Strategic framework for the Comprehensive Control of Cancer Cervix in South-East Asia Region
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Comprehensive Control of Cancer Cervix
in South-East Asia Region
Contents

Acronyms and abbreviations ....................................................................................................... vii
Executive summary ................................................................................................................... vi
Message from Regional Director ............................................................................................... viii

1. Introduction ...................................................................................................................... 1
2. Objectives ........................................................................................................................ 3
3. Cancer Cervix prevention strategies ................................................................................. 4
   3.1 Overview ................................................................................................................ 4
   3.2 Convergence between different health programmes .............................................. 5
4. Primary prevention: Introduction of HPV vaccine into national immunization programmes
   4.1 Introduction ............................................................................................................ 7
   4.2 Key strategic directions for introduction of HPV vaccine into national immunization programmes 10
5. Secondary prevention: Organizing cervical cancer screening programme ......................... 12
   5.1 Introduction .......................................................................................................... 12
   5.2 Key strategic directions for cancer cervix screening ................................................. 19
6. Augmenting facilities for cervical cancer treatment and palliative care ......................... 22
   6.1 Introduction .......................................................................................................... 22
   6.2 Organize facilities for staging and diagnostic work-up .......................................... 24
   6.3 Key strategic directions for improvement of palliative care services ....................... 25
7. Awareness, education and community mobilization ......................................................... 26
8. Advocacy ........................................................................................................................ 28
9. Annexes .......................................................................................................................... 29
Annex 1: Management of screen-positive women based on colposcopy and histologic diagnosis
Annex 2: Management of women with abnormal cytology based on colposcopy diagnosis, with or without biopsy confirmation
Annex 3: Management of VIA-positive women using single-visit screen-and-treat approach .............. 33

Annex 4: Management of screen-positive women based on colposcopy diagnosis (see-and treat-approach) alone .............. 34

Annex 5: Management of HPV-positive women using VIA to assess suitability for cryotherapy ................ description 35

Annex 6: Triaging of HPV-positive women by cytology or HPV genotyping ................................................. 36

Annex 7: Sample policy and advocacy brief for high-level decision-makers in the health ministry ................. 37

Annex 8: Score sheet for clinical supervision of VIA trainees ................................................................. 39

Annex 9: Cervical cancer burden and control initiatives in the South-East Asia Region ...................... 41
  i. Demographic profile of Member States ................................................................................................. 41
  ii. Cervical cancer burden in the Region ................................................................................................. 42
  iii. Cervical cancer control initiatives ................................................................................................. 43
      1. Bangladesh ................................................................................................................................. 43
      2. Bhutan ......................................................................................................................................... 44
      3. Democratic People’s Republic of Korea ......................................................................................... 44
      4. India ........................................................................................................................................... 45
      5. Indonesia ....................................................................................................................................... 45
      6. Maldives ....................................................................................................................................... 46
      7. Myanmar ...................................................................................................................................... 46
      8. Nepal ........................................................................................................................................... 46
      9. Sri Lanka ...................................................................................................................................... 47
     10. Thailand ....................................................................................................................................... 48
     11. Timor-Leste ................................................................................................................................. 48

Annex 10: Commonly used teaching materials for comprehensive control of cervical cancer ........ 50

Annex 11: Comprehensive Control of Cancer Cervix Data Collection Format .................................. 52

Annex 12: List of Contributors .................................................................................................................. 63
### Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGC</td>
<td>atypical glandular cells</td>
</tr>
<tr>
<td>ASC-H</td>
<td>atypical squamous cells—cannot exclude a high-grade intraepithelial lesion</td>
</tr>
<tr>
<td>ASC-US</td>
<td>atypical squamous cells of undetermined significance</td>
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<tr>
<td>CIN</td>
<td>cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>FIGO</td>
<td>International Federation of Gynaecology and Obstetrics</td>
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<tr>
<td>GAVI Alliance</td>
<td>formerly the Global Alliance for Vaccines and Immunisation</td>
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<tr>
<td>HPV</td>
<td>human papillomavirus</td>
</tr>
<tr>
<td>HSIL</td>
<td>high-grade squamous intraepithelial lesion</td>
</tr>
<tr>
<td>LBC</td>
<td>liquid-based cytology</td>
</tr>
<tr>
<td>LEEP</td>
<td>loop electrosurgical excision procedure</td>
</tr>
<tr>
<td>LSIL</td>
<td>low-grade squamous intraepithelial lesion</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>PATH</td>
<td>Program for Appropriate Technology in Health</td>
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<tr>
<td>SCC</td>
<td>squamous cell carcinoma</td>
</tr>
<tr>
<td>UICC</td>
<td>Union for International Cancer Control</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Populations Fund</td>
</tr>
<tr>
<td>VIA</td>
<td>visual inspection with acetic acid</td>
</tr>
<tr>
<td>VILI</td>
<td>visual inspection after application of Lugol's iodine</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

The overall objective of the Strategic framework for the Comprehensive control of cancer cervix in South-East Asia Region is to offer broad guidelines to Member States of the World Health Organization (WHO) South-East Asia Region to develop or strengthen their national cervical cancer control programme through the judicious use of primary prevention (human papillomavirus (HPV) vaccination) and secondary prevention (cervical cancer screening and treatment) strategies. The framework is based on a situational analysis of the Member States regarding their preparedness and capacity to introduce new cervical cancer control measures. The document has also taken into account emerging scientific evidence related to new technologies and novel paradigms in cervical cancer screening and to the safety and efficacy of the vaccines. The framework recognizes that although there is an overwhelming need in the Region to introduce measures to reduce cervical cancer deaths, some countries may not be able to initiate prevention programmes in an organized manner due to competing health priorities. Such countries should try to augment cancer treatment and palliative care services, and simultaneously plan for demonstration/pilot projects in cervical cancer vaccination and screening.

Nine member countries of the South East Asia Region (Maldives and Timor-Leste not included, as no data available) account for more than one third of the global burden of cervical cancer but lacked effective and organized cervical cancer control program. In some of these countries the number of women dying from cervical cancer annually is comparable to the number of maternal deaths during child birth. Prevention of deaths of middle aged women from cervical cancer through effective control will help these countries advance towards achieving the Millennium Development Goal.

The framework should be read in conjunction with the WHO guidance note Comprehensive cervical cancer prevention and control: a healthier future for girls and women (2013), which recommends that HPV vaccination of 9 to 13 year old girls combined with regular screening of women older than 30 years are the most effective tools for cervical cancer control. The framework presents a brief regional situational analysis, based on inputs from national experts, which may be useful in planning country-specific strategies. The situational analysis has also identified gaps and unmet needs in the health systems of these countries related to cervical cancer control.

The various service delivery models that can be adopted to incorporate HPV vaccination into national immunization programmes are also discussed. A holistic approach, utilizing the opportunity of reaching adolescent girls to provide other age-specific health interventions along with vaccination, will be most beneficial programmatically. It is well appreciated that at the current commercial cost, the vaccines are out of bounds for the public health programmes of countries in the Region. The vaccines are WHO prequalified, thus low- and middle-income countries are eligible to procure them through the GAVI Alliance at the greatly subsidized cost of US$ 4.5 per dose. Even if the vaccines become affordable, there are many other logistic issues and programmatic challenges that the countries need to address, which are discussed in the document. The framework proposes to strengthen public–private partnership and engage the private sector (both non-profit and for-profit)
to mobilize additional resources and technologies to produce the vaccines indigenously, which can drastically reduce the cost and make HPV vaccination programmes sustainable in the long run.

The framework discusses the determinants of a successful and organized screening programme, and feasible options that the countries can adopt. It recommends that cervical cancer screening services should be organized as a functional continuity across different levels of health-care delivery, from community to first-level health centres and to referral hospitals, so as to ensure high coverage of the target population and linkage between screening and treatment.

Augmentation of cancer treatment services and improving palliative care are also crucial components of cervical cancer control that are discussed in the framework.

Key messages

- Cervical cancer causes a significant number of deaths in the South-East Asia Region, even though it is preventable through judicious implementation of screening and vaccination.
- HPV vaccination of 9 to 13 year old girls is a safe and effective method of primary prevention for cervical cancer.
- Member States should explore the programmatic feasibility of introducing the new vaccine and seek sustainable financing options such as negotiating with manufacturers to bring down prices, seeking support from GAVI Alliance and promoting indigenous production.
- Member States should introduce or augment cervical cancer screening programmes by adopting the most feasible strategies, such as screening using visual inspection with acetic acid (VIA) and treatment with cryotherapy.
- Services should be made accessible, especially to the more socially disadvantaged women, to ensure high participation of the target population and high compliance of screen-positive women to diagnosis and treatment.
- There should be convergence between cancer control activities and the different programmes dealing with reproductive, child and adolescent health.
- Treatment facilities should be augmented and effective palliative care services should be made available for women with invasive cervical cancer.
Message from the Regional Director

Cancer of the cervix is the second most common cancer in women worldwide, and in some developing countries it is the leading cause of cancer death. Globally each year, about half a million women develop cervical cancer, and about 275,000 women die of the disease. In terms of prevalence, an estimated 1.4 million women worldwide are living with cervical cancer. In 2008, there were almost 200,000 new cases of cervical cancer in Member States of the World Health Organization (WHO) South-East Asia Region, giving an incidence of almost 25 per 100,000 and mortality rate of almost 14 per 100,000.

The vast majority of cases and deaths from cervical cancer are unnecessary, because efficacious and potentially effective modalities exist for its prevention and management—including primary prevention by vaccination, and secondary prevention by screening to detect and treat early disease. Unfortunately, the majority of women in developing countries still do not have access to cervical cancer prevention programmes. The consequence is that, often, cervical cancer is not detected until it is too late to be cured. An urgent effort is required if this situation is to be corrected. All women have the right to accessible, affordable and effective services for the prevention of cervical cancer.

The low level of programme effectiveness is due to two main reasons. Firstly, although screening and early detection have been available for several decades and have been the mainstay of prevention, the requirements for designing and implementing such a programme are complex and need very sound and strong management. Secondly, the potential and promise of primary prevention through the human papillomavirus (HPV) vaccine is severely limited by its high costs, which are not within the reach of most developing nations. Gross inequalities have been observed in women’s abilities to access screening programmes, as it is observed that women in urban areas and those with a high economic status are screened as often as required (and sometimes even more often), while women who are poor, uneducated and living in rural areas do not have a screening test even once in their lifetime. A strong health system is crucial to ensure screening programmes work; unfortunately, this does not exist in many developing countries.

A great deal of experience and evidence-based knowledge are available for the prevention and treatment of cervical cancer, and its related mortality and morbidity. With the objective to work and support Member States in developing or strengthening their national cervical cancer control programme, through judicious use of primary prevention (HPV vaccination) and secondary prevention (cervical cancer screening) strategies, as well as strengthening cervical cancer treatment and palliative services, the WHO Regional Office for South-East Asia has facilitated the development of this Strategic framework for the comprehensive control of cervical cancer in South-East Asia to reduce the burden of the disease in the Region. The framework is based on a situational analysis of
Member States regarding their preparedness and capacity to introduce new cervical cancer control measures, and has taken into account the emerging scientific evidence related to new technologies and novel paradigms in cervical cancer screening, as well as the safety and efficacy of HPV vaccines.

The Regional Office will be working with Member States to introduce effective, organized control programmes for cervical cancer – as recommended in the framework – and call upon all stakeholders for concerted and coordinated actions. Together, we can significantly reduce the heavy burden of cervical cancer and its consequences in the South-East Asia Region.

Dr Poonam Khetrapal Singh
WHO Regional Director for South-East Asia
Strategic framework for the Comprehensive Control of Cancer Cervix in South-East Asia Region
Introduction

Cervical cancer is a major public health problem in the South-East Asia Region of the World Health Organization (WHO), contributing nearly 35% of the global burden of disease. Mortality rates from cancer cervix are also very high in the Region, due to the late stage at diagnosis and suboptimal therapeutic facilities. Cervical cancer can be prevented through a two-pronged strategy: vaccination of adolescent girls against the human papillomavirus (HPV), the causative agent for cervical cancer, and population-based organized cervical cancer screening and treatment. Although either of the interventions in isolation can achieve a significant reduction in mortality, a comprehensive approach – involving health education, vaccinating girls before initiation of sexual activity, screening women for precancerous lesions and treatment before progression to invasive disease – is the most efficient and cost-effective way to control the disease.

Amidst competing health priorities, control of cervical cancer has never been considered a priority and, with resource and logistics constraints, countries in the South-East Asia Region have lacked effective screening programmes. Bhutan is the only country in the Region to implement a population-based HPV vaccination programme, while Sri Lanka has achieved relatively high coverage with screening.

Some Member States in the Region have made significant achievements in the reduction of maternal mortality in recent years. Implementation of cervical cancer control programmes will keep them on track to achieve the Millennium Development Goals (MDGs), one of which is improving women’s health through universal access to sexual and reproductive health services (Goal 5b: Universal access to reproductive health). Saving lives from cervical cancer will also contribute to the 2010 United Nations (UN) Secretary-General’s Global Strategy for Women’s and Children’s Health and to the 2011 Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases.

The HPV vaccine is unique and its introduction is challenging in many ways – not only is it the first vaccine developed to prevent any cancer, but the vaccine is also gender-specific, targeting adolescent girls who are difficult to reach through other health intervention programme. There is a great need to educate the public, health professionals and health planners. It has to be emphasized to policymakers that WHO, United Nations Populations Fund (UNFPA), Union for International Cancer Control (UICC), International Federation of Gynaecology and Obstetrics (FIGO) and other organizations that influence public health policies globally, have unanimously endorsed HPV vaccination as a safe and effective cervical cancer prevention option. Such endorsement is based on robust and consistent evidence gained from clinical trials and also from the reported experience of using the vaccine in national programmes in more than 50 countries worldwide. While preparing the ground for the vaccine introduction, governments have to negotiate with vaccine manufacturers to reduce the price to an affordable range, and also to look for sustainable funding options within or outside the country.

Several research studies in the past decade have successfully identified new screening tests as suitable alternatives to Pap smear cytology, especially for programmes in resource-limited settings. Simpler
paradigms of diagnosis and treatment have been evaluated and accepted. Such interventions are cost-effective and affordable means to ensure wide coverage of the target population and achieve high compliance to treatment of screen-detected cases, factors that are crucial to the success of a screening programme. Individual countries can now decide to adopt the most suitable screening, diagnostic and treatment modalities from a range of options, depending on programmatic feasibility and capacity of their health systems.

Simultaneous with planning for the preventive strategies, it is also important to organize facilities for appropriate treatment of invasive cervical cancers (such as radical surgery, radiation therapy or chemotherapy, alone or in combination). Most countries in the South-East Asia Region are deficient in this aspect. Palliative care to provide relief from the physical and psychological sufferings of advanced cancer is a critical part of a comprehensive cancer control programme. An effective strategy to deliver palliative care should be organized at the health facilities, community level and home by a trained team of clinicians, nurses and health workers.

This framework acknowledges that no single model can apply to all countries, or even within an individual country, in the South-East Asia Region. The Member States must design and implement cervical cancer control programmes tailored to the needs and realities of their national and subnational settings, employing a rational mix of community, outreach and facility-based clinical services. The framework emphasizes the need to focus on marginalized groups, and proposes strategies and differentiated packages for responding to various situations. There will always be some trade-offs when strategies are selected not because they perform best, but because they reduce the barriers to access and are programmatically feasible and affordable. The success of the cervical cancer control programme will finally depend on the pragmatic selection of service delivery models with good centralized control and a built-in system of quality assurance.
Objectives

The overall objective of the strategic framework for comprehensive control of cancer cervix in South-East Asia is to guide and assist Member States to develop or strengthen national strategies to improve cervical cancer control activities; to reduce the burden of morbidity, disability and death from cervical cancer; and, to promote women's health.

The specific objectives of the framework are to help countries to prepare country-specific protocols to:

1. Introduce or scale up delivery of HPV vaccine to girls aged 9 to 13 years through a coordinated multisectoral approach involving national immunization, cancer control, reproductive and adolescent health programmes.

2. Implement or scale up organized cervical cancer screening programmes utilizing evidence-based, cost-effective interventions through effective service delivery strategies across the different levels of health care.

3. Strengthen health systems to ensure equitable access to cervical cancer screening services for all eligible women, with particular attention to socioeconomically disadvantaged population groups.

4. Augment management facilities for invasive cancer cervix and introduce palliative care services into the health system as part of a comprehensive cancer control programme.

5. Encourage/create convergence with related health programmes to ensure a coordinated and operationally feasible approach for cervical cancer control within the health system.

6. Initiate/augment a structured and coordinated advocacy and educational campaign so that the benefits of cervical cancer control are universally available and accessible.
Cervical cancer prevention strategies

3.1 Overview

Cancer of the uterine cervix is a preventable cancer. It develops slowly over 10 to 15 years as a consequence of HPV infection. HPV is a common sexually transmitted infection, which is highly prevalent among young sexually active men and women. The vast majority of infected individuals get rid of the virus within a few months due to activation of their natural immune system. Women remaining persistently infected with certain carcinogenic types of HPV are at a greater risk of developing cervical cancer. Out of nearly 35 types of HPV that infect the genital tract, 15 are designated as high-risk carcinogenic types. Of these, HPV 16 and 18 are the two most common high-risk types, implicated in 65% to 80% of all cervical cancers. Protecting adolescent girls through vaccination against the two most carcinogenic HPV types is a safe and effective primary prevention strategy against cervical cancer. Two commercially produced HPV vaccines are widely available in almost all countries in the South-East Asia Region, and it is feasible for some countries to obtain the vaccine for the national immunization programme at an affordable cost.

Persistent HPV infection leads to a preneoplastic change in the epithelial layer of the cervix. This change, known as cervical intraepithelial neoplasia (CIN), is graded as CIN1, CIN2 or CIN3 depending on severity. CIN1 lesions, also referred to as low-grade squamous intraepithelial lesions (LSIL) are due to transient HPV infections and regress spontaneously or remain static. However, around 30% to 50% of CIN2 and CIN3 lesions, together referred to as high-grade squamous intraepithelial lesions (HSIL), will progress to invasive cancer if they remain undetected and untreated. Hence, CIN2 and CIN3 are known as true cervical cancer precursors. Secondary prevention of cervical cancer is feasible through the detection and treatment of disease at the HSIL stage by cervical cancer screening. The objective of cervical cancer screening is to apply a simple test to detect the disease at the precancerous stage and ensure appropriate treatment before invasive cancer sets in. It is well established that detection and treatment of CIN and early invasive cancers through organized cervical cancer screening programmes can reduce mortality rates from the disease by 60% to 80% in the screened population.

Several simple and low-cost screening strategies have evolved over the past few years that can be adopted for population-based screening programmes in countries. A comprehensive national policy for HPV vaccination and cervical cancer screening can save women's lives, be cost-effective and contribute towards attainment of the MDGs to improve women's lives.

Appropriate and timely treatment of invasive cervical cancer and the introduction of palliative care services for patients with advanced cancer are strategies for tertiary prevention that limit disabilities, improve quality of lives and prevent deaths. The continuum of preventive strategies for cervical cancer over the lifespan of women is shown in Figure 1.
3.2 Convergence between different health programmes

In all countries of the South-East Asia Region, the public health system is overburdened and has limited capabilities to stretch resources to include additional health programmes. The managers of the new cancer cervix control programme have to take cognizance of this reality and plan service delivery models in such a way that there is no disruption of ongoing work; but, at the same time, some of the responsibilities and resources can be shared across different programmes. A proposed model of service delivery for both HPV vaccination and cervical cancer screening components utilizing the existing health infrastructure and bringing in convergence between similar health programmes is shown in Figure 2.

The target population for HPV vaccination (9 to 13 year old girls) is difficult to reach, since the adolescent girls attend the health facilities infrequently. Accessing the target population through schools is certainly a viable option; unfortunately, however, many Member States in the Region have high drop-out rates for girls after primary education. Despite this, health programmes targeting this age group of girls (such as immunization against tetanus, sexual and adolescent health, anaemia prevention, etc.) provide good opportunities to reach and vaccinate them against HPV. Such convergence of programmes is mutually beneficial, since multiple interventions can be completed in a limited number of visits. Likewise, women targeted for cervical cancer screening can be accessed through the various reproductive health and non-communicable disease programmes. Through integration of cancer cervix control activities with the existing health infrastructure, the need for additional staff, equipment and space can be minimized. Training modules can also be combined to reduce the number of work days lost to staff training. Another major advantage of programmatic convergence is utilization of a common health management information system.
Figure 2. Key roles of different health-care levels, and sharing of resources and responsibilities, to deliver comprehensive cervical cancer control

<table>
<thead>
<tr>
<th>National cancer control programme</th>
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<tbody>
<tr>
<td>Policy and guidelines</td>
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<tr>
<td>Funding and resources</td>
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<tr>
<td>Monitoring, evaluation and quality assurance</td>
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<table>
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<tr>
<th>Tertiary hospitals/oncology settings</th>
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<tbody>
<tr>
<td>Treatment of invasive cancers</td>
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<tr>
<td>Diagnostic facilities, colposcopy and biopsy</td>
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<tr>
<td>Treatment of precancers, especially by LEEP</td>
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<tr>
<td>Capacity-building in colposcopy, treatment, cytology and histology; training of trainers</td>
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<table>
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<tr>
<th>Secondary level (provincial/district hospitals)</th>
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<tbody>
<tr>
<td>Colposcopy, biopsy, treatment of CIN</td>
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<tr>
<td>Cytology and histology laboratories</td>
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<tr>
<td>HPV vaccination and screening with VIA/Pap smear</td>
</tr>
<tr>
<td>Training for VIA/Pap smear providers, cytotechnicians, educators and counsellors</td>
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<table>
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<tr>
<th>Primary level (primary/community health centres)</th>
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<tr>
<td>HPV vaccination and screening with VIA/Pap smear</td>
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<tr>
<td>Treatment by cryotherapy</td>
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<tr>
<td>Health education and community mobilization</td>
</tr>
<tr>
<td>Refresher training in VIA/Pap smear, and training health workers to raise awareness</td>
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<tr>
<td>Train and utilize staff already engaged in similar services</td>
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<tr>
<td>Utilize the cold chain and other existing facilities</td>
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<tr>
<td>Make use of the data collection and surveillance system for other programmes</td>
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LEEP loop electrosurgical excision procedure
Primary prevention: Introduction of HPV vaccine into national immunization programmes

4.1 Introduction

HPV vaccination is most effective if administered prior to sexual debut and exposure to HPV infection. As per WHO recommendations, girls aged 9 to 13 years should be vaccinated against HPV through effective, affordable and equitable delivery strategies.\(^1\) Vaccinating a single age cohort within the target age range is also a cost-effective approach in resource-limited countries: there will be a smaller number of girls to be vaccinated and it is logistically simpler. The girls below the age of 15 years need only two doses of the vaccine with an interval of six months between the doses. High coverage of the target population and ensuring adherence to the two dose schedule are key factors for the success of the HPV vaccination programme. The current high cost of HPV vaccines is a major limitation for their widespread use in countries of the Region, especially in national immunization programmes. As the vaccines are prequalified by WHO, low- and middle-income countries are eligible to procure them through the GAVI Alliance at a greatly subsidized cost. While seeking assistance from GAVI Alliance, it should be kept in mind that the Alliance usually supports a new vaccination programme for a limited period of time. Due consideration should therefore be given to ensuring the country has the capability to fund the programme after GAVI Alliance support is withdrawn. Besides the sustainable financing mechanism, developing a service delivery strategy to access pre-adolescent girls is also challenging for public-funded immunization programmes. While waiting for the price to come down and vaccines to become affordable for immunization programmes, opportunistic vaccination of adolescent girls who can afford to pay out-of-pocket should be encouraged.

4.1.1 Service delivery models

To ensure high coverage of girls belonging to the target age group, countries may adopt either, or both, of the following service delivery models.

A. School-based vaccination

A school-based delivery strategy can be adopted if a high proportion (more than 70%) of adolescent girls attend school and the schools are willing to participate in such health intervention programmes. A high level of coordination with the education sector, involving the ministry, administrators and teachers, is required. The vaccination schedule has to be synchronized with school holidays and examination dates. Consideration should be given to integration with other school-based health intervention programmes, especially those targeting adolescent girls. Involving parents and obtaining their explicit consent is important and may be necessary for the success of a school-based strategy. Parent–teachers meetings provide good opportunity to discuss the vaccine along with other health
issues. There should be a contingency plan to capture the girls who are not in school. This can be implemented through outreach services or by allowing the out-of-school girls to join the school attendees on the days of vaccination. Such contingency plan should be made effective for both the doses of the vaccine and especially target the socio-economically disadvantaged population.

B. Health Centre Based Vaccination

The health system should have adequate capacity to induct a new vaccine into the existing vaccine delivery services. The new vaccine has to be administered through the primary and secondary health facilities. Getting access to the adolescent girls will be a challenge, since they do not attend such services routinely. Mechanisms have to be developed to inform the girls and their parents to attend the health facilities on the days of vaccination, keep track of the girls to ensure compliance to both the doses and ensure availability of the vaccines in required numbers and on requisite dates. In countries with well developed adolescent health programs, the adolescent health clinics can be utilized for HPV vaccination along with health education. A contingency plan should be in place to reach out to the non-compliant populations through community outreach programs.

4.1.2 Procurement and logistics

The vaccine procurement policy, logistic plan to deliver the vaccines maintaining the cold chain and to supply other consumables, and the protocol for vaccination should be laid down prior to rolling out the programme. Like any other vaccination programme, the programme managers are expected to regulate vaccine procurement, supply chain, temperature monitoring, storage and transport capacities, and report regularly on progress against targets, stock levels and wastage rates. The logistics of the new vaccine delivery should be sustainable and synchronized with immunization and other health interventions.

4.1.3 Capacity-building

Additional human resources may not be necessary if the HPV vaccine delivery strategy is based on existing vaccination programmes. Orientation training and supervision of existing staff are critical components of a delivery strategy. Capacity-building should be organized for health staff at primary and secondary level facilities. If a school-based vaccine delivery strategy is adopted, teachers and other supportive staff need to be well informed and a short orientation training may be useful. Specified funds should be available for the preparation of manuals and training materials. The providers should be appropriately supervised and their competency assessed in a structured manner.

4.1.4 Screening in presence of vaccination programme

Cervical cancer screening should be introduced or continued, even if a HPV vaccination programme is in place. In every country, for at least a few decades, there will be large numbers of women who will not qualify for the vaccine and will need protection through screening. The vaccinated population will also need screening in future, since nearly 30% of cancer cervix is caused by HPV types not targeted by currently available vaccines. The vaccinated population may require less frequent screening as they are at much lower risk, although the current recommendation is to follow the routine schedule of screening as per individual country protocol. Countries are discouraged to mobilize resources from a successful screening programme to introduce the HPV vaccination programme.
4.1.5 Monitoring and surveillance

HPV vaccination, like any public health intervention, requires constant monitoring and feedback on performance. This will enable programme managers to evaluate the quality of programme performance and direct or modify the interventions. In immunization programmes, performance monitoring is dependent on two key indicators:

- vaccination coverage;
- disease surveillance data (data on impact of vaccination on disease burden reduction).

HPV vaccination coverage should be monitored both in terms of proportion of girls in the target age group vaccinated and proportion of vaccinated girls receiving both the doses of the vaccine. Disease surveillance data for HPV vaccines are more difficult to obtain, since detection of infection or outbreaks is not the endpoint of surveillance as the vaccine aims to prevent cancer. Ideally, the vaccine database should be linked to the screening database through a common health information system, and the number of vaccinated women receiving abnormal screening results should be monitored. Linking the vaccine database to a cancer registry will provide information on HPV vaccine efficacy in the prevention of cervical cancer in the long run. In the South-East Asia Region, neither vaccine databases nor cancer registries are well organized within countries. Several process indicators should also be monitored, including the regular supply of vaccines, appropriate maintenance of the cold chain and maintenance of records.

Continued surveillance is crucial to detect and report side-effects and complications from the new vaccine. Every country has its own mechanism for reporting vaccine-related adverse events. Rather than duplicating efforts, this same reporting mechanism should be utilized for the HPV vaccine. The health authorities should ensure that all reported serious adverse events are appropriately investigated to establish causality.

Case-study: Introduction of HPV vaccination into the national immunization programme in Bhutan

A pilot project to vaccinate 12 to 18 year old girls was conducted in 2009 and 2010, using quadrivalent vaccines donated by Australian Cervical Cancer Foundation, Brisbane.

With strong political patronage and a sustained educational campaign, the project achieved high coverage of the target population.

The compliance to all three doses was excellent, with only 2.1% drop-out rate between first and third doses.

The project used a combination of the school-based approach and the health facility-based approach to achieve high coverage.

Since February 2011, the HPV vaccine has been introduced into the national immunization programme to vaccinate the girls reaching the age of 12 each year.

The current vaccination project is supported by the national Government, with the donation of vaccines by Australian Cervical Cancer Foundation committed until 2015.
4.2 **Key strategic directions for introduction of HPV vaccine into national immunization programmes**

The most crucial element in the introduction of HPV vaccine into existing vaccination programmes is informed decision-making by policy-makers in consultation with the various national stakeholders. The challenges of a gender-specific vaccine to prevent a sexually transmitted infection, feasibility of accessing the adolescent girls, capacity of the health system to achieve high coverage, and sustainable funding options to procure the vaccine are some important considerations. Using the framework, countries should draft a national protocol to be followed by all health-care levels involved in the vaccination programme.

The following strategic directions will help Member States of the South-East Asia Region augment their health systems to introduce the new vaccine.

**4.2.1 Strategic direction 1: Define the target population**

1. The vaccine should be given only to girls until there is a new recommendation for vaccinating boys.
2. Countries can decide to vaccinate all girls in the target age group of 9 to 13 years initially, and then fix one specific age at which girls will be vaccinated every year.
3. Vaccinating a single age cohort considered most accessible to the school-based health programme or to the health facilities is also acceptable.

**4.2.2 Strategic direction 2: Arrange for sustainable financing**

1. Sustainability should be ensured prior to the launch of a nationwide programme and, if necessary, countries may wait until the vaccine price becomes affordable.
2. Countries eligible for donations from GAVI Alliance may approach the Alliance for initial support to the programme, provided they can sustain the programme even when GAVI support is withdrawn after a few years.
3. The start-up cost for introduction of new vaccine for the first year (estimated to be US$ 3 per girl) and the operational cost of vaccine delivery every year (estimated to be US$ 4.20) should be considered, along with the cost of vaccine, while budgeting for the HPV vaccination programme.
4. Countries with appropriate capabilities should promote research for indigenous production of the vaccine.

**4.2.3 Strategic direction 3: Select appropriate delivery and coverage strategy**

1. An appropriate delivery strategy should be selected to ensure highest coverage of the target age group.
2. A school-based vaccination programme may be considered if a good proportion of girls attend middle and high schools in the country.
3. Vaccination can be done in health facilities at the primary and the secondary level.
4. A combination of both delivery strategies, along with an outreach or campaign approach to vaccinate geographically remote populations and a targeted approach for socioeconomically disadvantaged populations, will ensure high coverage.

5. Whatever delivery strategy is selected, maintenance of the cold chain, uninterrupted supply of consumables and high coverage with all the doses of the vaccine should be ensured.

4.2.4 Strategic direction 4: Integrate immunization, surveillance and other related health interventions

1. The health system should be strengthened to reduce barriers to immunization and improve post-vaccination surveillance for adverse events.

2. A programme officer/focal person at the national/regional level should be responsible for planning and execution of services, coordination between various levels and quality assurance.

3. The opportunity of reaching adolescent girls through the HPV vaccination programme should be utilized to deliver other health services targeted to the same population.

4. Regular programme evaluations should be conducted at local, district and national levels and should be linked with routine immunization coverage evaluation surveys.

Key strategic directions

- Define the target population
- Arrange for sustainable financing
- Select appropriate delivery and coverage strategy
- Integrate immunization, surveillance and other related health interventions
Secondary prevention: Organizing population-based cancer cervix screening

5.1 Introduction

An organized cancer screening programme should be population-based, and controlled and sponsored by the public health delivery system; it should follow a uniform guideline, achieve a reasonable coverage of the target population and have efficient linkage between screening and treatment of the screen-detected cases. The essential components of an organized programme are shown in Figure 3. An opportunistic strategy alone (screening women when they visit health facilities due to other reasons) cannot achieve the expected coverage and is inefficient both in terms of resource utilization and effectiveness in reducing cervical cancer mortality.

Figure 3. Different components of an organized cervical cancer screening programme

Every country has to adopt its own national guideline and protocol based on the broad principles given below.

5.1.1 Defining the target population and frequency of screening

An organized screening programme should have a clearly identified target population who should be screened at predetermined intervals and not earlier. The target age for cervical cancer screening and its frequency are decided based on understanding of the natural history of the disease, screening test to be used, realistic assessment of the need and aspirations of the population, and available resources.

Countries with resource constraints should not screen women prior to 30 years of age, since cervical cancer is very rare before this age and screening women at a younger age detects many
low-grade lesions that are self-limiting and will never progress into cancer. **Optimal utilization of resources is achievable if screening is limited to the age group in which there is maximum possibility of detecting high-grade precursor lesions (CIN2 and CIN3).** This age group is generally considered to be between 30 and 49 years. An individual programme can choose the 30 to 49 years age range, or can extend the upper age limit to 59 years if logistics and resources permit.

Screening women at frequent intervals will exhaust an insufficient workforce and available financial resources, and the incremental benefit is limited. The screening interval should not be less than five years in countries with limited resources and many competing health priorities. The screening frequency can be increased to 10 years if a highly sensitive test such as detection of HPV DNA is used. Even a single round of screening around the age of 40 years with high coverage of the target population can achieve a reasonable reduction in cervical cancer deaths where there are limited resources.

**All efforts should be made to achieve high coverage (nearly 80%) of the target population; this, rather than the frequency of testing, will determine the success of the screening programme.**

5.1.2 Identifying appropriate screening test

An ideal screening test should be simple, acceptable to the women, less time-consuming, affordable and reasonably accurate. A test that provides an immediate result is programmatically advantageous, since the test-positive women can be advised or further managed in the same visit.

Pap smear cytology has been used successfully in many resource-rich countries. Conventional Pap smear or liquid-based cytology is used, based on available resources. However, cytology has certain drawbacks that limit its usefulness especially in resource limited settings. It requires a laboratory infrastructure and highly skilled workforce that may not be easily available in many countries. The stringent quality control required for optimum performance of the test may not be feasible where health facilities are not equitably distributed. Pap smear does not provide the result immediately and smear-positive women need to be recalled when results are available from the laboratory. Such additional visits are inconvenient for the women and increase drop-out rates. Pap smear cytology can only be used in countries where quality-assured laboratory facilities exist, competent cytopathologists and cytotechnicians are available in adequate number to do reporting within a reasonable time frame, and a functional recall system can be established.

Visual inspection after application of acetic acid (VIA) is a moderately sensitive test that is feasible in most health infrastructure situations, even in limited resource countries. The other advantages of the test are: it can be performed by trained nurses or health workers; consumables are readily obtainable; it is inexpensive; and, the results are immediately available. However, the limitations of VIA are its subjective nature and low positive predictive value leading to a high number of unnecessary referrals.

VIA is most effective in screening women aged under 50 years, as the test accuracy tends to diminish in older postmenopausal women. The target age range best suited to a VIA-based screening programme is 30 to 49 years. An individual country may decide to screen women below 50 years by VIA and older women by cytology, if resources permit. **Using different tests for different target populations within the same programme is logistically complex and difficult to sustain.**

Tests to detect high-risk HPV DNA have been widely evaluated worldwide and observed to be more sensitive than other screening tests. Using such a sensitive test has the inherent advantage of
allowing the screening interval to be extended to 10 years for screen-negative women. The tests are objective, reproducible and can be done in large numbers within a limited time by technicians after a short training period. The major drawback of the test is the high cost, which is a deterrent to its introduction in the screening programmes of most countries in the South-East Asia Region. However, from a programmatic viewpoint, the HPV DNA test could be more cost-effective as it avoids more frequent screening, detects a higher number of high-grade precancers and early cancers, and thereby prevents more cervical cancer deaths.

Individual countries can initiate the screening programme using low technology tests, and may consider the introduction of more sophisticated tests as the programme becomes better organized and more resources are available.

5.1.3 Screening test facilities and providers

Cancer cervix screening services should be community-oriented to ensure greater accessibility, which in turn will improve participation of the target population. Primary and secondary level health-care facilities are ideal to perform VIA or collect smears for cytology. If such centres are too far from a particular locality and women are not willing to travel that far, temporary clinics can be set up (mobile outreach approach) at suitable locations to improve coverage. Screen-positive women should be properly counselled and guided at the time of report delivery so that they can travel to the next level of health facility for further evaluation and treatment. A robust linkage system between the screening centres at primary or secondary level and the referral facilities at secondary or tertiary level has to be developed.

A list of personnel involved in different screening tests along with the test characteristics is given in Table 1.

<table>
<thead>
<tr>
<th>Screening test</th>
<th>Sensitivity to detect CIN2+</th>
<th>Specificity to detect CIN2+</th>
<th>Test provider</th>
<th>Personnel for processing and interpretation</th>
<th>Major limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional cytology</td>
<td>53%</td>
<td>96.3%</td>
<td>Doctor / nurse / midwife / reproductive health care provider</td>
<td>Cytotechnician/ cytopathologist</td>
<td>Result not immediately available Laboratory necessary Highly trained personnel required Low to moderate sensitivity</td>
</tr>
<tr>
<td>Liquid-based cytology</td>
<td>79.1%</td>
<td>78.8%</td>
<td>Doctor/nurse / midwife / reproductive health care provider</td>
<td>Cytotechnician/ cytopathologist</td>
<td>Same as conventional cytology Expensive</td>
</tr>
<tr>
<td>HPV DNA</td>
<td>96.1%</td>
<td>90.7%</td>
<td>Doctor / nurse / midwife / reproductive health care provider</td>
<td>Laboratory technician</td>
<td>Result not immediately available Laboratory necessary Expensive</td>
</tr>
<tr>
<td>VIA</td>
<td>80%</td>
<td>92%</td>
<td>Doctor / nurse / midwife / reproductive health care provider</td>
<td>Not necessary</td>
<td>Sensitivity moderate High false-positives Subjective, performance variable and depends on training of providers</td>
</tr>
</tbody>
</table>
5.1.4 Evaluation and management of women with abnormal screening tests

In an ideal situation, all screen-positive women should be further evaluated by colposcopy followed by biopsy of suspected abnormal areas. In such circumstances, treatment decisions are made after receiving the biopsy report (see Annex 1). However, triaging with colposcopy or receiving a biopsy report prior to treatment of precancers is not mandatory. Alternative approaches are discussed in the following section.

All high-grade lesions should be treated. CIN I lesions may be treated if follow-up cannot be ensured, or if a lesion persists or progresses after one year, or if a lesion is detected in immunocompromised women.

All grades of CIN can be treated by loop electrosurgical excision procedure (LEEP), in which the entire abnormal area of the cervix is excised. Disease confirmation is done along with treatment, as the entire specimen is sent for histology. **LEEP facilities can be arranged at secondary and/or tertiary care hospitals where gynaecologists and other clinicians can be trained to perform the procedure.** LEEP is also justified in situations where no lesion is visible colposcopically, but cytology is persistently showing high-grade abnormalities (HSIL or atypical squamous cells—cannot exclude high-grade intraepithelial lesion (ASC-H)), or when colposcopy is unsatisfactory and cytology is HSIL or ASC-H (see Annex 2).

**Cryotherapy is a safe, simple and effective technique to treat selective CIN lesions of any grade.** Cryotherapy can be used to treat lesions that are occupying less than three quadrants of the cervix, are not extending inside the endocervical canal, and can be covered by the tip of the cryotherapy probe. Cryotherapy is not suitable for any lesion suspicious of invasive cancer or glandular disease. Nurses can be trained to perform cryotherapy, especially at primary care facilities, if that is acceptable to the health system of the country.

Hysterectomy should not be practiced for the treatment of CIN lesions. All invasive cancer cases should be referred to appropriate facilities for further management based on FIGO clinical staging.

**Follow-up** of treated patients can be continued at the primary or secondary facility where patients were originally screened. The same test that was performed initially can be used to screen these women on an annual basis for three years. Women tested negative on three consecutive rounds of screening can be returned to the less frequent screening protocol applicable to the normal population.

5.1.5 Strategies to improve compliance

Colposcopy and treatment, if performed at separate sittings, involve multiple visits, inconvenience and additional expense for women thus leading to reduced compliance. Such multiple-visit approaches are logistically complex and increase programme costs. Any of the following strategies can be adopted to reduce the number of visits and improve compliance to diagnosis and treatment.

- **Screen-and-treat strategy** (single-visit approach) (see Annex 3): In a VIA-based programme, if colposcopy and/or histology are not practicable, VIA-positive women should be evaluated for cryotherapy at the same visit. Cryotherapy can be performed in the same sitting as VIA if the lesion is suitable for cryotherapy. Thus, in a single-visit approach, screening and treatment can be completed in the same session. Women with lesions not suitable for cryotherapy should be referred to a colposcopy centre for appropriate management.
• **See-and-treat strategy** (see Annex 4): A colposcopically suspected high-grade precursor lesion can be treated during colposcopy without waiting for confirmation of diagnosis by histology. If the lesion is treated by cryotherapy, a punch biopsy should be obtained prior to the procedure. The results of the biopsies obtained either during cryotherapy or LEEP are reviewed at a later date. Screening, colposcopy and treatment can be completed in a single visit if the woman is screened by VIA and the facilities are available at one place.

• **Using VIA to assess suitability for cryotherapy for HPV-positive women** (see Annex 5): Women who test positive for oncogenic HPV can have VIA by a trained provider. Any acetowhite area detected on the cervix should be evaluated for suitability of cryotherapy. Cryotherapy can be done during the same sitting if the lesion is amenable to the procedure. Women not suitable for cryotherapy are to be referred for colposcopy and further management.

Fewer visit approaches improve programme efficiency by increasing compliance to treatment and are more cost-effective in spite of the inherent risk of overtreatment. Overtreatment is acceptable from the programmatic point of view, since complications of treatment are minimal and linkage between screening and treatment can be ensured. Screen-and-treat strategy is best practiced at the primary or secondary levels of health care.

If HPV testing is used for primary screening, test-positive women can be triaged with a second test used sequentially. Instead of referring HPV-positive women directly for colposcopy, they can be subjected to Pap smear cytology or HPV genotyping for types 16 and 18 (see Annex 6). HPV-positive women with abnormal cytology should be referred for colposcopy, while Pap-negative women should have a repeat HPV test after one year. If the genotype assay detects presence of either HPV types 16 or 18, the woman should be referred for colposcopy since these two types are the most carcinogenic. Such a paradigm has the advantage of reducing colposcopy referrals, but may be programmatically challenging as repeat visits are required.

### 5.1.6 Record-keeping and data management

Maintenance of records, capture and storage of data related to various components of screening, and the generation of periodic reports are essential for an organized screening programme. It helps to improve the efficiency of the programme, monitor coverage and compliance, and perform quality assurance. Ideally, every woman in the programme should be registered with a unique identification number, which could be a unique national ID or a programme-specific unique number. A register and/or computerized database of all screen-positive women with their contact address and telephone number should be maintained at each screening centre as well as every colposcopy centre. Periodically, these records should be sent to the national coordination centre where a mechanism to check the compliance of screen-positive women to colposcopy and/or treatment should be established. **Efforts should be made to link the cervical cancer screening database with the health information system of the country and the cancer registry, if available.**

### 5.1.7 Monitoring, evaluation and quality assurance of the programme

Country-specific strategic plans should have a well defined quality assurance mechanism for all aspects of services through robust programme coordination and management. There are short-term parameters (outcome/performance indicators) and long-term parameters (impact indicators) for evaluating the programme. The impact indicators are reduction of Cancer cervix incidence and
reduction of death from disease. It takes years to get such information and it can be obtained only if a population-based cancer registry or a very organized health information system is in place, or through special surveys that are expensive to undertake. Outcome/performance indicators can be monitored on a regular basis to identify gaps and, based on this, modifications to programme strategies should be undertaken. Common performance indicators that are suggested for monitoring are listed below.

- **Coverage of the target population** (Number of women in the target age group screened/Total number of women in the target age group x 100).
- **Screening test positivity** (Number of women positive on screening test/Number of women screened x 100).
- **Compliance to colposcopy** (Number of women undergoing colposcopy/Number of women positive on screening test).
- **Compliance to treatment** (Number of women treated for CIN2+ on colposcopy or biopsy/Number of women detected to have CIN2+ on colposcopy or biopsy x 100).
- **Detection rates of CIN2, or worse disease** (Number of CIN2 or worse disease detected/Total number of women screened).
- **Positive predictive value of the test to detect CIN2 or worse disease** (Number of CIN2 or worse disease detected/Total number of women positive on screening test).

For quality assurance, the responsible programme officer should collect data from different service delivery levels using a standardized format, analyse these data in an objective manner and implement correctional measures based on the observed gaps.

### 5.1.8 Training of service providers

Competency-based training is required for service providers at the various levels to ensure appropriate quality of care. More than one centre at the tertiary level should be designated as a national or regional resource centre, and equipped with adequate equipment and materials to conduct training programmes. It is important to train a group of master-trainers through a training-of-trainers programme so that they can conduct training courses for other service providers. (Refer to Table 2 for details of the conduct of training programmes).

It is essential that after completion of training each trainee should undergo competency-based evaluation. (A format for evaluation of VIA trainees is given in Annex 8). During such an evaluation, the trainee should perform an adequate number of procedures under observation by a trainer. After the successful completion of training, the appropriate authority should certify all trainees. Programme managers have to ensure that only certified providers perform the tests. After training, the service providers need to be supervised until they achieve a satisfactory level of competency. All VIA providers need a short reorientation training at least once a year.
Table 2. Guidelines for conducting training programmes for service providers involved in cancer cervix screening programmes

<table>
<thead>
<tr>
<th>Service</th>
<th>Health professionals who can be trainers</th>
<th>Health professionals to be trained</th>
<th>Health set-up to conduct training</th>
<th>Competency to be achieved</th>
<th>Approximate duration of training</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIA</td>
<td>Trained doctors and nurses</td>
<td>Doctors, nurses, midwives and other reproductive health care providers</td>
<td>Secondary or tertiary level</td>
<td>Test procedure, interpretation, documentation, record keeping, pre- and post-test counselling</td>
<td>5 to 7 days</td>
</tr>
<tr>
<td>Obtaining Pap smear or samples for HPV test</td>
<td>Trained doctors and nurses</td>
<td>Doctors, nurses, midwives and other reproductive health care providers</td>
<td>Secondary or tertiary level</td>
<td>Collecting smear/sample, fixing smear, storage and transport of slides/samples, documentation, record-keeping, pre- and post-test counselling</td>
<td>5 to 7 days</td>
</tr>
<tr>
<td>Processing of Pap smears and cervical biopsies</td>
<td>Trained pathologists</td>
<td>Laboratory technicians</td>
<td>Secondary or tertiary level</td>
<td>Processing of smears and biopsy tissues, staining of slides, documentation, record-keeping, laboratory quality control</td>
<td>5 to 7 days</td>
</tr>
<tr>
<td>Interpreting cytology and histology</td>
<td>Trained pathologists</td>
<td>Laboratory technicians</td>
<td>Tertiary level</td>
<td>Interpretation, reporting, documentation, laboratory quality control</td>
<td>7 to 10 days</td>
</tr>
<tr>
<td>Processing of samples for HPV detection</td>
<td>Trained pathologists, microbiologists, technical persons</td>
<td>Laboratory technicians</td>
<td>Secondary or tertiary level</td>
<td>Processing of samples and conducting tests, interpretation, reporting, documentation, laboratory quality control</td>
<td>3 to 5 days</td>
</tr>
<tr>
<td>Colposcopy and treatment</td>
<td>Trained doctors</td>
<td>Gynaecologists, other doctors, nurses (for colposcopy and/ or cryotherapy only)</td>
<td>Tertiary level</td>
<td>Performing the procedure, interpretation of colposcopic findings, reporting, documentation, counselling before and after procedures</td>
<td>7 to 10 days</td>
</tr>
<tr>
<td>Awareness and education</td>
<td>Trained doctors, nurses, social workers, programme managers</td>
<td>All health personnel involved</td>
<td>Primary or secondary level</td>
<td>Counselling individually and in groups, use of the education tools and materials</td>
<td>1 to 2 days</td>
</tr>
<tr>
<td>Programme management</td>
<td>Public health specialists, programme managers</td>
<td>Programme managers, health administrators, laboratory in charge</td>
<td>Tertiary level</td>
<td>Programme management, financing, monitoring, evaluation and quality assurance</td>
<td>2 to 3 days</td>
</tr>
</tbody>
</table>
5.2 Key strategic directions for cancer cervix screening

Depending on the capacity and preparedness of the health system, individual countries should adopt any of the options under the strategic directions (listed below) to organize the national cervical cancer screening programme. Regionally-specific strategic directions are listed, based on possible scenarios that may be encountered within the health services of Member States. Utilizing the current framework, national experts, health administrators and other stakeholders need to discuss and prepare a national protocol that will be strictly adhered to while implementing various service delivery strategies within the country. If strategies differ between regions/provinces due to variations in the health infrastructure and resources, it should be clearly delineated in the protocol.

5.2.1 Strategic direction 1: Define the target population

1. Screening should start after 30 years of age and not exceed 60 years.
2. If VIA is used as the screening test, the upper age limit should preferably not exceed 50 years of age.
3. Initially some countries/regions may decide to implement once-in-a-lifetime screening, in which scenario the target age should be around 40 years.

5.2.2 Strategic direction 2: Define the frequency of screening

1. The screening interval for women should not be less than 5 years.
2. Countries may decide to opt for less frequent screening; for example, screening once in 10 years or twice in a lifetime (at ages 35 and 45 years).
3. Once-in-a-lifetime screening is also acceptable where there are limited resources.

5.2.3 Strategic direction 3: Identify a suitable screening test based on resources

1. VIA-based screening is the test of choice in low-resource settings.
2. Cytology-based screening is applicable where programmatically and financially feasible.
3. Introduction of HPV detection-based screening may be considered, if affordable.
4. Oncogenic HPV-positive women can undergo cytology or genotyping as a triaging test.

5.2.4 Strategic direction 4: Ensure management of the screen-positive women

1. All screen-positive women should be counselled, further evaluated and treated at appropriate facilities following the algorithm, as applicable.
2. Colposcopy, cryotherapy and/or LEEP services should be organized at secondary and higher service levels. At the tertiary level, all three facilities should be available.
3. Women should have easy access to treatment services to ensure high compliance. Linkage between screening and treatment is crucial for the success of the screening programme.
5.2.5 **Strategic direction 5: Organize capacity-building of human resources**

1. Identify training needs and human resources for service delivery.
2. Ensure competency-based training of all service providers at designated training centres, with proper resource persons and training materials.
3. Ensure quality of training with appropriate post-training follow-up.

5.2.6 **Strategic direction 6: Strengthen the health infrastructure and ensure convergence**

1. Identify facilities to organize the various services within the existing health infrastructure.
2. Ensure supply and maintenance of equipment and uninterrupted supply of consumables.
3. Select the best possible option for integrating the services with existing programmes so as to minimize additional resource requirements and achieve good coordination.
4. The cancer cervix screening programme should be part of national cancer control or non-communicable disease programmes, with additional inputs.
5. Countries should pursue a mass screening policy, continue with opportunistic screening and scale up from pilot programmes, if any, in the selected facilities.
6. Ensure an appropriate referral system for screening and management within the existing health system

5.2.7 **Strategic direction 7: Set up a mechanism for monitoring, evaluation and quality assurance**

1. A programme officer identified at the national/regional level should be responsible for implementation of services, coordination between various levels of service delivery, and quality assurance.
2. The cancer cervix control programme should be part of the health management information system.
3. The indicators to be used for monitoring and quality assurance of the programme, and how they will be monitored periodically, should be clearly defined.

**Key strategic directions**

- Define the target population
- Define the frequency of screening
- Identify a suitable screening test, based on resources
- Ensure management of screen-positive women
- Organize capacity-building of human resources
- Strengthen the health infrastructure and ensure convergence
- Set up a mechanism for monitoring, evaluation and quality assurance
Case-study: Cancer cervix screening pilot project in South India, 2004–2007

**Aim:** Screen all 30 to 60 year old women in two districts

**Test used:** VIA and visual inspection after application of Lugol’s iodine (VILI)

**Funding source and project supervision:** Provincial government; all services free of cost

**Test providers and facilities:** Doctors, nurses and midwives at primary health centres and district hospitals

**Colposcopy/biopsy providers and facilities:** Gynaecologists at district and medical college hospitals

**Treatment strategy:** Treatment based on colposcopy-guided biopsy results (three visits)

**Participation rate:** Good (number of women screened: 488 084)

**Test positivity:** 4.3%

**Compliance to colposcopy:** 56.5%

**Number of CIN1 detected:** 296 (detection rate 0.06%)

**Number of CIN2/CIN3 detected:** 103 (detection rate 0.02%)

**Positive predictive value of screening test** (among positive women who had colposcopy): 0.9%

**Number of women treated by cryotherapy/LEEP:** 40 (grade of CIN not specified)

The low detection rate of CIN2/3 due to poor compliance to colposcopy and the low rate of treatment of CIN2/3 emphasize the need to reduce the number of visits

Very low positive predictive value of the screening test implies necessity of appropriate training of providers
Augmenting facilities for cervical cancer treatment and palliative care

6.1 Introduction

Once a cervical cancer screening programme is implemented, an appreciable number of invasive cervical cancers will be detected. Ensuring the treatment of screen-detected cancers is the responsibility of the programme. Appropriate facilities to perform further diagnostic work-ups and to deliver stage-wise treatment for invasive cancer cases have to be developed in parallel with the screening programme. The facilities should be accessible and affordable to women, with an effective system of referral and linkage between the screening programme and treatment centres.

Palliative care aims at improving a patient’s quality of life, by employing what is called “active total care”. This means treating pain and other symptoms and, at the same time, offering social, emotional and spiritual support; if necessary, it extends to supporting the family in bereavement.

In countries of the South-East Asia Region, there is a lack of access to available and affordable treatment facilities for cervical cancer either due to insufficient resources or the distance from cancer treatment facilities, or both. In some countries, radiation therapy and chemotherapy facilities are non-existent. Patients and families generally have to migrate, leaving their home and source of income to seek treatment elsewhere. This puts the patient and family under tremendous financial and social stress and is often a reason for delayed or incomplete treatment, or the patient not starting treatment at all. It often leads to disease detection at such an advanced stage that curative treatment cannot be offered. Palliative care facilities are much needed to alleviate the suffering of these advanced cervical cancer patients.

To ensure that palliative care is available and accessible, a major thrust should be on a primary health care approach. To make palliative care effective, it is important to integrate palliative care into the health-care system, facilitate palliative care education and improve access to essential and affordable medicines such as morphine and other opioids. In countries of the South-East Asia Region, the use of morphine is less than adequate for patients and availability is uncertain due to regulatory controls and inadequate training of health-care providers.

6.1.1 Cancer Cervix staging

Histological confirmation of disease is essential prior to the initiation of treatment for invasive cancer. All cervical cancers have to be staged, as per the FIGO clinical staging guidelines. The basic diagnostic tests recommended to determine the stage of cancer cervix are:

- colposcopy;
- vaginal and rectal examination to inspect and palpate the growth and its extensions;
- cystoscopy and proctoscopy;
• ultrasonography of the abdomen and pelvis;
• x-ray examination of the lungs.

6.1.2 Treatment of Cancer Cervix

The treatment modality is decided based on the clinical stage of the disease, which also determines the survival rate. (Table 3). Early cervical cancer should be treated by radical hysterectomy with bilateral pelvic lymphadenectomy. Radiation therapy, with or without concomitant chemotherapy, is equally effective, although morbidity is higher than surgical management. More advanced cases should be treated by radiation therapy. Use of platinum-based chemotherapy concomitant with radiation therapy improves survival and should be considered, when feasible. The standard radiation therapy for cervical cancer is a combination of external beam radiation therapy and brachytherapy. All patients requiring radiation therapy may be considered for concomitant platinum-based chemotherapy.

<table>
<thead>
<tr>
<th>Cervical cancer stage</th>
<th>Treatment modalities</th>
<th>5-year survival rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>Conization/radical hysterectomy and pelvic lymphadenectomy</td>
<td>93%</td>
</tr>
<tr>
<td>IB</td>
<td>Radical hysterectomy and pelvic lymphadenectomy/external beam radiotherapy with brachytherapy</td>
<td>80%</td>
</tr>
<tr>
<td>IIA</td>
<td>Radical hysterectomy and pelvic lymphadenectomy/external beam radiotherapy with brachytherapy</td>
<td>63%</td>
</tr>
<tr>
<td>IIB</td>
<td>External beam radiotherapy with brachytherapy</td>
<td>58%</td>
</tr>
<tr>
<td>IIIA</td>
<td>External beam radiotherapy with brachytherapy</td>
<td>35%</td>
</tr>
<tr>
<td>IIIB</td>
<td>External beam radiotherapy with brachytherapy</td>
<td>32%</td>
</tr>
<tr>
<td>IVA</td>
<td>Individualized treatment with palliative intent</td>
<td>16%</td>
</tr>
<tr>
<td>IVB</td>
<td>Individualized treatment with palliative intent</td>
<td>15%</td>
</tr>
</tbody>
</table>


6.1.3 Organizing palliative care services

Adequate facilities for palliative care should be made available at the institutional level, secondary health-care level and, if possible, the community level. All physicians and nurses treating cancer patients must be aware of the basic principles of palliative care, so that patients can benefit during the continuum of their treatment. Home-based care, with the patient and family as the focal point, is the cornerstone of palliative care. The role of the family in the care of patients should be recognized and they should be empowered to cope with the situation. Medical and nursing undergraduate teaching must incorporate the principles of basic palliative care into their curriculum. Opioid analgesics such as codeine & oral morphine are absolutely necessary for the management of cancer pain and these drugs must be available for pain relief. Governments must ensure the adequate availability of opioids by making the rules for the procurement easy with a single window approach, empowering medical practitioners to prescribe, dispense & administer opioids according to the individual needs of patients and ensuring that an adequate supply of opioids is available to meet medical demand when patients need them. It is recognized that the efforts to prevent abuse of the oral opioids should not interfere with ensuring their availability for medical purposes.
6.2 Organize facilities for staging and diagnostic work-up

6.2.1 Strategic direction 1: Ensure early detection of cervical cancer

1. All screen-detected cervical cancer patients must reach an appropriate health facility for further management without appreciable delay.

2. Any woman presenting to the health facilities with symptoms suspicious of cervical cancer should have speculum examination of the cervix by a competent person.

3. All women with suspected cervical cancer are to be referred to an appropriate centre for colposcopy and/or biopsy.

4. Histopathology services should be available at least at the tertiary care level.

6.2.2 Strategic direction 2: Organize facilities for staging and diagnostic work-up

1. Facilities for clinical staging and other diagnostic work-up for cervical cancer are to be made available in the obstetrics and gynaecology department of all tertiary care centres.

2. Such facilities can also be extended to select secondary level facilities where trained gynaecologists are available.

6.2.3 Strategic direction 3: Arrange appropriate treatment based on stage of disease

1. Surgical management of early-stage cancer should be done in tertiary care centres where adequately skilled gynaecologists, surgeons or gynaecologic oncologists are available.

2. Radiation therapy and chemotherapy facilities should be made available in select tertiary care hospitals, including dedicated oncology centres.

3. The capacity of health systems should be improved to ensure that cancer patients can attend the treatment centres on time. Minimizing the waiting period for initiation of treatment and improving support to patients for logistic issues (such as travel and hospital stays) will improve compliance to prolonged treatment procedures.

Key strategic directions

• Ensure early detection of cervical cancer
• Organize facilities for staging and diagnostic work-up
• Arrange appropriate treatment based on stage of disease
6.3 **Key strategic directions for improvement of palliative care services**

6.3.1 **Strategic direction 1: Prepare the ground for palliative care services**

1. Perform a well conducted needs assessment exercise and identify the obstacles to good palliation as perceived by the local health-care providers.
2. Promote the concept of palliative care to policy-makers, health-care planners and administrators, as well as to the general public as they may not be aware of palliative care.

6.3.2 **Strategic direction 2: Organize the services**

1. Consider the model(s) of care that might best meet local needs and is/are feasible (hospital-based, home-based etc.).
2. Ideally, an inter-professional team including doctor, nurse, social worker, councillor, etc. is required to deliver the palliative care services. A dedicated team may not be available in all health set-ups, and sharing of staff with other medical services may be necessary.
3. All professionals working in palliative care for the first time will require training.

6.3.3 **Strategic direction 3: Ensure availability of drugs, including morphine**

1. Ensure the availability of essential drugs for the management of pain and other symptoms.
2. Access to an adequate and uninterrupted supply of oral morphine should be recognized as a basic right of the patients who need them.

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**Key strategic directions**

- Prepare the ground for palliative care services
- Organize the services
- Ensure availability of drugs, including morphine
Awareness, education and community mobilization

Health education and awareness are key components of a comprehensive cervical cancer control programme. Health education should be targeted towards high acceptance of the services by the community and improved compliance to various interventions related to cervical cancer control.

Some basic principles and suggestions are listed below.

1. Understanding the baseline knowledge and perceptions of the community is crucial to developing communication materials and communication strategies.

2. Messages should be target-specific, culturally appropriate and address common myths, misconceptions and fears related to a new vaccine or tests related to cancer.

3. The core messages should be consistent, irrespective of the community and setting, and as per the recommendations of the national guideline and protocol for cervical cancer control.

4. The key counselling message – that the disease can be prevented by adopting a healthy lifestyle, avoiding harmful practices and accepting the age-specific interventions (vaccination or screening) – needs to be stressed during training and awareness-building.

5. Educating girls to complete the vaccination course after the first or second dose and counselling screen-positive women to complete the diagnostic evaluation and treatment are essential to maintain high compliance.

6. Involving boys and male family members in the group counselling sessions usually improves acceptance of the programme. However, due consideration should be given to the fact that in some communities girls or women may feel embarrassed discussing certain issues in the presence of male family members.

7. A booklet in the local language containing answers to frequently-asked questions, along with pictorial depictions related to cervical cancer prevention using simple words, can be a very useful tool for educators.

Health education can be delivered at community or health facilities, or both. Health workers and volunteers at community or primary health facilities are the first point of contact with the community. It is they who deliver services, provide health information and obtain feedback from the community. They should be given a short orientation training so that they can inform and motivate parents to send their daughters for vaccination and encourage women to undergo screening. They can keep records of the vaccinated girls and screened women, and can remind girls to complete the vaccination course or counsel screen-positive women to reach the next level of health care for further evaluation and treatment. Local peer groups (teachers, politicians, religious leaders, etc.) and voluntary organizations can also be involved in group counselling meetings.
At health facilities, health education and counselling can be done by trained health workers, midwives, nurses and doctors. The target audience can be accessed in waiting areas, outpatient clinics and also through community outreach initiatives.

Health education messages are best imparted through direct face-to-face meetings. Printed materials such as booklets, flipcharts and posters in the local language aided by pictures, diagrams and charts can help convey the messages more effectively. Depending on the facilities and resources available, slide shows, video shows and street-plays can also be organized. A broad-based media campaign utilizing print and electronic media can improve the visibility of the programme and enhance participation rates.
Advocacy

The purpose of advocacy is to empower policy-makers to make informed decisions on programme needs, implementation and service utilization. Advocacy is also essential to ensure community participation and acceptance, and generate demand for the services from within the community.

The targets for advocacy and communication efforts should include the following:
- high-level decision-makers and advisors in relevant government sectors;
- members of civil society organizations;
- members of academic institutions and professional associations;
- administrators and managers at the health ministry and hospitals;
- health-care providers including physicians, nurses, midwives and school health workers;
- community leaders;
- media representatives.

The advocacy document should include brief and focused country-specific messages and regional data on cervical cancer incidence and deaths. It should also highlight the fact that the disease is preventable through a comprehensive approach. (A sample policy and advocacy brief for high-level decision-makers is included in Annex 7).

In countries in the South-East Asia Region, cancer cervix control is still not considered a health priority, although in many of these countries the number of deaths from cervical cancer is almost as high as maternal deaths. It should be highlighted to policy-makers that comprehensive cervical cancer control contributes towards the attainment of the MDGs by saving and improving quality of women’s lives.

A policy dialogue should be established. A document that clearly identifies strategies and service delivery guidelines based on the individual countries’ needs, priorities and capabilities is useful for the policy-makers. Programme leaders with adequate empowerment as well as high-visibility advocates or “champions” can play key roles in sustaining advocacy.
References


Annex 1

Management of screen-positive women based on colposcopy and histologic diagnosis

Screening test positive

Colposcopy; biopsy if lesion suspected

Histology diagnosis

Colposcopy and/or biopsy normal

CIN1

Follow-up

Persistent for 1 year/disease progression

Repeat screening after 3 years for cytology or HPV test, and after 5 years for VIA

CIN2/3

Cryotherapy/LEEP

Follow-up at 9–12 months (screening test/colposcopy)

Microinvasive cancer

Cold knife conisation/LEEP

Invasive cancer

Treatment based on stage

Follow-up

Screening test can be either cytology, VIA or HPV test.

Minimum number of visits required to complete screening and treatment – three.
Annex 2

Management of women with abnormal cytology based on colposcopy diagnosis, with or without biopsy confirmation

AGC: atypical glandular cells
ASC-H: atypical squamous cells—cannot exclude a high-grade intraepithelial lesion
ASC-US: atypical squamous cells of undetermined significance
SCC: squamous cell carcinoma

The number of visits required completing screening and treatment depends on whether treatment is done in the same visit as colposcopy (minimum two visits) or after histologic confirmation (minimum three visits).
Annex 3

Management of VIA-positive women using single-visit screen-and-treat approach

Minimum number of visits required to complete screening and treatment – one.
Annex 4

Management of screen-positive women based on colposcopy diagnosis ("see-and-treat" approach) alone

Screening test positive

Colposcopy

Normal

Suspected CIN

Assess if lesion is suitable for cryotherapy
1. No endocervical extension
2. Can be covered by cryoprobe
3. Limited to three quadrants
4. No suspicion of cancer

Invasive cancer

Treatment based on stage

Follow-up

Repeat screening after 3 years for cytology or HPV test and after 5 years for VIA

Suitable for cryotherapy

Cryotherapy (biopsy optional)

Follow-up at 9–12 months (screening test/colposcopy)

Not suitable for cryotherapy

Cold knife conisation/LEEP

Screening test can be cytology, VIA or HPV test.
Minimum number of visits required to complete screening and treatment – two.
If VIA is used as the screening test, and VIA and colposcopy facilities are available in the same facility, minimum number of visits required – one.
Annex 5

Management of VIA-positive women using single-visit screen-and-treat approach

HPV-positive

VIA

VIA-positive

Suspected cancer

Rescreen after 1 year

Assess if lesion is suitable for cryotherapy
1. No endocervical extension
2. Can be covered by cryoprobe
3. Limited to three quadrants
4. No suspicion of cancer

Refer for colposcopy and further management

Suitable for cryotherapy

Cryotherapy (biopsy optional)

Follow-up at 9-12 months with VIA

Not suitable for cryotherapy

Refer for colposcopy and further management
Annex 6

Triaging of HPV-positive women by cytology or HPV genotyping

- **Oncogenic HPV-positive**
  - Reflex cytology or genotyping for types 16/18
    - **Positive** → Colposcopy
    - **Negative** → HPV test after 12 months
      - **Positive** → Colposcopy
      - **Negative** → Routine screening
Annex 7

Sample policy and advocacy brief for high-level decision-makers in the health ministry

- Cervical cancer affects women at a relatively young age, usually in the fourth or fifth decades of life, and is among the leading causes of cancer deaths among this age group. The human, social and economic costs of losing women in their prime are huge.

- In most countries in South-East Asia, the number of women dying from cervical cancer is close to those dying from complications of childbirth. While maternal mortality has substantially reduced due to proactive measures, the number of women dying from cervical cancer has gone up by nearly 45% in the past two decades.

- Every cervical cancer death is unfortunate, as cancer cervix can be prevented by vaccination of young girls and systematic screening of adult women.

- Cervical cancer can be prevented because we know very well the natural history of the disease. Human papillomavirus (HPV), spread through sexual contact, causes cancer cervix. Although the infection is quite common in sexually active women, the majority of affected women clear the infection through natural immunity. Some women cannot get rid of the virus, and go on to develop a condition called cervical precancer. The precancerous condition progresses to full-blown cancer if it remains undetected and untreated. The total time gap between acquiring HPV infection and the development of cervical cancer can be 10 to 20 years.

- Safe and effective vaccines are available to protect against HPV types 16 and 18, which cause about 70% of cervical cancer cases. The vaccine should be given to pre-adolescent girls before they have sexual contact.

- The vaccine has been introduced in national immunization programmes in the majority of developed countries. A large number of developing nations have also introduced the vaccine after a substantial reduction in the price (US$ 4.50 per dose) due to support from GAVI Alliance.

- Within less than a decade after introduction of the vaccine, the number of women infected with HPV (types preventable by the vaccine) and the number of women affected by cervical precancers have significantly dropped in the vaccinated populations.

- The Global Advisory Committee on Vaccine Safety of the World Health Organization (WHO) observed in 2013 that even after distribution of 175 million doses of the HPV vaccine, its safety profile was quite reassuring.

- Cervical cancer screening to detect the disease at the pre-cancer stage linked with treatment of the conditions is one of the most rewarding and cost-effective health interventions. Organized screening programmes have reduced cervical cancer incidence and mortality by 50% to 75% in various countries.

- Cervical cancer screening has been found to be as cost-effective as hepatitis B immunization, or voluntary counselling and testing for HIV, or malaria prevention by the use of bed-nets.
• Screening and treatment facilities should be made accessible to all women belonging to a predetermined target age group. The success of the programme will largely depend on achieving high participation rates of the target women and ensuring the availability of good-quality treatment services to the screen-positive women. To ensure this, the capacity of the health system needs to be augmented and appropriate quality assurance measures should be instituted within the programme.

• Countries have to adopt a comprehensive cervical cancer control policy with a judicial combination of HPV vaccination and screening. Sufficient resources must be allocated within national budgets and appropriate guidelines and service standards should be in place before starting the programme.

• A comprehensive cancer control programme will avoid the untimely death of women, improve their quality of life, save the costs of treating women with advanced cancer, and help countries to achieve the MDGs.
## Score sheet for clinical supervision of via trainees

A. For each VIA provider, complete the following:

| Name of FACILITY: |  | Date  | |  |  | | Name of SUPERVISOR: |  |  |

**Directions:**
- Each form can be used to evaluate the trainee for performing VIA on five women
- Place “S” in case box if step/task is performed Satisfactorily
- Place “U” if it is performed Unsatisfactorily
- Place “X” if Not observed (Step, task, or skill not performed by participant during the evaluation)

### VIA counselling and clinical skills evaluation

<table>
<thead>
<tr>
<th>Pre-VIA counselling</th>
<th>Observations</th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
<th>Case 4</th>
<th>Case 5</th>
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<td>b.</td>
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<td>3.</td>
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</table>

### Pre-VIA activities

| 1.                  |              |        |        |        |        |        |
| 2.                  |              |        |        |        |        |        |
| 3.                  |              |        |        |        |        |        |
| 4.                  |              |        |        |        |        |        |
| 5.                  |              |        |        |        |        |        |

### VIA activities

| 1.                  |              |        |        |        |        |
| 2.                  |              |        |        |        |        |
| 3.                  |              |        |        |        |        |
| 4.                  |              |        |        |        |        |
5. Identifies the cervical os, squamocolumnar junction (SCJ), and transformation zone.

6. After telling the patient that she might feel a mild stinging sensation, applies acetic acid. Waits for precisely 1 minute to allow colour changes to develop.

7. Checks if cervix bleeds easily. Checks for any raised and thickened white plaques or dense acetowhite epithelium with well-defined margin.

8. Correctly diagnoses the VIA findings.

9. Removes any remaining acetic acid from the cervix and vagina with a swab. Disposes of swab.

10. Removes speculum and places it in appropriate container for disinfection.

**Post-VIA activities**

1. Wipes light source with 0.5% chlorine solution or alcohol.

2. Immerses both gloved hands in 0.5% chlorine solution. Removes gloves by turning inside out.

3. Discusses the results of VIA test with woman and answers any questions.

4. a) If VIA test is negative, tells woman when to return for repeat VIA testing.
   b) If VIA test is positive or cancer is suspected, discusses recommended next steps. After counselling, provides appropriate referral.

5. Records VIA test results and other findings in woman’s record and provides the card to the woman and asks her to retain it.
   a) Documents cervical lesion findings on cervical map.
   b) If required, documents referral and reason for referral.
   c) If treatment/referral is refused at time of screening, documents reason for delaying/refusing treatment/referral.

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**Score Sheet for Clinical Supervision of VIA Trainees (Contd.)**

**Comments:**

Pre-VIA Counselling:

Pre-VIA Activities:

Via Skill:

Post-VIA Activities:

Overall Performance:

**Recommendations:**
Annex 9

Cervical cancer burden and control initiatives in the WHO South-East Asia Region

Demographic profile of Member States

The countries belonging to the WHO South-East Asia Region are Bangladesh, Bhutan, Democratic People’s Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste. The Region in general has a high population density, and displays great inequities and diversities across and within countries in terms of socioeconomic indicators, ethnicity, religion, gender, geography, and quality of health care (Table A9.1). In designing appropriate strategies for cervical cancer control, it is crucial to recognize these inequities since they have an impact on access to essential health services, quality of care received and health outcomes.

Table A9.1. Socio-demographic profiles of Member States of the South-East Asia Region

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>Sex ratio</th>
<th>Urban</th>
<th>Population density</th>
<th>GDP per capita</th>
<th>Female literacy</th>
<th>Female life expectancy at birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>156 595</td>
<td>103.2</td>
<td>30.5</td>
<td>1 049.5</td>
<td>750</td>
<td>55.1 (2011)</td>
<td>71</td>
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<tr>
<td>Bhutan</td>
<td>754</td>
<td>115.8</td>
<td>34.8</td>
<td>15.3</td>
<td>2 560</td>
<td>45 (2005)</td>
<td>69</td>
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<tr>
<td>Democratic People’s Republic of Korea</td>
<td>24 895</td>
<td>95.5</td>
<td>60.4</td>
<td>203.3</td>
<td></td>
<td>100 (2008)</td>
<td>73</td>
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<tr>
<td>India</td>
<td>1 252 140</td>
<td>107.2</td>
<td>30.9</td>
<td>366.8</td>
<td>1 559</td>
<td>51 (2005)</td>
<td>68</td>
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<tr>
<td>Indonesia</td>
<td>249 866</td>
<td>101.3</td>
<td>49.9</td>
<td>126.4</td>
<td>3 563</td>
<td>92 (2011)</td>
<td>73</td>
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<td>Maldives</td>
<td>345</td>
<td>101.7</td>
<td>40.0</td>
<td>1 092.9</td>
<td>6 244</td>
<td>98 (2005)</td>
<td>78</td>
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<td>Myanmar</td>
<td>53 259</td>
<td>94.3</td>
<td>31.4</td>
<td>76.8</td>
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<td>16.8</td>
<td>182.4</td>
<td>699</td>
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<td>69</td>
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<td>21 273</td>
<td>96.4</td>
<td>18.3</td>
<td>316.4</td>
<td>2 922</td>
<td>90 (2010)</td>
<td>78</td>
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<td>44.1</td>
<td>129.4</td>
<td>5 480</td>
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<td>79</td>
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<td>103.3</td>
<td>29.5</td>
<td>72.6</td>
<td>1 179</td>
<td>53 (2010)</td>
<td>68</td>
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</table>

GDP – gross domestic product

Estimation of the expected number of target beneficiaries is one of the key requirements for planning a health programme. In any country, approximately one fourth of the total female population belong to the 30 to 49 years age group – the commonly recommended target age for cervical cancer screening. The number of girls estimated to be in each single age cohort from 9 to 13 years in the South-East Asia Region for 2013 is given in Table A9.2. The approximate number of girls requiring HPV vaccination each year can be calculated from the table.
Table A9.2. Estimated number of girls in different single age cohorts in Member States of the South-East Asia Region, 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Estimated female population (in thousands) in single age cohorts (9–13 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9 years</td>
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<tr>
<td>Bangladesh</td>
<td>1,529</td>
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<td>Bhutan</td>
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<td>Democratic People’s Republic of Korea</td>
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<td>India</td>
<td>11,853</td>
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<td>465</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>16</td>
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</tbody>
</table>

Cancer Cervix burden in the Region

Asia has the highest burden of cervical cancer among all the continents, primarily due to the lack of organized cervical cancer screening in countries. Current estimates indicate that every year 284,823 Asian women are diagnosed with cancer cervix, the third most frequent cancer among women. Countries in the WHO South-East Asia Region contribute nearly 175,000 new cancer cervix cases every year, which constitutes 35% of the global burden and 60% of the Asian burden of the disease. Every year, an estimated 144,434 women die from cancer cervix in Asia, of which 102,665 women are from countries in the WHO South-East Asia Region. Cancer Cervix incidence and mortality rates in Member States of the Region are given in Table A9.3. It is to be noted that most of these countries do not have a systematic method of data collection through a population-based cancer registry. The only source of such statistics is hospital-based cancer registries that collect data from patients attending hospitals for diagnosis and treatment. There is always a possibility of underreporting of the true incidence of cervical cancer if there is no robust method of data collection from the population. Maldives and Timor-Leste do not have cancer diagnostic and treatment facilities, and as a result have no information on cervical cancer incidence and mortality.

About 10.9% of Asian women are estimated to harbour cervical HPV infection at any given time, and 68.5% of invasive cervical cancers are attributed to HPV types 16 or 18. The observed prevalence of HPV in normal women is quite variable among the individual countries in the Region. To some extent, such variability can be explained by differences in the selection of study subjects and the HPV detection technology used. However, the proportion of invasive cancers attributable to HPV types 16 and 18 (the vaccine-preventable types) is almost uniformly between 65% and 70% in these countries, indicating the high degree of protection expected from the currently available vaccines against HPV.
Table A9.3. Cancer Cervix incidence and mortality in Member States of the South-East Asia Region (estimates for 2012)\textsuperscript{14}

<table>
<thead>
<tr>
<th>Country</th>
<th>Cancer Cervix incidence</th>
<th>Cancer Cervix mortality</th>
<th>Source of incidence and mortality data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of cases per year</td>
<td>No. of deaths per year</td>
<td>No PBCR; hospital-based data</td>
</tr>
<tr>
<td></td>
<td>ASR (per 100 000)</td>
<td>ASR (per 100 000)</td>
<td></td>
</tr>
<tr>
<td>Bangladesh</td>
<td>11 956</td>
<td>6 582</td>
<td>No PBCR; hospital-based data</td>
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<tr>
<td>Bhutan</td>
<td>37</td>
<td>19</td>
<td>No PBCR; hospital-based data</td>
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<td>DPR-Korea</td>
<td>1 881</td>
<td>1 119</td>
<td>No PBCR; hospital-based data</td>
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<td>India</td>
<td>122 844</td>
<td>67 477</td>
<td>PBCR in select areas (&lt;5% population covered)</td>
</tr>
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<td>Indonesia</td>
<td>20 928</td>
<td>9 498</td>
<td>No PBCR; hospital-based data</td>
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<tr>
<td>Maldives</td>
<td>14</td>
<td>7</td>
<td>No PBCR; no data</td>
</tr>
<tr>
<td>Myanmar</td>
<td>5 286</td>
<td>2 998</td>
<td>No PBCR; hospital-based data</td>
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<td>1 367</td>
<td>No PBCR; hospital-based data</td>
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<tr>
<td>Sri Lanka</td>
<td>1 721</td>
<td>690</td>
<td>No PBCR; hospital-based data</td>
</tr>
<tr>
<td>Thailand</td>
<td>8 184</td>
<td>4 513</td>
<td>PBCR in select areas (~40% population covered)</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>-</td>
<td>-</td>
<td>No PBCR; no data</td>
</tr>
</tbody>
</table>

ASR – age standardized rates; PBCR – population-based cancer registry

Cancer Cervix control initiatives

\textit{Bangladesh}

The National Cervical Cancer Screening Programme was launched in Bangladesh in 2005. The guidelines formulated by a national advisory board recommended screening of women aged 30 years or above by visual inspection after acetic acid application (VIA) at an interval of three years. A national coordinating centre at Bangabandhu Sheikh Mujib Medical University, Dhaka is responsible for training of all service providers, setting up screening and colposcopy centres across the country, ensuring steady supply of consumables, and monitoring and evaluation of the programme. Initially, VIA services were set up in district hospitals and in maternity hospitals situated at district headquarters. The screening services were subsequently expanded to subdistricts and rural health centres to improve access at the community level. Currently, screening is being offered at 57 district hospitals, 61 maternity clinics, 70 subdistrict hospitals and 50 rural health centres across the country. Nurses and gynaecologists attached to these centres are trained to perform VIA.

Referral centres for colposcopy and treatment have been set up at medical college hospitals in select districts maintaining a linkage with the screening centres. Colposcopy and treatment are performed by trained gynaecologists and non-specialist clinicians. If high-grade lesions are suspected on colposcopy, the women are offered immediate treatment ("see-and-treat") without waiting for histologic confirmation. This has substantially reduced the non-compliance to treatment observed in the initial phase of the programme. At present, nearly 100 000 women are being screened every year and VIA-positivity is consistently around 5%. The programme is still predominantly opportunistic with a high level of central coordination. Despite a nationwide awareness campaign, the participation rate is still moderate.
HPV vaccines are licensed in Bangladesh for opportunistic vaccination. There is no immediate plan to include the vaccine in the national immunization programme. There is no population-based cancer registry in the country.

**Bhutan**

A pilot project on cancer cervix screening was initiated in three districts in 2002. A national advisory committee recommended screening of 20 to 60 year old women using Pap smear cytology and referral of all positives to one designated colposcopy centre. The pilot project was completed in 2004 and reviewed in 2005. It was observed that Pap smears were of suboptimal quality (high rate of unsatisfactory smears) and, because the cytotechnicians were overburdened, there was a long reporting time for Pap smears. The loss to follow-up was high, with very few cytology-positive women attending the colposcopy centre. The programme was scaled up in 2005 by establishing new cytology laboratories and recruiting more trained cytotechnicians and pathologists. The number of centres with colposcopy and treatment facilities was also increased to four. Despite initial improvement in the performance of cytology, the programme remained ineffective due to lack of sustained motivation of staff, irregular supply of consumables and low participation rates. Recently, VIA by nurses has been introduced in select centres and a mobile outreach approach is being followed. The screening programme is still opportunistic with low uptake, and reaching women in geographically remote areas is a major challenge.

Under strong political patronage and support from external donors (Australian Cervical Cancer Foundation), a pilot project to vaccinate 12 to 18 year old girls was successfully conducted in 2009 and 2010. Since February 2011, the quadrivalent vaccine has been introduced into the national immunization programme. Every year, all girls reaching the age of 12 years are being vaccinated using a health facility-based approach. To date, no serious adverse event has been reported from the vaccinated girls.

There is no population-based cancer registry in the country.

**Democratic People’s Republic of Korea**

The facilities for managing invasive cervical cancer are poorly developed in the country. A national cervical cancer screening programme has recently been proposed as part of an overall improvement in health care for women. On the recommendation of a group of experts, a pilot project has been launched to screen women aged from 30 to 55 years by VIA in three regions. The rural clinics, rural hospitals and county/district hospitals have a list of beneficiaries (client list), from which it is possible to identify the women eligible for screening. Family health doctors, during their home visits, will counsel and motivate the eligible women to undergo screening. VIA will be done in rural and district/county hospitals by nurses and gynaecologists. Colposcopy and biopsy will be arranged at provincial hospitals, where specialist gynaecologists will be trained to do the procedures. The colposcopy clinic at the maternity hospital in the capital city of Pyongyang will be upgraded as the main referral centre and also as the national coordinating centre. A group of gynaecologists have been trained in India who will serve as the master-trainers.

HPV vaccines are not available in the country, and there is no population-based cancer registry.
India

In spite of the high burden of the disease in the country, there is no organized cervical cancer screening programme in India. Pap smear cytology facilities are available at select laboratories in urban areas, although their quality varies widely. Women are advised Pap smear by gynaecologists only if they have symptoms suggestive of cervical cancer or the cervix looks unhealthy on naked eye examination. The concept of routine screening of asymptomatic women is almost non-existent. A group of experts drafted national guidelines for cervical cancer screening in 2005. The recommendations were to screen women aged from 30 to 59 years using VIA and to set up a two-tier system to perform screening at primary health centres and colposcopy at district hospitals. Dissemination of the guidelines was poor and no action was taken on its basis. As a result, the public health system (at least at the primary and secondary levels) does not have any capacity or infrastructure to perform cervical cancer screening or manage screen-positive women with colposcopy and treatment. The level of awareness regarding cervical cancer and its prevention among health policymakers, health professionals and the general public is very low. A new programme for control of all major noncommunicable diseases including cancer was introduced in 2012, with dedicated funds for cancer control, through a community-oriented approach. The operational guidelines of the new programme recommend cervical cancer screening for women, although the details of implementation issues are lacking.

India is a vast country with much heterogeneity among the provinces in terms of political commitment to health care, socioeconomic situation and capacity of health systems. The need of the hour is to draft a pragmatic operational guideline for cervical cancer screening, based on which steps should be taken to integrate screening in health facilities, augment the capacity of the health system to make screening and colposcopy services accessible to women, and train a critical number of health-care providers to deliver the services.

Both bivalent and quadrivalent vaccines are licensed in India. The vaccines are being administered only to those girls and women paying from their own pocket. A demonstration project initiated by Program for Appropriate Technology in Health (PATH) in two provinces was stopped prematurely due to the reported deaths of vaccinated girls. Subsequent investigations into the causes of death did not find any causal association with the vaccine. The adverse media publicity associated with the reported deaths resulted in a very lukewarm acceptance of the vaccines, even in the private sector. There are well organized population-based cancer registries in several provinces under the National Cancer Registry Programme. Despite this, the population covered by all these registries together is less than 5% of the total national population.

Indonesia

A national cancer cervix screening programme was launched in the country in 2007, with the objective of screening 30 to 50 year old women every 5 years. The Cervical and Breast Cancer Prevention (CECAP) project developed a service delivery model that was piloted in the district of Karawang, east of Jakarta, from January 2007 to December 2011. The single-visit approach of screening by VIA followed by cryotherapy of VIA-positive women was evaluated. Although this single-visit approach was acceptable and could improve compliance to treatment, ensuring the steady supply of refrigerant gas for cryotherapy was a problem. The CECAP project was subsequently up-scaled and currently the services are being provided in 347 primary health centres situated in 23 provinces. However, services are grossly inadequate for the large target population and a lot of investment is required to improve the infrastructure and build capacity to ensure access of the entire female population to cervical cancer screening services.
Both HPV vaccines are available in the private market and are considered too costly to be considered for the national immunization programme. School-based vaccine delivery services have been very successful in achieving high coverage of other childhood vaccines. The existing health-promoting schools and adolescent-friendly health services programme targeted towards boys and girls aged from 6 to 19 years provide a great opportunity for introduction of HPV vaccines.

There is no population-based cancer registry; hospital-based cancer registries exist in 23 teaching hospitals.

**Maldives**

There is no radiation therapy facility in the country. Only those cervical cancer patients who can afford to go abroad have the opportunity for treatment. It is essential for the country to have a cervical cancer control programme, which is non-existent to date. Currently only one tertiary care hospital in the capital city of Malé has a laboratory equipped to process and read Pap smear cytology. Pap smears are advised only to women suspected of having cervical cancer and are rarely followed up with colposcopy.

A pilot cervical cancer screening project is being planned, to be implemented in Malé and another province. Women between 30 and 50 years of age will be screened by VIA performed by trained nurses. VIA-positive women will be referred to tertiary care hospitals in Malé where colposcopy units will be set up. Getting trained clinicians who can spare time for the programme is a major challenge for the country.

There is no plan to introduce HPV vaccines in the national immunization programme in the near future. There are no population-based or hospital-based cancer registries.

**Myanmar**

Myanmar has a high burden of cervical cancer due to the lack of any organized screening programme. Although a national cancer control programme was launched in 2008, the cervical cancer screening component was never organized appropriately to ensure access to the population.

HPV vaccines are available in the private sector. A policy for the introduction of new vaccines into the national immunization programme (drafted in 2012 and accepted by the Ministry of Health) advocated HPV vaccine, although as a second priority. The national immunization programme for other common vaccines has high coverage in the country. There are well developed school-based health intervention programmes as well as out-of-school adolescent health programmes that can be used for the delivery of HPV vaccines. However, financing and ensuring the logistics for a three-dose vaccine are challenges for the future HPV vaccination programme to overcome.

There are no population-based cancer registries. Hospital-based cancer registries function from three hospitals providing radiation therapy facilities.

**Nepal**

The national guideline on cervical cancer screening and prevention (drafted in 2010) recommended the use of VIA as the screening test and a single-visit approach (VIA followed by cryotherapy of VIA-positive women in the same sitting) to improve compliance to treatment. There was no concerted effort to roll out screening services, possibly because of other competing health priorities. In 2012,
the Family Health Division reorganized the cervical cancer screening programme to screen women aged from 30 to 60 years at least once in the next 5 years. The screening services are presently more community-oriented and additional midwives and nurses have been trained to perform VIA. A group of medical officers and gynaecologists has been trained in colposcopy and management of cervical precancers. Linkage between the screening centres and hospitals offering colposcopy services has been created and efforts are being made to connect the cervical cancer screening database to the medical information system.

The Nepal Network for Cancer Treatment and Research initiated vaccination of small cohorts of 12 to 14 year old girls each year, starting from 2008, with funding support from Australian Cervical Cancer Foundation. The country is yet to obtain sustainable funding to introduce the vaccine into the national immunization programme. Existence of other school-based health programmes for adolescent girls such as the measles-rubella vaccination campaign, de-worming or school nutrition programme offer a good opportunity to access the girls for HPV vaccination. The lack of a regular power supply makes maintenance of the cold chain a challenging task.

There is no population-based cancer registry in the country.

*Sri Lanka*

The Government of Sri Lanka initiated the “Well Woman’s Clinic” (WWC) programme with the support of UNFPA in 1996, focusing on reproductive health needs of women above 35 years of age. The programme is built on the existing primary health care infrastructure and integrated into existing MCH/FP package. PAP smear was introduced for cervical cancer screening in 1998. Guidelines and protocols for cervical cytology screening was first developed in the year 2006 and were subsequently revised in 2010. Since the cervical cancer screening coverage remained very low over the years a decision was taken in year 2007 to actively target the women of 35 years of age for organized screening. However, this decision to actively campaign for 35 year old women does not preclude any woman (especially women over 35 years) attending the WWC since these clinics offer screening services for other conditions such as hypertension and diabetes as well. Over the last three years a steady increase of the percentage coverage of the organized screening of the focus target group of 35 yr old women is noted. The Public Health Midwives identify the 35 year old women from the registers maintained at the Public Health Midwives Office (PHM’s office) and counsel them to undergo cervical cancer screening. Pap smears are collected by Medical officers or Public Health Nursing Sisters at the clinics. In 2012 women have had about 140,000 pap smears.

There are more than 900 Well Woman Clinics spread all over the country at present. These WWC clinics are linked to designated histopathology laboratories. At present there are 35 laboratories capable of processing and interpreting Pap smear cytology across the country. There is a 6-8 weeks of lag period between smear taking and delivery of reports. Sometimes the gap may be even longer since the technicians and the pathologists in certain centers are overloaded with their other routine work. The cytology reports are sent to the relevant Medical Officer of Health Office by the particular lab for distribution among the clients by the Public Health Midwife.

There are 20 colposcopy centres in country mostly situated in provincial hospitals or tertiary care centres. The linkages between the field and these colposcopy centres need further strengthening by designating these centres to defined geographic areas. The cytology reports are sent to the relevant Medical Officer of Health Office by the particular lab for distribution among the clients by the Public Health Midwife.
A proper monitoring system is in place for coverage of the target group at field level and the screening of slides at laboratory level, and some quality assurance aspects have been introduced in to the system such as 10% of the negative slides have to be screened by the pathologist and discrepancies reported in the monthly return which is sent to the Family Health Bureau by the laboratories, and a refresher training has been organised with pre and post training assessment for the cytoscreeners every other year.

There are 20 colposcopy centres in country mostly situated in provincial hospitals or tertiary care centres. The linkages between the field and these colposcopy centres need further strengthening by designating these centres to defined geographic areas. The monitoring of the follow up of the abnormal cytology needs strengthening.

Both bivalent and quadrivalent vaccines are available in the country. There is no immediate plan to introduce the vaccine the national immunization program.

The National Cancer Control program (NCCP) runs the hospital based cancer registries that collect data from the eight cancer treatment centres across the country. A population based cancer registry is being introduced on a step wise basis in the country.

**Thailand**

The national cervical cancer screening programme was launched in 2005 under the Department of Health and Department of Medical Services, with financial support from the National Health Security Office. The target age for screening is 30 to 60 years. The Department of Health is responsible for screening of women using VIA in select districts and the Department of Medical Services is responsible for screening women with Pap smears in the rest of the country. The coverage of the target population was poor until 2010, when the programme was reorganized by establishing linkages between the screening and colposcopy services and developing a mechanism of identifying non-compliant women. All the records pertaining to the screening programme are entered into a computerized screening registry. There was significant improvement in uptake of screening in 2010 and 2011, with the majority of women still being screened by Pap smear cytology. A single-visit approach (cryotherapy for VIA-positive women) is followed in places where women are screened by VIA.

There are population based-cancer registries in select provinces of the country. The first population-based cancer registry was started in 1986 in Chiang Mai. Subsequently, population based-cancer registries were established in Khon Kaen, Songkhla, Lampang and Bangkok.

**Timor-Leste**

There is no population-based cervical cancer screening programme in the country. Pap smear cytology is performed only on symptomatic patients and is of uncertain quality. There is no facility for colposcopy and management of cervical cancer precursors by cryotherapy or LEEP. Pap smear abnormalities are managed by hysterectomy. There is no radiation therapy facility and patients have to travel abroad, if they can afford to. There is no population-based or hospital-based cancer registry.

*The information about these initiatives was collected through a questionnaire, duly filled by experts, and shared and endorsed by country focal persons/programme managers (see Table A9.4).*
Table A9.4. Cancer Cervix control activities in Member States of the South-East Asia Region

<table>
<thead>
<tr>
<th>Countries</th>
<th>Nature of programme</th>
<th>Screening test used</th>
<th>Recommended target population</th>
<th>Coverage achieved</th>
<th>Link between screening and treatment</th>
<th>Nature of programme</th>
<th>Target age</th>
<th>Funding source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Opportunistic with good central coordination</td>
<td>VIA</td>
<td>30 years and above</td>
<td>Low</td>
<td>Good, through “see-and-treat” approach</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Opportunistic</td>
<td>Pap, VIA</td>
<td>20–60 years</td>
<td>Insignificant</td>
<td>Poor</td>
<td>Part of national immunization</td>
<td>12 years</td>
<td>External donation</td>
</tr>
<tr>
<td>Democratic People’s Republic of Korea</td>
<td>Nil. Pilot planned</td>
<td>VIA for pilot</td>
<td>30–55 years</td>
<td>–</td>
<td>NA</td>
<td>Vaccine not available</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>India</td>
<td>Opportunistic. Few pilot studies</td>
<td>Pap, VIA, HPV</td>
<td>30–59 years</td>
<td>Insignificant</td>
<td>NA</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Opportunistic. Few pilot studies</td>
<td>VIA</td>
<td>30–50 years</td>
<td>Insignificant</td>
<td>Good in places where “screen and treat” approach followed</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Maldives</td>
<td>Opportunistic</td>
<td>Pap</td>
<td>Not defined</td>
<td>Insignificant</td>
<td>NA</td>
<td>Vaccine not available</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Opportunistic</td>
<td>Pap</td>
<td>Not defined</td>
<td>Insignificant</td>
<td>NA</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Nepal</td>
<td>Opportunistic</td>
<td>VIA, Pap</td>
<td>30–60 years</td>
<td>Insignificant</td>
<td>NA</td>
<td>Small number vaccinated each year</td>
<td>12–14 years</td>
<td>External donation</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Opportunistic with good central coordination</td>
<td>Pap</td>
<td>35 years</td>
<td>High</td>
<td>Poor</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Thailand</td>
<td>Opportunistic with good central coordination</td>
<td>Pap, VIA</td>
<td>30–60 years</td>
<td>High</td>
<td>Good in places where “screen and treat” approach followed</td>
<td>Only opportunistic vaccination</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Opportunistic</td>
<td>Pap</td>
<td>Not defined</td>
<td>Insignificant</td>
<td>NA</td>
<td>Vaccine not available</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Source: Presentations at the WHO Expert Group Meeting held from 25 to 27 April 2013 in Chandigarh, India
Annex 10

Commonly used teaching materials for comprehensive control of cancer cervix

Visual inspection after acetic acid application (VIA)


JHPIEGO. Atlas of Visual Inspection of the Cervix with Acetic Acid (VIA). Available for purchase, contact: info@jhpiego.net

JHPIEGO. Visual Inspection for Cervical Cancer Prevention: An Interactive Training Tool. Available for purchase, contact: info@jhpiego.net

JHPIEGO. Visual Inspection of the Cervix Flash Card Set. Available for purchase, contact: info@jhpiego.net


Colposcopy

UICC UICC Cervical Cancer Curriculum. Demonstration available at: http://uicc.org/resources/cervical-cancercurriculum To access additional modules and materials, contact: cervicalcancer@uicc.org

Histology/cytology


Staging

ASCO. ASCO Multidisciplinary Cancer Management Course. Contact: mcmc@asco.org http://www.asco.org/mcmc

FIGO. Revised FIGO Staging for Carcinoma of the Vulva, Cervix, and Endometrium (2009). Freely available at: http://www.bgcs.org.uk/media/7f4b5fd0dd26474db0ae97073639d15b.pdf

LEEP/LEETZ


Planning and programme management


Annex 11

Situation Analysis
Cervical cancer prevention and control program

COUNTRY:

Contact information for the person responsible for completing the survey

<table>
<thead>
<tr>
<th>Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Position:</td>
<td></td>
</tr>
<tr>
<td>Organization:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td></td>
</tr>
<tr>
<td>Telephone number:</td>
<td></td>
</tr>
<tr>
<td>Date of Completion:</td>
<td></td>
</tr>
</tbody>
</table>

This survey has been prepared as a basic data collection instrument that can be used to gain knowledge about the situation of cervical cancer prevention and control programs in South East Asia Region. For this purpose, five sections have been considered: (I) Demographic data; (II) Burden of disease; (III) Cervical cancer prevention and control program; (IV) Information and monitoring systems; (V) Financing. You can provide any additional information and relevant comments at the end of each section.
## SECTION I

### DEMOGRAPHIC DATA

|   | Total population |   | Total men |   | Total women |   | Urban population |   | Rural population |   | Number of women aged 30-59 |   | Number of girls aged 9 |   | Number of girls aged 10 |   | Number of girls aged 11 |   | Number of girls aged 12 |   | If age breakup not available, Number of girls aged 10-14 yrs |   | Percentage of girls (Specify age like 9-13 yrs or 10-14 yrs) that completed primary school education |
|---|-----------------|---|-----------|---|-------------|---|------------------|---|------------------|---|-------------------------|---|------------------------|---|-------------------------|---|-------------------------|---|--------------------------|---|-------------------------------------------------------------|
| 1.1 | | | 1.2 | | | 1.3 | | 1.4 | | | 1.5 | | | 1.6 | | | 1.7 | | | 1.8 | | | 1.9 | | | 1.10 | | | 1.11 | | | 1.12 | | |

Note: Indicate year and source

### REMARKS:


### Burden of disease in the country

**Note:** For the questions where options are provided in column 2, please double click on the appropriate response to open the command box and click ‘default value – checked’.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Age adjusted Incidence rate of cervical cancer</td>
</tr>
<tr>
<td>2.2</td>
<td>Age adjusted Mortality rate associated with cervical cancer</td>
</tr>
<tr>
<td>2.3</td>
<td>Number of total cervical cancer cases newly detected per year</td>
</tr>
<tr>
<td>2.4</td>
<td>Number of deaths per year from cervical cancer</td>
</tr>
<tr>
<td>2.5</td>
<td>Has any HPV infection prevalence study in general population been done in your country?</td>
</tr>
<tr>
<td></td>
<td>□ Yes</td>
</tr>
<tr>
<td>2.6</td>
<td>Has any HPV infection prevalence study in cervical neoplasias been done in your country?</td>
</tr>
<tr>
<td></td>
<td>□ Yes</td>
</tr>
<tr>
<td>2.7</td>
<td>If yes, provide references &amp; mention HPV prevalence rates:</td>
</tr>
</tbody>
</table>
## SECTION III

**Cervical cancer prevention and control programs**

*Note: For the questions where options are provided in column 2, please double click on the appropriate response to open the command box and click ‘default value – checked’.*

### 3.1. GENERAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.1. Is there a national protocol/guideline for the prevention and Control of cervical cancer?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>3.1.2. If Yes, indicate the date it was prepared, by which organization, the period in which it is in effect, and its availability:</td>
<td>Date: Prepared by: Effective from: Available from website:</td>
</tr>
<tr>
<td>3.1.3. Is there a national cancer control program/policy?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>3.1.4. If there is a national cancer control program/policy who is the focal point/nodal officer?</td>
<td>Name: Designation: Contact details:</td>
</tr>
<tr>
<td>3.1.5. Mark the description that is most appropriate for the cervical cancer prevention and control program in your country</td>
<td>Organized at the national level Organized in selected areas Opportunistic screening only Screening rarely advised</td>
</tr>
<tr>
<td>3.1.6. Which of the following services are available in your country and what proportion of the women requiring the services can avail them?</td>
<td>Diagnosis by colposcopy &amp; biopsy ( %) Treatment of precancerous lesions ( %) Treatment of cervical cancer by surgery ( %) Treatment of cervical cancer by radiation and/or chemotherapy ( %) Palliative care ( %)</td>
</tr>
<tr>
<td>3.1.7. Are there clinical practice guidelines or protocols available about the following aspects of cervical cancer Prevention and control?</td>
<td>Screening tests Diagnostic tests Laboratories Treatment options for precancerous lesions Treatment of cervical cancer Programmatic guidelines No national protocol for any of the above</td>
</tr>
</tbody>
</table>
### 3.1.8 Which screening tests are included in the cervical Cancer control program or practised in opportunistic screening?
- **Pap smear**
- **VIA**
- **VILI**
- **HPV DNA test**
- **Combination (specify:**

### 3.1.9 No of laboratories offering cervical pathology / histopathology services:
- **At Tertiary Care level**
- **At Secondary care level**
- **At Primary Care level**

### 3.1.10 Are the laboratory facilities adequate for Screening and Diagnostic tests for Cervical Pre-cancer and Cancer?
- **Adequate and available across the country**
- **Inadequate, available in select centers**
- **Not available at all**

### 3.1.11 Are these laboratories accredited to any agency?
- **YES (Specify the agency)**
- **NO**
- **Don’t know**

**Remarks:**

### 3.2 PRIMARY PREVENTION: HPV VACCINATION

#### 3.2.1 Which of the HPV vaccines are licensed & available in your country?
- **Bivalent**
- **Quadrivalent**
- **Both**
- **None**

#### 3.2.2 Is there an HPV vaccination program financed by the government?
- **Yes**
- **No**

#### 3.2.3 Are there any demonstration projects to introduce the HPV vaccine was / is being conducted or planned by any governmental or non-governmental organization in any region in the country?
- **Yes**
- **No**

#### 3.2.4 If yes, specify:
- Since when
- Region/Area:
- Organization:
- Type of vaccine:
- Age group:
- Mode of contact with target group
- Total target group to be vaccinated
- Coverage with completed doses:
### 3.3. SECONDARY PREVENTION: SCREENING TESTS AND TREATMENT OF PRECANCEROUS LESIONS

<table>
<thead>
<tr>
<th>3.3.1.</th>
<th>What is the recommended age of the target population for screening in your country?</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3.2.</td>
<td>What is the recommended frequency of screening in your country?</td>
</tr>
<tr>
<td>3.3.3.</td>
<td>What percentage of the eligible women have been screened (coverage) over last five years?</td>
</tr>
<tr>
<td>3.3.4.</td>
<td>If no coverage data is available, please mention the number of women screened per year</td>
</tr>
<tr>
<td>3.3.5</td>
<td>Is there a unique identification number to trace women who availed of the screening services?</td>
</tr>
</tbody>
</table>

**Remarks:**

- **3.3.1.** What is the recommended age of the target population for screening in your country?
- **3.3.2.** What is the recommended frequency of screening in your country?
- **3.3.3.** What percentage of the eligible women have been screened (coverage) over last five years?
- **3.3.4.** If no coverage data is available, please mention the number of women screened per year.
- **3.3.5.** Is there a unique identification number to trace women who availed of the screening services?
3.3.6. What proportion of women screened have abnormal screening test?

3.3.7. What proportion of the screened women have CIN 2 or worse lesions?

3.3.8. What proportion of women detected to have cervical precancer are treated?

3.3.9. If women are referred to a higher facility for treatment of pre-cancerous lesions, is there a mechanism to ensure they receive the treatment (and are not lost to follow-up)

- Yes Specify ....................
- No

3.3.10. Which of the following options will be most suitable and acceptable in your country settings to ensure better compliance to treatment?

- Treatment based on biopsy results
- Treatment based on colposcopy result (see & treat)
- Treatment based on VIA result (Screen & treat)
- Any other

3.3.11. Which of the following treatment options are available to manage cervical pre-cancers in your country?

- Cryotherapy
- LEEP
- Cold Coagulation
- Cone biopsy
- Hysterectomy
- If other, specify _______
- None

3.3.12. Do you feel that replacing Pap smear cytology with an alternative test will improve screening program?

- Yes
- No

3.3.13. If yes, what will be your test of choice?

- LBC
- VIA
- VILI
- HPV test

3.3.14. Why (Specify reasons)

- Operational reasons
- Better compliance
- Improved access
- Increased coverage
- More feasible
- Easy to train
- Other (Specify) ..............

Remarks:
### 3.4. TREATMENT OF INVASIVE CANCER AND PALLIATIVE CARE

<table>
<thead>
<tr>
<th>3.4.1</th>
<th>What percentage of women diagnosed with cervical cancer are suitable for surgical treatment?</th>
<th>(   %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4.2</td>
<td>Is radiation therapy facility available in your country?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>3.4.3</td>
<td>Is palliative care facility available in your country?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>3.4.4</td>
<td>Are oral morphine preparations readily available to patients who require them?</td>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

**Remarks:**
### SECTION IV

#### 4.1. PROGRAM MONITORING & EVALUATION

*Note: For the questions where options are provided in column 2, please double click on the appropriate response to open the command box and click 'default value – checked'.*

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1. Is evaluation of the cervical cancer program (e.g., coverage, impact) performed with a standardized method and at established intervals?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4.2. If so, indicate the date of the last evaluation report and the agency in charge of preparing it:</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4.3. Is there a central health information system?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4.4. Is there a cancer registry? If so, specify whether it is a hospital- or population-based registry and the location:</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4.5. Is there an information system that provides for registry of women with abnormal screening results in order to ensure follow-up?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4.6. Is there a system that guarantees the quality during all stages of the screening test (i.e., sampling, transportation, processing, interpretation, reporting results, training) and the maximum time for each step?</td>
<td>Yes, No</td>
</tr>
</tbody>
</table>

Remarks:
## FINANCING

*Note: For the questions where options are provided in column 2, please double click on the appropriate response to open the command box and click ‘default value – checked’.*

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1. Is there a specific budget for the cervical cancer prevention and control program?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>5.2. Is any collaboration of international and local agencies/organizations available in order to strengthen the cervical cancer prevention and control program? If so, list these agencies/organizations and the areas in which they work:</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>5.3. At present do women pay out-of-pocket for the cervical cancer screening test?</td>
<td>□ Full payment □ Partial payment □ Free-of-charge</td>
</tr>
<tr>
<td>5.4. If the screening test result is abnormal, do women pay for the diagnostic tests (i.e., colposcopy, biopsy)?</td>
<td>□ Full payment □ Partial payment □ Free-of-charge</td>
</tr>
<tr>
<td>5.6. Must women pay out-of-pocket for access to palliative care?</td>
<td>□ Full payment □ Partial payment □ Free-of-charge</td>
</tr>
<tr>
<td>5.7. Is there a possibility that the expenses related to cervical cancer screening will be covered by medical insurance of the patients?</td>
<td>□ No □ Partly □ Fully</td>
</tr>
<tr>
<td>5.8. Is there funding for adolescent health services?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>5.9. Is there available budget for Reproductive health?</td>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

**Remarks:**
SECTION VI

GENERAL EVALUATION OF THE SITUATION

After analysis of the different components of the cervical cancer prevention and control program has been completed in the previous sections, you are requested to do a general evaluation of the situation. Complete the following questions by marking one of the 4 options:

H: High; M: Moderate; L: Low; U: Unknown
VS: Very satisfactory; S: Satisfactory; UN: Unsatisfactory; U: Unknown

<table>
<thead>
<tr>
<th>Question</th>
<th>VS</th>
<th>S</th>
<th>UN</th>
<th>U</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1. The burden of cervical cancer in your country is considered to be:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2. The need to improve the health services provided to women is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.3. The need to improve the health services provided to adolescents is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.4. The possibility of receiving external support and collaboration by organizations is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.5. How would you rate the current screening policies?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.6. The success of the current screening program is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.7. How would you rate the current adolescent immunization policies?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.8. The success of the current adolescent immunization program is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.9. The political interest in improving cancer control is considered to be:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.10. The political interest in improving cervical cancer control is considered to be:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11. The possibility that the government will finance strengthening of the screening services is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.12. The possibility that the government will finance introduction of the HPV vaccine is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.13. The feasibility of strengthening the screening programs in the future is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.14. The feasibility of introducing HPV vaccination programs in the future is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
Annex 12

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With the objective of supporting Member States to develop or strengthen their national cervical cancer control programmes – through the judicious use of primary prevention (human papillomavirus (HPV) vaccination) and secondary prevention (cervical cancer screening) strategies, as well as strengthening treatment and palliative services – the World Health Organization (WHO) Regional Office for South-East Asia has facilitated the development of this Strategic framework for the comprehensive control of cervical cancer in South-East Asia to reduce the burden of the disease in the Region.

The framework is based on a situational analysis of Member States in the South-East Asia Region regarding their preparedness and capacity to introduce new cervical cancer control measures. It has also taken into account emerging scientific evidence related to the new technologies and novel paradigms in cervical cancer screening, as well as the safety and efficacy of HPV vaccines.