American Society for Clinical Pathology

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The Pap Smear: A Life-Saving Test

The Papanicolaou or Pap smear test for cervical cancer has saved tens of thousands of lives since it was introduced in the early 1940s. Deaths from cervical cancer have decreased by more than 70% over the last 50 years during which the screening test has been widely used. Like every other medical test, however, the Pap test is not infallible.
Recent media coverage regarding several mishandled Pap smear tests in Milwaukee, Wis., may have cast doubt on the accuracy and reliability of Pap smear testing in the U.S. When properly done, the Pap smear test detects about 95 percent of cervical cancers and precancerous conditions. Yet, any test result is only as reliable as the individuals performing the procedure and many people are involved in a Pap smear test. Following are the approved procedures for this complex test.

The Pap smear test is a microscopic examination of a prepared glass slide containing a smear of cells. When the test is conducted according to professional guidelines, the cell sample is collected by a skilled physician or nurse from the opening and the outer portion of a woman's cervix. The Pap smear test is ideally part of a complete pelvic examination and cannot replace clinical examination by a physician.

Upon arrival at an accredited laboratory, the slide is appropriately stained to make the cells visible under a microscope. A certified cytotechnologist then examines the slide -- inspecting the entire sample for abnormal cells. Each smear contains from 50,000 to 300,000 cells and any abnormality is marked for further inspection by a board certified pathologist or cytopathologist (a specialist in cytology). Finally, results are carefully reported to the attending physician for appropriate patient follow-up.

Each step of the test is critical. First, the sample must be adequate, containing sufficient cells from the cervical area. Inadequate samples may result in an incomplete evaluation and are the major cause of inaccurate Pap smear results. The problem of inadequate samples can be minimized by the use of fairly new standardized terminology for reporting Pap test results. Called the Bethesda System, this reporting method was developed in 1988 by a panel of cytopathologists and cytotechnologists and the National Cancer Institute and requires a statement on the adequacy of the specimen. As a result, samples which are inadequate for interpretation, or less than optimal, will be clearly noted. In the event of an inadequate sample, another test should be performed.

Once obtained, the sample must be fixed on a labeled slide and the patient's medical history, including her age, risk factors and obstetrical and gynecological information, should accompany the slide to the laboratory. There, each sample is recorded to ensure proper identification and, if available, information on the patient's previous

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smears is retrieved to include with the history. These samples are then stained, cover-slipped, and dried in preparation for microscopic screening.

Next, cytotechnologists inspect the sample, systematically searching for abnormalities in the cells that may signal cancerous or precancerous conditions. This procedure requires appropriate education, experience and sufficient time to carefully examine and locate abnormal cells. To visualize this screening, imagine finding one or two misspelled words or misplaced punctuation marks in a 100,000 word manuscript. Any slide that raises a question of abnormality must be reexamined and interpreted by a pathologist.

Even among highly qualified certified cytotechnologists and board certified pathologists and cytopathologists, there is the possibility for error. These are known as false positives and false negatives. In false positives, abnormalities thought to be present do not actually exist. For example, the cellular changes which often indicate a cancerous condition prove, upon further examination, to be caused by a benign condition such as inflammation.

In the more dangerous false negatives, an abnormality is present but not detected. This may be due to inadequate samples, poor preparation or staining techniques, failure to detect abnormal cells or an interpretive error. Even in the best of laboratories, under the best conditions, there is a small but irreducible false negative rate. This is why the American Society for Clinical Pathology (ASCP) recommends an annual Pap smear test for all women who are or have been sexually active or who are 18 or older. Because cervical cancer usually develops very slowly, the yearly Pap smear test helps minimize the potential impact of a false-negative report. As with most diseases, the earlier cancerous or precancerous cervical conditions are detected, the greater the likelihood of a cure.

Concerns raised by the media about the quality of cytology testing services, especially Pap smears, was a major catalyst behind passage of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88). Under CLIA'88, all clinical laboratories must meet standards based on the complexity of the tests which they perform. Approximately 10,000 laboratory test systems, assays and examinations were evaluated and categorized into one of three major groups -- waived, moderate complexity or high complexity. The seven criteria used to determine test complexity took into account the characteristics and complexity of the test materials, instruments and procedures used; the knowledge, training and experience needed to perform the test; and the degree of interpretation and judgment required in the testing process.

The Pap smear test is categorized as a high complexity procedure. This means that inaccurate or erroneous test results are likely if the test is improperly performed or interpreted and that inaccurate or improperly interpreted tests could result in significant harm to the patient. Employing qualified personnel to perform the test and

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adhering to approved quality control procedures is critical. Good laboratories employ qualified personnel, allow sufficient time for screening, do not offer financial incentives to speed screening and rigorously follow approved laboratory methods and quality assurance procedures.

A woman can help assure the quality of her Pap smear sample by scheduling the exam at the optimum time, between the 12th and 16th days of the menstrual cycle. For best results, abstaining from intercourse for 24 hours and avoiding use of vaginal contraceptive products, medications and douches for 72 hours prior to the exam are advised.

- To aid in the accurate interpretation of the test, the patient should ask her physician these pertinent questions:

  Does the laboratory employ nationally certified cytotechnologists? Certification by the ASCP Board of Registry means that the cytotechnologist has completed academic requirements as well as clinical laboratory training and passed a national examination. Surveys show that certified personnel perform the most consistently accurate tests.

- What information accompanies the sample to the laboratory? The Pap smear test depends on human judgment, and the interpretation of the test sample is based in part on an accompanying patient history relating to cervical cancer risk factors. These include: onset of sexual activity at an early age, multiple sex partners and previous incidence of sexually transmitted diseases -- particularly condyloma (cervical warts) caused by the human papilloma virus (HPV).

- Will I receive a copy of the test results and an explanation of what they mean? Patient and physician should discuss test results and plan the next steps required. In the case of normal tests, scheduling an appropriate timetable for future examinations and Pap smears is important.

An abnormal Pap smear test does not necessarily mean cancer is present but that additional attention and interpretation is required. Follow-up on abnormal smears may include colposcopy (an examination of the vagina and cervix using a colposcope, a modified microscope, to directly observe the cervix under magnification), biopsy or repeat cytologic studies. If cancer or a precancerous condition is verified, specialists will advise on an appropriate course of therapy which may include surgery.