# Landscape assessment of opportunities for introduction of HPV DNA tests in Kenya: Executive summary

## INTRODUCTION

Like other countries in Eastern Africa, Kenya has a high rate of cervical cancer—an age-standardized incidence rate of 40.1 per 100,000, resulting in 4,800 new cases and nearly 2,500 deaths each year. To improve timely detection and treatment of precancerous lesions, the World Health Organization recently recommended HPV DNA testing as the primary screening method where resources permit. In order to assess opportunities for the introduction of HPV DNA testing as the primary screening method in Kenya, PATH held two meetings (2014 and 2016) with a total of 24 stakeholders and reviewed relevant policy documents. We aimed to understand the key decisions needed, the agencies responsible for decisions to approve the test, and major steps for implementing a change. Stakeholders who participated in the landscaping exercise also were asked about their perceptions of the potential advantages of HPV testing, anticipated barriers, and ways to overcome them.

## CURRENT CERVICAL CANCER SCREENING PROGRAM

The national government demonstrated its political commitment by publishing a three-year strategic plan in 2012, the *National Cervical Cancer Prevention Program*, and plans are under way for the development of a new plan for 2016 to 2020. Recommended screening methods included visual inspection with acetic acid (VIA), visual inspection with Lugol's iodine (VILI), cytology using conventional Pap smear, and HPV DNA testing. Current screening in public facilities is based primarily on a combination of VIA and VILI. Technical support is provided by the Ministry of Health's (MOH) Reproductive and Maternal Health Services Unit, and the Reproductive Tract Cancers Technical Working Group, but insufficient resources are available for a national prevention and treatment program. The national health management information system has begun including some indicators on cervical cancer screening and treatment in its system.

Because of minimal government funding, screening services are performed primarily by nongovernmental organizations with funding from international donors; thus, services are found in only a very small proportion of facilities. Training health care workers to perform VIA and VILI is relatively straightforward and inexpensive, but many providers are needed to achieve high coverage. Furthermore, interpreting the results is not simple, leading to variability in assessment; this necessitates frequent supportive supervision and refresher training, which are costly and logistically difficult. The sensitivity and specificity of VIA for detecting precancer are only moderate, resulting in unnecessary treatment and more frequent screening.

## PROCESSES FOR RECOMMENDATION OF HPV DNA TESTING

While HPV DNA testing is included as a possible method in the current strategic plan, the MOH will need to officially recommend it as the primary screening method. Meeting participants stated that in order for the MOH to make the change, evidence from in-country studies would be needed; two pilot projects now under way could provide this evidence. The MOH will also need cost-effectiveness information, including the cost of training laboratory personnel and the cost of community mobilization. The recent decentralization of health services in the country means that each county will need to decide whether to implement the change, once national policy has been changed. Participants at the meetings did not discuss the registration process that manufacturers of test equipment would need to follow to make the test commercially available because one low-cost HPV DNA test is already available in the private market in Kenya.

## ADVANTAGES AND DRAWBACKS OF HPV DNA TESTING

Advantages of HPV DNA testing are its high sensitivity, which allows longer screening intervals and improves the effectiveness of screening, and the possibility of self-collection of vaginal specimens, which may be culturally more acceptable and reduces the need for trained health care workers to perform pelvic exams. Disadvantages include the possible higher cost for the test itself—although cost-effectiveness studies show that this can be offset by decreases in cost for cancer treatment and repeat screening, and by reduction in the number of trained providers needed.

## IMPLEMENTATION OF TESTING

*Financing*

If HPV DNA testing is recommended as the primary screening method by the MOH, funding for test procurement and service delivery would need to come from both the national and county levels. Representatives from the MOH noted that support by donors and technical partners would be needed initially to help with introduction of screening generally. Stakeholders were of the opinion that screening should be a free service in order to reach all women in need of it.

*Screening*

Stakeholders noted that HPV DNA testing could be implemented at both higher- and lower-level health facilities, but if the lower levels are included, the availability of and training for community health workers will need to be assessed. Facilities where screening could be introduced include family planning clinics and other outpatient clinics where a large number of patients come and the long waiting times can be used for screening. An alternative to having women wait for test results is using mobile phones to inform clients when results are ready. Meeting participants also stated that an increase in screening resulting from introduction of HPV DNA testing would result in increased need for treatment services, so health workers, cryotherapy equipment, and other related services must be provided at the health facilities.

*Test processing*

Transfer of specimens to laboratories, distribution of results to clients, documentation/reporting systems, and linkages to the health facilities will need to be streamlined. Wherever the laboratory processing is performed, analyzing the specimens will require a trained technician, along with supervisory support.

## CONCLUSIONS AND NEXT STEPS

HPV DNA testing is a good option with significant advantages over VIA/VILI or Pap, and is likely to be more cost-effective. However, stakeholders noted that funding would need to come from both the national government and county governments. Before introduction, information on cost-effectiveness of implementation at different levels of the health care system is needed. It will be important to ensure that there is improved coordination between the health facilities and communities for implementation to be successful.

## FOR MORE INFORMATION

For a copy of the full landscaping report or for more information, please contact:
Jose Jeronimo, MD
jjeronimo@path.org

More information on cervical cancer programs at PATH is available at:
http://www.path.org/our-work/womens-cancers.php

PATH
www.path.org

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

STREET ADDRESS
2201 Westlake Avenue
Suite 200
Seattle, WA 98121 USA

MAILING ADDRESS
PO Box 900922
Seattle, WA 98109 USA

December 2016