

## PLANNING

Rapid planning process

## IMPLEMENTATION

Expand services in phases

## MONITORING AND SCALING

Learn as you go

Introducing and scaling up testing  
for human papillomavirus as part  
of a comprehensive programme for  
prevention and control of cervical cancer

**A STEP-BY-STEP GUIDE**

# Introducing and scaling up testing for human papillomavirus as part of a comprehensive programme for prevention and control of cervical cancer

A STEP-BY-STEP-GUIDE



**World Health  
Organization**

Introducing and scaling up testing for human papillomavirus as part of a comprehensive programme for prevention and control of cervical cancer: a step-by-step guide

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# Acronyms and abbreviations

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<b>BHI</b>	Basic Health International
<b>CHAI</b>	Clinton Health Access Initiative
<b>CIN</b>	cervical intraepithelial neoplasia
<b>CSO</b>	civil society organization
<b>EQA</b>	external quality assessment
<b>HPV</b>	human papillomavirus
<b>IQC</b>	internal quality control
<b>IVD</b>	in vitro diagnostic (medical device)
<b>LEEP</b>	loop electrosurgical excision procedure
<b>LLETZ</b>	large loop excision of the transformation zone
<b>LIMS</b>	laboratory information management system
<b>MOH</b>	ministry of health
<b>NAT</b>	nucleic acid test
<b>NGO</b>	nongovernmental organization
<b>PAHO</b>	Pan American Health Organization
<b>Pap</b>	Papanicolaou test
<b>PBCR</b>	population-based cancer registries
<b>PPP</b>	public–private partnership
<b>PSM</b>	procurement supply management
<b>QC</b>	quality control
<b>SLA</b>	service-level agreement
<b>SOPs</b>	standard operating procedures
<b>STI</b>	sexually transmitted infection
<b>TWG</b>	technical working group
<b>VIA</b>	visual inspection with acetic acid
<b>WHO</b>	World Health Organization

# Scope of the guidance

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This guidance is intended to be used by programme managers following the decision to introduce human papillomavirus (HPV) virological testing as a screening assay in their national cervical cancer prevention and control programme. The guidance includes a step-by-step process to be followed after the decision has been made to specifically introduce and/or scale-up HPV virological testing for screening, which would be followed up with adequate management within the context of cervical cancer prevention.

This guidance builds on the 2016 Pan American Health Organization (PAHO) HPV testing manual<sup>1</sup> and provides information for policy-makers, programme managers and heads of reference laboratories on the selection of an HPV virological test, quality control considerations, how to plan the logistical and practical aspects of HPV virological testing, and other practical considerations. It does not cover how to decide whether or not to introduce HPV testing, how to communicate HPV virological testing results to women, other screening methodologies beyond HPV virological testing, or strategies to identify barriers to screening and how to overcome them to increase screening coverage. These will be addressed in other World Health Organization (WHO) programmatic guidelines to increase access to screening and treatment to prevent cervical cancer. HPV virological technologies will be referred to as HPV tests in this guidance document.

The objective of this guidance is to present a practical reference document that provides a summary of and links for all the existing relevant WHO guidance for cervical cancer screening and diagnosis that can support the introduction of HPV testing for screening.

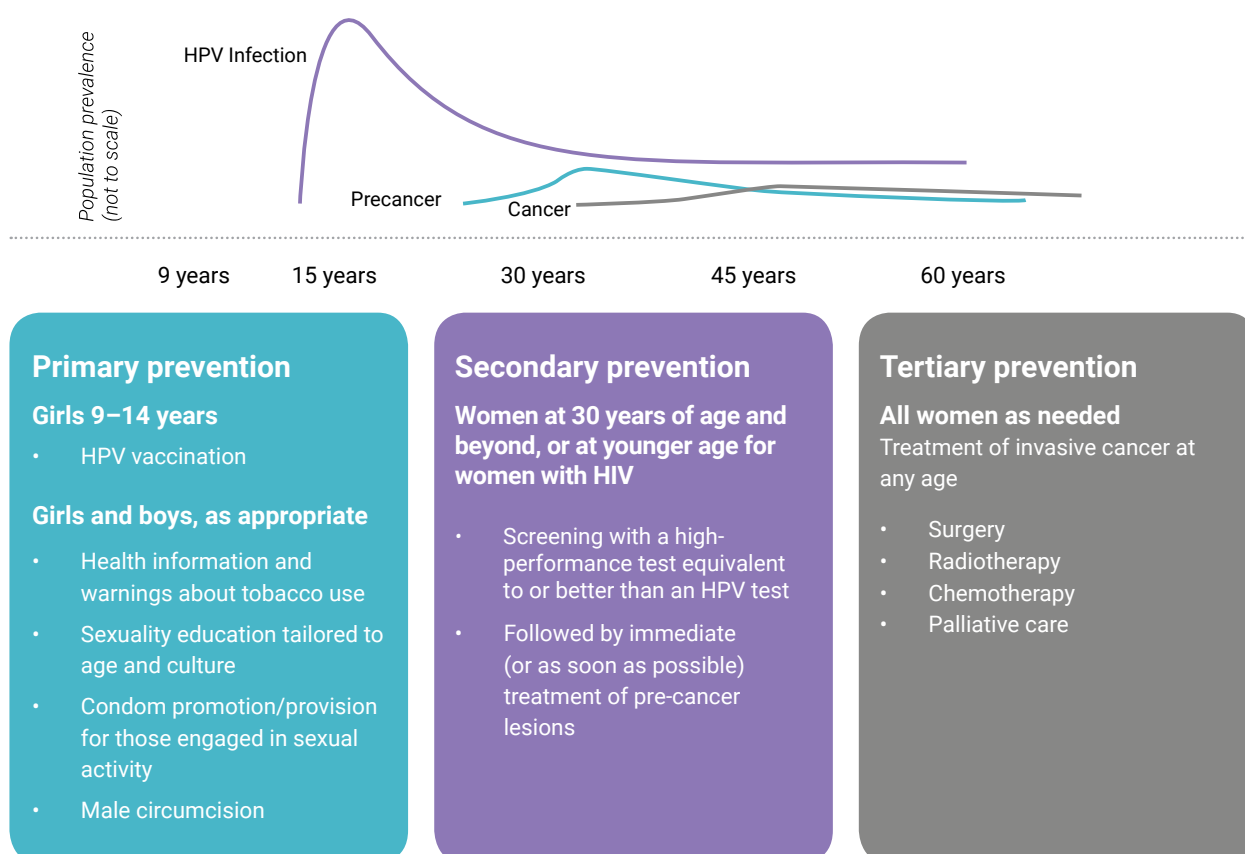
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<sup>1</sup> Pan American Health Organization. Integrating HPV testing in cervical cancer screening program: a manual for program managers. Washington, D.C.: PAHO; 2016 (<https://iris.paho.org/handle/10665.2/31393>, accessed 3 November 2020).

# Background

Since 2007, WHO has recommended a comprehensive, life-course approach to prevention and control of cervical cancer, which has formed the basis of the move towards elimination of this deadly public health problem (Figure 1).

**Figure 1. The life-course approach to cervical cancer prevention and control**



Source: Adapted and updated from WHO (2014).<sup>2</sup>

This comprehensive approach includes vaccination of girls aged 9–14 years, screening and diagnosis for all women in the target group based on the national guidelines, and access to treatment and management for all women with precancerous lesions and with cervical cancer. These represent the three strategic actions of the Global strategy towards eliminating cervical cancer as a public health problem,<sup>3</sup> which was adopted by WHO Member States at the Seventy-third World Health Assembly in 2020.<sup>4</sup>

<sup>2</sup> World Health Organization. Comprehensive cervical cancer control: a guide to essential practice, second edition. Geneva: WHO; 2014 (<https://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/>, accessed 10 November 2020).

<sup>3</sup> World Health Organization. Draft: Global strategy towards eliminating cervical cancer as a public health problem. Geneva: WHO; 2020 (<https://www.who.int/publications/m/item/draft-global-strategy-towards-eliminating-cervical-cancer-as-a-public-health-problem>, accessed 10 November 2020).

<sup>4</sup> Seventy-third World Health Assembly. Global strategy to accelerate the elimination of cervical cancer as a public health problem and its associated goals and targets for the period 2020–2030. Geneva: World Health Organization; adopted on 3 August 2020 (WHA73.2; [https://apps.who.int/gb/ebwha/pdf\\_files/WHA73/A73\\_R2-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R2-en.pdf), accessed 5 November 2020).

The Global Strategy states that in order to reach the elimination threshold of four cases of cervical cancer per 100 000 women a year by the end of the century, countries should reach the following targets by 2030 (the “90–70–90” targets) and maintain them from that point on:<sup>3</sup>

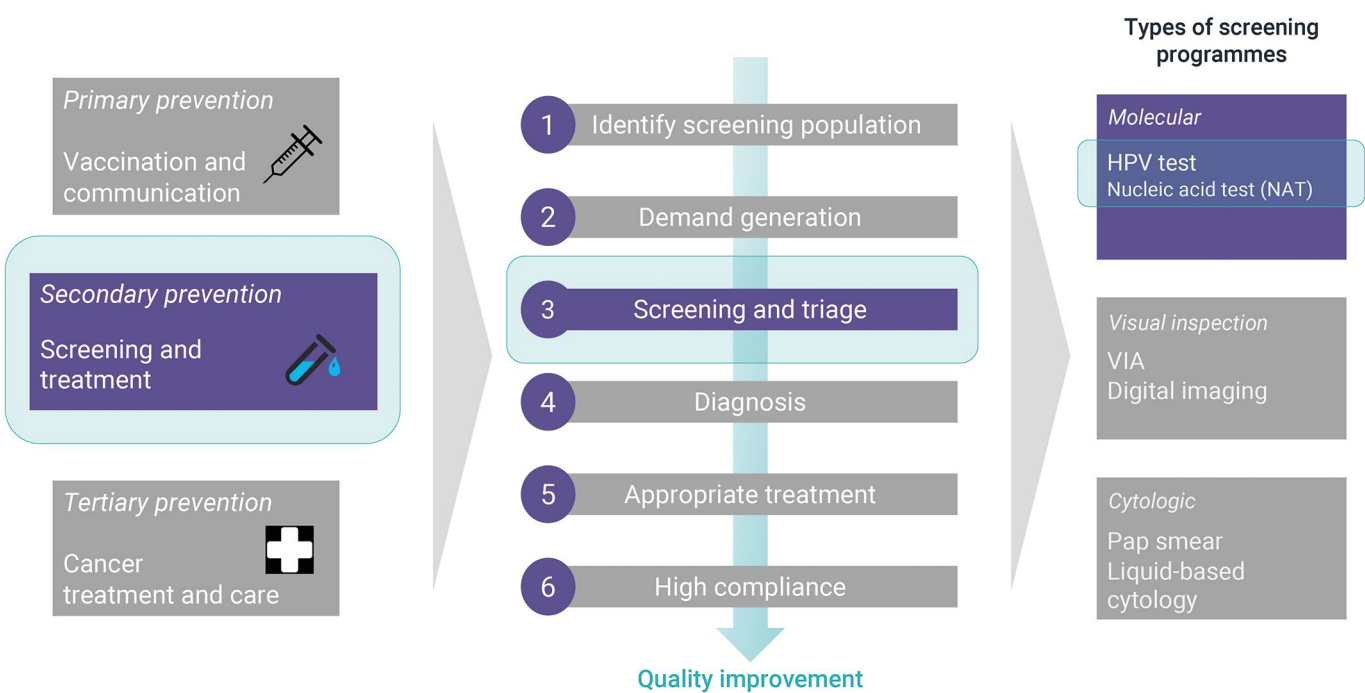
- **90%** of girls fully vaccinated with the HPV vaccine by the age of 15
- **70%** of women screened with a high-performance test by the age of 35, and again by the age of 45 (i.e. at least twice in their lifetime, a maximum of 10 years apart)
- **90%** of women with identified cervical disease receive treatment (i.e. 90% of women with pre-cancer treated and 90% of women with invasive cancer managed).

This guidance was developed on the request of WHO Member States to guide cervical cancer screening programmes to reach the 70% screening coverage target by 2030, using a high-performance test for screening, such as HPV testing, as recommended in the Global Strategy.

# Cervical cancer screening methodologies

As technological advances progress, national authorities and their implementing partners have an increasing number of screening and treatment algorithms that they can consider using within their national programmes. These include visual inspection methods (visual inspection with acetic acid [VIA] and digital imaging), conventional cytologic methods (Papanicolaou [Pap] smear and liquid-based cytology) and molecular methods (HPV virological tests, such as HPV nucleic acid tests [NATs]) (Figure 2).

**Figure 2. Screening methodologies**



In order to assist programme managers in choosing among the various methodologies, WHO has developed recommendations on the use of these different technologies depending on the contexts where the screening programmes will be implemented or expanded. For additional details and guidance on methodology selection and prioritization, refer to WHO's *Comprehensive cervical cancer control: a guide to essential practice, second edition*,<sup>5</sup> which is currently being updated.

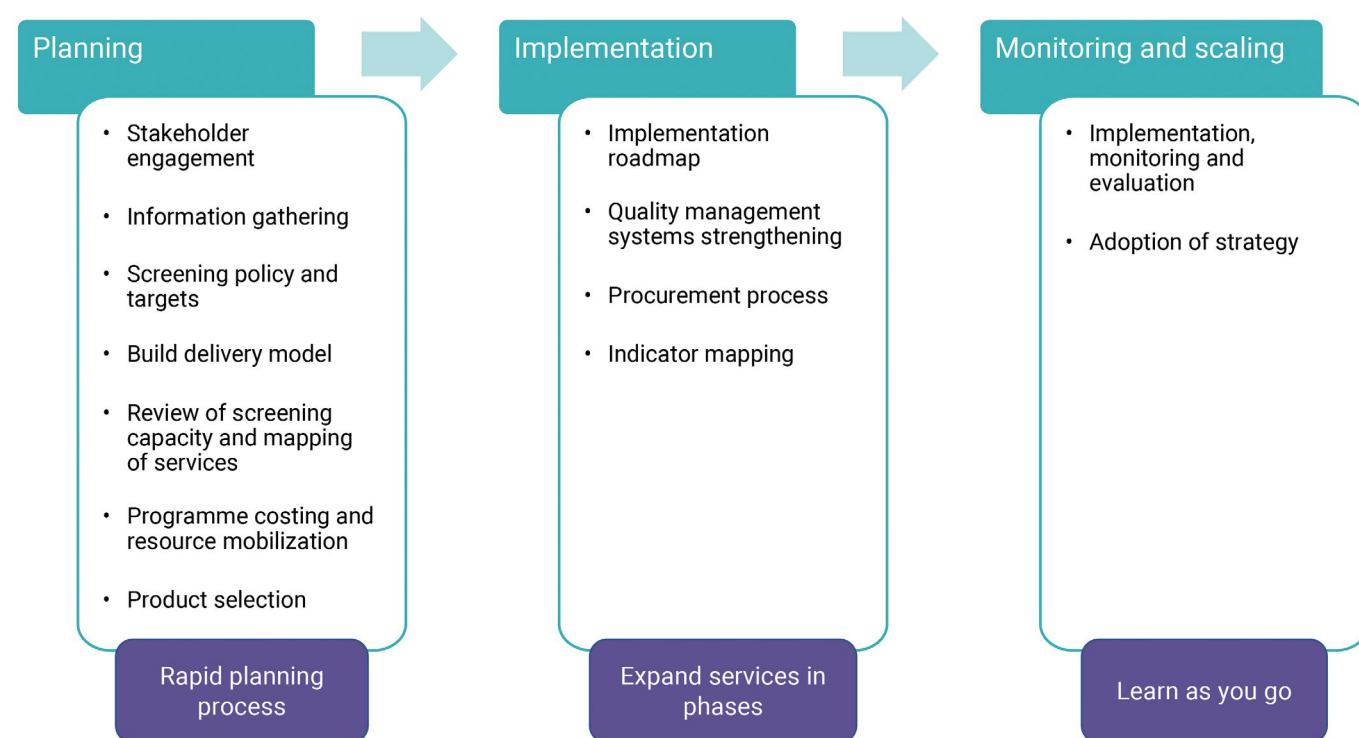
<sup>5</sup> World Health Organization. Comprehensive cervical cancer control: a guide to essential practice, second edition. Geneva: WHO; 2014 (<https://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/>, accessed 5 November 2020)

# Overview of the introduction of HPV testing for cervical cancer screening

As the best performing screening methodologies currently available on the market are HPV nucleic acid tests (NATs), it is important to have guidance for the introduction of HPV testing. This guidance is primarily based on the documented experience from countries that have already introduced HPV testing, and other testing programmes that have scaled up their use of molecular technologies such as testing for HIV, tuberculosis and SARS-CoV-2 (COVID-19). These experiences include those of WHO Member States that already had significant screening coverage using HPV testing, those with significant screening coverage using cytology, those with some screening coverage using a variety of methodologies, and those with no prior screening coverage at all. This guidance is part of a broader effort to address the various implementation and scale-up aspects of secondary prevention, one of the strategic actions of the Global strategy towards eliminating cervical cancer as a public health problem<sup>6</sup>—i.e. screening and treatment of precancerous lesions (specifically, 70% screening coverage and 90% of women with pre-cancer treated, by 2030).

A comprehensive framework for introduction of HPV testing is summarized in Figure 3.

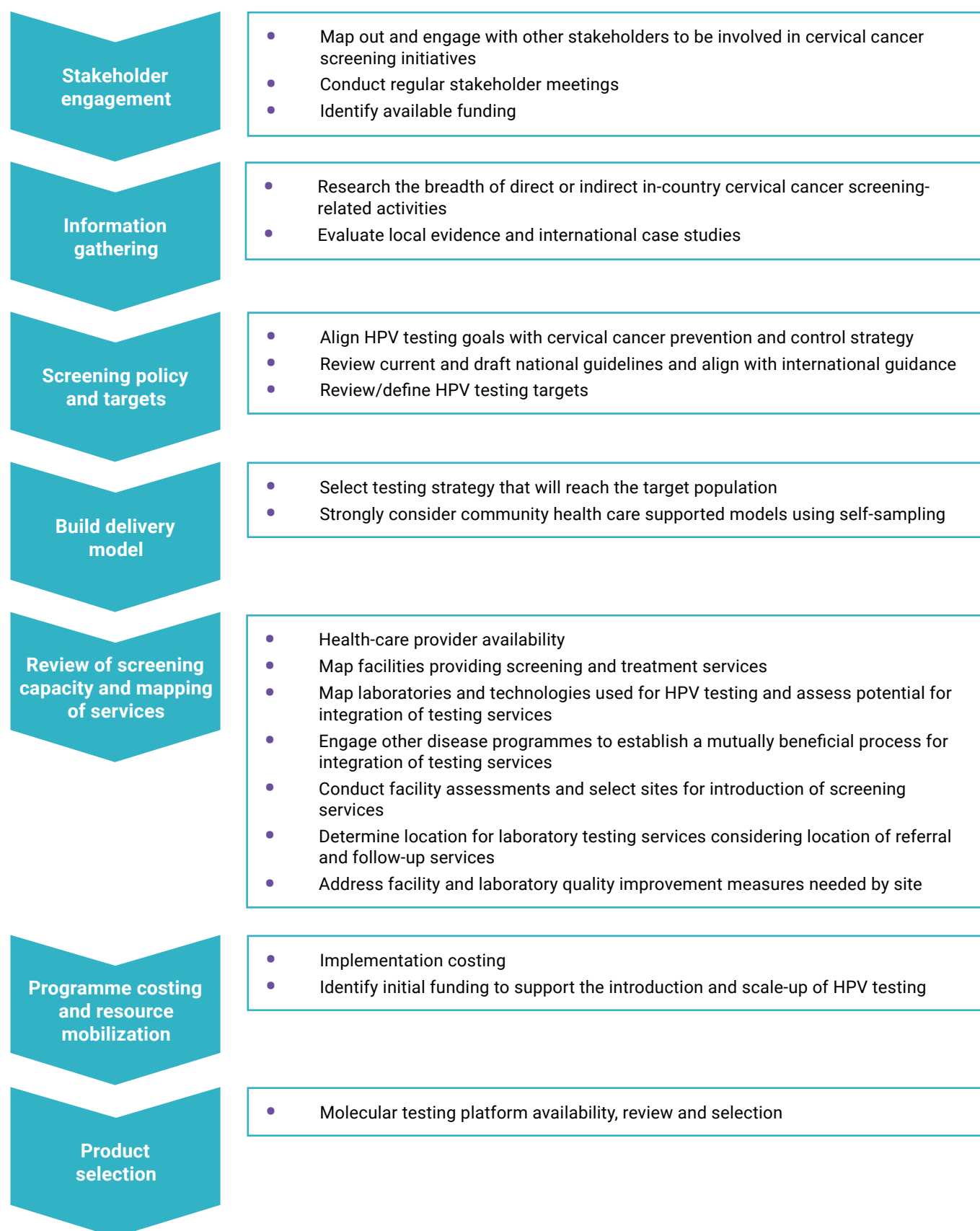
**Figure 3. Framework for introduction of HPV testing for cervical cancer screening**



<sup>6</sup> World Health Organization. Draft: Global strategy towards eliminating cervical cancer as a public health problem. Geneva: WHO; 2020 (<https://www.who.int/publications/m/item/draft-global-strategy-towards-eliminating-cervical-cancer-as-a-public-health-problem>, accessed 10 November 2020).

# Planning

**Figure 4. Planning phase considerations**



# 1 STAKEHOLDER ENGAGEMENT

## Map out and engage with other stakeholders to be involved in cervical cancer screening initiatives

Engage with current and anticipated partners to learn of all necessary and potential stakeholders, current dynamics, and resources available through each stakeholder.

**AIM: To provide clear understanding of the roles and responsibilities of all necessary stakeholders and understand the dynamics that may create challenges for the roll-out of HPV testing.**

*Important consideration:*

- Ensure that representatives of existing non-HPV laboratory and point-of-care testing services are included as stakeholders, particularly from programmes that use NAT technologies and/or those that primarily service women.

## Conduct regular stakeholder meetings

Generate input and build support in country through regularly scheduled stakeholder meetings with representatives of the ministry of health (MOH), medical laboratories, health-care providers, implementing partners, nongovernmental organizations (NGOs), civil society organizations (CSOs), academia, donors, international agencies, community representatives and leaders, and community health workers, among others.

**AIM: To gain buy-in and input from all relevant partners during planning, implementation and scale-up.**

### CASE STUDY: ZAMBIA

As part of their efforts to improve cancer policies, the Government of Zambia established the National Cancer Control Technical Working Group (NCC TWG). This group consists of members appointed by the Office of the Permanent Secretary of Zambia's Ministry of Health. Members include multidisciplinary experts and advocates, such as clinical oncologists, obstetricians/gynaecologists, oncology nurses, policy-makers, cooperating partners (funding agencies, implementing agencies), civil society and academia, among others.

The NCC TWG includes subcommittees that tackle specific cancer types or components of the cancer care continuum, including subcommittees on cervical cancer, breast cancer, childhood cancers, prostate cancer, treatment group and civil society advocacy group, as outlined in the National Cancer Control Strategic Plan.

The NCC TWG meets quarterly, while the subcommittees meet monthly. Introduction of HPV screening has been discussed in the cervical cancer subcommittee and brought to the NCC TWG meeting. This subcommittee has developed draft national guidelines for the introduction of HPV testing. Interdisciplinary approaches to advocate for improvement of cervical cancer services are key for changing the paradigm within the country's cervical cancer guidelines and policies.



**Reference material:**

- **Comprehensive cervical cancer control: a guide to essential practice, second edition – Section 2**
- **Control integral del cáncer cervicouterino: guía de prácticas esenciales, segunda edición – Sección 2**
- **La lutte contre le cancer du col de l'utérus: guide des pratiques essentielles, deuxième édition – Section 2**
- **Controle integral do câncer do colo do útero: guia de práticas essenciais – Section 2**
- **European guidelines for quality assurance in cervical cancer screening**

## Identify available funding

Assess the budget (i.e. ministry of health budget) currently available for cervical cancer screening and treatment, as well as the expected budgetary impact of a new or expanded programme, and the resources that can potentially be mobilized to support the programme.

**AIM: To understand and map available resources for the implementation of HPV testing.**

*Important considerations:*

- Resources for installation, calibration and maintenance (preventive and corrective) might be found in other medical testing programmes.
- Consider ways to collaborate to co-finance these overheads, which benefit all citizens.

## 2 INFORMATION GATHERING

### Research the breadth of direct or indirect in-country cervical cancer screening-related activities

Review the current landscape of cervical cancer screening activities, including the existing screening strategy/algorithm, health-care provider and laboratory staff training, service capacity, community outreach programmes and previous HPV testing pilot efforts.

**AIM:** (i) To determine how cervical cancer screening aligns with other activities across the agenda for the elimination of cervical cancer; and (ii) To determine how the introduction of HPV testing might be integrated into existing testing programmes that use molecular technologies.



#### *Reference material:*

- Draft: Global strategy towards eliminating cervical cancer as a public health problem (WHO, 2020)
- Beginning with the end in mind: planning pilot projects and other programmatic research for successful scaling up
- Avoir le but a l'esprit des le debut: la planification des projects pilotes et d'autres recherches programmatiques pour un passage a grande echelle reussi

### Evaluate local evidence and international case studies

Review WHO guidance and any existing evidence from HPV research or pilots of HPV testing implementation locally, regionally and globally, to provide more country context.

**AIMS:** (i) To provide evidence of the need for improved cervical cancer screening and treatment strategies during stakeholder discussions; (ii) To guide development of an HPV testing strategy.



#### *Reference material:*

- Integrating HPV testing in cervical cancer screening programs: a manual for program managers
- Incorporación de la prueba del virus del papiloma humano en programas de prevención de cáncer cervicouterino: manual para gerentes de programas de salud
- Outcomes for step-wise implementation of a human papillomavirus testing-based cervical screen-and-treat program in El Salvador (Alfaro et al., 2020)

### 3 SCREENING POLICY AND TARGETS

#### Align HPV testing goals with cervical cancer prevention and control strategy

This should include cervical cancer screening and treatment strategies, and targets for coverage. In countries with no mechanism to review the strategy due to lack of centralized data management, an audit of local outcomes against the accepted guidelines can be used.

**AIM: To have a clear goals and targets aligned with overall MOH priorities.**



##### *Reference material:*

- Draft: Global strategy towards eliminating cervical cancer as a public health problem (WHO, 2020)
- WHO screening and treatment: recommendations to prevent cervical cancer in all women (in development, title to be confirmed, available in 2021)
- IARC handbook of guidelines on cervical cancer screening (in development, title to be confirmed, available in 2021)

#### Review current and draft national guidelines and align with international guidance

Determine whether changes to national guidelines are necessary prior to implementation and/or scale-up of HPV testing.

**AIM: To identify any misalignment and undertake policy updates where necessary.**



##### *Reference material:*

- WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention
- Directrices de la OPS/OMS sobre tamizaje y tratamiento de las lesiones precancerosas para la prevención del cancer cervicouterino
- Lignes directrices de l'OMS pour le dépistage et le traitement des lésions précancéreuses pour la prévention du cancer du col de l'utérus
- WHO guidelines: use of cryotherapy for cervical intraepithelial neoplasia
- Lignes directrices de l'OMS: utilisation de la cryothérapie pour le traitement de la néoplasie cervicale intraépithéliale
- WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions

## Review/define HPV testing targets

Local stakeholders should decide the frequency of HPV testing based on initial available resources. Cost-effectiveness modelling shows that screening even just twice in a lifetime with an HPV test (in accordance with the “90-70-90” targets for 2030) is a key element of the strategy to achieve the elimination of cervical cancer, defined by a threshold of not more than four cases a year per 100 000 women by the end of the century.<sup>7</sup>



### **Reference material:**

- **Impact of HPV vaccination and cervical screening on cervical cancer elimination: a comparative modelling analysis in 78 low-income and lower-middle-income countries (Brisson et al., 2020)**
- **Secondary Prevention of Cervical Cancer: ASCO Resource-Stratified Clinical Practice Guideline (Jeronimo et al., 2016)**
- **Impact of scaled up human papillomavirus vaccination and cervical screening and the potential for global elimination of cervical cancer in 181 countries, 2020–99: a modelling study (Simms et al., 2019)**

<sup>7</sup> World Health Organization. Draft: Global strategy towards eliminating cervical cancer as a public health problem. Geneva: WHO; 2020 (<https://www.who.int/publications/m/item/draft-global-strategy-towards-eliminating-cervical-cancer-as-a-public-health-problem>, accessed 10 November 2020)

## 4 BUILD DELIVERY MODEL

### Select testing strategy that will reach the target population

Current WHO recommendations on the use of HPV tests as cervical cancer screening tests recommend an HPV test followed by either (i) immediate treatment or referral for all women who screened positive or (ii) an additional 'trriage test' for all women who screened positive followed by treatment or referral for all women who also have a positive triage test. *The updated WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention* (which will be published in 2021) closely reviewed evidence on the benefits and harms of several different strategies.<sup>8</sup> Each country needs to determine which strategy is the best fit in their context, acknowledging that a national programme may decide to recommend more than one strategy if this is needed for programmes in different settings within the country.<sup>9</sup>

**AIM: To align the primary HPV testing strategy with available and accessible in-country diagnostic and treatment services, MOH priorities and relevant patient demographic and prevalence data.**

*Important considerations:*

- In particular, consider whether or not there is a need for a follow-up triage test after a positive HPV test result, and balance this need against the risk of loss to follow-up.
- Different strategies can be considered for different country contexts, and in some cases they may even be needed within the same country, depending on sociodemographic variables.



#### **Reference material:**

- **WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention**
- **Directrices de la OPS/OMS sobre tamizaje y tratamiento de las lesiones precancerosas para la prevención del cancer cervicouterino**
- **Lignes directrices de l'OMS pour le dépistage et le traitement des lésions précancéreuses pour la prévention du cancer du col de l'utérus**
- **Integrating HPV testing in cervical cancer screening programs: a manual for program managers**
- **Incorporación de la prueba del virus del papiloma humano en programas de prevención de cáncer cervicouterino: manual para gerentes de programas de salud**
- **European guidelines for quality assurance in cervical cancer screening – Section 3: Methods for screening and diagnosis**

8 The 2013 publication (new version not yet available): Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention: WHO guidelines. Geneva: WHO; 2013 ([https://www.who.int/reproductivehealth/publications/cancers/screening\\_and\\_treatment\\_of\\_precancerous\\_lesions/en/](https://www.who.int/reproductivehealth/publications/cancers/screening_and_treatment_of_precancerous_lesions/en/), accessed 11 November 2020).

9 Broutet N, Jeronimo J, Kumar S, Almonte M, Murillo R, Huy NVQ, et al. Implementation research to accelerate scale-up of national screen and treat strategies towards the elimination of cervical cancer. Geneva: World Health Organization; 2020 (<https://www.who.int/docs/default-source/cervical-cancer/implementation-research-cxca-elimination>, accessed 13 November 2020).

## Strongly consider community health care supported models using self-sampling

Strongly consider inclusion of self-sampling for HPV testing as an additional approach to sampling in cervical cancer screening programmes where HPV tests are used.<sup>10</sup> Determine whether the product is validated for this specimen collection methodology. Where health-care facilities are stretched, community health workers may serve key roles in delivering a self-care model using self-sampling, ensuring proper linkages for follow-up, as needed. Self-sampling strategies may include facility-based self-sampling as well as outreach programmes or campaigns. Screening strategies enabling women to collect specimens in their own homes could be considered where feasible; however, the availability of private space, the potential risk of violence against women and other risk factors must be carefully evaluated.

### *Important considerations:*<sup>11</sup>

- HPV self-collected specimens can achieve high sensitivity and specificity, similar to that of HPV specimen collection performed by a health-care provider.
- Self-collected specimens are seen as highly acceptable in terms of privacy, convenience, time and effort saved, cost-effectiveness, ease, comfort (including decreased embarrassment, pain and anxiety), speed, safety and user-friendliness.
- The option to self-collect a specimen for testing is generally associated with increased uptake of cervical cancer screening services and is a critical strategy to reach the global target of 70% screening coverage by 2030.



### **Reference material:**

- **WHO Consolidated guideline on self-care interventions for health: sexual and reproductive health and rights – Recommendation 21**
- **WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer – Section 2.2.2.2**
- **WHO recommendations on self-care interventions human papillomavirus (HPV) self-sampling as part of cervical cancer screening**
- **Integrating HPV testing in cervical cancer screening programs: a manual for program managers – Section 10: HPV testing using self-sampling**
- **Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses (Arbyn et al., 2018)**
- **Effect of self-collection of HPV DNA offered by community health workers at home visits on uptake of screening for cervical cancer (the EMA study): a population-based cluster-randomized trial (Arrossi et al., 2015)**
- **The feasibility and acceptability of self-sampling and HPV testing using Cepheid Xpert® HPV in a busy primary care facility (Woo, 2019)**

10 The guidance here is in line with the following WHO guidance: World Health Organization. WHO consolidated guideline on self-care interventions for health: sexual and reproductive health and rights. Geneva: WHO; 2019 (<https://apps.who.int/iris/bitstream/handle/10665/325480/9789241550550-eng.pdf>, accessed 10 November 2020).

11 Adopted from (i) Pan American Health Organization. Integrating HPV testing in cervical cancer screening program: a manual for program managers. Washington, D.C.: PAHO; 2016 (<https://iris.paho.org/handle/10665.2/31393>, accessed 3 November 2020) and (ii) World Health Organization. WHO recommendations on self-care interventions: human papillomavirus (HPV) self-sampling as part of cervical cancer screening. Geneva: WHO; 2020 (<https://apps.who.int/iris/handle/10665/332333>, accessed 11 November 2020).

## 5 REVIEW OF SCREENING CAPACITY AND MAPPING OF SERVICES

### Health-care provider availability

Document the availability of providers for screening and treatment, including laboratory technicians, nurses, physicians, pathologists, microbiologists and oncologists.

**AIM: To understand the national capacity for implementing HPV screening and the potential impact across the full continuum of care.**

*Important consideration:*

- Community health workers and women champions can be mobilized to educate and inform community members about primary screening and self-sampling, if support and linkages for follow-up are clearly defined.



#### **Reference material:**

- **Service availability and readiness assessment (SARA)**
- **Planning and implementing cervical cancer prevention and control programs: a manual for managers – Chapter 4: Assessing program needs**
- **Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes**
- **Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus**
- **Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino**

### Map facilities providing screening and treatment services

Map the numbers of clinics performing screening, clinics providing triage and treatment of precancerous lesions, and referral hospitals providing cancer treatment and care. Assess the current situation of infrastructure and capacity at health-care facilities to understand the potential for adding HPV screening services; the assessment should cover existing services such as family planning, HIV and other clinics.

These efforts will help to estimate the feasibility of delivering HPV screening services and to project the impact of using HPV tests for cervical cancer screening on the need for treatment of precancerous lesions and referrals for advanced diagnosis and treatment. By mapping the needs of the programme against existing capacity for screening and diagnosis, availability of health-care providers, and availability of treatment for precancerous and advanced-stage lesions, programmes will be able to identify key gaps and build the necessary capacity to support the introduction of HPV testing.

**AIMS: (i) To assess the existing and required services; (ii) To identify gaps in capacity across the screening and treatment care cascade; and (iii) To ensure sustainable capacity across the entire care cascade.**



**Reference material:**

- Service availability and readiness assessment (SARA)
- Planning and implementing cervical cancer prevention and control programs: a manual for managers – Chapter 4: Assessing program needs
- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes
- Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus
- Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino

## Map laboratories and technologies used for HPV testing and assess potential for integration of testing services

Map the number and location of services provided and equipment available for the introduction of HPV testing, and for quality management systems. In particular, consider programmes such as HIV, tuberculosis, SARS-CoV-2 (COVID-19), viral hepatitis and sexually transmitted infections (STIs). Planning for additional capacity should account for this existing infrastructure and should address any limitations in infrastructure, funding, policies and human resources. Reassess the relevant procurement policies.

**AIM: To document the national capacity for HPV testing (both current capacity and expected readiness for the implementation and scale-up of HPV testing).**



**Reference material:**

- Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks
- Éléments à prendre en considération pour l'adoption et l'utilisation de dispositifs de dépistage conjoint des maladies au sein de réseaux de laboratoires intégrés
- Considerações para a adoção e utilização de dispositivos de rastreio multi-doença nas redes de laboratórios integradas
- Service availability and readiness assessment (SARA)
- Planning and implementing cervical cancer prevention and control programs: a manual for managers – Chapter 4: Assessing program needs

## Engage other disease programmes to establish a mutually beneficial process for integration of testing services

Integration should be supported by a central coordinating mechanism across all disease programmes leveraging multi-disease testing platforms. Country guidelines on multi-disease testing should be used and may focus on the following areas, among others:

- Regulatory approval (pre-market assessment and marketing authorization)
- Product selection
- Site selection for setting up HPV testing
- Integrated specimen referral systems
- Standard operating procedures (SOPs) and training for users
- Ensuring capacity for supervision, monitoring and conducting training
- Clinician training and demand generation
- Inventory management, including procurement
- Quality management systems for testing services
- Post-market surveillance (user feedback on the quality of products used)
- Data management and integration.

**AIM: To establish integration frameworks in order to maximize available resources, reduce costs, and more rapidly and efficiently scale up testing services.**



### **Reference material:**

- **Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks**
- **Éléments à prendre en considération pour l'adoption et l'utilisation de dispositifs de dépistage conjoint des maladies au sein de réseaux de laboratoires intégrés**
- **Considerações para a adoção e utilização de dispositivos de rastreio multi-doença nas redes de laboratórios integradas**

## Conduct facility assessments and select sites for introduction of screening services

Gain buy-in from health-care facility leadership and develop timelines for the introduction of HPV testing (accounting for a phased introduction process).

Critically important in selecting sites for screening services is knowledge of the coverage of population-based cancer registries (PBCR). In order to measure and document the impact of screening services, information must be linkable with PBCR data (to demonstrate downstaging of cancers diagnosed, and reduced cervical cancer incidence over time) and information from death registration (to demonstrate reduced cervical cancer mortality). This is only possible when screening services and PBCR cover residents in the same geographic region.

**AIM: To finalize the selection of sites for screening introduction.**



#### **Reference material:**

- **Service availability and readiness assessment (SARA)**
- **Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 4**
- **Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 4**
- **Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 4**

### **Determine location for laboratory testing services considering location of referral and follow-up services**

Building on site selection for screening and the mapping of existing screening services, colposcopy services, locations for treatment of precancerous lesions, and management of suspected invasive cancer services, this next step is when programmes must align HPV testing capacity with anticipated screening and treatment needs.

**AIMS: To determine where screening services are to be offered (on-site versus referral), whether screening and treatment can be offered at the same facility, and which testing laboratories would service which screening sites.**

#### *Important considerations:*

- Assess the location of testing, the implications for expected turnaround times, and the rates of results return. Where possible, consider the use of point-of-care (on-site) HPV testing to allow for same-day treatment after a positive screening result.
- Find solutions to expedite the return of results to minimize loss-to-follow-up and maximize linkages to care.
- Consider offering a variety of models based on geography, target population and available resources.
- Ensure locations for specimen collection and HPV testing laboratories are appropriately linked to minimize turnaround times and optimize laboratory testing capacity.
- Conduct a diagnostic network optimization exercise<sup>12</sup> to optimize the specimen transport routes and the utilization of HPV testing infrastructure.

12 "Diagnostic network optimization or mapping exercises help to define the optimal mix of devices, identify the most appropriate locations where the devices should be placed and design the referral network links, if necessary. Several tools, some of which are open access, currently exist to support diagnostic network optimization". Source: World Health Organization. Molecular diagnostics integration global meeting report, 10–12 July 2019, Geneva, Switzerland. Geneva: WHO; 2020 (<https://www.who.int/publications/i/item/molecular-diagnostics-integration-global-meeting-report>, accessed 11 November 2020).



**Reference material:**

- Planning and implementing cervical cancer prevention and control programs: a manual for managers – Chapter 5: The program action plan
- Integrating HPV testing in cervical cancer screening programs: a manual for program managers
- Incorporación de la prueba del virus del papiloma humano en programas de prevención de cáncer cervicouterino: manual para gerentes de programas de salud
- Diagnostic network optimization:
  - WHO Molecular diagnostics integration global meeting report (p. 10)
  - The Laboratory Efficiency and Quality Improvement Planning (LabEQIP) Tool

### Address facility and laboratory quality improvement measures needed by site

Engage with partners and suppliers to ensure training, commodities and site improvements are completed. Sites may lack the necessary personnel, equipment, test kits, consumables, instruments, quality control (QC) products, infrastructure, or related treatment supplies. It is important to clearly articulate needs and associated costs to determine what can be supported through existing channels and funding and to what extent there is a need for additional funding mobilization.

**AIM: To fully equip all target sites with the personnel, commodities and improvements necessary to provide HPV testing.**



**Reference material:**

- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 4
- Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 4
- Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 4

## 6 PROGRAMME COSTING AND RESOURCE MOBILIZATION

### Implementation costing

In order to adequately identify and solidify funding for programme introduction and scale-up, the HPV testing programme should be analysed for costs. Indicative prices can be used for the products as the final prices for instruments, reagents and consumables will only become known at the time of signature of the procurement contract. Depending on the chosen HPV strategy (or strategies), the components to be considered for inclusion in the programme may include:

- Education and community mobilization
- Training of personnel
- Specimen collection and processing (instruments, reagents and consumables)
- Specimen sample transportation and results return
- All-inclusive cost per patient test (see Table 2 on p. 35)
- QC costs including reagents and consumables used for QC, lot-to-lot verification, competency and proficiency testing
- Other direct and indirect costs



#### **Reference material:**

- **Planning and implementation cervical cancer prevention and control programs: a manual for managers – Chapter 5: The program action plan**
- **Integrating HPV testing in cervical cancer screening programs: a manual for program managers – Section 3**
- **Incorporación de la prueba del virus del papiloma humano en programas de prevención de cáncer cervicouterino: manual para gerentes de programas de salud – Section 3**
- **Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks**
- **Éléments à prendre en considération pour l'adoption et l'utilisation de dispositifs de dépistage conjoint des maladies au sein de réseaux de laboratoires intégrés**
- **Considerações para a adoção e utilização de dispositivos de rastreio multi-doença nas redes de laboratórios integradas**
- **WHO Cervical cancer prevention and control costing (C4P) tool**
- **Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 5**
- **Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 5**
- **Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 5**

## **Identify initial funding to support the introduction and scale-up of HPV testing**

Once the funding requirements have been determined, identify whether resources are currently available based on the initial mapping of funding, whether additional resources will be required, and where the new resources will come from. Maximize existing resources by mobilizing and coordinating the contributions of each stakeholder and all concerned in-country NGOs and CSOs to ensure the success of implementation.

## 7 PRODUCT SELECTION

### Molecular technology platform availability, review and selection

Any platform or product must be selected based on transparent and fair procurement practice. Product review should consider three main criteria (details for each are provided below):

1. Performance considerations
2. Accessibility considerations
3. Operational considerations

**AIM: To identify an HPV testing service delivery model and preferred products that fit within the budgetary, programmatic and operational requirements of the national testing strategy.**

#### 1. PERFORMANCE CONSIDERATIONS FOR SELECTING PRODUCTS

- **Genotype detection:** Relevant genotypes to be detected are HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 (with 66 and 68 acceptable but not preferable) by pooled detection or individual detection. Testing for extended high-risk HPV genotypes beyond those for clinical purposes risks recalling a high proportion of patients for follow-up. Discourage testing for low-risk HPV types in national screening programmes.
- **Performance thresholds:** Minimum thresholds for clinical sensitivity and specificity identify all women who are at risk of having or developing high-grade precancerous lesions (CIN2 or greater), yet should not be so analytically sensitive that they identify infection that is not likely to progress to disease (criteria in Table 1).
- **Specimen collection and specimen type:** These should be validated across multiple media and specimen collection kits, intended for use either by health-care providers or self-sampling, and should have adequate acceptability and ease of use.

**Table 1. Clinical sensitivity and specificity criteria**

Performance parameter	Sample specification	Performance
Sensitivity	At least 60 cervical specimens from a population-based screening cohort of women ≥ 30 years with histologically confirmed CIN2 or greater	At least 90% of the sensitivity of the standard comparator for detection of CIN2 or greater
Specificity	At least 100 cervical specimens from a population-based screening cohort of women ≥ 30 years with histologic confirmation of no CIN2 or greater present	At least 98% of the specificity of the standard comparator for detection of CIN2

Source: WHO (2020).<sup>13</sup>

13 World Health Organization. WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer. Geneva: WHO; 2020 ([https://www.who.int/medical\\_devices/publications/tech\\_specs\\_precancerous\\_Lesions\\_cervical\\_cancer\\_devices/en/](https://www.who.int/medical_devices/publications/tech_specs_precancerous_Lesions_cervical_cancer_devices/en/), accessed 4 November 2020).

## 2. ACCESSIBILITY CONSIDERATIONS FOR SELECTING PRODUCTS

### *Supplier considerations:*

- Regulatory approvals and donor procurement policies – these are critical for timely registration and to confirm the eligibility of products for procurement with public money
- Company experience and track record in resource-limited settings and capacity for post-market surveillance
- Comprehensive service-level agreements (SLAs) to ensure adequate servicing and device uptime

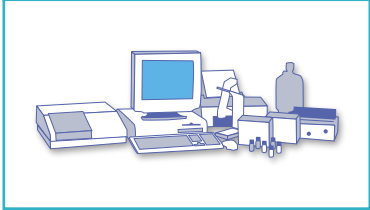
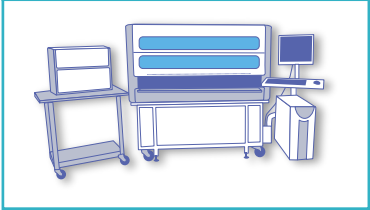
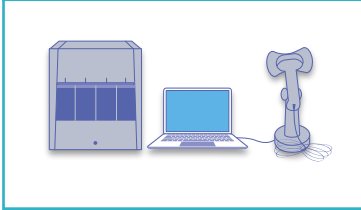
### *Cost considerations:*

- **Affordable pricing:** Leveraging global pricing ceilings, competitive tenders and pooled volumes
- **Assessment of all-inclusive cost per patient result:** Proprietary reagents and consumables, controls, instruments, service and maintenance, distributor margin, procurement and distribution costs, errors and failures (see Table 2 on p. 35)
- **Considerations for cost set-up:** Cost of ancillary equipment, required changes to infrastructure, generic consumables, quality assurance material, maintenance contracts, staff time, consortium pricing and multiple platforms for competitive pricing

### 3. OPERATIONAL CONSIDERATIONS FOR SELECTING PRODUCTS

- **Testing method:** Manual, automated, point-of-care or near-patient testing (see details in Figure 5)
- **Instrument fleet:** Existing platforms in country, excess testing capacity
- **Infrastructure requirements:** Power supply, climate control, dust, instrument footprint, ancillary equipment, additional rooms for extraction and amplification, and health-care facility tier
- **Quality assurance:** Use existing external quality assessment (EQA), internal quality control (IQC); compatible with external quality control material
- **Logistics:** Cold-chain requirements (refrigerated versus frozen), storage requirements and shelf life
- **Technical support:** Availability in the country or region (especially for automated systems), training, maintenance, service, warranty and help desk
- **Ease of use:** Number of steps, automation, protocol, job aids, existing human resources (particularly for point-of-care testing), workflow, cross-contamination risk, barcoding systems, and maintenance and cleaning required
- **Safety and waste:** Biohazard risk (closed or open system), solid and liquid waste management requirements
- **Data management:** Connectivity, data back-up and storage, results reporting, and interoperability with laboratory information management system (LIMS)
- **Durability:** Life span of instruments, planned obsolescence, company experience and track record
- **Polyvalence (utility for other purposes):** Infant HIV diagnosis, HIV viral load, tuberculosis, SARS-CoV-2, hepatitis B and C, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, outbreak surveillance, etc.

**Figure 5. Comparison of different HPV nucleic acid testing technologies**

Testing method	Manual	Automated	Point-of-care or near-patient testing
			
<b>Manual steps</b>	Maximum	Limited	Limited
<b>Operator qualifications</b>	Experienced in laboratory procedures	Trained for specific automation	No laboratory experience needed; focused device training
<b>Throughput</b>	Small to moderate batch testing	High volume batch testing, but random access available	Single specimen, but can combine multiple modules to increase volume
<b>Infrastructure requirements</b>	<p>Vast majority of methods require reagent-grade water, continuous, reliable power supply</p> <p>Requires appropriate chemical and biohazard waste management</p>	<p>Reagent-grade water, continuous, reliable power supply, significant laboratory footprint</p> <p>Requires appropriate chemical and biohazard waste management</p>	<p>Continuous, reliable power supply</p> <p>Requires appropriate chemical and biohazard waste management</p>
<b>Advantages</b>	Lower initial investment	High throughput, limited operator involvement	Facilitates “screen and treat” programmes, no laboratory experience needed to operate
<b>Limitations</b>	Labour-intensive	High initial investment; large footprint	Low throughput (though moderately scalable to increase capacity)

Source: WHO (2020).<sup>14</sup>

14 World Health Organization. WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer. Geneva: WHO; 2020 ([https://www.who.int/medical\\_devices/publications/tech\\_specs\\_precancerous\\_Lesions\\_cervical\\_cancer\\_devices/en/](https://www.who.int/medical_devices/publications/tech_specs_precancerous_Lesions_cervical_cancer_devices/en/), accessed 4 November 2020).

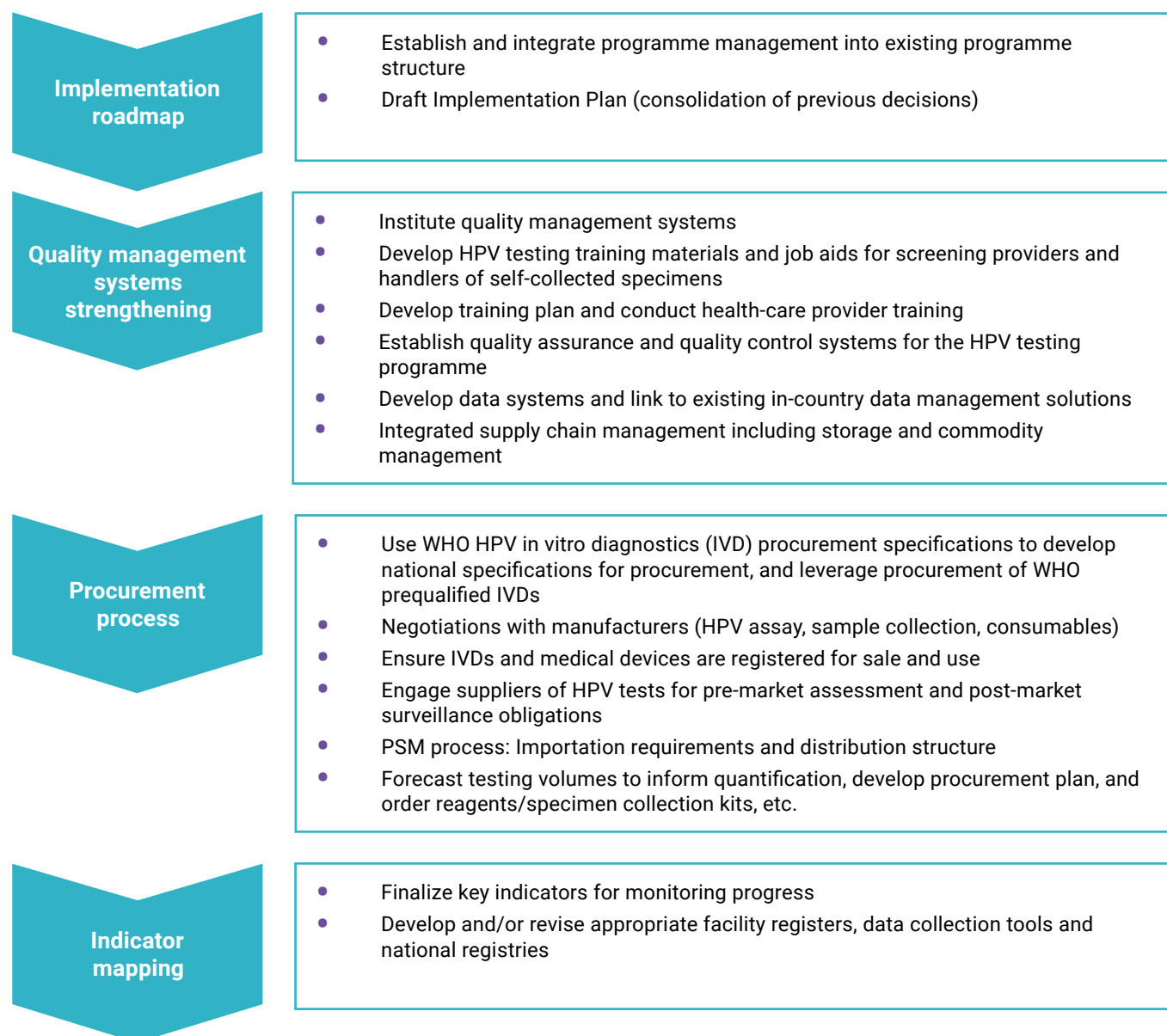


**Reference material:**

- Screening and treatment of pre-cancerous lesions for secondary prevention of cervical cancer: technology landscape
- Guidance for procurement of in vitro diagnostics and related laboratory items and equipment
- Lignes directrices pour l'achat de dispositifs médicaux de diagnostic in vitro et articles et équipements de laboratoire connexes
- WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer – Annex 2B: Technical specifications for HPV NAT IVDs
- Integrating HPV testing in cervical cancer screening programs: a manual for program managers
- Incorporación de la prueba del virus del papiloma humano en programas de prevención de cáncer cervicouterino: manual para gerentes de programas de salud
- Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks
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# Implementation

**Figure 6. Implementation phase considerations**



# 1 IMPLEMENTATION ROADMAP

## Establish and integrate programme management into existing programme structure

Identify and engage with other MOH teams and with implementing partners like NGOs and CSOs that can be leveraged to support particular components of the strategy (e.g. training programmes in districts, demand generation with target populations). Also consider the role of public–private partnership (PPP) with private laboratories or in-vitro diagnostics (IVD) manufacturers, where practical.

**AIM: To integrate with existing programme management structures, while maximizing existing resources and mobilizing the relevant strengths of all concerned in-country NGOs and CSOs.**



### *Reference material:*

- **Comprehensive cervical cancer control: a guide to essential practice, second edition – Section 2**
- **Control integral del cáncer cervicouterino: guía de prácticas esenciales, segunda edición – Sección 2**
- **La lutte contre le cancer du col de l'utérus: guide des pratiques essentielles, deuxième édition – Section 2**
- **Controle integral do câncer do colo do útero: guia de práticas essenciais – Section 2**

## Draft Implementation Plan (consolidation of previous decisions)

Develop the Draft Implementation Plan alongside relevant country stakeholders. Consider a stepwise approach:

- Beginning with the end in mind: Plan pilot projects and other programmatic research for successful implementation – from introduction to scale-up of HPV testing for the purpose of screening in the context of a comprehensive cervical cancer prevention and control programme.
- Consider regional/geographic, population-group or other factors as a basis for effective phased implementation.

**AIM: To outline a clear strategy, objectives and monitoring framework.**

### *Important consideration:*

- Phased timelines allow resources to grow in line with growing demand in the country, and allow for learnings from the first phase to be leveraged for the next.



#### **Reference material:**

- **Planning and implementation cervical cancer prevention and control programs: a manual for managers – Chapter 5: The program action plan**
- **Beginning with the end in mind: planning pilot projects and other programmatic research for successful scaling up**
- **Avoir le but a l'esprit des le debut: la planification des projects pilotes et d'autres recherches programmatiques pour un passage a grande echelle reussi**
- **Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks**
- **Éléments à prendre en considération pour l'adoption et l'utilisation de dispositifs de dépistage conjoint des maladies au sein de réseaux de laboratoires intégrés**
- **Considerações para a adopção e utilização de dispositivos de rastreio multi-doença nas redes de laboratórios integradas**

### **CASE STUDY: ALBANIA**

Cervical cancer is the second most common type of cancer among women of reproductive age in Albania, with most cases diagnosed at stages III and IV. Until recently, the cervical cancer control efforts were limited to providing opportunistic Pap smear tests, with only a few cytology laboratories, located mostly in Tirana, the capital city. Most rural health centres did not have qualified personnel or equipment for gynaecological sampling and women had to travel to an urban health-care facility to have a sample taken, then they had to transport the samples themselves to the cytology laboratory. It was not possible for this set-up to include quality assurance throughout the screening pathway.

The Ministry of Health decided to rethink their strategy, and a WHO mission took place in 2017 that provided detailed recommendations – notably to introduce HPV testing and to set up a screening quality assurance system. In 2019, Albania officially moved to HPV testing. The use of free self-administered tests is expected to make HPV testing more attractive to women, and steps are being taken to reduce costs and improve quality. The HPV tests are interpreted in a central laboratory, and primary health care personnel are trained to ensure the quality of the tests.

## 2 QUALITY MANAGEMENT SYSTEMS STRENGTHENING

### Institute quality management systems

Implement the 12 building blocks or quality systems essentials (QSEs) using the WHO Laboratory Quality Stepwise Implementation (LQSI) tool (see Figure 7).

**AIM:** To institute the systems needed to control, assure and manage the quality of the laboratory's HPV testing processes as well as triage testing, where relevant.

**Figure 7. Twelve components of a quality management system: quality system essentials (QSEs)**



Source: WHO (2015).<sup>15</sup>



#### Reference material:

- WHO Laboratory Quality Stepwise Implementation tool
- WHO Manual for organizing a national external quality assessment programme for health laboratories and other testing sites
- WHO Human papillomavirus laboratory manual
- WHO Technical workshop on the role of laboratory detection of human papillomavirus in global disease prevention and control

15 World Health Organization. Laboratory Quality Stepwise Implementation (LQSI) tool. Geneva: WHO; 2015 (<https://extranet.who.int/lqsi/node/336>, accessed 10 November 2020).

## Develop HPV testing training materials and job aids for screening providers and handlers of self-collected specimens

- a. **Conduct training needs assessments and plan for reorientation of service providers:** Review the existing plan and facilities for training of service providers engaged in cervical cancer screening and management. It may be necessary to revise the training plan to include new providers (e.g. laboratory technicians) and also to incorporate the modified screening and management protocol into the training programme. Programme managers in charge of various health-care facilities (at the level of district, region or other administrative unit) also need to be reoriented to the new scheme. Appropriate facilities need to be identified to provide adequate hands-on training for skills development.
- b. **Review existing training resources and adapt them to the new process:** It may be necessary to modify the contents of the resources used for training to ensure that they incorporate the updated screening and management guidelines for HPV technologies, including for training of laboratory technicians and laboratory managers. Preparing SOPs for various skills (counselling, screening, treatment, performing HPV tests, etc.) will be very useful for training and as a handy on-the-job reference.
- c. **Develop self-collection materials:** In addition, development of self-collection materials should be considered where relevant, including training tools and instructional SOPs to assist patients to adequately self-collect a specimen for HPV testing. In parallel, training programmes and job aids should be developed for health-care providers on educating patients in self-collection.

**AIMS:** (i) To adequately train and sensitize health-care providers on HPV testing and linkages to care; (ii) To strengthen triage services if included in the testing and treatment strategy; (iii) To adequately educate and equip patients for self-collection of specimens; (iv) To increase the acceptability of self-collection among health-care providers; and (v) To ultimately facilitate the process of diagnosis and treatment for women with self-collected HPV specimens for testing.



### **Reference material:**

- Colposcopy and treatment of cervical precancer (IARC, 2017)
- Atlas of colposcopy: principles and practice (IARC, 2020)
- Virtual course on comprehensive cervical cancer control (PAHO)
- Cervical cancer screening and management of cervical pre-cancers (WHO, 2020)
- PAHO communication materials: educational booklets on HPV
- Health literacy toolkit for low- and middle-income countries: a series of information sheets to empower communities and strengthen health systems
- International Gynecologic Cancer Society (IGCS) Global Curriculum & Mentorship Program

## Develop training plan and conduct health-care provider training

Develop training programmes designed to both inform and sensitize health-care providers (i.e. screening and treatment staff, laboratory staff, MOH staff, etc.) to the HPV screening technology and updated screening and management guidelines, while also allowing for facility-specific refinement of patient and sample flow. It is crucial to identify facility-based leads to drive demand and communicate ongoing challenges and progress to central programme management.

Refresher training sessions should be planned for and conducted at regular intervals or in response to external quality assessment (EQA).

**AIM: To maximize patient impact and improve demand with a well trained and sensitized workforce.**



### **Reference material:**

- **Virtual course on comprehensive cervical cancer control (PAHO)**

## Establish quality assurance/quality control systems for the HPV testing programme

Testing providers should ensure:

- A quality management system that describes the operation in a well documented manner and that promotes a continuous process for improving the performance.
- Participation in EQA schemes, where the major component is the testing of a blinded “proficiency panel” that has been produced by an outside and independent agency.



### **Reference material**

- **International HPV Reference Center: Proficiency panel**
- **WHO HPV laboratory manual – Section 2.2.3: Harmonization and standardization of HPV assays**

## Develop data systems and link to existing in-country data management solutions

- a. **Laboratory information management systems (LIMS):** Ensure functionality to monitor specimens through arrival, acceptance (or rejection), processing, testing, result and report.
- b. **Screening register:** Ideally, a screening register supports the system. Develop or adapt existing cervical cancer screening registry data platforms that can track cervical screening data on individual women. It should receive identifying, contact and demographic information describing screened women, together with HPV test results from laboratories via an interface with LIMS. This should be used to support notification of results, follow-up of screen-positive women and referral to treatment, and treatment outcome should also be recorded subsequently. Where colposcopically directed biopsy or large loop excision of the transformation zone/loop electrosurgical excision procedure (LLETZ/LEEP) are performed, the platform should also record pathology results.
- c. **Link screening data sources to relevant data systems:** Identify and link additional data management systems with the screening register and enable connectivity of NAT platforms used for HPV testing. Where relevant, establish linkage to LIMS, electronic medical records (EMR), patient referral or scheduling systems, cancer registries and District Health Information Software 2 (DHIS2) database.

**AIM: To allow for programmatic monitoring, patient tracking and management, and clinical decision-making.**



### **Reference material:**

- **Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 1: Rapid situational assessment of data and data systems**
- **Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 1**
- **Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 1**

## CASE STUDY: MALAYSIA

The introduction of self-sampling HPV DNA testing provides opportunities to significantly increase the uptake of cervical screening by enabling task shifting. Cervical screening has conventionally been undertaken in busy clinics by health-care professionals, necessitating a pelvic examination; this can now be simplified. In this multi-ethnic setting, approaching different types of communities had different sets of challenges. There is no “one size fits all” method. For example, self-sampling HPV DNA testing, as a self-administered intervention, empowers women from different backgrounds to organize screening within their communities outside the clinical setting, in line with the WHO self-care model. Volunteers can be mobilized to adapt to the physical and social settings of the communities, offering customized education and raising awareness. These women serve as links between communities, forming a network of women who can continue to educate, disseminate information and even perform the screens to complement screening in primary care facilities. However, women who are more comfortable with an HPV test administered by a health-care professional can still access this option.

The ability to go mobile, to use digital platforms, and the simplicity of the screening test itself allow for successful transition from cytology-based screening to HPV testing. In a pilot project (Program ROSE) we used a web-based digital platform, adapted to suit the needs of a middle-income country, communicating with women by text messages on their mobile telephones, particularly to link women to follow-up services (colposcopy).

Contact and demographic information describing screened women should be used together with HPV test results to support notification of results and follow-up of screen-positive women; subsequently any treatment required could also be recorded. De-identified (anonymized) data can then be used to monitor key indicators to continuously improve aspects of the programme, such as screening coverage and follow-up rates.

## Integrated supply chain management including storage and commodity management

Ensure a coordinated supply system for specimen collection devices and collection media to the screening facilities, and supply of reagents and other consumables to the laboratory or other screening sites. A manager also needs to be identified.



### **Reference material:**

- **CHAI Monitoring and uptake tools and resources – HIV tools that can be adapted for HPV commodity monitoring:**
  - **CHAI Rapid Consumption Monitoring Tool**
  - **CHAI Outil de Surveillance de la Consommation**
  - **CHAI National ARV Stock Status Dashboard**

### 3 PROCUREMENT PROCESS

Use WHO HPV in vitro diagnostics (IVD) procurement specifications to develop national specifications for procurement, and leverage procurement of WHO prequalified IVDs

**AIM:** To ensure transparent and fair procurement processes with value for money.



**Reference material:**

- WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer – Section 8
- WHO procurement of in vitro diagnostics and related laboratory items
- OMS lignes directrices pour l'achat de dispositifs médicaux de diagnostic in vitro et articles et équipements de laboratoire connexes
- In vitro diagnostics and laboratory technology: WHO prequalified in-vitro diagnostics

#### Negotiations with manufacturers (HPV assay, specimen collection, consumables)

Engage with suppliers to submit offers to tenders (invitations to bid/requests for quotations/requests for proposals) and where possible secure all-inclusive pricing (see Table 2), which is the standard for molecular testing platforms. Consolidate volumes across various funding streams or procurement channels to increase negotiating leverage and reduce cost.

**AIM:** To establish pricing and contract terms that maximize affordability and allow for sustainability and scalability of the programme.



**Reference material:**

- WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer – Section 8
- Guidance for procurement of in vitro diagnostics and related laboratory items and equipment – Section: Procurers of IVDs
- Lignes directrices pour l'achat de dispositifs médicaux de diagnostic in vitro et articles et équipements de laboratoire connexes – Section: Organismes d'achat de DMDIV

**Table 2. Key components of an all-inclusive pricing agreement**

Category		Description
A	Instrument placement	Equipment needed to process specimens placed free of charge; includes site inspection, installation, basic connectivity and ongoing training
B	Reagents and consumables	All reagents and consumables needed to produce a test result in the lab including controls, calibrators and all supplies needed to process specimens collected in preferred collection media
C	Service and maintenance	Cost of servicing and maintaining the testing platform and related equipment, including preventative maintenance, repairs and replacements, and any necessary modifications and updates
D	Freight and logistics	Delivered at place (DAP) to the testing site inclusive of import customs clearance and unloading at destination point; includes cost of export customs clearance, carriage, insurance and distribution (excludes VAT only)
E	Control and calibration	The cost of assays used for control and calibration purposes that do not produce a result for the patient is factored into the all-inclusive price
F	Errors and failures	Free-of-charge replacement of tests that fail due to documented instrument errors; corrective action training for labs with high rates of user errors

Note: The all-inclusive price does not include ancillary costs; for example, those associated with specimen collection, specimen transport, laboratory staff time, laboratory infrastructure, generic laboratory supplies (e.g. primary collection tubes, disposable gloves), inventory management, or general administration and overhead costs. The price does not include the following additional equipment necessary to run the assays: centrifuge, vortex mixer and precision pipette.

Source: adapted from CHAI-developed internal reference for pricing agreements.

## CASE STUDY: TURKEY

In 2014, Turkey redesigned the cervical screening programme including the call/recall system, producing a centralized, real-time and fully automated monitoring system of individual screening status, which uses a single centralized diagnostic laboratory. The programme has a long-term agreement with the HPV diagnostics industry (Mega HPV Laboratory), which was set up as the result of an out-source central tender covering the whole country and screening of 15 million women in five years (followed by a further five-year contract). Under this agreement, all the costs of HPV devices, kits, Pap smears, screening software, etc., are covered by the company that was allocated the contract and the government pays a fixed price per screened patient, without guaranteeing a minimum payment to the company. Using the criteria for the most validated international HPV tests as a basis (Meijer guidelines),<sup>16</sup> the government had the five most prominent companies compete with each other for the contract to provide the 15 million HPV DNA screening tests, which therefore resulted in a very cost-effective price. Currently, similar international guidelines can open the competition to more than 10 companies and central tenders covering the whole country may result in even more competitive tenders. The resulting system allows for traceable, real-time monitoring of screening visits and specimens.

16 Meijer CJ, Berkhof J, Castle PE, Hesselink AT, Franco EL, Ronco G, et al. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. *Int J Cancer*. 2009;124(3):516–20. doi:10.1002/ijc.24010.

## CASE STUDY: ARGENTINA

In Argentina, HPV testing was introduced through the Jujuy Demonstration Project (JDP),<sup>17</sup> a four-year population-based study (2011–2014), led by the Argentinian National Cancer Institute, to evaluate large-scale programmatic introduction of HPV testing. After the study, in 2015, the Ministry of Health initiated the scaling-up of HPV-testing and at present eight provinces use it for primary cervical screening in all or in a portion of their public health institutions.<sup>18</sup> HPV tests are purchased through an international tender.<sup>19</sup> The tests have to be approved by the national regulatory agency (ANMAT); the successful companies will provide the tests, collection kits, consumables, laboratory equipment (including processing), storage and freezing equipment, and will also provide training to the HPV laboratory staff. Expiration dates of kits and consumables cannot be less than 10 months from the moment they are delivered to the HPV provincial laboratories. The contracted companies are also in charge of shipping the kits, consumables and equipment to the designated laboratories, as well as being responsible for undertaking any modifications needed to the laboratory buildings. An analysis of the challenges arising during this process<sup>20</sup> identified the issues of HPV tests not being produced in the country and with a purchase price set in US dollars; this means that a change in the currency market could impact the country's capacity to purchase the tests, as might changes in the import/export conditions.

17 Arrossi S, Thouyaret L, Laudi R, Marin O, Ramirez J, Paolino M, et al. Implementation of HPV-testing for cervical cancer screening in programmatic contexts: the Jujuy Demonstration Project in Argentina. *Int J Cancer*. 2015;137(7):1709–18. doi:10.1002/ijc.29530.

18 Arrossi S, Paolino M, Laudi R, Gago J, Campanera A, Marín O, et al. Programmatic human papillomavirus testing in cervical cancer prevention in the Jujuy Demonstration Project in Argentina: a population-based, before-and-after retrospective cohort study. *Lancet Global Health*. 2019;7: e772–83.

19 Ministerio de Salud y Desarrollo Social de Argentina. Documento de licitación para adquisición de test de VPH. No date ([http://www.salud.gob.ar/images/stories/Licitaciones-msal/Ver\\_Pliego%20PMAPSECNT2-49-LPI-B.pdf](http://www.salud.gob.ar/images/stories/Licitaciones-msal/Ver_Pliego%20PMAPSECNT2-49-LPI-B.pdf), accessed 11 November 2020).

20 Arrossi S. El impacto del test de VPH en los programas de tamizaje en América Latina: el caso de Argentina. *Salud Pública de México*. 2019;61.

## Ensure IVDs and medical devices are registered for sale and use

Use the WHO prequalification process and collaborative registration procedure for IVDs<sup>21</sup> to accelerate registration of prequalified products.

- WHO assists Member States to improve their regulatory procedures for medical devices including IVDs through WHO prequalification, collaborative registration procedure for IVDs (applicable to prequalified products), the WHO Global model regulatory framework for medical devices including IVD medical devices, and the WHO Global Benchmarking Tool for evaluation of national regulatory systems (see links provided below).
- It is ultimately the responsibility of the programmes to determine the level of assessment that is appropriate for the setting; however, **it is not recommended that each country or screening programme conduct a performance evaluation for the HPV NAT that is selected.** If conducted, these should focus on ensuring the usability of products rather than repeating aspects of the WHO prequalification assessment.

**AIM: To accelerate product procurement and implementation.**



### *Reference material:*

- **In vitro diagnostics and laboratory technology: public reports of WHO prequalified IVDs**
- **Second WHO Model list of essential in vitro diagnostics**
- **Collaborative registration procedure for IVDs**
- **WHO Global model regulatory framework for medical devices including IVD medical devices (2017)**
- **WHO Global Benchmarking Tool for evaluation of national regulatory systems**

21 Collaborative procedure between the World Health Organization (WHO) and National Regulatory Authorities in the assessment and accelerated national registration of WHO-prequalified In Vitro Diagnostics (IVDs) (<https://www.who.int/news-room/articles-detail/call-for-comments-on-collaborative-procedure-for-ivd-s>, accessed 6 November 2020).

## Engage suppliers of HPV tests for pre-market assessment and post-market surveillance obligations

Ensure suppliers are aware of their regulatory obligations for pre-market assessment and post-market surveillance.

**AIM:** To ensure that HPV tests continue to meet the same quality, safety and performance requirements as when they were initially placed on the market.



### **Reference material:**

- WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices: WHO Medical device technical series
- Le modèle de cadre réglementaire mondial de l'OMS relatif aux dispositifs médicaux incluant les dispositifs médicaux de diagnostic in vitro
- Глобальная рамочная модель ВОЗ по регулированию медицинских изделий, в том числе медицинских изделий для диагностики in vitro Серия техотчетов ВОЗ по медицинским изделиям
- Post-market surveillance of in vitro diagnostics
- Lignes directrices pour la surveillance post commercialisation des dispositifs médicaux de diagnostic in vitro (DIV)
- пострегистрационный надзор за медицинскими изделиями для диагностики in vitro

## PSM process: Importation requirements and distribution structure

Identify a procurement supply management (PSM) process, necessary stakeholders (in-country economic operators [authorized representatives, importers, distributors], national medical stores, revenue authority, customs, etc.) and associated roles and responsibilities. These may be dependent on the supplier.

*Important consideration:*

- A clear process will mitigate any delays in implementation and help identify any unforeseen costs.



### **Reference material:**

- WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer – Section 8
- Guidance for procurement of in vitro diagnostics and related laboratory items and equipment
- Lignes directrices pour l'achat de dispositifs médicaux de diagnostic in vitro et articles et équipements de laboratoire connexes

## Forecast testing volumes to inform quantification, develop procurement plan, and order reagents/specimen collection kits, etc.

Forecasts should rely heavily on learnings from previous country experiences (i.e. patient acceptance rates, ramp-up period). Quantifications should be conducted alongside the annual laboratory quantification exercise; however, forecasts should be reviewed and updated more frequently, particularly in the early phases of implementation.

The procurement plan should outline responsibilities for the MOH, national medical stores, implementing partners and individual testing facilities.

*Important consideration:*

- Accurate forecasting and PSM planning ensure timely arrival of necessary commodities and minimize wastage due to expired products and stock-outs.



### **Reference material:**

- **Laboratory forecasting tool (e.g. ForLabs)**

### **THREE KEY PROCUREMENT CHANNELS INCLUDE:**

1. Ministries of health and their programmes, and NGOs in official relations with WHO, can procure WHO prequalified IVDs by accessing WHO's long-term agreements with suppliers of prequalified IVDs, by contacting their local WHO country office.<sup>22</sup> In the WHO Region of the Americas, governments can purchase products through the **PAHO Strategic Fund**.
2. UNICEF Supply Division **Supply Portal**
3. Direct engagement with supplier representatives

<sup>22</sup> World Health Organization. 'About WHO: How we buy'. Geneva: WHO; 2020 (<https://www.who.int/about/finances-accountability/procurement/how/en/>, accessed 10 November 2020).

## 4 INDICATOR MAPPING

### Finalize key indicators for monitoring progress

Align goals with tangible indicators that can best demonstrate success.

**AIMS:** (i) To have a clear monitoring framework for the cervical cancer screening programme; and (ii) To ensure comprehensive and consistent data collection.

### Develop and/or revise appropriate facility registers, data collection tools and national registries

**AIMS:** To adapt, update and strengthen the whole monitoring system to support the new framework.

- a. **Population census:** Access population census information to establish eligible members of the target population for screening. This will be needed to assess progress towards reaching 70% of women with cervical cancer screening.
- b. **Cervical cancer screening registries:** Provide an efficient and accurate way to track individual women regarding cervical cancer screening services received, type of screening, screening outcome, referral to diagnosis and treatment, and treatment outcome. Cervical cancer screening registries can provide information on any indicator needed by age, geographic region and screening outcome. Such a registry is useful not only to the programme managers for reporting indicators, but also helps service providers to track women and improve on service delivery.
- c. **Population-based cancer registries:** Leverage and revise previously developed tools based on country-specific indicators. Only population-based cancer registries can provide data on cervical cancer incidence. Linkage of data between screening and cancer registries enables the evaluation of the screening test performance (where poorer than expected sensitivity and/or specificity might lead to unacceptable levels of misdiagnosis), and enables measurement of the impact of screening services in the population.
- d. **Death registration:** Strengthen death registration with cause of death information, access death registration information that is linkable with information from the cervical cancer screening registry, cancer registry and hospital records.

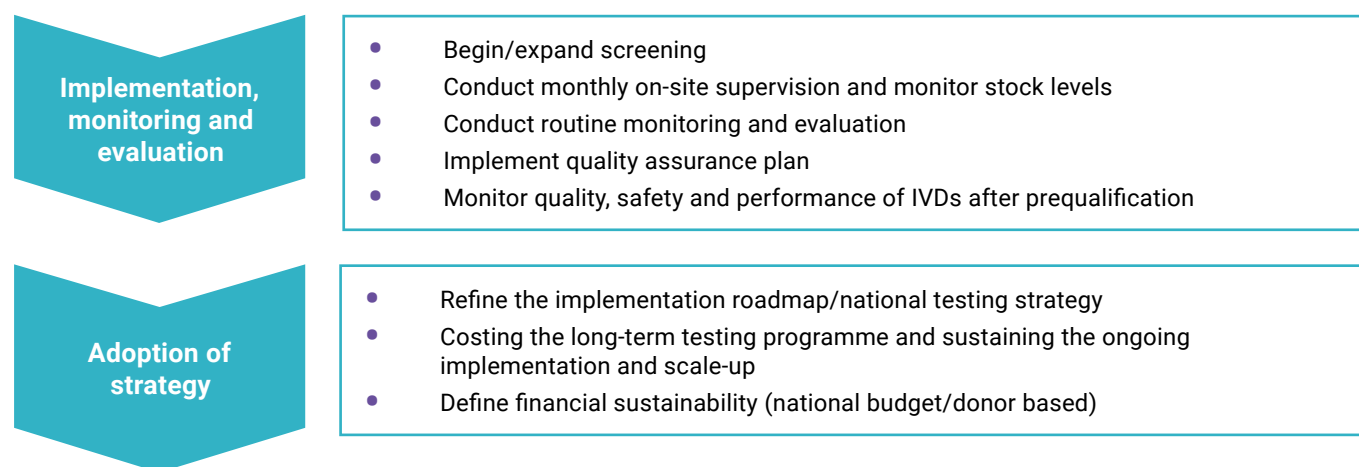


#### **Reference material:**

- **Manual for cancer registry personnel (IARC, 1995)**
- **Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 1**
- **Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 1**
- **Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 1**

# Monitoring and scaling

Figure 8. Monitoring and scaling phase considerations



## 1 IMPLEMENTATION, MONITORING AND EVALUATION

### Begin/expand screening

Deploy the testing and treatment strategy at initial pilot sites for approximately 3–6 months to gather information about strengths and weaknesses in the proposed system, which must be addressed before expanding services nationally. Following this pilot stage, review operational and programmatic learnings to inform scale-up to additional sites. Consider beginning expansion of testing outside of pilot sites in parallel with pilot site monitoring.

**AIMS:** (i) To allow real-life pilot-testing of the testing and treatment strategy and service-delivery approach; and (ii) To provide important information on corrective actions that may be needed before expanding services to a larger area.



#### Reference material:

- Planning and implementing cervical cancer prevention and control programs: a manual for managers – Chapter 5: The program action plan

## Conduct monthly on-site supervision and monitor stock levels

Ensure alignment with the PSM plan to adequately monitor stock levels of reagents and consumables, conduct regular visits and meetings with site supervisors, gain feedback from health-care providers to optimize the flow of procedures, review data collection tools for accuracy/completeness, and review quality assurance screening results for trends.

**AIMS:** (i) To adjust procedures and protocols or tools as needed; (ii) To improve data reliability; and (iii) To limit stock-outs/expiries.



### *Reference material:*

- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 4
- Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 4
- Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 4

## Conduct routine monitoring and evaluation

- Collect qualitative and quantitative data for analysis, using selected data tools.

**AIM:** To gather reliable and comprehensive data for monitoring programme effectiveness.



### *Reference material:*

- Cancer Screening in Five Continents (CanScreen5) project – data collection tools
- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 3
- Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 3
- Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 3

## Implement quality assurance plan

Incorporation of HPV testing data into the broader cervical cancer screening registry and managing ongoing quality assurance are critical to monitor national and regional screening coverage and to revise/refine the overall cervical cancer screening and treatment strategy.



### **Reference material:**

- **European guidelines for quality assurance in cervical cancer screening**

## Monitor quality, safety and performance of IVDs after prequalification

Ensure suppliers act on feedback received from users, and conduct trend analysis and literature reviews. Periodically review the WHO-maintained list for any relevant IVD safety alerts or WHO information notices for users.

**AIMS:** (i) To encourage IVD users to submit their feedback where product problems occur; and (ii) To ensure the manufacturer reports certain incidents to the national regulatory authority, which should maintain a public inventory of IVD field safety notices.



### **Reference material:**

- **Post-market surveillance of in vitro diagnostics**
- **Lignes directrices pour la surveillance post commercialisation des dispositifs médicaux de diagnostic in vitro (DIV)**
- **пострегистрационный надзор за медицинскими изделиями для диагностики in vitro**
- **WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices: WHO medical device technical series**
- **Le modèle de cadre réglementaire mondial de l'OMS relatif aux dispositifs médicaux incluant les dispositifs médicaux de diagnostic in vitro**
- **Глобальная рамочная модель ВОЗ по регулированию медицинских изделий, в том числе медицинских изделий для диагностики in vitro Серия техотчетов ВОЗ по медицинским изделиям**
- **Safety information for medical devices including in vitro diagnostics**

## 2 ADOPTION OF STRATEGY

### Refine the implementation roadmap/national testing strategy

Use data-driven adjustments from ongoing monitoring and evaluation on a regular basis. Include a periodic review of the testing and treatment strategy and associated delivery models to adjust the testing strategy as conditions and resources change.

### Costing the long-term testing programme and sustaining the ongoing implementation and scale-up

Assess the costs of the long-term HPV testing programme, including commodities, human resources and systems-related costs.

**AIMS:** To inform budgeting and to develop a sustainable, costed national plan.



#### *Reference material:*

- Cost effectiveness and strategic planning (WHO-CHOICE): One Health Tool
- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes – Section 5
- Améliorer les données disponibles pour une prise de décision informée: ensemble d'outils pour les programmes de lutte contre le cancer du col de l'utérus – Section 5
- Mejores datos para tomar decisiones: caja de herramientas para los programas de prevención y control del cáncer cervicouterino – Sección 5

### Define financial sustainability (national budget/donor based)

Review in-country budgets, assign national budget line items to accommodate HPV testing, and/or engage with donors to sustain funding for the screening programme.

**AIM:** To identify funding availability, both for the short and long term, to sustain the HPV testing programme.



#### *Reference material:*

- Cervical cancer prevention in El Salvador (CAPE) – An HPV testing-based demonstration project: changing the secondary prevention paradigm in a lower middle-income country (Maza et al., 2017)
- The cost-effectiveness of implementing HPV testing for cervical cancer screening in El Salvador (Campos et al., 2019)

## CASE STUDY: EL SALVADOR

In El Salvador, there was phased introduction of a low-cost HPV test that was developed by Qiagen with the support of the Bill & Melinda Gates Foundation and PATH. El Salvador and Rwanda were the first two countries to be recipients of the QIAGENcares donation programme. This allowed El Salvador to introduce HPV testing into the public sector in settings with limited resources. The Ministry of Health (MOH) in collaboration with the non-profit organization Basic Health International (BHI) were able to demonstrate through the Cervical Cancer Prevention in El Salvador (CAPE) demonstration project that implementing a screen-and-treat programme using HPV testing for primary screening was a feasible option within the public sector.<sup>23, 24</sup> As part of the Scale-Up Project for Cervical Cancer Prevention,<sup>25</sup> the MOH and BHI were able to scale this programme up to cover one of the five regions of the country. After the donation programme (public–private partnership) ended, the MOH was able to secure additional funding through their external cooperation department, which allowed them to expand the programme to two more regions of the country, and subsequently, through the support of the World Bank, El Salvador was able to expand HIV testing to a fourth region of the country. Now that these initial programmes are ending, it is expected that the government will include the procurement of HPV tests in the national federal budget, thus ensuring sustainability and coverage of all five regions of the country with primary HPV screening.

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- 23 Maza M, Alfaro K, Garai J, Velado MM, Gage JC, Castle PE, et al. Cervical cancer prevention in El Salvador (CAPE) – An HPV testing-based demonstration project: changing the secondary prevention paradigm in a lower middle-income country. *Gynecol Oncol Rep.* 2017;20:58–61. doi:10.1016/j.gore.2017.02.011.
- 24 Alfaro K, Maza M, Felix JC, Gage JC, Castle PE, Alonzo TA, et al. Outcomes for step-wise implementation of a human papillomavirus testing-based cervical screen-and-treat program in El Salvador. *JCO Global Oncology.* 2020;6:1519–30. doi:10.1200/GO.20.00206.
- 25 Scale-Up Project for Cervical Cancer Prevention: Establishing Routine Use of HPV Testing to Prevent Cervical Cancer in Low-Resource Settings. PATH; 2015 (<https://www.path.org/resources/scale-up-project-for-cervical-cancer-prevention-establishing-routine-use-of-hpv-testing-to-prevent-cervical-cancer-in-low-resource-settings/>, accessed 10 November 2020).

**For more information, please contact:**

**Department of Sexual and  
Reproductive Health and Research**

World Health Organization  
20 Avenue Appia, 1211 Geneva 27  
Switzerland

Email: [srhrp@who.int](mailto:srhrp@who.int)

[www.who.int/reproductivehealth](http://www.who.int/reproductivehealth)

**Department of Regulation  
and Prequalification**

World Health Organization  
20 Avenue Appia, 1211 Geneva 27  
Switzerland

Email: [rapidalert@who.int](mailto:rapidalert@who.int) and [diagnostics@who.int](mailto:diagnostics@who.int)

[www.who.int/our-work/access-to-medicines-and-health-products](http://www.who.int/our-work/access-to-medicines-and-health-products)  
[www.who.int/health-topics/substandard-and-falsified-medical-products](http://www.who.int/health-topics/substandard-and-falsified-medical-products)  
<https://extranet.who.int/pqweb/in-vitro-diagnostics>

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