



Media Briefing Sheet

NEED FOR NATIONAL GUIDELINES

Each year approximately 3.5 million women are told that they have some degree of abnormality on their Pap test and require additional evaluation or followup. Until 2001, government and professional organizations had not developed uniform standards defining the best way to manage these women. As a result, women with similar Pap test abnormalities were managed differently, depending on by whom and where they were seen. This led to both overtreatment and undertreatment. Overtreatment can lead to injury without reducing cancer risk, while undertreatment can allow cancers to develop. Inequities in treatment also lead to confusion and anxiety.

In 2001, the American Society for Colposcopy and Cervical Pathology convened a Consensus Conference to establish national guidelines for the management of abnormal Pap tests and cervical cancer precursors. In the years following that conference, new knowledge arose, and gaps in the initial guidelines became apparent. New insights into age-based variation in cervical cancer and in the prevalence of human papillomavirus (HPV), the virus that causes cervical cancer were published and combination testing using Paps and HPV tests was approved to improve the sensitivity of cancer screening.

DEVELOPMENT OF CONSENSUS GUIDELINES

1. To address the need for national guidelines for managing women with abnormal Pap tests, the American Society of Colposcopy and Cervical Pathology (ASCCP) decided in 2000 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 3,300 members whose primary mission is the education of healthcare providers about the diagnosis and management of diseases of the lower female reproductive system, especially cervical cancer and its precursors.

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 healthcare agencies involved in cervical cancer screening in the United States and asked if they would participate in the development of new guidelines.

For the 2006 Consensus Conference, twenty-nine national medical organizations and Federal health care agencies agreed to participate. These are listed on the Consensus Conference webpage www.asccp.org/ConsensusGuidelines/ConsensusGuidelinesOverview. Over 100 representatives from the participating organizations and agencies met together at the NIH September 18-19, 2006 to produce the revised Consensus Guidelines.

3. The process for developing the 2001 and 2006 Consensus Guidelines was relatively unique. We incorporated internet-based discussion groups to obtain input from clinicians from around the world, after committees of experts reviewed the medical literature. Draft guidelines were critiqued on web-based platforms and international conference calls, then revised and, for the 2006 Conference, were presented September 18-19, 2006 in Bethesda.
4. The new 2006 guidelines remain the most comprehensive and up-to-date evidenced-based, national guidelines.

As with the 2001 guidelines, each recommendation was 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 has been especially controversial, the National Cancer Institute (NCI) completed in 2001 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 and 2006 Consensus Guidelines.

The 2006 Consensus Guidelines for cytology and histology were published in the *American Journal of Obstetrics & Gynecology* 2007;197(4): 2007; 346-55 and 2007;197(4):340-345, respectively. Algorithms to both sets of guidelines were published in the October 2007 issue of the *Journal of Lower Genital Tract Disease* and are available on the ASCCP website at www.asccp.org.

WHAT IS NEW AND IMPORTANT IN THE CURRENT GUIDELINES FOR WOMEN

1. Adolescents and young women are defined as 13 to 20 years of age (i.e., 13th to 21st birthdays) and face a very low immediate risk of cervical cancer, yet they have high rates of HPV. HPV infections can cause changes in Pap tests. Most women will clear these HPV infections without treatment and face low long-term risk of cancer. Aggressive evaluation of Pap abnormalities in these young women can result in treatment that can cause injury and increase the risk of preterm delivery and other pregnancy problems. New guidelines recommend following adolescents with borderline Pap abnormalities without colposcopy unless the Pap changes persist over time. Whereas previously adolescents and young women with high-grade Pap abnormalities were followed only in exceptional circumstances, they now can be followed if colposcopy fails to reveal high-grade cancer precursors. Adolescents with confirmed cancer precursors still have a substantial risk of clearing these abnormalities, and new guidelines outline a strategy for following them without intervention unless the changes persist.
2. Most CIN1 will regress spontaneously and CIN1 uncommonly progresses to CIN2,3 (about 10% when CIN1 is preceded by ASC-US, ASC-H, or LSIL cytology). One very important change in the 2006 Guidelines is the initial recommendation to follow CIN1 without treatment without distinction between satisfactory and unsatisfactory colposcopy. In the 2001 guidelines, women with CIN1 and an unsatisfactory colposcopy would have been recommended for an excisional procedure. The 2006 guidelines recommend follow-up whether the colposcopy is satisfactory or not.
3. Pregnant women are never treated for cancer precursors because of the risks of hemorrhage and pregnancy loss. Given this, new guidelines recommend less intensive evaluation of Pap abnormalities during pregnancy.
4. Since HPV rates decline with age, high-risk HPV testing has been newly identified as a potentially useful triage strategy for women with low grade Pap changes.
5. Some 10% of women will have productive HPV infections at any one time; most will have normal Pap tests and little cancer risk. Some women are now being screened at 3 year intervals with a combination Pap/HPV test to improve the sensitivity of screening. Women with combination Pap/HPV test results who are found to have negative Paps but positive HPV tests should be followed in a year with another combination test, with colposcopy and possible treatment only if the Pap test becomes abnormal or the HPV infection persists.
6. Glandular cells inside the cervix are an infrequent but increasingly common site for cancer. New guidelines revise management for women with glandular abnormalities on Pap testing and prescribe management of glandular cancer precursors.