Innovation in biochemical cervical cancer screening

In 2003, PATH launched the START project to develop rapid, low-cost, and easy-to-use tests to screen for cervical cancer, the leading cause of cancer-related deaths among women in developing countries. In the past three years, significant progress has been made by private-sector collaborators on two biochemical tests, and PATH has begun accelerating work with public-sector partners to make these tests accessible to women most in need.

Meeting the need for appropriate screening tools

Where the burden of cervical cancer is greatest, resources for screening are most limited. Biochemical tests can reduce the cost, need for health worker training, and frequency of testing associated with screening programs. With Digene Corporation and Arbor Vita Corporation, PATH has worked to develop two such tests:

- A **batch test** developed with Digene detects DNA from the virus that causes cervical cancer (human papillomavirus [HPV]) and will allow processing of multiple specimens in two hours or less, making it suitable for broad-scale campaigns.
- A **strip test** developed with Arbor Vita detects the viral protein biomarker E6, which is believed to be associated with aggressive precancerous cervical lesions. The format is similar to that of a pregnancy strip test, allowing individual client testing at home or in a health care setting. Results will be available within 15 minutes.

Research partners in China and India (Cancer Institute, Chinese Academy of Medical Sciences; Tata Memorial Center; and Nargis Dutt Memorial Cancer Hospital), and the International Agency for Research on Cancer (IARC) in France, are helping verify that these tests are safe, accurate, reliable, and acceptable to women and health care providers.

Milestones in research and clinical studies

In 2005, the project made significant progress toward preparing these two tests for the market—in both the development and the clinical testing required to make them accessible to the women who need them.

PATH (Lisa Moy)

PATH improves the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.

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Test development

- PATH and Digene expect to wrap up development of the batch test in 2007. The final version will screen for at least 13 HPV types known to cause cervical cancer. Design advances are further reducing the test's cost, complexity, and reliance on equipment and supplies.
- PATH and Arbor Vita have succeeded in improving the sensitivity of the strip test. A grant from the U.S. National Institutes of Health has enabled further work to refine the test's design and optimize the sample collection process.

Clinical studies

- China completed its third year of screening in 2005, and with the approval of the India Council of Medical Research PATH initiate similar clinical studies in India. These screening programs reached almost 10,000 women in China and India, also supplying specimens vital for new test validation.
- State-of-the-art databases were established to support clinical, monitoring, and evaluation efforts.
- To study the predictive validity of E6 and other biomarkers, the project is following up women in China and India with early-stage precancerous cells.

Acceptability among users

Through interviews and surveys, women, health care providers, and policymakers in China and India have guided the development of these tests.

In 2006:

- PATH's research in China allowed us to estimate the direct costs associated with screening and prevention. In India, PATH is updating cost-effectiveness data—essential for policymakers—as more specific information becomes available.
- PATH assessed the preferences of a range of audiences in both China and India, with results suggesting that the tests will be equally acceptable in both countries.

Support from policymakers

PATH and our partners have been working to win support from policymakers, helping pave the way for introduction of these two tests:

- PATH brought together a global advisory group of HPV researchers and technical experts each year to evaluate our progress.
- The project team has generated considerable support for the new tests through its presence at international conferences and meetings, including, in 2005, the International Symposium on HPV and Cervical Cancer, the International Papillomavirus Conference, and a World Health Organization technical workshop on cancer prevention.
- *HPV Today*'s February 2006 issue features an article on the new tests and their role in cervical cancer prevention.
- The team has established strong relationships with government leaders in China and India, building an information pipeline to create understanding of and demand for the tests.
- PATH has been approached by representatives from 24 countries that express a keen desire to be among the first to use and evaluate the new tests.
- The World Health Organization recently concluded that testing for HPV DNA is an acceptable screening method and emphasized the need for low-cost tests.

Commitment to equal protection

Field testing these screening tools will expand knowledge about how they can best be used in low-resource settings—and set the stage for widespread introduction. Joint commitment between PATH and others in industry and in public health will help bring protection against cervical cancer to women who are most at risk of this fatal, preventable disease.

PATH (John Sellors)