New guidelines for reporting and treating cervical lesions.

News Briefs

NEW GUIDELINES TO IMPROVE CYTOLOGICAL REPORTING AND TREATMENT OF CERVICAL LESIONS

Information provided in two articles in the April 24 issue of JAMA (2002;287:2114-2119, 2120-2129) and an article from the May 8 issue (2002;287:2382-2390) is expected to improve care for women with abnormal Pap test results.

The first article, The 2001 Bethesda System, Terminology for Reporting Results of Cervical Cytology, is the first update since 1991 for the system that cytopathology labs use in reporting Pap test results. The second article, 2001 Consensus Guidelines for the Management of Women With Cervical Cytological Abnormalities, provides recommendations for evaluation and treatment of women with abnormal Pap test results.

The third article, Cost-effectiveness of Alternate Triage Strategies for Atypical Squamous Cells of Undetermined Significance, uses mathematical modeling to consider the effectiveness and cost-effectiveness of several evaluation strategies for women with inconclusive cervical cytology results. Although this paper was published two weeks after the management guidelines, the guideline group requested the modeling study and used its results to develop the guidelines.

Before 1988, labs in the United States used several different reporting systems, including grades of CIN and dysplasia, and Papanicolaou classes I through V, sometimes leading to inconsistent communication with doctors treating women with abnormal Pap test results.

This changed with development of The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses (commonly known as TBS) in 1988. The system was initially updated in 1991 and again in 2001, based on the most recent Bethesda conference. Teams of experts organized the latest scientific evidence with input from more than 400 professionals as well as patient advocates and representatives from 44 professional societies. In addition, the teams considered at least 1,000 comments submitted via the Internet.

Although much of the 2001 Bethesda System is similar to the 1991 version, there are several new features:

• According to the 2001 system, the cytology report should indicate whether the lab received a direct smear or a liquid-based cytology sample as well as whether the lab used any ancillary methods (such as HPV testing) or computerized screening.

• Specimen adequacy is reported as satisfactory or unsatisfactory. The 1991 system’s “satisfactory but limited…” category was discontinued.
A new term, “negative for intraepithelial lesion of malignancy,” will encompass cases previously classified as “within normal limits” and “benign cellular changes.”

In the 1991 system, atypical squamous cells of undetermined significance (ASCUS) cases were subdivided into three groups—“favor reactive,” “favor a squamous intraepithelial lesion (SIL),” or “not otherwise specified.” In the 2001 system, there are only two classes of atypical squamous cells (ASC)—“atypical squamous cells of undetermined significance (ASCUS)” and “ASC, cannot exclude high-grade SIL (ASC-H).” The new classification is in keeping with the current focus on detecting and treating high-grade SILs.

The second JAMA article is also the product of a group effort. More than 100 experts in diagnosis and treatment of precancerous cervical conditions, including representatives of 29 professional organizations, were brought together by the American Society of Colposcopy and Cervical Pathology (ASCCP). Following a meeting in fall 2001 (also held in Bethesda, MD) and an exchange of information via the Internet, the experts agreed on a series of recommendations for caring for women with abnormal Pap test results.

“The guidelines bring new technologies to the screening arena,” said Carolyn Runowicz, MD, a gynecological oncologist and Vice Chair, Department of Obstetrics and Gynecology at St. Luke’s-Roosevelt Hospital in New York, and a member of both the American Cancer Society’s (ACS) National Board of Directors and the ACS Gynecologic Cancer Advisory Committee.

“Currently existing guidelines were developed prior to the advent of liquid-based cytology and sensitive molecular methods for detecting high-risk types of HPV,” said Runowicz. “The data presented at the consensus conference support incorporation of these new technologies into the screening and work-up processes.”

One important recommendation is for women with the most common type of abnormal Pap result. Before the guidelines, women diagnosed with atypical squamous cells of undetermined significance (ASCUS) may have undergone either several repeated Pap tests or a colposcopy. According to the new guidelines, many women who have liquid-based sample collections or have samples for HPV testing co-collected at the same time their Pap smears are prepared will not have to return to their doctor to have several Pap samples collected the following year.

With either of these collection strategies, the lab can do “reflex testing” for high-risk HPV types if the initial cytological report is ASCUS. If the HPV result is negative, colposcopy would not be necessary.

Use of HPV testing to help resolve the problem of ASCUS Pap test results is one aspect of the new guidelines that will affect the most women because ASCUS results are so common. However, the ASCCP guidelines provide recommendations for other SILs and for glandular lesions as well.

Using mathematical modeling techniques, Jane J. Kim, MS, and colleagues from the Harvard School of Public Health and the Columbia College of Physicians and Surgeons reported that simply ignoring ASCUS results provides less cancer-risk reduction than approaches that include some kind of follow-up. They found that among the follow-up approaches, HPV testing is more effective and less expensive than repeating the Pap test twice. Furthermore, HPV testing provides the same reduction in cervical cancer risk as doing a colposcopy in every woman, but is considerably less expensive.

The study’s senior author Sue J. Goldie, MD, MPH, said, “HPV testing essentially provides all women with equivocal Pap results with rapid information about their true cancer risk. Women who test HPV-negative (about 40 to 60 percent) can be immediately reassured they..."
do not have a precancerous condition, do not need a colposcopy, and can return to a regular screening schedule.”

The model incorporates a wide range of information about the likelihood of women with abnormal cytology results or positive HPV tests eventually dying of cervical cancer, the costs of cytology, HPV testing, other diagnostic tests like colposcopy, and the cost of treating women with cervical cancer.

Of course, a large randomized clinical trial that compares each of the combinations of tests would be the ideal source of information for guideline development. However, such a study would be extremely difficult to conduct. Because cervical cancer is relatively rare in countries where screening is already an established practice, it would probably require participation of hundreds of thousands (or even millions) of women. And because cervical cancer takes many years to develop, the results of such a clinical trial would take years to obtain.

“Millions of women every year are told that they have an abnormal Pap test result and require further testing,” said Debbie Saslow, PhD, Director of Breast and Cervical Cancer at the American Cancer Society. “Often this means more frequent Pap tests, and for many women it means a colposcopic exam,” Saslow said. “With the new HPV DNA test, a negative result can save many of these women from further evaluation, an important advance to cervical care.”

“However, many women will be told that they have HPV, the sexually-transmitted virus associated with cervical cancer,” Saslow said. “It is important that providers explain some basic facts about HPV and the natural history of cervical cancer to women who receive a positive test result.”

“The virus is very common, particularly in younger women, and the virus usually goes away on its own without causing any problems,” Saslow said. Doctors and other health care providers “need to be prepared to address questions related to the transmission of HPV and any implications a positive test result may have regarding patients’ sexual relationships.”

“Having these guidelines available will result in more educated patients and providers,” Runowicz said. “By highlighting the advances in screening, hopefully more women will avail themselves of annual gynecologic exams and periodic cytologic screening.”

Cancer mortality rates continued to fall in the United States during the years between 1993 and 1999, according to a consensus report by five government and private health organizations.

The Annual Report to the Nation on the Status of Cancer, 1973-1999, Featuring Implications of Age and Aging on the US Cancer Burden was published in the May 15 issue of Cancer (2002;94:2766-2792). The report was the journal’s fifth yearly “report card” to the nation.

This year it was compiled by the American Cancer Society (ACS), the National Cancer Institute (NCI), the North American Association of Central Cancer Registries, the Centers for Disease Control and Prevention, and the National Institute on Aging. The initial Report to the Nation was issued four years ago and documented the first sustained decline in cancer mortality rates.

“The good news in this report is the continuing fall in cancer death rates by slightly more than one percent per year between 1993 and 1999,” said John R. Seffrin, PhD, Chief Executive Officer of the ACS.

But this year’s report stated that the actual numbers of cancer cases and deaths were up because the age-standardized incidence rate (expressed in new cases per 100,000 people per