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FOR CERVICAL CANCER PREVENTION:
PRACTICAL EXPERIENCE FROM PATH**

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Comprehensive Cervical Cancer Prevention and Control

Programme Guidance for Countries



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Comprehensive Cervical Cancer Prevention and Control

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Introduction and Purpose of Guidance

Cervical cancer, caused by sexually-acquired infection with human papillomavirus (HPV), continues to be a public health problem worldwide as it claims the lives of more than 270,000 women every year. In high-income countries early diagnosis and treatment of precancerous lesions has led to a significant reduction in the burden of disease. Because of poor access to high quality screening and treatment services the majority of cervical cancer deaths (85%) occur in women living in low- and middle-income countries. The difference in cervical cancer incidence between developing countries and high-income countries is likely to become more pronounced when infection with common oncogenic HPV types is prevented by vaccinating a high proportion of adolescent girls.

Vaccinating girls and women before sexual debut, and therefore before exposure to HPV infection, provides an excellent opportunity to decrease the incidence of cervical cancer over time. As these vaccines protect against HPV types responsible for about 70% of cervical cancers, there will be a continued need to screen women who have been vaccinated as well as those who have not been vaccinated. Therefore, a comprehensive approach to cervical cancer prevention and control should involve vaccinating girls and women before sexual debut, and screening women for precancerous lesions and treatment before progression to invasive disease.

Screening for precancerous lesions can be done in several ways including, cervical cytology (Pap tests), visual inspection of the cervix with acetic acid [VIA] or testing for HPV DNA. Each of these methods has specific advantages, disadvantages and health systems requirements that countries should consider when planning screening programmes (See Annex 1). Demonstration projects on both vaccination and screening-and-treatment programmes in low- and middle-income countries have shown tremendous promise, but weaknesses in their health systems highlight challenges with scale-up of these efforts. Therefore, sustained success of high quality prevention programmes will require not only using evidence-based, cost-effective approaches but also strengthening of national health systems.

Taking into consideration the public health importance of cervical cancer and the challenges and opportunities presented by rapidly developing technologies, United Nations Population Fund (UNFPA) decided to develop programme guidance for UNFPA Country Offices and programme managers in Ministries of Health and partner agencies when developing or updating their cervical cancer prevention and control programmes. Programme managers from Ministries of Health and UNFPA Country Offices of seventeen countries with substantial experience in cervical cancer prevention and control, and technical experts from seven partner agencies (the GAVI Alliance, IPPF [International Planned Parenthood Federation], Jhpiego, PAHO [Pan American Health Organization], PATH, UICC [Union for International Cancer Control] and WHO [World Health Organization]) who play a prominent role in developing and introducing new technologies and innovative cervical cancer prevention programmes, convened in December 2010 in New York to share information and experience and develop programme guidance based on lessons learned. This document is the product of this collaborative effort.¹

¹ Full list of participants can be found in Annex 3.

Guidance for National Strategies and Programming for Cervical Cancer Prevention

National strategies to address cervical cancer prevention and control should be a part of a comprehensive approach that includes prevention with HPV vaccination for young girls, screening and treatment for women diagnosed with precancerous lesions, and treatment and palliative care for women with invasive cervical cancer. In order to have an impact on cervical cancer mortality these programmes must have universal coverage of the targeted population and financing for long-term sustainability. Programme planning and implementation should specifically consider characteristics of the national health system to avoid duplication of efforts or developing disease-specific, vertical programmes.

Leadership and governance

The following are key recommendations for governments and their development partners when considering a strategic plan for cervical cancer prevention and control:

- A national normative framework should be developed to ensure equitable access for all women to quality services currently available or planned for cervical cancer prevention, as well as those that will become available from technological advancements. Norms or standards should be developed as the first enabling step for making preventative services available for all women.
- Ministries of Health should lead efforts regarding cervical prevention and control programmes as part of national reproductive health programmes.
- Ministries should create a multi-disciplinary committee or task force on cervical cancer to coordinate all activities and utilization of resources within the country. This task force should involve and engage with all key stakeholders and decision-makers, including:
 - Donor agencies and international organizations
 - Civil society organizations
 - Academic institutions
 - Scientific societies
 - Non-health sector government agencies
 - Non-Governmental Organizations (NGOs), particularly those addressing women's health and sexual and reproductive health issues
 - Private sector partners
- Cervical cancer prevention and control efforts led by Ministries of Health should utilize existing programmes in non-health Ministries in order to leverage resources. Engagement with private sector partners and NGOs to support cervical cancer prevention, for example through encouraging corporate social responsibility or subsidizing commodities and services is recommended.

- Cervical cancer prevention and control programmes should be designed to target and ensure accessibility to all women of the target age, especially those in marginalized groups (e.g. in lower quintiles of socioeconomic categories, in remote areas, etc.) in order to have any substantial impact on decreasing cervical cancer and related morbidity and mortality.
- Governments must allocate sufficient resources within national budgets and have appropriate guidelines and service standards before starting and scaling-up prevention and control programmes. Initiating programmes with external donations should only be accepted if Ministries of Health have the capacity to sustain programmes after donor funding has been exhausted. Long-term planning of the key elements should include:
 - Human resources management and training
 - Procurement and maintenance of commodities
 - Quality control measures
 - Information and registry systems
 - Monitoring, evaluation and follow-up systems
 - Advocacy and informational materials
 - Opportunities for palliative care for advanced cancer
- Governments should take a health systems approach when initiating and scaling-up comprehensive cervical cancer prevention and control programmes to avoid establishing stand-alone, disease-specific initiatives and to ensure long-term sustainability. When planning prevention programmes, it is important to recognize that: (1) access to treatment of precancerous lesions is a necessary prerequisite for an effective cervical cancer screening programme; (2) screening and pre-cancer treatment should be part of a package of essential health services; (3) delivery of services should ideally be through primary health care services, or as close to the community-level as possible; and (4) there should be universal (or as close to universal) coverage of services.
- With Ministries of Health taking the lead, it is important for cervical cancer programmes to engage all levels of the health system while involving all non-health and private sector stakeholders as much as possible. This should take into consideration current health system structures, human resource capacity, funding mechanisms, health information systems, and access to health services. Decision-making at all levels should be evidence-based.

Financing

- Based on the current health financing mechanism of the country, a mix of public and private funding and out-of-pocket fees should cover the costs of prevention services. Irrespective of the funding mechanism, specific attention should be paid to ensure access to services for disadvantaged groups and subsidy of services, either partially or fully.
- The principles and guidelines articulated in the WHO-UNICEF Joint Statement on Vaccine Donation² are applicable to other types of health products, equipment, and supplies necessary for cervical cancer prevention (such as screening tests). The minimum requirements for accepting donations include:

² http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.09_eng.pdf

- Suitability – donations should be consistent with the goals, priorities and practices of screening and treatment programmes of the recipient country.
 - Sustainability – prior to the donation of materials/equipments, efforts should be initiated to ensure sustainable, continued use of materials and equipment beyond the period of donation.
 - Informed – decision-makers of national cervical cancer prevention programmes in the recipient country should be informed of all the donations.
 - Supply – any donated supplies should have a shelf life of at least 12 months from receipt of donation. All donated equipment should be fully functional and include all the necessary accessories and supplies for its operational use. In addition, training on the use, operation and maintenance of equipment should be arranged prior to or shortly after delivery of the donation.
 - Licensed – material and equipment should comply with existing regulatory and licensing requirements of the recipient country.
- Acceptance of donations of tests, kits and equipment for screening and treatment should take into account suitability of their use in existing infrastructure and human resource capacity of the recipient country.

Service delivery

- Screening interventions should ideally be delivered through primary health care or as close to the community as possible. In countries where other vertical programmes for sexual and reproductive health, sexually transmitted infections (STI), oncology, and/or adolescent and youth services exist, cervical cancer prevention should be integrated into these services. Developing a new vertical programme specifically for cervical cancer prevention should be avoided.
- Services should be made accessible to disadvantaged women and maintain high levels of confidentiality and respect. Based on conditions of the country, specific region, or population being targeted innovative approaches to screening through self-sampling, service delivery through mobile clinics, or a combination of the two may be tested and utilized if proven effective.
- When starting a cervical cancer prevention and control programme, cytology-based screening is not advisable, as sensitivity of this methodology is low and health systems requirements to ensure good quality and adequate coverage are high. If appropriate, a combination of different screening modalities followed by treatment may be used depending on the geographical area, infrastructure and human resource capacity in the country. It is essential that programme managers and decision-makers are well-informed to assess strengths and weaknesses of the different screening methods before their introduction and use.
- Where substantial investments in cytology-based approaches for screening have already been made, assessments should be done to determine whether to continue strengthening these programmes or improve their quality and coverage through introduction of other screening methods (VIA or HPV DNA tests).

- Establishing screening programmes without effective follow-up to treat those with precancerous lesions will result in little or no impact on overall cervical cancer mortality rates. Therefore, regardless of which strategy is selected for screening programmes, special attention must be given to strengthening referral systems and having well defined links to higher levels of health care delivery for tracking women with positive screening results.
- The algorithm for programmes to treat women with precancerous lesions should be chosen based on the resources and health systems infrastructure in the country. A screen-and-treat approach with VIA followed by cryotherapy for treatment (by minimizing delay and the number of visits between screening and treatment) may be suitable for most low-resources settings. Screening with VIA can be provided at all levels of health care, including at the primary health care level. Linkages to services providing LEEP (Loop Electrosurgical Excision Procedure) or cold knife conization with or without colposcopy should be provided when cryotherapy is not indicated, based on the country guidelines.

Human Resource Management

- Human resources are one of the crucial elements when designing cervical cancer prevention and control programmes. Different methods for screening and treatment may have different human resource needs. When planning for human resource needs, programme managers should take into account:
 - Geographical distribution and availability of screening tests
 - Motivation of staff
 - Attrition of staff over time
 - Supervision, management and governance
 - Training for counseling and screening, treatment of precancerous lesions and invasive cancer, laboratory services, and maintenance of equipment
- Whenever possible, task shifting and task sharing should be encouraged to avoid human resource shortages, provide services as close to the community as possible, and minimize cost. For instance, evidence suggests that screen-and-treat programmes with VIA and cryotherapy can be optimized with task sharing, as they can be safely administered by trained mid-level providers as well as by physicians.

Technology and Equipment

- UNFPA, WHO and other partner agencies developing/updating standards for cervical cancer prevention and control should accelerate efforts and disseminate current guidance documents widely.
- Programmes in countries must consider proper management of procurement processes, storage and distribution of equipment, commodities and supplies, quality control, maintenance and transport mechanisms.
- Financing regarding procurement of commodities should take into consideration costs associated with maintenance of the purchased materials and equipment.

Health Information Systems

- Existing health information systems and registries should be strengthened to ensure effective data collection. Health information systems for cervical cancer should be able to monitor coverage of screening and adequate treatment using WHO indicators, and strengthen cancer registries to measure programme impact. Health information systems should also create or strengthen databases to track women with abnormal test results in need of treatment and those receiving care.
- Quality and completeness of registered data must be ensured. Providers and managers responsible for handling data should be educated and trained to properly collect and manage data, as well as using it to guide decision-making to improve the quality of services.
- Whenever possible, operational research should be focused on filling gaps in information based on the needs of the country, and should generate data to guide decision-making.
- A vertical system of data collection only for cervical cancer programmes should be avoided.



Photo: Yalçın Uguz

Integration of HPV Vaccine Delivery into Health Systems

The principles highlighted in the WHO position paper on HPV vaccines³ recommend introduction of these vaccines into national immunization programmes when certain conditions are met. The following are general recommendations for introducing HPV vaccine at the country level:

Leadership and Governance

- An introduction plan for HPV vaccination should be created. This plan should be reflected in the country's immunization programme comprehensive multi-year plan (cMYP) and should be part of comprehensive cervical cancer prevention and control strategy of the country.
- Vaccination activities should be coordinated with other health packages and services for young people and information on the continued need for screening and early treatment of cervical cancer. Vaccination activities can also serve to disseminate information on screening and early treatment of women in older age groups who are not eligible for vaccination but are good candidates for screening and early treatment.

Financing

- Financing HPV vaccines is currently one of the biggest obstacles in the implementation and scale-up of a vaccination programme. Therefore, negotiated price information by single countries or regions should be made public, in order for other countries and regions to leverage similar prices. Different mechanisms of price negotiations and financing may be used when planning a programme.
- Price negotiation and economies of scale may be achieved through competitive bidding or conjoint purchase mechanisms, such as the GAVI Alliance and the PAHO Revolving Fund.
- Negotiating prices through "advanced market commitment" schemes could guarantee purchase over a prolonged period of time.
- Initiating vaccination programmes with external donations should only be accepted if Ministries of Health have the capacity to sustain the programmes after donor funding has been exhausted. Other principles and guidelines on accepting donations are articulated in the WHO-UNICEF Joint Statement on Vaccine Donation.⁴

³ <http://www.who.int/wer/2009/wer8415.pdf>

⁴ http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.09_eng.pdf

- Financing HPV vaccine delivery costs (including transportation, cold chain, vaccine administration, injection equipment and disposal, safety and coverage monitoring, communication and human resources) is another important obstacle in the implementation and scale-up of a programme. Since there is no definitive evidence on which delivery modality is most cost-effective, more work needs to be done in order to evaluate the most affordable and sustainable delivery method in the country.

Procurement and Logistics

- Sustainability of programmes should also take into account logistical and operational issues, and involve the community. This should include coordination between government sectors at the ministerial level, international agencies, civil society organizations, and communities in order to assure proper implementation and sustainability of programmes.
- Planning procurement and logistical support depends largely on the selected vaccination strategy, and requires population-level data.
- Plans for HPV vaccine procurement should take into account adequate cold chain infrastructure.



Photo: Helène Caux / UNFPA

Human Resources Management

- Delivery strategies based on existing vaccination programmes and programme staff may not require additional human resources. However, training and supervision of staff are critical components of a delivery strategy, and will require specific funds for preparation of guidelines, manuals, training materials and methods to evaluate competencies. Supervision of staff should use existing human resource infrastructure, and aim to strengthen procedures and schedules.

Service Delivery Modalities

- There is no definitive evidence on which vaccine delivery modality is most effective. Therefore, countries should adopt a delivery modality or combination of strategies (routine or “campaign”) and settings (school, health service, and community) to affordably achieve the highest coverage of vaccinations.
 - For delivery through school-based vaccination programmes it is crucial to formalize coordination efforts with the education sector at the ministerial and other levels, including teachers. Vaccination schedules must be synchronized with school calendars. Additional strategies should be devised to reach girls not attending schools or who have missed vaccination days at school. While school-based programmes may benefit from existing and well performing school health programmes, these are not prerequisites.
 - Vaccinations at local health centers could facilitate delivery of a comprehensive intervention package, but will have to consider rates of target population covered by these centers.
 - Irrespective of delivery modalities, countries should consider whether vaccination should be voluntary or mandatory, and whether it requires written or implied consent.

Health Information Systems

- Monitoring for coverage, effectiveness, impact, usage (loss and wastage), and safety of vaccines should be planned and use existing systems as much as possible. Collection of coverage data can be challenging, and should include disaggregated data by dose and age at delivery site. Nominal registries may be useful for collecting coverage information and ensuring proper follow-up, but may require unique national identifiers. With appropriate technical support, vaccine impact evaluations may be done using HPV prevalence studies in certain settings. WHO recommends that all countries establish or enhance cancer registries to be able to evaluate the impact of cervical cancer prevention activities, including HPV vaccination programmes and cervical cancer screening programmes.
- Demonstration projects may be a good mechanism to identify gaps and opportunities for scale-up of HPV vaccines delivery.

Advocacy and Community Mobilization

The purpose of advocacy, communication, and community mobilization is to empower individuals to make informed decisions on programme design and service utilization. It is essential to engage community and professional groups to ensure community participation and acceptance. Informing target audiences regarding key messages on cervical cancer prevention should be done well in advance of programme introduction. United Nations organizations and other technical experts should increase advocacy efforts and awareness to reach country level staff and partners. The following are key recommendations when planning an advocacy and community mobilization strategy:

- Advocacy and communication efforts should target:
 - High level decision-makers and advisors in relevant government sectors, civil society organizations, academic institutions, professional associations, insurance companies, and social security agencies
 - Managers in Ministry of Health, hospitals, clinics, and laboratories
 - Health care providers including physicians, nurses, midwives and school health workers
 - Community leaders and members
 - Media representatives
- Key stakeholders should develop an advocacy plan well before implementation of vaccination, screening and treatment programmes. This includes identifying the main objectives of the overall plan, policies required for a comprehensive programme, and behavioral changes needed by policy-makers, health care providers, women, and community members.
- Messages for communication should be carefully adapted to the situation and target audience, and include comprehensive strategies for prevention and control of cervical cancer (vaccination of young girls, screening and treatment of older women). Messaging should include evidence-based technical information, along with political and emotional information and story-telling when appropriate. See Annex 2 for specific messages for target audiences.
- Opportunities to deliver information and messaging to adolescents to improve health education on human immunodeficiency virus (HIV), other STIs prevention, and other relevant reproductive health issues should be considered as appropriate.
- Messages should be disseminated using existing, effective channels of communication. Use of mass media – through health, women’s and youth magazines, radio and television shows – can be effective in reaching large proportions of the target population, but should be done strategically. Using internet and SMS technologies can be useful in providing accurate information and countering misinformation. Messages regarding utilization of prevention services should be focused in areas where these services are planned or currently available.

- High-visibility advocates or “champions” should be encouraged to speak publicly and publish articles about cervical cancer prevention and control. However, these champions should be selected, trained and monitored carefully.
- Special focus should be given to targeting marginalized and hard-to-reach groups such as minority language or ethnic groups and refugees. Collaborating with civil society organizations may be a way to overcome barriers in reaching these marginalized groups. Advocacy and communication through peer outreach with customized materials for each group is recommended.



Photo: Tom Weller / UNFPA

Annex 1: Methods of screening for cervical cancer

Characteristics	Conventional Cytology	HPV DNA tests	Visual inspection with acetic acid, VIA
Sensitivity	47-62%	66-100%	67-79%
Specificity*	60-95%	62-96%	49-86%
No. visits required for screening and treatment	2 or more	2 or more	1 or 2
Health systems requirements	Requires highly trained cytology technicians and cytopathologists; microscope, stains, slides; transport system for specimens and results and a system for informing and tracking positive cases	Requires trained lab worker, electricity, kits, reader; transport system for specimens and results	Requires training and regular supervision; no equipment, few supplies
Comments	Assessed over the last 50 years in a wide range of settings in developed and developing countries. Test must be repeated every few years due to low sensitivity	Assessed over the last decade in many developed country settings; just beginning in developing countries. Due to high sensitivity screening may be done with less frequency	Assessed over the last decade in many settings in developing countries with good results

* Specificity for high grade lesions

Annex 2: Advocacy and communication messaging for different target audiences

Core messages for all target audiences

- Basic information on cervical cancer and HPV infection
- Universality of HPV infection
- Disease burden in the country; prevention strategies and the effectiveness and safety of different interventions
- Emphasis that both vaccination and screening are necessary
- Information on other relevant adolescent health issues such as prevention of HIV and other STIs, prevention of pregnancy should be considered as appropriate

Messages for high-level decision-makers

- Disease burden and comparison with other key national health issues
- Benefits of improved cervical cancer prevention programming, including public health benefits and financial benefits (savings in future cancer treatment costs and continuing productivity by adult women)
- Impact of new programs on budgets, health systems, and Millennium Development Goals and other national or global indicators

Messages for managers and health care providers

- Impact on existing services, and benefits of the programme
- Opportunities for using cervical cancer prevention to promote other health services such as adolescent health, and sexual and reproductive health services
- Necessary systems requirements including procurement, reporting, call and recall, and quality control
- Service provision and counseling skills related to cervical cancer (training)

Messages for clients

- Specifics of what services are provided and how they are performed
 - Information regarding vaccine dosage and schedules required, and target age
 - Schedule for screening, target age and treatment options
 - Specifics on where and when services will be offered
 - Costs of different services
 - Respond to rumors, misinformation, client assumptions
-

Annex 3: Acknowledgements

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