



Media Briefing Sheet

NEED FOR NATIONAL GUIDELINES

1. Each year approximately 3.5 million women are told that they have some degree of abnormality on their Pap test and require additional workup or follow-up. Unfortunately, until now, government and professional organizations had not developed uniform standards defining the best way to manage these women. As a result, women with abnormal Pap tests may be managed quite differently depending on by whom and where they are seen.

This can lead to inequities in health care such that poor women receive different care than women with access to the newest technologies.

This can lead to confusion and anxiety, to overtreatment placing women at risk for injury, and to undertreatment placing women at risk for the development of cervical cancer.

2. Since 1988, the terminology used for classifying abnormal Pap tests has been developed under the sponsorship of the National Institutes of Health (NIH) and is known as the Bethesda System. The latest revision of the Bethesda System was devised in the Spring of 2001. Some changes in the terminology that were based on advances in the science of cervical cancer prevention left clinicians unsure about the best management for women whose tests might be classified in these new categories.
3. Recently a number of new technologies have been developed that are beginning to replace the old Pap test. These are liquid-based cervical cytology which has been shown to be more accurate than the older Pap test and testing for human papillomavirus or HPV, a DNA tumor virus which is found in almost all women with cervical cancer.

Despite the potential advantages of such new technologies, clinicians have had no national recommendations on the best way to incorporate them into clinical practice.

DEVELOPMENT OF CONSENSUS GUIDELINES

1. To address the need for national guidelines for managing women with abnormal Pap tests, last year the American Society of Colposcopy and Cervical Pathology (ASCCP) decided to bring together experts in cervical cancer prevention to develop comprehensive guidelines for the management of women with abnormal Pap tests.

The ASCCP is a non-profit professional organization of 3,900 members whose primary mission is the education of health care providers about the diagnosis and management of cervical disease.

2. Pap tests are taken by a variety of clinicians, not just gynecologists and are performed in a variety of settings. These include internists, family practice doctors, nurse clinicians in family planning clinics, and clinicians working in college and public health clinics. Guidelines developed by one professional society or organization might not be appropriate for clinicians performing cervical cancer screening in other settings. In consequence, the ASCCP approached all of the professional societies, organizations, and health care agencies involved in cervical cancer screening in the United States and asked if they would participate in the development of new guidelines

Twenty-nine organizations and national health care agencies agreed to participate. These are listed in an enclosed sheet. 121 representatives from the participating organizations and agencies meet together at the NIH September 6-9, 2001 to produce the Consensus Guidelines.

3. The process for developing the Consensus Guidelines was relatively unique. We incorporated internet-based Discussion Groups to obtain input from clinicians from around the world.
4. The new guidelines are the first evidenced-based, national guidelines that take into account the findings of the recent National Cancer Institute's ASCUS / LSIL Triage Study (ALTS) clinical trial.

Each recommendation is given a grade as to how strong the evidence is to support it and whether the Consensus Conference participants thought a particular management option should always be considered, or whether there are multiple options that are equally effective.

Because management of lesser Pap test abnormalities is especially controversial, the National Cancer Institute (NCI) recently completed a large randomized clinical trial of the management of women with abnormal Pap tests that is referred to as ALTS. ALTS has produced a considerable amount of new data on the best way to manage women with abnormal Pap tests.

The investigators conducting ALTS participated in the development of the 2001 Consensus Guidelines and provided published and unpublished data to the Consensus Conference.

WHAT IS NEW AND IMPORTANT IN THE CURRENT GUIDELINES FOR WOMEN

1. The most common abnormal Pap test result is called ASC-US, or atypical squamous cells of undetermined significance. Approximately 1 in 20 Pap tests are diagnosed as ASC-US and almost 1 in 4 women will have an ASC-US Pap test result at some point in their lifetime. Most women with ASC-US do not have a significant cervical lesion and only about 1 in a 1,000 will have a cervical cancer. However, women with ASC-US are at considerable risk for having a high-grade cervical cancer precursor lesion (about 1 in 10) and require some form of additional follow-up.

Women with ASC-US are managed using a variety of different approaches in the United States. The Consensus Conference evaluated the data supporting these different approaches and found that three are safe and effective.

They include repeating the Pap test at least twice over an 8 - 12 month period to see if the abnormality persists, inspection of the cervix with a magnifying device (colposcope) and obtaining cervical biopsies of abnormal appearing areas, and testing for human papillomavirus (HPV).

However, for women who are screened using liquid-based cervical cytology, which is now the predominant method used in the United States, the Consensus Conference attendees agreed that HPV DNA testing is considered the preferred method of evaluation. This is because HPV DNA testing is as sensitive as the other methods, and the original sample used for the Pap test reported as ASC-US can be tested. About half of women with an ASC-US Pap test will be HPV DNA negative and these women do not need any further evaluation. They can simply have a repeat Pap test done in one year, which is quite convenient for patients

Additionally, a comprehensive cost-effectiveness analysis that was presented at the Consensus Conference and which will appear in an upcoming issue of JAMA shows this approach would save a considerable amount of money. For women being screened using the older conventional Pap test, HPV DNA testing does not offer the same advantages unless a separate specimen is collected and saved specifically for future HPV DNA testing in the advent of an ASC-US test is obtained (i.e., co-collection).

2. Except for women with ASC-US, the Consensus Conference judgment was that all other women with abnormal Pap tests need to undergo a colposcopic examination (i.e., inspection of the cervix using a microscopy) and cervical biopsies of abnormal appearing areas.

This includes women with low-grade cytological abnormalities referred to as LSIL. Older guidelines, including those developed in 1994 under the

sponsorship of the National Institutes of Health (NIH) had suggested that these women could simply be followed with repeat Pap tests.

- 3.** The Consensus Guidelines also provide comprehensive recommendations for the management of the almost 1 million women each year in the United States who are found at colposcopy have a cervical cancer precursor. The guidelines detailing how best to manage women with cervical cancer precursors should be published separately in the near future.