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Innovation in cervical cancer screening

New tests offer hope for women in the developing world

Two new tests which detect infection with the types of human papillomavirus (HPV) that cause cervical cancer promise to bring better protection to women. Designed by the private sector—in partnership with PATH—for use in low-resource settings, these molecular and biochemical screening tools are an innovative answer to the challenge of preventing cervical cancer in the developing world.

Meeting the need for appropriate screening tools

Despite the availability of vaccines for HPV, millions of women in the developing world—even those who receive HPV vaccination—will continue to need cervical cancer screening. Affordable, appropriate tools that detect cervical abnormalities before they turn cancerous are extremely important—and new tests detecting HPV are designed to meet that need. The World Health Organization has confirmed the role HPV testing can play, stating in its recommendations that "there is sufficient evidence that testing for human papillomavirus infection as the primary screening modality can reduce cervical cancer incidence and mortality rates."[1]

The *Fast*HPV DNA Test (QIAGEN) and the Arbor Vita Cervical Cancer Test (Arbor Vita Corporation) offer an increased potential for global cancer risk reduction, while improving cost-effectiveness and decreasing the need for health worker training associated with existing screening programs. The aim is to make rapid, accurate testing feasible and accessible at lower levels of the public health care system.

*Fast*HPV Test

The *Fast*HPV Test is a molecular test that detects 14 oncogenic HPV types and is designed to inexpensively and effectively screen several women at a time. Available at a preferential public-sector price, it yields results in approximately 2.5 hours—opening the possibility of screening and treatment in a single visit. Once integrated into health systems at the district or county level, a screen-and-treat approach could dramatically reduce loss-to-follow-up as well as the attendant financial and human costs. There is also a strong possibility that the test can be used with self-


PATH/Nicole Cruyer

"There is sufficient evidence that testing for human papillomavirus infection as the primary screening modality can reduce cervical cancer incidence and mortality rates."[1]

For more information

For more information about the *Fast*HPV Test or Arbor Vita's Cervical Cancer Test—or PATH's other work in cervical cancer prevention—please contact:

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obtained vaginal samples (as an optional approach to the usual provider-obtained cervical specimen), decreasing the need for a speculum exam and enhancing test acceptability for women. The test's high level of accuracy is particularly important to women in resource-poor settings, who may be screened only once or twice in their lifetime.

The *Fast*HPV Test is expected to be commercially available in low- and middle-income countries by the end of 2008. PATH will be assisting with public-sector introduction to examine the utility of *Fast*HPV in country-specific screening programs. We look forward to forming partnerships with governmental and nongovernmental organizations, as well as public health representatives from countries where demonstration projects will take place.

Arbor Vita Cervical Cancer Test

The Arbor Vita Cervical Cancer Test is a lateral-flow (strip) test designed to detect increased expression of the viral protein biomarker E6 (a protein necessary for cervical cancer to occur) and identify women at high risk for cervical cancer. The test is intended for use at health facilities with basic laboratories. It will allow screening and treatment within a single visit, a prerequisite for expanding screening in remote areas, where women may have difficulty reaching such services. Ongoing clinical studies are establishing its accuracy in identifying women with precancerous lesions and its validity in predicting the risk of cancer in the future.

Tests developed to fit the setting

Because these tests are designed specifically for low-resource settings, PATH conducted testing and validation in countries where the need is greatest. Between 2003 and 2007, PATH's research partners—the Cancer Institute, Chinese Academy of Medical Sciences (CICAMS), Cancer Foundation of China (CFC) and the International Agency for Research on Cancer, in conjunction with Tata Memorial Hospital and Nargis Dutt Memorial Cancer Hospital—screened more than 21,000 women from China and India, collected specimens for test development use, and offered free treatment as appropriate. Local laboratory workers assisted with validation and field-testing of prototypes. Feedback from local partners helped verify that these tests are acceptable to women, health care providers, and other stakeholders.


PATH, Roger Peck

Next steps to introduction

PATH's goal is not just to support the development of these promising technologies, but to ensure that new screening tools are appropriate for the settings where they will be used. As *Fast*HPV moves toward commercial availability, many countries have begun plans for public health demonstration projects that will guide introduction and commercialization of this test. The evidence provided will help decision-makers tailor cervical cancer screening options to their countries' needs and resources.

At the same time, in collaboration with the US National Cancer Institute and CICAMS/CFC, we plan to conduct further studies of the clinical utility of the Arbor Vita Cervical Cancer Test in China. These studies will determine whether the test is useful as a screening tool and as a means to predict the risk of progression to cancer.

PATH continues to work with industry partners to develop strategies that address the needs of the public sector in low-resource settings. Each test might play a role in the unique context of a country or region across the globe—as part of sustained, wide-scale public health screening and treatment programs for women.

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[1]International Agency for Research on Cancer (IARC), World Health Organization. IARC *Handbooks of Cancer Prevention: Cervix Cancer Screening*. Vol. 10. Lyon, France: IARC*Press*; 2005.