

## *WOMEN'S HEALTH:*

### *REDUCTION OF COSTS THROUGH IMPROVED EARLY DETECTION*

According to a WHO study, cervical cancer is the second most common cause of death worldwide for women. Each year about 500,000 women contract the disease, and about 300,000 die of it. But the chances of healing are almost 100 percent if the diagnosis is made prior to the development of severe disease. Modern diagnostic possibilities such as PCR and genetic chips that can identify the cause of disease prior to symptoms appearing can help to set new standards in early detection and treatment. Such early diagnosis represents a revolutionary step in the prevention of cancer and will benefit health systems: extremely precise molecular genetic screening tests will provide more accurate early diagnosis drastically reducing the need for expensive and invasive treatment.

Cervical cancer is almost exclusively (99.8%) caused by human papilloma viruses (HPV). Today the standard in preventive care is the PAP test, which is a 50 year old cytological test designed to detect cellular abnormalities indicative of early disease. The introduction of HPV, the known viral cause of cervical cancer, will allow earlier and more accurate detection of risk greatly reducing disease burden and costs.

#### **Facts & Figures**

- Of the 160 million smears that are taken each year as few as 50% are able to detect early cell abnormalities that are precursors to cervical cancer. Thus, smear examinations provide important indications of possible disease, but they sometimes miss cell abnormalities or existing disease and often make further tests necessary to determine whether or not a woman is truly at risk.

- In the USA alone, about 2 million women must undergo further tests every year. Further examinations can include regular follow-up PAP tests until three consecutive normal readings are found or invasive colposcopy and biopsy procedures. These tests take up valuable time and health resources. In addition there is a psychological burden undergone by patients, many of whom are not actually at risk but rather are victims of an inaccurate test result.

With the new generation of HPV-DNA tests, the Amplicor HPV test by Roche Diagnostics, which diagnose the presence of virus often before degenerated cells occur, at-risk patients can be quickly detected, then subjected to more frequent gynecological monitoring and/or treatment. Thus, the use of innovative diagnostics in prevention can help to reduce incidence rate, save money spent on superfluous but cost-intensive subsequent examinations and reduce the costs for the health system as a whole<sup>1</sup>.

The combination of PAP tests and HPV in primary screening for all women over 30, for example, could offer security for nearly 100% of patients in the near future. Especially in countries with an above average incidence of the disease, HPV screening could reduce the burden on the health systems. This is because HPV testing would provide almost 100% negative predictive value and examinations for about 90% of the population who are PAP and HPV negative could be extended from every one or two years to up to three to five years due to the fact that the time from HPV infection to the development of disease is usually 15-20 years.

- It is estimated that 50% of the US female patients with an unclear/equivocal PAP test – i.e. about 1 million women – would also have a negative result for the HPV test; this means that these patients are healthy and that the PAP test was a false positive. In these cases, therefore, women would stay in the normal screening population and further expensive tests and medical interventions would be unnecessary.

In Europe, Roche Diagnostics has put its first PCR IVD test kit, the Amplicor HPV test, for the human papilloma virus on the market. In the USA the American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society and the Association of Reproductive Health Professionals have already recommended HPV-DNA testing and included it in the screening and prevention guidelines for women of 30 years and over. Both in the US and in

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<sup>1</sup> Petry et al, in print

France for instance, the costs of the HPV preventive medical examination are covered by health authorities. Although the HPV test is more expensive than the PAP test alone, it is widely recognized that the use of HPV testing as part of the cervical cancer screening program is cost-effective.

The AMPLICOR HPV test detects all 13 high risk genotypes of the virus. To improve the effectiveness and accuracy of the preventive medical examination even more – and reduce the costs of subsequent therapies – alongside the existing Amplicor products Roche Diagnostics is developing a new PCR-based test which enables 37 HPV genotypes to be detected. This test can be used as a subsequent test or confirmation test in the event of positive results and provides information about the genotype of the pathogen, thus supporting the obstetrician/gynecologist or oncologist in the selection of the appropriate therapeutic measures. In future, HPV diagnostics can be carried out even faster and with greater cost efficiency: Roche Diagnostics is currently developing an automated real-time PCR test for use on the Cobas TaqMan Analyzer.

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