

## **SCREENING GUIDELINES FOR HPV AND CERVICAL CANCER**

Many governments around the world, now recognizing the importance of HPV screening in preventing cervical cancer, are either reviewing data or considering screening programs for HPV testing. By adding HPV screening to Pap testing, women at high risk for development of pre-cancerous and cancerous lesions can be identified and the choice of appropriate follow-up and individualized treatment can be improved. Another potential benefit of HPV DNA screening is that it can reduce Pap screening frequency for women not found to be at high risk to every three to five years, which is more cost-effective than annual Pap tests.

### **Need for HPV DNA testing to interpret inconclusive results of Pap tests**

An important unmet medical need remains that of determining which women with “inconclusive” (also termed equivocal or borderline) Pap results – where very mild abnormalities are identified and the presence of a pre-cancerous state of cervical cells is unclear – are at risk for significant cervical disease. Inconclusive Pap tests occur in about 3% to 5% of all Pap tests. Each year in the US, over 2 million women are diagnosed as having inconclusive Pap tests.

These inconclusive Pap tests, also known as ASC-US (atypical squamous cells of undetermined significance) require some form of further medical investigation. Only 10% of women with an ASC-US result have a high-grade, pre-cancerous condition of the cervix, and only 1% of women with an ASC-US result have cervical cancer.

## **In the United States**

Determining which women with abnormal Pap tests are at risk for significant cervical disease and treating them presents a major public health challenge. The American College of Obstetricians and Gynecologists (ACOG), the American Society for Colposcopy and Cervical Pathology (ASCCP), the American Cancer Society (ACS), the National Cancer Institute (NCI), and the Association of Reproductive Health Professionals (ARHP) have all updated their screening guidelines to include HPV DNA testing as part of routine cervical cancer screening for women at the age of 30 and older.

When HPV DNA testing following ASC-US Pap results is adopted as standard practice, it is estimated that only one-half of the 2 million patients with equivocal Pap results obtained each year in the US will be HPV DNA-negative and will not require follow-up with further, often more invasive examinations.

## **In Europe**

In 2003, the European Commission of the Council of the European Union (EU) proposed that its member states offer established methods of cancer screening to their population. Acceptance of the cancer screening guidelines by the EU is expected later in 2004. Pap smear screening for cervical abnormalities was recommended by the European Commission for women beginning between the ages of 20 and 30. Also, the European Commission stated that, once the effectiveness (i.e., the positive predictive value) has been proven for newer techniques, such as liquid-based cervical cytology and testing for high-risk HPV infection, these technologies could be used in screening cervical specimens.

## In Australia

In July 2004, the Australian Commonwealth Minister of Health and Ageing granted approval for public funding for the use of HPV testing to monitor effectiveness of treatment of high-grade intraepithelial abnormalities of the cervix. Under the protocol recommended by the Medical Services Advisory Committee (MSAC), high-risk HPV testing would be administered one year after a woman is treated for this condition, and then again at 24 months.

Reimbursement for the procedure is expected to come into force in November of this year.

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