Course Title: Thin Prep PAP Smears

Number of Clock Hours: 3
Course Title #5240303

Course Introduction

There is a new laboratory test that is gaining popularity as a cancer screening tool for cervical cancer. This course reviews the importance of the familiar Papanicolaou (PAP) stain and well as introducing the professional to the Thin Prep technique.

Course Objectives

Upon completion of this continuing education course, the professional will be able to:

1. Appreciate the importance of following the correct procedures for performance of the PAP smear.

2. Explain how the Thin Prep system is an improvement.

3. Compare the advantages of the conventional PAP smear over the Thin Prep system.

4. List the disadvantages of the conventional PAP smear when compared to the Thin Prep system.

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Thin Prep PAP Smears

The Papanicolaou (Pap) test is the most effective cancer-screening test in medical history. The incidence of cervical cancer detection by means of the Pap smear has reduced cervical cancer by seventy percent during the past fifty years (Blair, 53). The Pap test begins with a physician or other healthcare provider collecting a sample of cells from the cervix. These cells are squamous epithelial cells. When stained with Pap smear dyes, normal healthy squamous cells can be differentiated from cancer cells (squamous cells with intraepithelial lesions).

The extremely successful Pap smear has been improved. In 1996 and 1999, the FDA approved the Thin Prep Pap Test and the AutoCyte PREP System, both liquid-based Pap tests that replace the conventional Pap smear method. These new technologic developments in Pap testing offer improved detection of cervical disease (Blair, 53). In order for practitioners in the medical field to effectively implement the newest techniques, it is important to understand them and to follow the procedures accordingly.

Conventional Pap smears do not have a high degree of sensitivity for detection of squamous intraepithelial lesions (cancer cells) (Tench, 912). It is important to continuously seek the newest methods of cervical cancer in order to decrease the incidence of this disease in women.

Squamous intraepithelial neoplasia and cancer of the cervix are problems in sexually active mature women (Vassilakos, p. 11). Regular screening of asymptomatic women for cervical cancer by means of the conventional Pap smear has effectively reduced cervical cancer in the past one half century by as much as 70 percent, quite significant progress in this important field. However, the conventional Pap smear is not sensitive enough to detect precancerous abnormalities, resulting in the further development in disease before the woman seeks more testing and treatment, and some of the slides are not usable. The Pap smear method has brought considerable improvement in the situation, but the more effective Thin Prep tests enable practitioners to fine-tune the process, gaining a higher degree of detection, earlier in the disease process. This higher detection is extremely important for the higher quality of life of the women served and their reproductive health as well.

Conventional Pap smears are inexpensive and easy to perform. Insurance companies readily reimburse the small fee. Among the medical community, there has been some uneasiness that perhaps the newer Thin Prep tests would be too expensive and that Medicare and insurance companies would not want to pay for the newer test.

How do the conventional Pap smears work? The conventional Pap smears are spread directly onto a glass slide, which is interpreted, by a histologist or cytologist in the lab, tying up considerable person hours. In contrast, the newer methods use mechanized robot-like machines to interpret the results, speeding up the process considerably. Some professionals have been uncertain about the accuracy of the speedier Thin Prep semirobotic testing (Blair, 54). Conventional smears sometimes result in an uneven distribution of cells on the slide, as they are manually spread directly onto a glass slide. However, the AutoCyte PREP and ThinPrep (the two brand names) allows the clinician to place the Pap sample directly into a liquid medium, which is sent to the pathology laboratory. In the lab, a processor makes a homogeneous thin-layer slide specimen and discretely stains each thin-layer specimen, yielding a final product that is ready for evaluation by the cytotechnologist (Blair, 54).
How is this relevant to your work as a medical assistant? Early detection of cancer is an extremely important area of medical assisting, as the quality of reproductive life and quality of life in general is greatly diminished by cervical cancer. Women have learned to have the Pap smear every year (sometimes more frequently) in order to forestall possible cancer but the thought of greatly increasing the efficiency and sensitivity of such testing is indeed exciting and relevant for all medical professionals.

Earlier detection means earlier intervention, and less disease for the women served. As the baby boom population swells into late maturity, more and more women will want these tests and reliable results. The semiautomatic nature of the Thin Prep lab work and interpretation means that the ultimate expense in time spent will be less. It likely as the newer methods and processes are streamlined the costs will go down, and the new method will be more or less comparable to the conventional Pap smear, causing little difficulty with insurance reimbursement.

Regardless of the cost, the aim of medicine is always to improve and protect the health of the women served, and it is very likely that the Thin Prep liquid-based methods assist in that aim, as they are more efficient and higher in reliability without over-diagnosing.

Four recent research projects evaluated the effectiveness of the AutoCyte PREP method and one study looked at the Thin-Prep method of Cytyc Corp. Research reported by Hessling summarizes a split-sample, blinded evaluation of matched thin-layer preparations and conventional smears from 2,438 patients. This particular study was enriched by including 260 cases of high-grade squamous intraepithelial lesions and cancer cases from an earlier study. Some of those cases were difficult to diagnose, revealing very few abnormal cells on the slides. In this study the preparations were evaluated multiple times by both cytology professionals and relatively inexperienced evaluators in order to determine whether or not the degree of experience of the lab person would change the interpretation of the smears (Hessling, 880). The results showed that the lesser-experienced evaluators found equivalent performance between the conventional Pap smear and the liquid-vial method. However, the experienced cytologists were able to demonstrate a statistically significant improvement in detection of both low grade and high-grade squamous intraepithelial lesions using AutoCyte PREP slides (Hessling, 886).

The next AutoCyte research study (Marino and Fremont-Smith) shows greater sensitivity with the AutoCyte method. Of the 15,534 AutoCyte PREP cases that were collected, the AutoCyte PREP demonstrated a statistically significant increased detection of low grade squamous intraepithelial lesions (47 percent) and high grade squamous intraepithelial lesions (116 percent) when compared to conventional Pap smears processed during the same time period (Marino & Fremont-Smith, 358). These increases are important. The researchers concluded that the AutoCyte method was better and resulted in fewer unsatisfactory smears (as is sometimes a problem with the conventional Pap smear method).

A study performed in January of 1999 by W. Tench reveals similar results to the previous two—“In routine use, AutoCyte PREP is both practical and significantly more effective in the detection of squamous intraepithelial lesions as compared with conventional Pap smears” (Tench, 912). 10,367 cases using conventional Pap smears were compared to results of 2,231 cases using AutoCyte PREP thin-layer slides for the next year. Biopsy follow-up data were reviewed when they were available. Tench concurs with Marino and Hessling, that the overall quality of cellular presentation was much improved using the
liquid vial method, eliminating many unsatisfactory slides, and the degree of detection was significantly better (Tench, 916).

Other researchers found similar results. Large patient groups from the same population were studied using the conventional Pap smear method versus the AutoCyte method. Cytologic results were compared to histologic diagnosis to estimate the relative sensitivities and specificity of the preparations. The findings were the same as the others summarized, plus the finding that overdiagnosis (false positive) was not a problem (Vassilakos, 16).

The study of a different brand, Thin-Prep manufactured by Cytyc Corp of Boxborough, Massachusetts, analyzed 400 split samples. The paired samples were separated, and independently analyzed and classified. If there was surgical pathology material available, it was reviewed and compared to the cytologic diagnosis (Biscotti, 9). The Thin-Prep showed significantly more abnormal results (22 percent), including more atypical squamous cells of undetermined significance (9.5 percent). The Thin-Prep method showed no false negatives (Biscotti, 13). The conventional Pap smear showed a few false negatives, meaning that some of the women had cancer of the cervix but it was not detected by the Pap smear. Biscotti and his colleagues concluded that the Thin-Prep method is superior to conventional Pap smears.

To put this all together even further, all of the AutoCyte studies and the Thin-Prep study revealed that the degree of detection is higher with the liquid-vial method, without over diagnosis. Clinical trials with the ThinPrep test showed a 65 percent increase in the detection of precancerous epithelial cell abnormalities and a 50 percent reduction in unsatisfactory specimens. Studies using the AutoCyte PREP show increased detection of precancerous and cancerous lesions of the cervix, a 39 percent decrease in unsatisfactory slides, and a 44 percent decrease in suboptimal specimens (Blair, 54).

Are these new tests reimbursed by insurance companies? Congress approved a raise in the Medicare payment for Pap smears to $14.60, more than double the previous payment. Collection devices add approximately $8 to $10 to the cost for the liquid vial method, but the increased efficiency in processing makes the additional cost of materials insignificant. Labor costs are less for the liquid-vial method because of the robot like mechanical method of processing the slides. Insurance coverage for liquid-based Pap tests is becoming more prevalent with a higher reimbursement than for conventional Pap smears (Blair, 55). Blair reports, as well, that an imaging system is under development, an instrument, which will scan and evaluate cervical specimens for diagnostic interpretation. This sensitive machine will zero in on only the sections of the slide that the cytologist needs to look at. Only slides prepared by the ThinPrep processor can be submitted for ThinPrep imaging interpretation. Another company, Veracel, Inc., is developing a similar system, but the FDA has not yet approved either system.

The conventional Pap smear is an alternative method to the liquid-vial methods. Its efficiency and reliability is well-known. It has done a great deal to reduce the incidence of cervical cancer in women, is easy to use, and reliable, if not particularly sensitive. TriPath Imaging has manufactured AutoPap, a computerized scanning device which is approved by the FDA for use in scanning conventionally prepared Pap smear slides, assisting the cytologist with diagnostic interpretation. This machine performs the primary analysis of conventional Pap smears and selects out abnormal slides that need to be reviewed by the cytotechnologist and cytopathologist (Blair, 56).
Should medical practices shift to this new method of detecting cervical cancer? A medical practice would do well to change over to either of the two types of thin prep Pap tests, if the insurance ramifications pose no difficulties for the practice or the patient. The slight logistical inconvenience of becoming accustomed to different materials, methods, and interpretation are very much worth the increased detection. Medical assistants may need to learn how to handle the vials and submit to the labs, but it is worth the effort because of the higher level of detection.

The consumable supplies for both ThinPrep and AutoCyte are designed and supplied by the respective companies. Collection of the cervical sample for a ThinPrep Pap Test is done with either a small broom like device or a plastic spatula and an endocervical brush device. The AutoCyte PREP System uses a broom like device such as Cervex Brush (Blair, 53). This small device is like a brush, which is used to lift sample cells from the woman’s cervix.

Instead of smearing the uterine cervical sample directly on a slide, as in the conventional method, the collection device is simple placed into a vial of liquid preservative. The ThinPrep Pap Test uses methanol preservative solution, and the AutoCyte PEP uses an ethanol-based preservative. The clinician rinses the collection devices in the preservative fluid and discards the collection device. The clinician places the brush into a transport vial that removes the brush head entirely from the applicator stick. The vials are then capped and transported to the laboratory for processing and slide preparation. The patient’s sample can be preserved in the liquid vial for several weeks until the slides are prepared.

In the laboratory, a semiautomated robotic system prepares thin layer slides from the fluid sample. Cytyc’s processor, the ThinPrep 3000 is capable of preparing up to 80 gynecologic slides very quickly. It reads a bar code from the sample vial and prints and verifies the number on the ThinPrep microscope slide before process in order to eliminate the possibility of slide mislabeling (Blair, 54). The AutoCyte automated system also stains the slide, further saving personnel time.

In contrast to a conventional Pap smear, the end result for both automated systems is a representative slide with minimal cervical mucus, red and white blood cells, and epithelial cellular clumping. Such advantages allow the cytotechnologist to see only the material needed in order to make a valid judgment (Blair, 54). Such efficiency improves the diagnosis dramatically, as extra material makes the slide difficult to read.

It seems that using the liquid-vial method of cervical testing will greatly improve the detection for cervical squamous cells in gynecology patients. The differences in cost are small, and difficulties in insurance claims, payment, and coverage can be handled after an initial adjustment time period. It is predicted that a medical staff can learn the new procedure rather quickly.
Questions
Thin Prep and PAP Smears #5240303

1. What is the purpose of Pap smears?
   a. To test for pregnancy
   b. To test for cervical cancer
   c. To test for heart disease
   d. All choices

2. Which is not an advantage of the new methods of Pap smears?
   a. Lower cost
   b. Higher detection rates
   c. Earlier detection
   d. None of the choices

3. Cervical squamous epithelial cells are normally __________ cells.
   a. optical
   b. healthy
   c. cancer
   d. pre-cancer

4. Research shows that the newer thin prep Pap smears are better than the previous method.
   a. True
   b. False

5. The new method of Pap smears is __________.
   a. slightly less expensive than the previous method
   b. much less expensive than the previous method
   c. much more expensive than the previous method
   d. slightly more expensive than the previous method

6. Which tool is used in the new thin prep method?
   a. A slide
   b. A microscope
   c. A small brush
   d. Sterile glass

7. With the thin prep method, after taking the cervical specimen, it is placed in a(an) __________.
   a. vial
   b. envelope
   c. spoon
   d. none of the choices
8. Laboratory processing for thin prep Pap smears is faster because __________.
   a. the employees are less skilled
   b. the materials are less expensive
   c. it is partly automated
   d. the technicians work on overtime

9. With the older method of Pap smears, the specimen is placed on a __________.
   a. table
   b. database
   c. slide
   d. brush

10. AutoCyte PREP and ThinPrep are __________.
    a. clinical laboratories
    b. research companies
    c. types of surgical needles
    d. brand names

11. A false negative means that there is cancer and it was not detected.
    a. True
    b. False

12. The new thin prep Pap smears have __________.
    a. greater accuracy
    b. earlier detection
    c. more sensitive detection
    d. All choices

13. The former method of Pap smears sometimes results in __________.
    a. premature detection
    b. extra material on the slide
    c. cure for the condition
    d. None of the choices

14. Thin prep Pap smear methods have been __________.
    a. adequately researched
    b. researched with human subjects
    c. through clinical trials
    d. All choices
15. Pap smears have reduced the incidence of cervical cancer in women ________ during the past 50 years.
   a. 10 percent
   b. 20 percent
   c. 50 percent
   d. 70 percent

16. An alternative device for specimen gathering with the thin prep method is a(an) ________.
   a. envelope
   b. syringe
   c. spatula
   d. slide

17. Thin prep Pap smears would be an aspect of a gynecology practice.
   a. True
   b. False

18. Thin prep Pap smears are ________ than the previous method.
   a. as sensitive
   b. more sensitive
   c. equally sensitive
   d. less sensitive

19. Clinical trials with the ThinPrep test showed which of the following?
   a. A 65% increase in detecting precancerous epithelial cell abnormalities
   b. A 50% reduction in unsatisfactory specimens
   c. Neither
   d. Both

20. Women should generally get a Pap smear how often?
   a. Every 3 months
   b. Every 6 months
   c. Once a year
   d. Every 10 years

*end of test*