In addition, during appointments, the organization's electronic health record should prompt the provider to schedule appropriate screenings for any anatomical structure that is present (e.g., Pap test for a transgender male).

Review Laboratory Policies and Procedures

Action Recommendation: Ensure that cervical cytology laboratory results are clearly and accurately documented and communicated to the referring healthcare provider using a reporting nomenclature such as the Bethesda System.

Action Recommendation: Review laboratory policies and procedures to ensure compliance with CLIA regulations and to ensure that documentation of clinical history is required on requisition forms to identify patients at high risk of cervical cancer.

Action Recommendation: Determine whether appropriate mechanisms are in place to reduce the risk of misidentification of Pap smear slides in the laboratory.

To avoid litigation related to cervical cancer misdiagnosis, it is important to be proactive throughout the screening process—from taking a patient's history to following up in a timely manner with a patient after receiving test results. It is also important that cytology laboratory reports contain clear terminology, a proper interpretation of the Pap smear slide, a clearly stated recommendation by the laboratory, and a proper clinical follow-up by the ordering clinician. Several areas were identified by The Doctors Company as common areas where mistakes can be made that can expose the facility to litigation: patient profile, screening recommendations, management of abnormal Pap test/smear, appropriate follow-up, documentation, and communication.⁵

Patient profile. To avoid risks, a complete patient history should be taken, and patients at high risk for cervical cancer should be identified and closely followed. Treatment of high-risk patients includes providing adequate HPV and HIV screening, timely Pap smears, yearly pelvic exams, and comprehensive patient education.⁵

In addition, the documentation of patient clinical history on laboratory requisition forms is a significant area of liability risk for primary care providers and laboratories. CLIA specifies that requisition forms for laboratory tests must include the following³⁷:

- "The patient's name or unique identifier
- The sex and age or date of birth of the patient
- The test to be performed
- The source of the specimen, when appropriate
- The date and time of specimen collection
- For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy
- Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable"

Absence of the patient's clinical history may increase the risk of delayed or missed diagnosis if a test result from a patient with a history of abnormal Pap tests, biopsy, or treatment is reviewed only once by a cytologist. However, obtaining a comprehensive patient history may be challenging, as patients may have seen multiple healthcare providers and may have incomplete records. Educating clinical staff and patients on the important role of clinical history in cervical cancer screening may result in improved documentation.

Screening recommendations. The Doctors Company recommends that clinicians adhere to recommended cytology guidelines (for more information, refer to [Cervical Cancer Screening Guidelines](#)), but notes that these recommendations do not preclude the need for comprehensive yearly exams.⁵

Management of abnormal Pap test/smear. Clinicians should follow up with patients who have abnormal screening results. Such patients should be retested with the appropriate testing and follow-up regimen, as indicated by current guidelines.⁵

Appropriate follow-up. According to The Doctors Company, establishing a reliable mechanism for tracking diagnostic testing and test results will significantly reduce exposure to claims asserting delay in diagnosis. Such a mechanism must ensure that all diagnostic studies, consultations, and test results are received and reviewed, and that the results are sent to and reviewed by the physician before they are placed in the patient's chart.⁵

Documentation. The Doctors Company states that, in many scenarios, "an otherwise medically defensible claim is compromised by inadequate documentation." Documentation should seek to "create a chronological word picture of the assessment, diagnosis, treatment plans, and outcomes," and should detail the following⁵:

- Instructions to the patient (e.g., follow-up, further testing, referral to specialist) and clinical care decisions
- Any telephone instructions provided
- Signed consent forms that specify the risks, benefits, and alternatives of the diagnostic study or treatment
- Informed consent conversations
- Medical rationale supporting the clinician's assessment, the diagnosis established or pending, and the treatment plan and subsequent alterations in conjunction with the patient's clinical status
- The patient's understanding of the need for subsequent studies
- When documenting, the clinician should ask the question, "Will I be able to justify my actions retrospectively?"

In addition, risk managers should be aware of a document from the [American Society of Cytopathology](#) that discusses guidelines for review of gynecologic cytology samples in the context of investigation, litigation, or potential litigation. The guidelines emphasize that the reporting of a false-negative Pap smear is not necessarily evidence of practice below the accepted standard of care and should be made available to defense attorneys, liability insurers, and healthcare risk managers involved in selecting or retaining experts to review Pap smears.³⁸

Communication. It is important that all members of the clinical team and the patient communicate effectively, particularly when conveying a cancer diagnosis. Clinicians should be ready to allow the patient time to process the news while still providing written information about therapeutic options and support resources for the patient.⁵ Ariadne Labs' [Serious Illness Care Program](#) is a multicomponent, structured communication intervention that consists of a [Serious Illness Conversation Guide](#) for providers and a [What Matters to Me: A Workbook for People with Serious Illness](#) for patients.

CLIA Requirements

Risk managers should be aware of requirements under CLIA and review laboratory policies and procedures to ensure compliance. For details, refer to [42 CFR § 493.1274](#). Additional information about CLIA can be found in [The Clinical Laboratory Improvement Amendments](#).

The Bethesda System

To ensure appropriate clinical management of the patient, the results of Pap tests must be clearly and accurately documented and communicated to the referring healthcare provider. The Bethesda System is the standard classification system used to report cervical cytology results. It was developed to unify the terminology used for reporting results and thus aid in managing cervical epithelial abnormalities. First proposed in 1988, it has undergone several revisions. Most recently revised in 2014, this terminology includes the following³⁹:

- **Specimen adequacy.** Each laboratory must report whether the sample was adequate and if the quality of the smear was satisfactory. Clinicians should check whether the test has been marked "satisfactory" or "unsatisfactory."
- **Interpretation/results.** This is where most of the important findings are reported. There are four sections: negative for intraepithelial lesion or malignancy, other—endometrial cells present in a woman age 45 or older, epithelial cell abnormalities, and other malignancies.
- **Squamous abnormalities.** These include atypical squamous cells of unknown significance (ASCUS), cells where HSIL or high-grade changes cannot be excluded (ASC-H), low-grade squamous intraepithelial lesion (LSIL), HSIL, and squamous cell carcinoma.
- **Glandular abnormalities.** These include atypical cells, not otherwise specified (AGC); atypical cells, favor neoplastic; adenocarcinoma in situ; and adenocarcinoma.
- **Other malignancies.**

The Bethesda System includes more than just terminology to report Pap test results. As an aid to achieving accurate and uniform interpretation of Pap smears, a joint task force of the American Society of Cytopathology and the National Cancer Institute developed the [Bethesda System for Reporting Cervical Cytology: Online Access](#)—a web-based collection of cervical cytology images, complementing its Bethesda System atlas of images, educational materials, references, sample reports, and other items. The web-based collection includes hundreds of images, including "classic" examples of an entity as well as images that were selected to illustrate interpretive dilemmas or "borderline" cytomorphologic features that may not be interpreted the same way by all pathologists.⁴⁰ The collection also includes a self-test to allow users to compare their interpretations of specimens with those of others.

Avoiding Patient Misidentification

Patient identification errors are common and can pose a significant threat to patient safety. Clinically significant misidentification errors can occur at any point in the laboratory testing process. Factors that may contribute to specimen mislabeling in the laboratory can include the following (ECRI and the ISMP PSO)⁴¹:

- Failure to have or to follow protocols
- Labeling of samples by nonlaboratory personnel
- Batch processing of multiple specimens
- Centralized label printing
- Poor handling or disposal of labels

The following are some best practices to reduce the likelihood of patient identification errors; these recommendations can apply to cytology collection (ECRI and the ISMP PSO)⁴¹:

- Use two patient identifiers (e.g., patient name and date of birth) to confirm the person's identity at the beginning of each encounter.
- Avoid "leading" the patient when asking for identifiers—for example, use statements such as, "Please tell me your name and date of birth," instead of, "Are you John Doe?"
- Confirm patient's identity before labeling specimen containers. Staff should not label containers until the specimen has been collected. After double-checking identification information for the patient, attach the label to the container in the patient's presence. It's best to carry multiple preprinted specimen labels for only one patient at a time so the wrong one is not used.

Follow Up with Patients

Action Recommendation: Encourage physicians and other healthcare providers who perform cervical cancer screening to notify patients about when to have their next screening.

Action Recommendation: Evaluate policies and procedures concerning follow-up after screening tests to ensure that patients receive their results and that patients requiring additional care are not lost to the system.

Because cervical cancer is most treatable when it is caught early, providers must emphasize to patients the importance of scheduling and receiving periodic screening. ACOG states that healthcare providers should encourage patients to complete studies essential for patient care, such as Pap tests and mammograms, within an acceptable time frame, and that offices providing such services should establish a simple, reliable tracking and reminder system to facilitate communication, improve patient safety and quality of care, and minimize missed or delayed diagnoses.⁴²

In addition, it is important to follow up with patients about their cytology results, and follow-up appointments should be scheduled, as necessary. Many facilities are using patient portals to notify patients of test results, although notifying a patient with a letter or phone call is also acceptable, provided that the method adheres to the regulations in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). For information on tracking results from outside laboratories, refer to the guidance article, [Test Tracking and Follow-Up](#).

According to ACOG, the following characteristics are important for any reminder system, whether electronic or paper based⁴²:

- **"Policies and procedures.** An office policy and procedure on tracking should be developed with input from the staff. All office members should agree to follow the same protocols. The

policy should address how to contact the patient and how to document the follow-up in the patient's chart. Time frames for when to expect test results should be defined, and a protocol should be established for handling delayed or missing reports.

- **HIPAA compliance.** When contacting patients, whether by mail or electronically, health care providers and their staff must follow the [HIPAA] regulations. Care also must be taken to limit the amount of information disclosed by way of voice mail or to other individuals who may answer the call without prior consent. Instead, it may be preferable to leave a name and telephone number, asking the patient to call the office.
- **Specificity.** The reminder system should contain specific data and dates, including the dates for receipt of information and timelines for notifying the patient.
- **Central Location.** The reminder system should be centrally located in the office and should not be kept in individual patient charts. Reminders should be accessible to the entire staff.
- **Reliability.** The tracking system should not be the responsibility of a single individual. Office staff should be cross-trained so that the system is reliable and efficient. It should be updated and monitored regularly."

ACOG also states that practitioners should remind patients about the importance of keeping any postoperative visits and other follow-up appointments and should document any instances of a missed appointment in the medical record. Providers should also attempt to contact patients who miss appointments to help them reschedule.⁴²

Foster Nonpunitive Error Reporting in a Safety Culture

Action Recommendation: Foster the development of a safety culture that embraces nonpunitive reporting for laboratory system problems and errors.

Risk managers should ensure that staff and employees who identify and report system problems and errors are appropriately acknowledged for their efforts. Reporting such errors should be viewed as more than fulfilling regulatory requirements; it should be seen as necessary for patient safety. The organization should foster a supportive, nonpunitive culture and a true accountability to deliver safe patient care. To embed such a culture requires true leadership commitment to build and maintain the trust of staff. For more information, refer to [Event Reporting](#).

* Situations that pose an imminent and serious threat to patient health or a significant hazard to the public

Related Resources

Risk Manager's Toolbox

- [Ready, Set, Go: Cervical Cancer Screening](#)
- [Make a Plan: Cervical Cancer Screening](#)

Guidance, Assessments, and Training

- [Culturally and Linguistically Competent Care](#)
- [Event Reporting](#)
- [Event Reporting in Aging Services](#)
- [Health Literacy](#)
- [Obstetrical Liability](#)
- [Test Tracking and Follow-Up](#)
- [The Clinical Laboratory Improvement Amendments](#)

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Classifications

DIAGNOSTICS, THERAPEUTICS AND EQUIPMENT

Diagnostic Equipment | Diagnostic Techniques and Procedures | Clinical Laboratory Techniques

DISCIPLINES AND OCCUPATIONS

Pathology, Clinical | Gynecology