

Scale-Up project for cervical cancer prevention

Establishing routine use of HPV testing to prevent cervical cancer in low-resource settings

BACKGROUND

Cervical cancer kills about 266,000 women every year, with more than 85 percent of those deaths in low-resource countries. Fortunately, in the last decade there have been multiple advances in the fight against cervical cancer, including the introduction of vaccines to prevent infection with the two most common types of human papillomavirus (HPV). Nevertheless, there is still a need for precancer and cancer screening for nearly a billion women aged 30 years or older who are already sexually active and most likely will not benefit from current HPV vaccines. In 2014, the World Health Organization (WHO) released new guidelines recommending HPV DNA testing for primary screening for cervical cancer. New HPV DNA tests specifically designed for low-resource settings, including the *careHPV*[™] test (developed by PATH and QIAGEN, with support from the Bill & Melinda Gates Foundation), have made this technology more affordable for low- and middle-income countries.

CareHPV screening is more sensitive than visual inspection with acetic acid (VIA) or the Papanicolaou (Pap) smear, whether using cervical or vaginal samples (including vaginal samples self-collected by women without the need for a speculum examination). These benefits suggest that the test can be used to expand cervical cancer screening coverage in low-resource areas. Technical assistance to countries and seed funding from PATH are designed to help accelerate expanded coverage.

EXPECTED OUTCOMES

The Scale-Up project seeks to reduce cervical cancer incidence through improved and expanded screening using HPV testing. This will be achieved through three primary outcomes:

1. Adoption of HPV DNA testing as the primary screening mechanism for detecting cervical precancer and cancer in Central American countries.



PATH/Mike Wang

2. Establishment of a regional procurement system to secure access to diagnostics in Latin America, including HPV DNA testing.
3. Assessment of opportunities for introduction of HPV DNA testing in three African countries and development of introduction strategies, where feasible.

As a direct result of this project, hundreds of thousands of women in Central America will be screened and treated during the project period, greatly reducing their risk of developing cervical cancer. In addition, guidelines, skills, and strategies will be put in place to continue and expand screening and treatment services to millions of additional women in subsequent years. A regional procurement mechanism will enable countries in Latin America to purchase HPV DNA tests at affordable prices; PATH is working in close collaboration with the Pan American Health Organization (PAHO) to achieve this. And health systems in three African countries will move closer to readiness for introduction of HPV DNA testing, with a clearer understanding of the local landscape for cervical cancer screening and identification of critical next steps for introduction of *careHPV*.

INTRODUCTION OF CAREHPV IN CENTRAL AMERICA

The countries involved in the Scale-Up project include Guatemala, Honduras, and Nicaragua. Through a

partnership with Basic Health International, PATH is also supporting work in a fourth country, El Salvador, where the government has already begun using *careHPV*.

All project activities, including community education and recruitment, sample collection and handling, testing, follow-up of screen-positives, and treatment are being implemented by the respective ministries of health (MOH). Project work in each PATH country will include these phases:

Preparatory phase (6-18 months): In each country, PATH, in partnership with a local nongovernmental organization, is working with the MOH on:

- Development and validation of community education materials.
- Training of health workers in counseling women to self-collect adequate vaginal samples and in labeling and transportation of the samples to the lab.
- Training of lab technicians to run the HPV DNA test correctly.
- Training of health workers in the proper interpretation of test results and in appropriate follow-up with clients.
- Development of a follow-up system to ensure that women with positive results are promptly scheduled for pelvic examination, visual evaluation, and appropriate treatment.
- Development of algorithms, based on new WHO guidelines, for management of women according to their HPV status.

Introductory phase (18 months): In each of the three PATH countries, the project is procuring sufficient tests to screen 110,000 women. Each country begins with an initial 10,000 tests during a pilot, with the goal of identifying potential barriers.

National responsibility and consolidation phase: After using donated HPV tests for 18 months, each government assumes responsibility for procuring and deploying *careHPV* in the project areas in subsequent years.

Technical and policy support phase: Following consolidation, Scale-Up continues helping each government ensure that all activities are developed according to a standard protocol. The project also helps governments plan for expansion of activities to other regions of each country.

EVALUATION

Project outcomes are being measured in several ways. PATH and its local partners are documenting:

- The number of women screened with HPV DNA testing. These data come either from routine national service statistics or from screening registers, depending on usual country practice.
- Increases in screening coverage. We are comparing historical data on the number of women screened in prior years using VIA with the number of HPV tests performed in those same areas. We expect to find an increase in the number of women screened per year.
- A set of indicators to track the expansion of overall screening and treatment services in the project areas, including the number of women screened using any method, method used, ages of the women screened, time since last screening, positivity rate of the screening methods, and the number of screen-positive women treated. Together, these indicators allow for a comprehensive assessment of a screening system.

FOR MORE INFORMATION

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Cervical cancer programs at PATH:
www.path.org/our-work/cervical-cancer.php



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