

“Cancer screening is one of our most effective tools against cancer.”

New Mexico Ob/Gyn

CHAPTER

3

Cervical Cancer Screening

Screening Method and Guidelines

Pap Smears

Pap smear screening is a rapid method for detecting cervical dysplasia and *in situ* cancer, as well as invasive cancer. A Pap smear evaluates cells harvested from the ectocervix and endocervix for abnormal changes associated with the development of cervical cancer. The introduction of the Pap smear 50 years ago is largely responsible for the national decline in cervical cancer mortality.

Frequency of Pap Smear Screening

In 1988, consensus recommendations were developed by the American College of Obstetricians and Gynecologists, the American Nurses Association, the American Cancer Society, the National Cancer Institute, the American Medical Association, the American Academy of Family Physicians, and the American Medical Women's Association. Recommendations include:

- All women who have been sexually active or who have reached 18 years of age should have an annual cervical smear (Pap) and pelvic examination.
- After a patient has had three or more consecutive, satisfactory, normal annual examinations, the cervical smear may be performed less frequently at the discretion of her health care provider. The U.S. Preventive Services Task Force (USPSTF) recommends that the Pap test be performed at least every three years, depending on the presence of risk factors for cervical cancer (1996). Pelvic exams should continue as routine practice.
- There is insufficient evidence to recommend for or against an upper age limit for screening, but recommendations can be made on other grounds to discontinue regular testing after age 65 in women who have had regular previous screening in which the smears have been consistently normal (USPSTE, 1996).
- When considering the effectiveness of Pap smear screening after total hysterectomy for benign disease, there are conflicting guidelines. However, "the practice of vaginal cytology screening after hysterectomy for benign disease does not meet the criteria of the US Preventive Services Task Force as indicated by the low burden of suffering of vaginal carcinoma, the lack of mortality data suggesting vaginal cytology screening alters the natural history of disease, and unfavorable test characteristics," (Fetters et al., 1996). A review of vaginal smear supported the recommendation that routine surveillance should be considered only for women with a history of cancer of the genital tract or *carcinoma in situ* because of their increased risk of disease (Pearce et al., 1996).

Recommendations for Screening

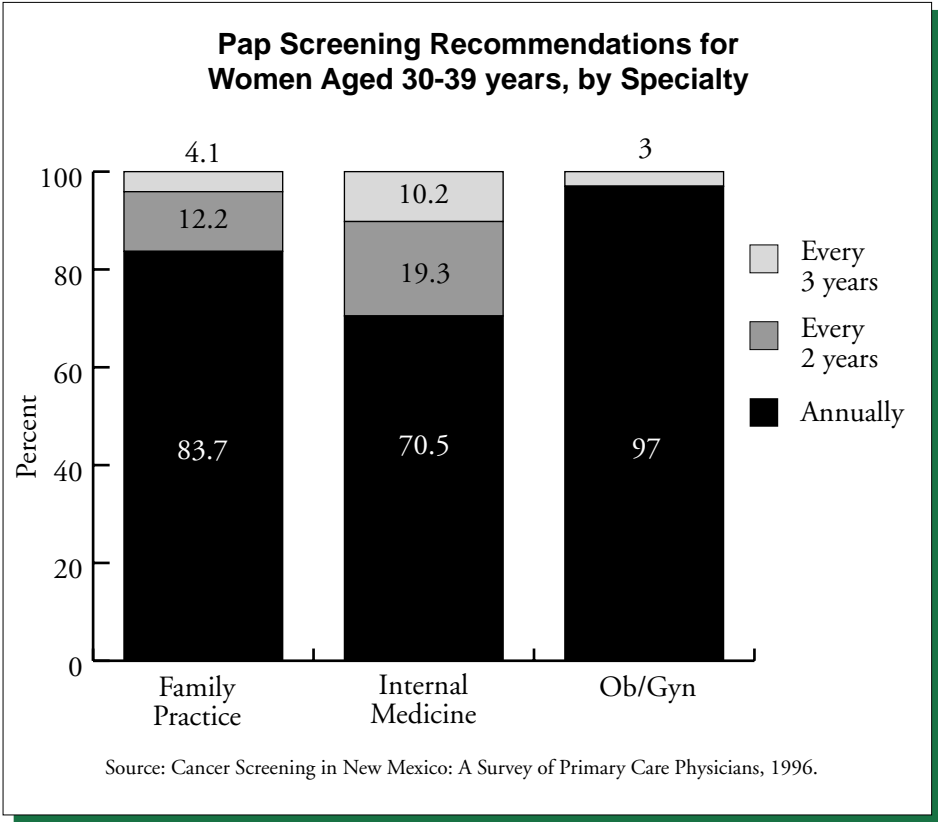
The New Mexico Health Care Provider's Perspective

The following information on pages 24-28 is taken from “Cancer Screening in New Mexico: A Survey of Primary Care Physicians” conducted in 1996. Because primary care physicians play an essential role in cancer prevention and screening, their recommendations and practice have major implications for New Mexico's women.

Eligible respondents were practicing physicians specializing in internal medicine, family medicine and obstetrics and gynecology (Ob/Gyn). Eligible respondents spent greater than 30% of their time in primary care and had graduated from medical school in 1993 or earlier. Of the 592 eligible physicians, 89 internal medicine, 123 family practice and 67 Ob/Gyn responded for an overall response rate of 47%. Recommendations for cervical cancer screening varied by specialty and patient's age.

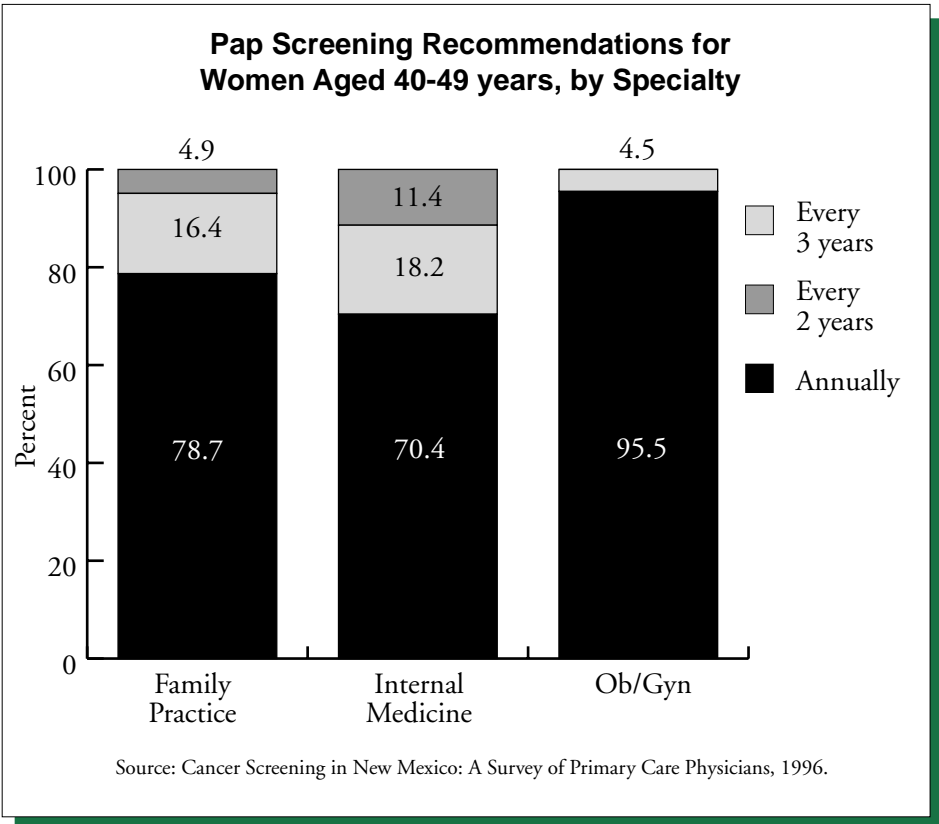
Pap Screening Recommendations for Women Aged 30-39 Years, by Specialty:

The vast majority (97%) of Ob/Gyns recommended annual screening compared to 70.5% of internists and 83.7% of family practice physicians.



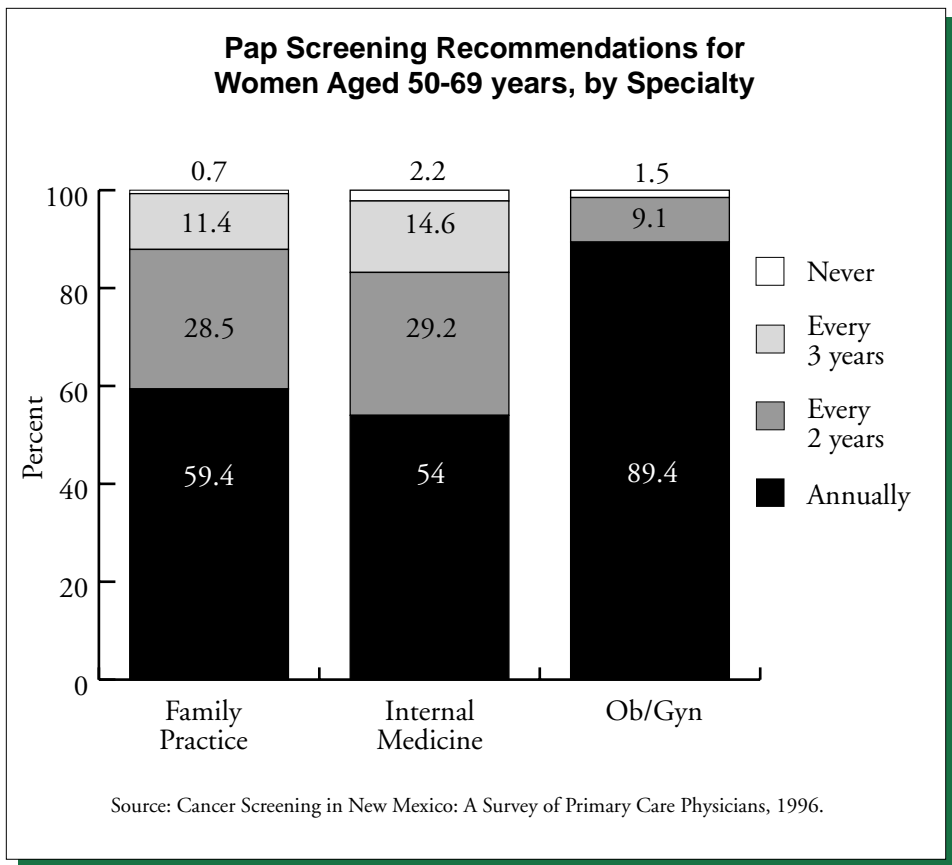
Pap Screening Recommendations for Women Aged 40-49 Years, by Specialty:

This variation by specialty continued with this age group of women. Ob/Gyns continued to recommend annual screening while only 78.7% of family practice and 70.4% of internal medicine physicians recommended annual screening for their patients.



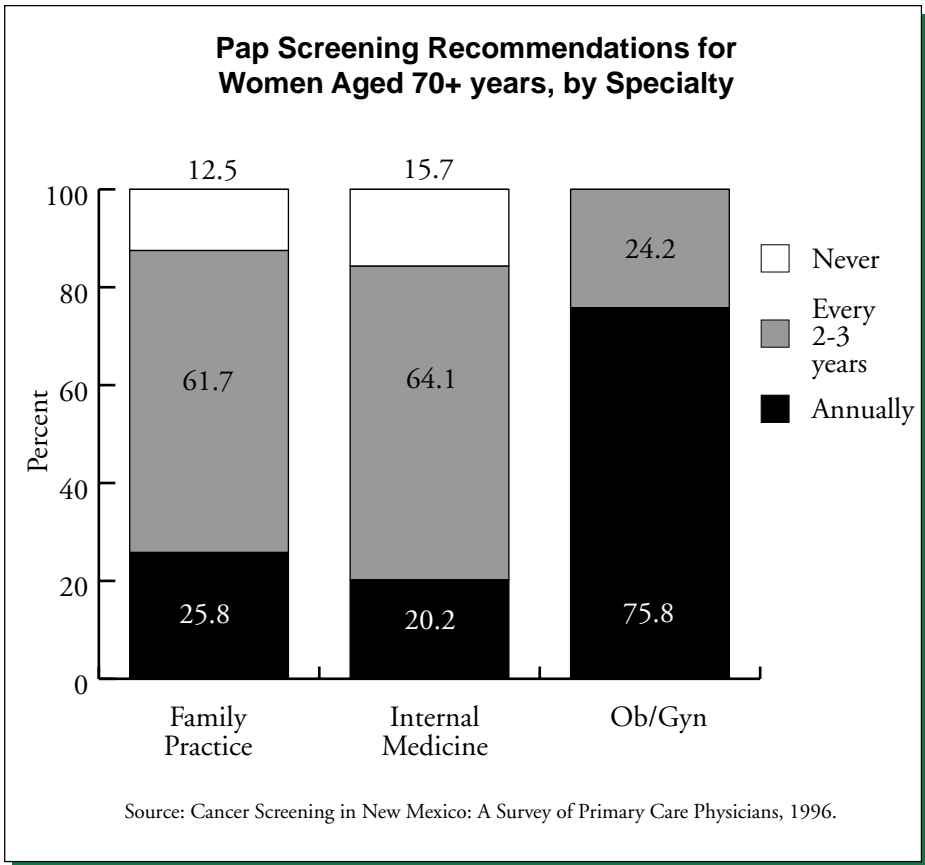
Pap Screening Recommendations for Women Aged 50-69 Years, by Specialty:

As a patient ages, family practice and internal medicine physicians increasingly recommend less frequent Pap smear screening. This is consistent with the recommendations that screening can be performed less frequently at the discretion of the health care provider and based on the patients' risk factors. A small percent (2.2% of internal medicine and 0.7% of family practice physicians) no longer recommend any screening for women in this age group.



Pap Screening Recommendations for Women Aged 70+ Years, by Specialty:

Physicians were asked “If a woman has consistently normal Pap smears, at what age do you stop Pap smears?” Almost all (97%) Ob/Gyns and over half of family physicians (52%) and internists (51%) reported that they did not stop screening. For those who continued to screen for cervical cancer over the age of 70, 75.8% of Ob/Gyns continued to recommend annual screening while the majority of internists (64.1%) and family practice physicians (61.7%) recommended less frequent screening.



Overall, the majority (77%) of physicians reported they had cancer screening policies or protocols in their practices. Only 6.3% reported that they did not need policies. Ob/Gyns most frequently reported having a screening policy for cervical cancer (73.1%), followed by internists (67.8%) and family practitioners (57.7%). Several studies have shown that those physician practices that have screening policies in place are more likely to use them. However, tracking and reminder systems may play a more important role in increasing preventive care in busy primary care practices. With the trend toward increased quality assurance monitoring with managed care, practices should develop consistent standards that are measurable and supported by the medical literature.

For further information on the survey results contact:

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Screening Methods

Patient Preparation before the Appointment

When an appointment is scheduled for a Pap smear, the patient should be advised that the likelihood of getting a high quality Pap smear is increased by putting nothing in the vagina for 48 to 72 hours prior to the examination.

Patient Preparation for a Pap Smear

- No intercourse or other penetrative sex
- No tampons
- No douching
- No vaginal medications or lubricants
- No vaginal contraceptive

The Patient Education Page at the end of this handbook provides first step information to patients who are scheduled for or are considering a Pap smear.

Patient Preparation before the Examination

Knowing what will occur during the examination helps the patient relax, reduces anxiety, and makes performing the examination easier. Helping the patient keep warm and comfortable also helps her relax, easing the examination. As physical discomfort and embarrassment have often been stated as reasons women do not return for regular screening or recommended follow-up, the following information should be considered when preparing the patient for the exam.

- ✓ Conduct the sexual history and as much of the education and other discussion as possible while the patient is fully clothed. Under these circumstances she is likely to be more open and comfortable in her discussion.
- ✓ Ask the patient whether she has had a Pap smear before. Explain that the examination includes inspection of the external genitalia, vagina, and cervix, as well as performance of a Pap smear and a bimanual examination. Make sure the patient understands the terminology.
- ✓ Show the speculum to the patient. Explain how it works and the sounds it makes—the rattle of the metal speculum's knob, the clicks of the plastic speculum.
- ✓ Explain that the examination should not be painful, although it may be uncomfortable.

- ✓ Ask the patient to let the health care provider know if she experiences pain; the technique may be altered or the problem may be solved by something as simple as removing a hair caught in the speculum.
- ✓ Encourage the patient to ask questions at any time before, during, or after the examination. Many patients are unlikely to raise questions or concerns unless explicitly invited to do so by their health care provider.
- ✓ Introduce any additional persons in the room. Explain their purpose for being there, and in the case of students, ask permission.
- ✓ Be explicit about how much to disrobe. This will prevent the patient from fully disrobing unnecessarily.
- ✓ Draw curtains (especially if the table faces the door) and provide drapes to ensure modesty.
- ✓ Cover metal footrests with cloth—socks or oven mitts may be used—to protect bare feet.
- ✓ Provide a blanket if the patient is cold and especially if she must wait for the health care provider.
- ✓ Provide a pillow for lower back or head support.
- ✓ Inquire if the patient would be more comfortable sitting with the back of the table raised up slightly. With the table at a 33 degree angle, the health care provider and patient will be able to see each other's faces without constricting the abdomen.

Pap Smear Collection

The most important step in cervical cancer detection is obtaining a quality Pap smear by using correct collection techniques. Always label the slide with a graphite pencil with the patient's name before the Pap smear is taken. Warm the speculum with either a heating pad or warm water. Avoid the use of lubricants since they can inhibit the proper staining of cellular material on the slide. Proceed at a relaxed pace and explain each step of the procedure to the patient.

To ease insertion of the speculum, have the patient relax the vaginal muscles. Ask the patient to squeeze her vaginal muscles around the inserted finger as if she's holding back urine and then ask the patient to relax these muscles (Kegel exercise). Pull down gently on the perineum, enlarging the vaginal opening. Insert the speculum over the inserted finger at a 45° angle. Then adjust closer to 90° to locate cervix, as finger is removed. Maintain downward pressure on the speculum throughout the examination. After inspecting the cervix, if necessary, gently and carefully use a large cotton applicator to remove excess mucous secretions from the cervical os. Do this without disturbing the epithelium and prior to obtaining the smear.

When removing the speculum, return it to a 45° angle before it exits the vagina.

Effective collection and evaluation are not inseparable. Approximately two-thirds of “false negative” Pap smears of the cervix are due to sampling (i.e., collection) problems while one third is due to laboratory error.

Interacting with the Patient During the Examination

- ✓ Explain each step before and during the examination (“I’ll be inserting the speculum now. You’ll feel some pressure.”).
- ✓ Each time contact is initiated, warn the patient that she will be touched (“I’m going to touch you now.”). Touch in a neutral spot, such as the thigh, before proceeding to the genitals. This practice conveys respect and sensitivity and helps the patient relax.
- ✓ Minimize touching, in general.
- ✓ Make a “V” in the drape. This facilitates interaction between the patient and health care provider during the examination and allows the health care provider to see facial expressions that may reveal symptoms not expressed verbally.
- ✓ Maintain frequent eye contact.
- ✓ Do not interact with an assistant or student *about* the patient in front of her. Always include the patient in any discussions about her examination.
- ✓ Avoid language that has painful, violent, or sexual connotations and medical terminology that might not be understood:
 - Speculum *bills*, rather than *blades*.
 - Tighten the knob* on the speculum, avoiding the word *screw*.
 - Examine*, rather than *feel* or *palpate*.
 - Insert* or *place*, rather than *stick in* or *put in*.
 - Remove* rather than *withdraw* or *pull out*.
 - Table*, not *bed*.
 - Footrests*, not *stirrups*.
 - Relax your legs open*, not *spread your legs*.
- ✓ Point out anatomy to the patient and explain anatomical terms that may not be fully understood, such as cervix and urethra.
- ✓ After the examination, explain that there may be some spotting as a result of the Pap smear.

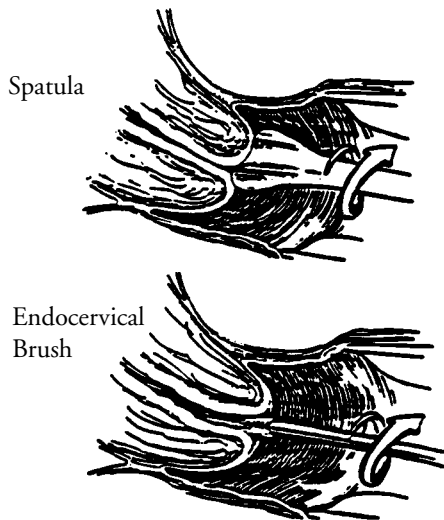
Obtaining the Pap Smear

It is most important that an adequate sample be taken from the squamocolumnar junction (the transformation zone), transferred to the cytology slide, and immediately fixed with a commercial fixative.

The location of the squamocolumnar junction can be identified by a change in color and texture between the squamous and columnar epithelia. The squamous epithelium appears pale pink, shiny, and smooth. The columnar epithelium appears reddish with a granular surface.

- ✓ Have the slide, endocervical brush, and spatula in hand. Collect the ectocervical sample before the endocervical sample. Wait to fix the slide until both specimens have been collected. Use a commercially prepared cytology fixative. Avoid the use of hair spray or other fixatives.
- ✓ If the squamocolumnar junction cannot be identified, place the elongated edge of the spatula into the cervical os; press firmly and rotate 90-180 degrees.
- ✓ If the squamocolumnar junction is identified on the ectocervix, obtain the sample using the same end of the spatula. Make sure that the spatula stays in contact with the ectocervical surface.
- ✓ Obtain the endocervical sample using the endocervical brush. Place the brush gently in the cervical os and rotate 90-180 degrees to ensure that all of the endocervical canal is sampled. This is particularly important if the health care provider finds an enlarged or gaping endocervical os.

Obtaining a Sample Using the Spatula and Endocervical Brush



Special Considerations

- For a patient who has had a **hysterectomy**, use the regular elongated tip of the spatula to scrape the area of the vaginal cuff with special attention to the crypts of the cuff.
- For a patient who has a **lesion** on the vaginal wall, use a **separate spatula** to scrape the margins to secure cells. **Prepare a separate slide and laboratory form.** Describe the lesion and location. Refer for evaluation.
- For a patient who has **vaginal/cervical dryness**, moisten the cervical spatula with normal saline.
- For a patient who is **pregnant**, use the regular elongated tip of the spatula, the endocervical brush for endocervical collection, or a cotton tip applicator moistened in saline to collect the endocervical specimen. Do not force the brush into the os.
- Collect the Pap smear prior to other samples for wet mounts or testing for **sexually transmitted diseases**.
- For a patient who is menstruating, if it is unrealistic for her to return at another time, clean the blood off the cervix using gauze or sponge forceps.

In the presence of frank bleeding, the Pap smear should be obtained as cancer cells may be present. However a negative Pap smear does not exclude cancer in this situation. Symptoms that may be due to neoplasia should be completely evaluated.

If the patient has an active vaginal infection, the accuracy of the Pap smear may be significantly reduced.

An inadequate Pap smear should be repeated, particularly for a patient who has previously had an abnormal Pap test.

Slide Preparation

When using one slide for Pap smear collection, transfer material to the slide as follows:

- ✓ Transfer the cellular material from the spatula down the length of the slide.
- ✓ Turn the spatula over to superimpose material in the same manner.
- ✓ Transfer the cellular material from the endocervical brush onto the same slide by rolling the endocervical brush from left to right.

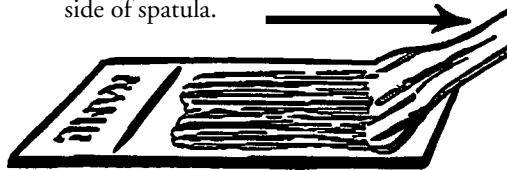
Avoid zigzagging motions with all samples.

Proper fixing is vital. Spray with fixative **immediately** since air-dried cells cannot be interpreted. Use commercially prepared cytology fixatives (hair spray is not a fixative and should not be used). Hold the spray container at least 10 inches away to ensure coating and to prevent dispersal and destruction of the cells by the propellant. No more than 5-10 seconds should elapse between smearing and spraying of the slide. When fixing the slide, leave the slide flat to avoid washing cells down one side. If fixative leaks off the slide while lying flat, too much fixative may have been used. **Protect the frosted end of the slide** with your thumb or paper while spraying (the preliminary lab number can wash off during processing if fixative is applied to the frosted end of the slide).

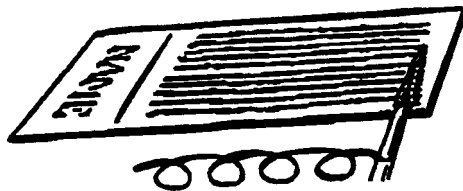
Air dry the slide completely before wrapping. Slides should be flat while drying. Place the slide in the center of the mailer.

The Two-Step Method for Spatula and Endocervical Brush

- 1 Spread material from each side of spatula.



- 2 On same slide, roll endocervical brush.



Reporting Systems and Terminology

The Bethesda System

As our understanding of cervical cancer and its precursor lesions has evolved, a variety of reporting systems for cervical cytology has emerged. When large-scale cervical cytology screening was introduced in the 1950s, the reporting system devised by Dr. Papanicolaou was used almost exclusively. This consisted of a numerical reporting system of five classes, expressed as the Roman numerals I through V with Class I denoting no cytologic abnormality and Class V denoting cells diagnostic of malignancy. The classification system was based upon the detection of malignant cells on cervical smears; the issue of precancerous lesions was not addressed.

As cytology gained acceptance as a diagnostic method, cytopathologists advocated replacing the numerical system with readily understandable diagnostic terms. With the emergence of the concept of cervical precursor lesions, James W. Reagan, MD, promulgated the use of the term “dysplasia” to designate these intraepithelial lesions. Morphologic criteria were delineated for slight, moderate, and severe dysplasia and for squamous cell *carcinoma in-situ* (CIS), based upon the assumption that dysplasia and CIS were separate lesions in behavior and, possibly, in etiology.

Although some cytopathologists claim diagnostic success with use of this system, studies have shown a lack of interobserver reproducibility in subdividing cervical intraepithelial lesions into the five separate diagnostic categories:

- I. Human Papilloma Virus (HPV) effect
- II. Slight
- III. Moderate
- IV. Severe dysplasia
- V. *Carcinoma in situ* (CIS)

As the reporting terminology became more complex, laboratories that were unwilling to abandon the Papanicolaou classification system modified it and created their own versions of the Papanicolaou numerical classes. Thus, communication among pathologists was often confusing at best. In December 1988, the National Cancer Institute sponsored a workshop to address this “diagnostic confusion” and to develop a uniform reporting system for cervicovaginal cytology which became known as The Bethesda System.

Subsequently, modifications were made after a second meeting convened in 1991. The Papanicolaou numerical class system is **no longer acceptable** for reporting diagnoses.

The Bethesda System is considered to have the following advantages:

- A uniform diagnostic terminology to improve communication both among cytopathologists and between cytopathologists and health care providers.
- A descriptive diagnosis of atypical squamous cells of undetermined significance (ASCUS) and of atypical glandular cells of undetermined significance (AGUS).
- The inclusion of changes associated with Human Papilloma Virus (HPV) such as koilocytosis along with cervical intraepithelial neoplasia (CIN) within the category of low-grade squamous intraepithelial lesion (LGSIL). In other words, use of terminology that reflects current understanding of the pathogenesis and biology of cervical neoplasia.
- Evaluation of specimen adequacy as an integral part of the report.
- Consideration of the report as a clinical consult.

The terms “low-grade squamous intraepithelial lesion” (LGSIL) and “high-grade squamous intraepithelial lesion” (HGSIL) are used to describe the categories of squamous cell precursors of cancer. These were previously categorized as dysplasia (with the degree described), CIS, and cervical intraepithelial neoplasia (CIN).

Pap Smear Terminology Comparison Chart

Expected Histology	Bethesda System	CIN System
Unknown	Unsatisfactory (Reason Given)	Unsatisfactory
Normal	Within Normal Limits Benign Cellular Changes: Infection, Reactive Change	
Squamous Metaplasia		
Atypia Squamous Metaplasia	Atypia (ASCUS) (AGUS)	
Mild Dysplasia	Low Grade SIL: HPV Mild Dysplasia	CIN1
Moderate Dysplasia	High Grade SIL: Moderate Dysplasia	CIN2
Severe Dysplasia		Severe Dysplasia CIS
Carcinoma In Situ (CIS)	Squamous Cell Carcinoma Adenocarcinoma	CIN3
Invasive Cancer		

Quality Control in the Laboratory

Effective Pap smear collection is extremely important for detecting cervical abnormalities and providing timely treatment. Effective collection includes:

- ✓ Appropriate timing in the menstrual cycle to collect a sample of cervical and endocervical cells (including the zone of transformation) without excessive debris.
- ✓ The proper application and fixation of that sample to a slide.
- ✓ The proper (including labeling) and timely submission of the slide to a qualified laboratory.

Effective evaluation is dependent upon the adequacy of information about the patient's history as well as current information (e.g., last menstrual period, hormonal therapy) provided with the smear(s). In addition, accurate reading (as measured by false positive and false negative rates) of adequately collected smears and the timely reporting of clearly written results to the submitting health care provider are important.

Cytotechnology Laboratory Quality Assurance

Laboratory Effectiveness

Accurate statistics about quality of cytology laboratories in New Mexico are not available. Laboratories in the state have, however, informally reported "false negative" rates from 10% to 25%. These rates correlate well with national rates reported in the medical literature. Laboratory-associated "false negatives" most frequently occur with low-grade lesions.

In a large national study, the quality of 74% of smears was considered "satisfactory," 25% "satisfactory with limitations" that often required repeating, and 1% "unsatisfactory" that definitely required repeating (Curtis, 1993).

Current Regulations for Laboratory Quality Assurance

The final regulations for the Clinical Laboratory Improvement Act of 1988 (CLIA 1988) were published in the Federal Register on February 28, 1992. These regulations defined the minimum quality assurance requirements. Cytology laboratories in the state report performing repeat readings on a randomly selected 10% of specimens read each day. As in all areas of health care, laboratories are under pressure to cut their costs while improving quality assurance through the addition of new technologies. Although cost does increase with the addition of automated technology, several labs expressed the opinion that this will become a standard of care in the near future. Providers should be aware of quality assurance.

Cytotechnologists in New Mexico

Current guidelines exist that limit the number of slides read daily by a cytotechnologist to a maximum of 100. Cytotechnologists in the state prefer reading a maximum of 60 to 70 slides daily to assure accuracy. Some laboratories, using new technology, provide additional support for their technologists and patients by re-reading large samples of specimens (as much as 25%) as an additional safety measure.

Recommendations to Improve Sample Quality

- ✓ Encourage private laboratories to provide regular feedback on the quality of Pap smears submitted by health care providers.
- ✓ Establish a method of monitoring the quality of smears from individual health care providers.
- ✓ Estimate the rate of suboptimal or unsatisfactory Pap smears and the frequency with which health care providers recommend that patients return for a second Pap smear. Estimate the frequency with which those patients actually return for repeat screening.
- ✓ Conduct continuing education seminars for health care providers to improve the quality of Pap smears.
- ✓ Establish an active surveillance system to detect and investigate sentinel cases of invasive cervical cancer. This would include a review of previous negative Pap smears from such patients, thereby assisting in accurately estimating the rate of false negatives.
- ✓ Monitor false-positives, since cost of follow-up of these results is increasing.

To Improve Sample Quality and Reading

At least three large laboratories in the state reported that they repeatedly offer provider training on current collection techniques and the best techniques to use. They also report that few providers access this training in spite of increased incidence of “unsatisfactory” or “limited” specimens. Providers most frequently request training on the correct form to use or other administrative tasks. Recognition that sample quality is every bit as important as laboratory quality should encourage providers to seek this training.

New Technologies

New technologies provide adjuncts to cervical cancer screening.

Autopap provides automated cytology scanning with interpretation. It is primarily used as a secondary screening to enhance laboratory quality control. Autopap rescreens all satisfactory slides read as “within normal limits” and selects 10% of the slides most likely to be false negatives for review by cytotechnologists.

Papnet provides computerized selective rescreening of all slides read as “within normal limits,” creates a digitized image of the entire slide, and selects 128 of the most questionable fields of each slide for review by a cytotechnologist or pathologist.

Cervicography is a visual adjunct to cervical screening. Because one limitation of the Pap smear is the false-negative rate, cervicography is being considered for screening and/or secondary triage. The advantages include the following: it is simple to perform, less expensive and noninvasive than colposcopy and biopsy. If cervicography is performed concomitantly with a screening Pap smear, it may improve the false-negative rate. If it is used to distinguish women with an abnormal Pap who should be referred for immediate colposcopy from those for whom follow-up with repeat Pap smears is appropriate, it may also effectively decrease the false-negative rate. However, Nuovo et al. concluded that before this test is accepted as a useful screening adjunct, further study is needed (In press). Cervicography is not currently FDA approved for primary screening.

