Report of the Regional meeting on prevention of cervical cancer through HPV vaccination

New Delhi, India, 5–7 June 2018
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**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIP</td>
<td>Advisory Committee on Immunization Practices</td>
</tr>
<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
</tr>
<tr>
<td>AFHS</td>
<td>adolescent-friendly health services</td>
</tr>
<tr>
<td>ASANDA</td>
<td>National Health Insurance</td>
</tr>
<tr>
<td>CCSP</td>
<td>Cervical Cancer Screening Programme</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>HPV</td>
<td>human papillomavirus</td>
</tr>
<tr>
<td>IEC</td>
<td>information, education and communication</td>
</tr>
<tr>
<td>MAC</td>
<td>multiple age cohorts</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>PHC</td>
<td>primary health centre</td>
</tr>
<tr>
<td>PIE</td>
<td>post-introduction evaluation</td>
</tr>
<tr>
<td>RVAP</td>
<td>Regional Vaccine Action Plan</td>
</tr>
<tr>
<td>VIA</td>
<td>visual inspection with acetic acid</td>
</tr>
<tr>
<td>VVM</td>
<td>vaccine vial monitor</td>
</tr>
</tbody>
</table>
1. Introduction

Comprehensive control of cancer of the cervix in the South-East Asia Region is guided by the “Strategic framework for the comprehensive control of cancer cervix South-East Asia Region”, developed in 2015 with the overall objective of guiding and assisting Member States to develop or strengthen national strategies to improve cervical cancer control activities. The Regional Vaccine Action Plan (RVAP) (2016–2020) aims to introduce new vaccines and related technologies. Human papillomavirus (HPV) is one of the three priority new vaccines considered under the RVAP.

WHO recognizes the importance of cervical cancer and other HPV-related diseases as global public health problems and recommends that HPV vaccines be included in national immunization programmes. HPV vaccines should be introduced as part of a coordinated and comprehensive strategy to prevent cervical cancer and other diseases caused by HPV. In 2018, the World Health Assembly called on Member States to move for global eradication of cervical cancer.

Regional meeting on prevention of cervical cancer through HPV vaccination

A regional meeting on the prevention of cervical cancer through HPV vaccination was held in New Delhi, India from 5–7 June 2018 with the overall objective of strengthening the capacity of Member States for the prevention of cervical cancer through HPV vaccination and other prevention strategies.

The specific objectives of the meeting were as follows.

(1) Provide information on the epidemiology of HPV infections, the global and regional progress in the introduction of the HPV vaccine, the rationale for HPV vaccination and various strategies for prevention of cervical cancer.

(2) Strengthen decision-making for the introduction and national roll-out of the HPV vaccine, including developing proposals for submission to Gavi.

(3) Provide information on planning for the introduction of the HPV vaccine and post-introduction monitoring and evaluation.

(4) Build a consensus on the integration of activities for the prevention of cervical cancer at the country level.

All Member States, except the Democratic People’s Republic of Korea, participated in the consultation. In addition, four partners of the global HPV vaccination leadership group participated. The list of participants and detailed programme are in Annexes 1 and 2. Dr Neena Raina, Acting Director, Family Gender and Lifecycle, WHO South-East Asia Region, inaugurated the consultation and delivered the opening address on behalf of Dr Poonam Khetrapal Singh, the Regional Director (Annex 3). Dr Md. Altaf Husain, Programme Manager, Expanded Programme on Immunization (EPI) Ministry of Health and Family Welfare, Bangladesh and Dr Pradeep Halder, Deputy Commissioner, Immunization, Ministry of Health and Family Welfare, India, co-chaired the meeting. Dr Deepa Gamage, Dr Htar Htar Lin and Dr Suchada Jiamsiri were the rapporteurs.
2. **Global overview of HPV infection and cervical cancer**

Human papillomavirus causes the most common viral infection of the reproductive tract and is the cause of a range of conditions, both among females and males. These include precancerous lesions that may progress to become cancerous. Although the majority of HPV infections do not cause symptoms or disease and resolve spontaneously, persistent infection with high-risk HPV genotypes may result in disease. In women, persistent infection with specific oncogenic types of HPV (most frequently types 16 and 18) may lead to precancerous lesions which, if untreated, may progress to cervical cancer.

The prevalence of HPV worldwide among women with normal cytological findings was estimated to be 11.7% (95% confidence interval (CI): 11.6–11.7%). Country-specific adjusted HPV prevalence in cervical specimens ranged from 1.6% to 41.9% worldwide. Age-specific HPV prevalence peaked at younger ages (<25 years), with a prevalence of 21.8% (95% CI: 21.3–22.3%), and a lower prevalence plateau at middle ages.

HPV types 16 and 18 are the most frequent types worldwide, HPV-16 being the most common type in all regions. Other oncogenic types are types 31, 39, 51, 52, 56, 58, and 59. Women infected with a given HPV type may be co-infected or subsequently infected with several types which may cause cervical lesions. Persistent infection with oncogenic, high-risk HPV genotypes is strongly associated with the development of cervical cancer. HPV-16 and HPV-18 were the most common HPV types in invasive cervical cancer (HPV-16 from 61.5 to 62.1%, and HPV18 from 6.9 to 7.2%). HPV types 16, 18, 45, 31, 33, 52, and 58 account for approximately 90% of the squamous cell carcinomas which are positive for HPV DNA.

The International Agency for Research Cancer estimated that 630,000 new HPV-related cancers occurred globally in 2012, of which 530,000 were cervical cancers. The majority (>85%) of cervical cancer cases occur in the low- and lower-middle-income countries because these countries lack screening and treatment services. There were an estimated 266,000 deaths from cervical cancer worldwide in 2012, accounting for 7.5% of all female cancer deaths.

WHO recognizes the importance of cervical cancer and other HPV-related diseases as global public health problems and recommends that HPV vaccines be included in national immunization programmes. WHO recommends two doses of the HPV vaccine for girls in the age group of 9–14 years, separated by a minimum interval of six months. While there is no maximum interval, it is recommended that the second dose be administered within 12–15 months of the first dose. For girls age ≥15 years, three doses of HPV vaccine are recommended.

3. **HPV vaccines**

The currently licensed HPV vaccines prevent cervical cancer by preventing infection by various HPV types. The vaccines are the most effective when administered to a person prior to exposure to HPV. Three HPV vaccines are currently pre-qualified by WHO.

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(1) A bivalent vaccine (Cervarix®, produced by GlaxoSmithKline) – protects against two HPV types (16 and 18) that cause the majority of cervical cancers

(2) A quadrivalent vaccine (GARDASIL®/Silgard®, produced by Merck & Co.) – protects against HPV types 16 and 18, as well as HPV 6 and 11, which are responsible for anogenital warts

(3) A 9-valent HPV vaccine (GARDASIL 9®, produced by Merck & Co.) which additionally protects against HPV types 31, 33, 45, 52 and 58

These three vaccines are compared in Table 1.

Table 1. Summary of HPV vaccine characteristics

<table>
<thead>
<tr>
<th>ATTRIBUTES</th>
<th>BIVALENT (CERVARIX®)</th>
<th>QUADRIVALENT (GARDASIL®/SILGARD®)</th>
<th>9-VALENT (GARDASIL 9®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine type</td>
<td>Recombinant L1-capsid virus-like particles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virus-like particles of HPV in the vaccine</td>
<td>16,18</td>
<td>6,11,16,18</td>
<td>6,11,16,18 31,33,45,52,58</td>
</tr>
<tr>
<td>Disease protection</td>
<td>Cervical cancer (and premalignant genital lesions of the cervix, vulva and vagina)</td>
<td>Cervical cancer (and premalignant genital lesions of the cervix, vulva and vagina)</td>
<td>Cervical cancer (and premalignant genital lesions of the cervix, vulva and vagina) Genital warts</td>
</tr>
<tr>
<td>Cross-protection against HPV types</td>
<td>31, 33, 45</td>
<td>31, 45</td>
<td></td>
</tr>
<tr>
<td>Number of doses required</td>
<td>9–14 years 2</td>
<td>&gt;15 years 2</td>
<td>2 2</td>
</tr>
<tr>
<td></td>
<td>&gt;15 years 3</td>
<td></td>
<td>3 3</td>
</tr>
<tr>
<td>Dosing interval (flexibility)</td>
<td>0 and 6 months (no maximum interval but suggested interval not more than 12–15 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of administration</td>
<td>Intramuscular injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of protection *</td>
<td>9.4 years 10 years</td>
<td>6.6 years</td>
<td></td>
</tr>
<tr>
<td>Presentation and type of vaccine vial monitor (VVM)</td>
<td>1-dose vial; VVM 30 2-dose vial; VVM 30</td>
<td>1-dose vial; VVM 30</td>
<td>1-dose vial;</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Severe allergic reaction to any vaccine component after first dose</td>
<td>Severe febrile illness Known to be pregnant</td>
<td></td>
</tr>
</tbody>
</table>

* Minimal duration of protection as per current evidence
Seventy-one countries in the world have introduced the HPV vaccine in their national immunization programmes. On the basis of many very large high-quality studies, the Global Advisory Committee on Vaccine Safety has found no new adverse events of concern.2

According to the information in the WHO data base, the HPV vaccine is among the more expensive new vaccines across all income groups. The current average price of a dose of vaccine for the lower-middle-income countries is US$10.42, upper-middle-income countries US$15.65, and high-income countries, US$31.67. Gavi gets one dose of vaccine for US$4.5 and the Pan American Health Organization revolving fund gets vaccine for US$8.5. It is pertinent to note, however, that the HPV vaccine is less expensive per fully-immunized girl on a two-dose regimen when compared to PCV and rota, and that the cohort of girls is around half the size of the cohort for infant immunization.

4. Gavi support for HPV vaccination

Gavi has provided support to countries for HPV vaccination since 2013. The objective of the Gavi initial HPV demonstration programme was to enable countries to gain experience before the nationwide introduction of the vaccine, with a special focus on understanding the feasibility of the intervention. The demonstration project targeted a limited number of girls (15,000 girls) per country. The national introduction was limited to a cohort of one age (or grade) and there were several requirements for deciding on national-level introduction, including an updated cancer plan, adolescent health assessment, a coverage survey, costing (budgeting), and a post-introduction evaluation (PIE).

Following the recommendation by WHO’s Strategic Advisory Group of Experts on immunization to target multiple cohorts for a better and quicker impact, Gavi revised the guidelines in December 2016 to allow countries to target multiple age cohorts (MAC), in addition to the routine cohort among girls of 9–14 years of age. Accordingly, in the first year, Gavi supports the introduction of the vaccine to multiple age cohorts of girls of 9–14 years of age (routine cohort plus additional MAC). In subsequent years, support continues for the routine cohort. The Vaccine Introduction Grant for the introduction year is determined as $2.40 per girl in the routine cohort and co-financing applies to this cohort. In addition, in the first year, for additional cohorts an operational cost of $0.65 per girl targeted is provided and there is no co-financing. These funds are made available for the year of introduction and there is flexibility to use them over a longer time frame.

Although demo programmes, like for other vaccines, no longer exist, countries can decide to phase introduction. The country will receive vaccines through Gavi (with only co-financing costs) until it is transitioned from Gavi support. During the accelerated transition phase, co-financing ramps up yearly by 20%, from 20% to 100% of the Gavi vaccine price. Manufactures have guaranteed the Gavi price for the years following transition. Some recently transitioned countries that have not introduced the HPV vaccine with Gavi support may still be able to negotiate access to the Gavi HPV price with manufacturers. In 2016, Gavi set a target of vaccinating 40 million girls by 2020. Though Gavi has approved proposals to vaccinate 25 million girls by 2020, the new HPV strategy has lost some of its momentum due to a shortage of vaccine supply. Merck & Co. informed Gavi in June 2017 that the volume of

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vaccine requirement for the new strategy had not been planned for. Gavi is working with Merck to address the shortage, and supply constraints are likely to be eased by 2020. There is also a shortage in the supply of the GlaxoSmithKline-produced Cervarix, and the constraints are likely to be eased by 2022. To effectively plan for the supply of this costly vaccine, countries are encouraged to apply immediately. This would ensure that the vaccine is available 18–24 months after the application has been approved.

5. **Cost-effectiveness analysis of HPV vaccination**

Even though the cost of the HPV vaccine is relatively high, there is a cost reduction over time due to the reduction of treatment costs for cervical cancer. Research shows that the vaccine is highly cost-efficient, particularly for low-income countries.

Conducting a cost-effectiveness analysis of the HPV vaccination will help to advocate for vaccination and securing internal and/external financial resources, to select the right mix of interventions to optimize the health-care budget, and to facilitate tender negotiations between purchasers and vaccine manufacturers. Sixteen studies of cost-effectiveness have been conducted in the developing countries and the results suggest that vaccination is cost-effective, especially when there are few secondary prevention options. According to a systematic review of the current evidence on HPV vaccination, there is no conclusive proof to show that the 9-valent vaccine is more cost-effective than the bivalent and quadrivalent vaccine. The addition of HPV vaccination to cervical screening is a cost-effective strategy for most countries in the Region, based on the WHO Commission on Macroeconomics and Health threshold.5

WHO has developed a generic costing and planning tool for the prevention and control of cervical cancer. The WHO Cervical Cancer Prevention and Costing (C4P) tool has been developed specifically to assist low- and middle-income- countries in planning strategies for controlling cervical cancer. The tool has been built in MS Excel and consists of two independent modules:

- HPV (human papillomavirus) vaccination for girls of 9–13 years of age
- cervical cancer screening and treatment for women.

Both modules generate financial and economic costing estimates for programmes, either to project future costs or to retrospectively evaluate programme spending. The output is displayed in terms of total cost, cost per fully immunized girl and cost per dose. Costs are broken down by cost component and recurrent/capital costs. The tool also provides access to underlying calculations and assumptions, and is pre-populated with the required data and linked to data sources.

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6. Regional overview of HPV infection, cervical cancer and control measures

The prevalence of HPV among women with normal cytology in the Region was estimated to be 14% (95% CI: 13.0–15.0). In 2012, the estimated number of new cases in the Region was 175,000. The estimated number of deaths due to cervical cancer was 94,000, accounting for 17% of female cancer deaths. Thirty-three per cent of the new cases of cervical cancer in the world and 35% of cervical cancer deaths occur in the Region. Cervical cancer is the second most common cause of mortality due to cancer among females in the Region. The age-standardized cervical cancer incidence rates in the countries vary from 11 per 100,000 women in the Maldives to 22 per 100,000 females in India. The cervical cancer mortality varies in the Region from 5 per 100,000 females in Sri Lanka to 12.4 per 100,000 females in India. Myanmar, Bangladesh and Nepal closely follow the incidence and mortality rates observed in India.

In 2015, the “Strategic framework for the comprehensive control of cancer cervix, South-East Asia Region” was developed. The overall objective of the strategic framework is to assist Member States to develop or strengthen their national strategies to improve activities to control cervical cancer, 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:

➢ introduce or scale up the delivery of HPV vaccine to girls aged 9–13 years through a coordinated multisectoral approach involving national immunization, cancer control, and reproductive and adolescent health programmes;

➢ 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;

➢ strengthen health systems to ensure equitable access to cervical cancer screening services for all eligible women, with particular attention to socioeconomically disadvantaged population groups;

➢ augment management facilities for invasive cervical cancer and introduce palliative care services into the health system as part of a comprehensive cancer control programme; and

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

A training package on a comprehensive approach to cervical cancer screening and management of cervical pre-cancers has been developed in the Region. It provides strategies for a screen-and-treat programme that builds upon the existing evidence-based WHO global guidelines. WHO has supported countries in the Region to develop cervical cancer prevention and control programmes to decrease the incidence of cervical cancer, as well as the morbidity and mortality. The programmes included primary, secondary and tertiary prevention activities, and access to palliative care. Prior to the availability of vaccines, early detection by screening all women in the target age group, followed by the treatment of detected pre-cancerous lesions was the strategy used to prevent cervical cancers. However,

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there are large inequities in access to effective screening and treatment for cervical cancer. Table 2 provides the status of cervical cancer screening, and the link between screening and treatment in the countries of the Region.

Table 2. Screening for cervical cancer in the South-East Asia Region in 2018

<table>
<thead>
<tr>
<th>Country</th>
<th>National screening programme</th>
<th>Type of national screening</th>
<th>Most widely used test</th>
<th>Target population (years)</th>
<th>Coverage achieved (%)</th>
<th>Link between screening and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>Opportunistic, hospital-based</td>
<td>VIA</td>
<td>&gt;30</td>
<td>&lt;10</td>
<td>Good, through “see-and-treat” approach</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>Opportunistic, hospital-based</td>
<td>VIA Pap smear</td>
<td>20–60</td>
<td>50–70</td>
<td>Poor</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>Yes</td>
<td>Organized, population-based</td>
<td>VIA</td>
<td>30–55</td>
<td>&gt;70</td>
<td>NA</td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>Opportunistic, hospital-based</td>
<td>VIA, HPV, Pap smear</td>
<td>30–59</td>
<td>&lt;10</td>
<td>NA</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>Organized, population-based</td>
<td>VIA</td>
<td>30–50</td>
<td></td>
<td>Good, through “see-and-treat” approach</td>
</tr>
<tr>
<td>Maldives</td>
<td>Yes</td>
<td>Organized, population-based</td>
<td>Pap smear</td>
<td>Not defined</td>
<td></td>
<td>Screen and refer to further treatment</td>
</tr>
<tr>
<td>Myanmar</td>
<td>No</td>
<td>PAP smear</td>
<td>Not defined</td>
<td></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Nepal</td>
<td>No</td>
<td>Organized, population-based</td>
<td>VIA, Pap smear</td>
<td>30–60</td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Yes</td>
<td>Organized, with good central coordination</td>
<td>Pap smear</td>
<td>&gt;35</td>
<td>10–50</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Opportunistic, with good central coordination</td>
<td>VIA and Pap smear</td>
<td>30–60</td>
<td>10–50</td>
<td>Good, through “see-and-treat” approach</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Yes</td>
<td>Opportunistic, hospital-based</td>
<td>Pap smear</td>
<td>Not defined</td>
<td>&lt;10</td>
<td>NA</td>
</tr>
</tbody>
</table>

Adolescent health and school health programmes provide information to adolescents on health behaviours, safe sex, the harmful effects of substance use, nutrition, physical activity, etc. Table 3 shows the status of the implementation of adolescent-friendly health services (AFHS) and school health programmes in countries in the Region.
Table 3. Adolescent-friendly health services in the Region, 2018

<table>
<thead>
<tr>
<th>Country</th>
<th>Geographic coverage of AFHS implementation</th>
<th>Number of AFHS facilities</th>
<th>Sites for AFHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>40 / 60 districts</td>
<td>224 / 224</td>
<td>NGO and private school health</td>
</tr>
<tr>
<td>Bhutan</td>
<td>20 / 20 districts</td>
<td>15</td>
<td>School</td>
</tr>
<tr>
<td>India</td>
<td>All 35 states</td>
<td>Not available</td>
<td>NGO and private school health</td>
</tr>
<tr>
<td>Indonesia</td>
<td>196 / 477 districts</td>
<td>2011 / 8187</td>
<td>NGO</td>
</tr>
<tr>
<td>Maldives</td>
<td>2 / 20 atolls</td>
<td>2 / 2 hospitals</td>
<td>Youth Health Café (MoYAS); NGO</td>
</tr>
<tr>
<td>Myanmar</td>
<td>18 / 75 townships</td>
<td>18 / 18</td>
<td>School</td>
</tr>
<tr>
<td>Nepal</td>
<td>10 / 75 districts</td>
<td>94 / 550</td>
<td>School</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Limited</td>
<td>Not available</td>
<td>NGO, school health</td>
</tr>
<tr>
<td>Thailand</td>
<td>711 / 927 districts</td>
<td>Not available</td>
<td>Schools</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>2010</td>
<td>Not available</td>
<td>Marie Stopes Clinic</td>
</tr>
</tbody>
</table>

7. Progress in introduction of HPV vaccine in the Region

The RVAP 2016–2020 envisages that the Region should be free of vaccine-preventable diseases, and all countries should provide equitable access to high-quality, safe, efficacious and affordable vaccines and immunization services throughout the life course. Goal 7 of the plan focuses on the introduction of new vaccines and the HPV vaccine as a priority.

The countries presented their experiences related to identifying the disease burden due to cervical cancer, deciding on the introduction of the HPV vaccine, cost considerations and budgeting for the vaccination, demonstration projects, linking with school immunization, communicating for the introduction of the HPV vaccine, and post-introduction evaluations. During the group work, each country reviewed the decision-making process and road map for the introduction of the HPV vaccine. The following is the summary of progress made in each country and the key planned actions.

**Bangladesh**

On the basis of the disease burden of cervical cancer, an HPV demonstration project was initiated in 2016 to ascertain the ability and readiness to scale up the introduction of the HPV vaccine nationwide. The bivalent vaccine was used and 30,860 girls (schoolgoing children in Grade 5 and 10-year-old children not going to school) were targeted in the first-year cohort. The administrative coverage of HPV1 was 94.3% and that of HPV2, 94%. In the second-year cohort, the administrative coverage of HPV1 was 99.5% and that of HPV2, 99.4%. A coverage evaluation survey was conducted in January 2017, and HPV1 coverage was found to be 88.2%, while HPV2 coverage was 87.1%. Although the coverage in all four rural subdistricts was more than 91%, HPV2 coverage of the urban subdistricts was 66.7%.
Post-introduction evaluation, involving national and international experts, was conducted during the vaccination of the children of the first cohort with the second dose. The key conclusions of the PIE were that the HPV demonstration project had been well implemented; the recipients, their parent and teachers, and the overall community were satisfied; and the combined delivery strategy of vaccination in the schools and community had worked well.

Bangladesh conducted a cost analysis of the demonstration project. The financial cost for a fully immunized child, minus the cost of the vaccine, was US$1.18; including the cost of the vaccine, it was US$ 2.26. The economic cost of a fully immunized child, without counting the cost of the vaccine, was US$4.3. Including the vaccine cost, it was US$18.4. Based on these information cost analyses for the national scaling up was conducted. The cost of vaccinating a child is not very high when combined school-based and community-based programmes are considered. Further, the drop-out rate is lower if girls are fully vaccinated via school-based delivery. On the basis of the findings of the HPV coverage survey and costing study, Bangladesh will follow a school- and community-based approach for national scale-up of the HPV vaccine. Bangladesh is planning to develop and submit an HPV application by September 2018 to Gavi.

*Bhutan*

Cervical cancer is the most common female cancer in Bhutan. According to an HPV prevalence study conducted in 2012, 73% of women with cervical cancers harboured HPV type 16 and 18, while the rest had types 31, 45, 58 and 59. Among the general population, the prevalence of HPV was 26%, the highest (33%) being among women of ≤24 years of age. In a study conducted in 2014, 8% of pap smears had cytological abnormalities; 24 CIN3 and 4 ICC were histologically confirmed. Even after additional testing with a sensitive E7 PCR, no infections with vaccine-targeted HPV types were detected among the vaccinated women (n = 34), compared to 6% prevalence among unvaccinated women of a similar age (p=0.215).

The Government of Bhutan, in partnership with the Australian Cervical Cancer Foundation and Merck's Gardasil Access Program, initiated the HPV vaccination programme in 2010 to reduce the incidence of cervical cancer in Bhutan, and became the first country in the Region and the first low-middle-income country to implement a national HPV vaccination programme. A pilot phase was conducted in 2009/2010, using the quadrivalent vaccine. A total of 3167 girls between the ages of 11 and 13 years were vaccinated and 94% coverage with three doses of the HPV vaccine was achieved. Nationwide, an HPV vaccination campaign was conducted for 12- to 18-year-old girls, targeting 47,888 children, and 96% coverage was achieved with three doses of the vaccine. In 2011, the HPV vaccination was integrated into the routine immunization schedule for girls at 12 years of age and provided through health facilities. However, administration coverage was 60% in 2011, and 68% in 2012 and 2013. Hence in 2014, the HPV vaccination strategy was shifted to school-based vaccination for all girls in Grade 6 because 97% of girls are enrolled in schools. The vaccination for out-of-school girls at 12 years of age was continued at health facilities.

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*Tshomo et al Human papillomavirus infection in Bhutan at the moment of implementation of a national HPV vaccination programme* BMC Infectious Diseases 2014 14:408
School health coordinators in each school coordinate with the nearest health centre on the schedule for HPV vaccination for girls in Class 6. They submit a line list of eligible girls to the health workers a few days before the vaccination and motivate children to attend school on vaccination day. If there are absentees on vaccination day, the health workers are informed so that they can arrange for vaccination in the outreach clinics. Coverage with two doses of HPV vaccine was increased to more than 95% in 2016 and 2017.

In 2013, two school-based HPV urine surveys were conducted to evaluate the effectiveness of the vaccine. The number of female students (median age: 19 years, 5th–95th percentile: 18–22) enrolled for the study was 973. The participants self-collected a first-void urine sample according to a validated protocol. HPV prevalence was obtained using two PCR assays that differ in sensitivity and type spectrum, namely GP51/GP61 and E7-MPG. In Bhutan, 92% students have been vaccinated. HPV6/11/16/18 prevalence by GP51/GP61 was lower among vaccinated than unvaccinated students, but the confidence interval was broad. The study concludes that it is feasible to carry out urine surveys to monitor HPV vaccination and quantifies the effectiveness of the quadrivalent vaccine in women vaccinated after pre-adolescence.9

Currently, the Government of Bhutan is fully funding the HPV vaccination through the national health trust fund and obtains the vaccine at the prices agreed upon with the manufactures and Gavi. There is a multisectoral partnership, with the Ministries of Education and the local government conducting advocacy and fixing responsibilities and accountability to help in the mobilization of students/target audience during the vaccination period.

India

On the basis of the disease burden analysed through the studies conducted by the Indian Counsel of Medical Research, the National Technical Advisory Group for Immunization has recommended national introduction of the HPV vaccine. The state of Punjab started HPV vaccination in 2016 as a state initiative in two districts. In 2016, 10,000 girls in Grade 6 of government schools were targeted. In 2017, 15,000 girls were targeted. The vaccine was purchased through UNICEF at the Gavi price. Sikkim is planning for a state-wide introduction, targeting 31,000 girls from 9 to 14 years of age through the school and outreach strategy. Following that, 9-year-old girls will be targeted yearly. PIE is planned for Punjab and Sikkim. National introduction of the vaccine would have to be phased, with the vaccine to be purchased at the Gavi price.

Indonesia

According to the basic health survey conducted in 2013, the incidence of cervical cancer was high, at 80 per 100,000 population. On the basis of the disease burden and the cost-effectiveness analysis, The National Immunization Technical Advisory Group (NITAG), Indonesia recommended a school-based demonstration programme. Six provinces with the highest prevalence were selected for the demonstration programme that would employ school-based immunization. In 2016, a demonstration programme was started in two districts in Jakarta. Girls in Grade 5 (at 11 years) were to be given HPV1 and those in Grade 6 (at 12 years) were to be given HPV2. At the beginning of the academic calendar, the primary health centre (PHC) coordinates with schools or educational institutions to obtain data on the target

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9 Francheschi et al. / Urine testing to monitor the impact of HPV vaccination in Bhutan and Rwanda Int. J. Cancer: 139, 518–526 (2016)
populations. Before implementation, the headmaster gives a notification letter to the parents. However, if there are sick children, they will be immunized later in the PHC, following a recommendation letter from the school. Although basic formal education in elementary school is compulsory in Indonesia, there are still some children who do not attend schools due to unavoidable reasons. These children were vaccinated at the PHC and other public health facilities.

The quadrivalent vaccine was used. The vaccine for the demonstration project in Jogjakarta Province was supported by Gavi. The HPV vaccine for the other provinces, such as Jakarta, East Java, South Sulawesi and North Sulawesi, were co-funded by the Central and local governments.

The coverage of the HPV1 vaccine in the demonstration districts of the province of Jakarta was 92%. In 2017, the coverage in three districts in the first year of implementation reached 95%. Various communication strategies, such as workshops, counselling, information, education and communication (IEC) materials, social media, and media briefing, were used. Indonesia is currently obtaining the vaccine for a high cost. It is planning to conduct PIE in 2018. High-level advocacy to the government and Gavi will be required to access Gavi prices for the HPV vaccine.

**The Maldives**

In 2017, the Maldives comprehensively reviewed the disease burden of HPV and the cost benefits of the introduction of the HPV vaccine. According to the National Health Insurance (ASANDA), from 2013 to June 2015, 35 “malignant neoplasms of cervix uteri” and 16 “malignant neoplasms cervix uteri unspecified” were reported. According to a published study on the knowledge, attitude and practices of women of reproductive age, risk factors are present for the prevalence of cervical cancer (22.1% have first sex before 17 years of age, 37.3% marry before 18 years, 33.2% have more than one marriage, 5.1% are current smokers 5% were past smokers, and 59.7% are exposed to passive smoking).

Since currently, data on cervical cancer are collected from patients registered in the ASANDA, there are plans to enhance coordination between reproductive health units and disease surveillance units to strengthen surveillance for cervical cancer. In January 2018, a screening facility was established at the central level to conduct visual inspection with acetic acid (VIA). On the basis of the current evidence, the Maldives Technical Advisory Group on Immunization recommended the HPV vaccination. The cost of providing two doses per girl at the price at which the HPV vaccine is available in upper middle-income countries is US$27.6. The total birth cohort in the Maldives is about 7800 per year and thus, the cost of the vaccine for the female child cohort of 3900 is US$112,282. Rough cost–benefit estimates demonstrate that the introduction of the vaccine will save US$1 million in the management of HPV diseases annually. Accordingly, the return from the investment of US$1 in the HPV vaccine is US$6. The Ministry of Health is exploring various aspects related to the introduction of the HPV vaccine. In the initial year, girls between 9 and 14 years of age will be targeted for a multicohort immunization activity (MAC). This would be followed by yearly vaccination of girls in Grade 5. Since more than 99% of children attend schools, the HPV vaccination will be integrated into the existing school health programme. Two doses will be provided with a six-month interval between them. Children not attending schools will be identified through home visits. The vaccine requirement would be 46,800 (23,400*2) for the
MAC and 3900 doses annually. Currently, the government is exploring the possibility of procuring the vaccine. Public and school health officers will conduct advocacy and communication activities. Sensitization programmes will be held for parents and health workers, using IEC materials and media. Six months after its introduction, the coverage of the vaccine will be monitored through routine EPI monitoring and PIE.

**Myanmar**

Cervical cancer ranks as the second most frequent cancer among all women in Myanmar. According to GLOBOCAN 2012, the incidence of cervical cancer is 20.6 per 100,000 population and the mortality is 12.3 per 100,000 population. According to Ministry of Health data, in 2017, 6434 women were diagnosed with cervical cancer and 3536 died from the disease. Sentinel surveillance data reveal that from 2008–2014, HPV 16 was present in 60.4%–83.7%, HPV 18 in 4.1%–12.5% and HPV 31 in 6.2–21.9% of women from the different sites from which samples were selected.

Various sources of data indicate the prevalence of HPV risk factors in Myanmar. UNAIDS estimates that in 2015, there were 220,000 people living with HIV, 12,000 new HIV infections and 9700 AIDS-related deaths. Of people who inject drugs, 2.9% have syphilis and 5.8% of female sex workers have syphilis. Among women of the age of 20–49 years, 19% were married before the age of 18 years.

The United Nations Global Joint Programme on Cervical Cancer Prevention and Control selected Myanmar as the first country in the Region to include in the programme. A national coordination body to oversee and coordinate the prevention of cervical cancer and control initiatives has been established. The strategies are to introduce the HPV vaccine; increase women’s access to screening for cervical cancer; improve access to the diagnosis of the disease, treatment and palliative care; improve cervical cancer surveillance; eliminate lost to follow-up; and establish a population-based cancer registry by 2019.

Myanmar prefers the quadrivalent HPV vaccine and plans to vaccinate 10–14-year-old girls. This will be followed by vaccination through routine immunization at 9 years of age. Since the school enrolment for secondary education is 60%, the vaccination strategy will be a combination of school-based and outreach immunization. Myanmar has submitted an application to Gavi for the national introduction of the HPV vaccine in 2020.

**Nepal**

In 2009, a study was conducted to assess the burden of HPV across the country, covering data from seven major hospitals where cancer is diagnosed and treated.\(^\text{10}\) Data on 4397 cancers were reviewed. Cervical cancer was the leading cause of cancer, accounting for 21.4% of all cancers identified. According to GLOBOCAN 2012, the incidence of cervical cancer in Nepal was 32.4/100,000 women in the age group of 15–44 years. Mortality was 17.6 per 100,000 women. In all, there were 3504 cases and 1872 deaths.

Nepal conducted the HPV Vaccine Demonstration Programme in Kaski and Chitwan districts from February 2016–March 2017, with support from Gavi. It integrated the demonstration project with the adolescent sexual reproductive health intervention and

Cervical Cancer Screening Program (CCSP) in all health facilities in the two districts. Two doses of Cervarix are given six months apart to Grade 6 girls and out-of-school girls of the age of 10 at health facilities. The Nepal Cancer Care Foundation, together with WHO, has conducted training on VIA at health posts for three days, and on VIA and cryotherapy at PHCs and hospitals for six days in two demonstration districts. The result of the PIE revealed that the HPV vaccine was well accepted by health workers and the community, and there was good coordination between the Ministry of Health, the Ministry of Education and the cancer screening programme. However, reaching out to girls who were out of school posed a challenge. According to the HPV vaccination coverage survey, the coverage of the vaccine was 97%, but there were gaps in knowledge and awareness of the HPV vaccine and cervical cancer. A survey of screening for cervical cancer at the HPV demonstration project revealed that the coverage was 40%, which was lower than the coverage of the HPV vaccine (97%). It was found in the PIE that 79% of cervical cancer screening was done in the public sector and 49% of women had not been informed that screening was free of charge. Of the cases in which VIA was performed under the CCSP, 4.23% were positive for VIA. However, there are several challenges to sustainability, such as low coverage of screening, limited logistics and supplies for cryotherapy, poor compliance on referral and further secondary prevention interventions.

On the basis of the recommendation of National Committee of Immunization Practices, the National Immunization Programme plans to submit an application to Gavi in September 2018 to introduce HPV vaccination in 2019/2020. However, CCSP and secondary prevention continuity is uncertain. The plan for introducing the HPV vaccine is to deliver two doses of the vaccine six months apart to Grade 6 schoolgirls and out-of-school girls of the age of 10 years at health facilities. The opportunity for vaccinating a multi-age cohort and the age window for a multi-year cohort will be discussed. Other health interventions to prevent cervical cancer will also be strengthened. These include adolescence health interventions and screening for cervical cancer in health facilities.

**Sri Lanka**

Cervical cancer is the second commonest female cancer and accounts for 10–12% of all female cancers. There are 800–1000 new cervical cancer cases per year.\(^{11}\) Around 2000 viral warts are treated in clinics for sexually transmitted disease in a year.\(^{12}\) Country-specific data on the prevalence of HPV are not routinely available and a research study (descriptive cross-sectional study) was carried out in 2009. The prevalence of HPV among clinically normal women was identified as 3.3% (95% CI 3.2–3.4) and that of HPV genotype 16 and 18 was identified as 1.2% (95% CI 1.15–1.25).

The coverage of the existing cervical cancer screening programme gradually progressed from 10% in 2009 to 50% in 2017. A case control study was conducted to identify the risks of HPV, and population attributable risk was identified as 85% for any HPV genotype and 69% for vaccine-preventable genotypes. This information has been used as the baseline for the decision-making procedure for the introduction of the HPV vaccine in the country. The National Immunization Summit, held in 2015, considered that HPV vaccination was the priority vaccine to be introduced. An expert working group was appointed to review the country-specific disease burden data, including the cost implications. The recommendations

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11 National Cancer Control Programme data  
12 National STD AIDS Control Programme data
were brought to the Advisory Committee on Communicable Diseases, which is the NITAG in the country. NITAG decisions were implemented by the immunization implementation authority, the Central Epidemiology Unit of the Ministry of Health.

Sri Lanka integrated the HPV vaccination programme with the school health programme. The school-based programme, in which the first dose of the vaccine was administered to girls in Grade 6 in all districts, was implemented in October 2017. This is a rolling programme, in which a medical inspection is conducted in each school, with a micro-plan prepared at the beginning of the year. Up to May 2018, 77% of districts have achieved above 80% coverage. Sri Lanka plans to monitor the HPV programme regularly through the existing monitoring system at all levels to ensure the quality of services and high coverage. The target is 80% coverage within the first 2 years and >90% coverage after 2 years for both doses. Coverage will be monitored quarterly through a Web-based immunization system and regional epidemiologists will make quarterly reviews to address gaps and improve coverage.

Sri Lanka will procure the vaccine from UNICEF to ensure sustained supplies and monitor storage and cold chain facilities closely. The advocacy and communication plan will continue for the next 5 years and PIE will be conducted in September 2018.

**Thailand**

Thailand’s health structure for decision-making on the introduction of a new vaccine has three components. The Advisory Committee on Immunization Practices (ACIP) evaluates the disease burden and the feasibility of the programme. The National Drug System Development Committee evaluates the regulatory requirements for the registration of the vaccine through the National Essential Drug List Subcommittee. The Promotion and Prevention Subcommittee of the National Health Security Board approves the finances on the basis of the necessity of the vaccination and cost–benefit assessments. Further, the programmatic feasibility should be proven in a pilot project and the outcome of the pilot should be promising effects, e.g. it should indicate public acceptance.

In 2012, the ACIP reviewed and considered the burden of cervical cancer and the suitability of the HPV vaccine, and also assessed its cost-effectiveness. In 2013, it assigned a working group to develop an HPV vaccine pilot project. In 2014, a pilot project was implemented in one province and considering the convincing success of the pilot project, the ACIP decided to introduce the HPV vaccine in the EPI programme in 2015. The HPV vaccine was administrated to Grade 5 schoolgirls nationwide in July–September 2017 and January–March 2018.

**Timor-Leste**

Timor-Leste plans to focus on exploring the prevention and control of cervical cancer, e.g. it will carry out a study on the disease burden of cervical cancer, and conduct a cost-effectiveness analysis for the HPV vaccination to support policy decisions and the development of HPV vaccination strategies. Advocacy will be carried out with policy-makers and there will be coordination between the relevant departments in the Ministry of Health, other ministries and partners to ensure that it is sustainable to integrate the HPV vaccination with the existing immunization programme. The Ministry of Health will also work in coordination with Gavi to explore opportunities to access affordable HPV vaccine as a post-transition country.
8. Planning for introduction of HPV vaccine and integration with adolescent health and reproductive health programmes

The key considerations involved in the introduction of the HPV vaccine are the choice of vaccine and the target group for vaccination, service delivery strategy, dosing schedule, additional attention to reaching special populations, training of health-care providers and vaccinators, availability of the vaccine, integration with other related health programmes, communication and social mobilization strategies, and readiness assessment. The experiences of Bangladesh, Bhutan, Indonesia, Nepal, Sri Lanka and Thailand in the national introduction of HPV and demonstration projects are summarized in Chapter 7. See Annex 4 for a detailed document shared during the meeting on decision-making for the introduction of the HPV vaccine.

Lessons learned from HPV demonstration projects and the national introduction of the vaccine in African countries from 2015 to 2017 have been shared on the basis of a comprehensive review of the HPV vaccine delivery experience in 37 low- and middle-income countries conducted by PATH and London School of Health and Tropical Medicine. Factors associated with high coverage are strategies using schools and collaboration with the education sector at the national and local levels; the inclusion of approaches to reach out-of-school girls; comprehensive social mobilization, including the use of ‘credible influencers’; and the use of vaccination registers and cards. Factors associated with low coverage are delivery strategies focusing only on health facilities; ineffective coordination and planning with schools; delay in the receipt of social mobilization and school-delivery funds; not providing girls who missed the first dose with a second opportunity; parents’ hesitation in accepting the vaccine due to the fear of adverse effects; and lengthy consent procedures. Finally, schools were chosen as vaccination sites to maximize coverage as delivery strategies including a school component effectively captured most 9–14-year-old girls. The delivery of all doses within one school year minimized dropouts, but was resource-intensive.

There are opportunities for linkages with the adolescent health programme in the Region. It is important to adopt an integrated approach to disease control activities when there are common target populations, co-morbidities, common underlying behaviours, and the same services delivery channels to the same communities. All Member States have school health programmes, while 10 have national or subnational adolescent health programmes. The provision of the package of services is clinic-based, school-based or community-based. The services commonly provided through the school health programme are general examination, including testing for vision and hearing, growth, education, awareness, mental health, dental health, deworming, screening for noncommunicable diseases, nutritional status, referral and vaccination.

There are opportunities for linkages with maternal and reproductive health. Nine countries have a national screening programme for cervical cancer (see Table 2). The coordination and implementation of screening are good in Bhutan, DPR Korea, Sri Lanka and Thailand, the coverage of screening being at least 50%. Integrating the prevention of cervical cancer with maternal and reproductive services means offering a broad set of services during the same appointment, at the same service delivery site, and from the same provider. Contact opportunities provided by screening of all women in the target age group, followed by treatment of detected precancerous lesions can prevent a proportion of cervical cancers.
9. **Social mobilization and communication**

There is a global HPV communication repository. The resources and guides in it include a message framework, an advocacy pack, a risk and crisis communications guide, interpersonal communication and job aids, community alliance guide, digital dialogue guide, monitoring and evaluation guide, field notes on communication planning and branding guide.

Global experiences have shown that communication planning and technical assistance should commence months in advance. Effective community mobilization activities need to be implemented through multiple channels at least one month prior to vaccination. There has been too much focus on the development of printed material and national-level advocacy. Strategies and interventions for face-to-face persuasion and reaching out-of-school girls have not received the required attention. In some countries, the critical cadres of health promotion officers and village health workers have not been involved in communication and training activities. Delays in the disbursement of funds have prevented timely completion of training and communication activities. Sometimes, there was no budget projection for post-introduction implementation and the second dose. The most important influencers were trained personnel (41.2%) and family and community members (30.8%). Speaking to teachers and family members were strong predictors of vaccine uptake. Overall, the main sources of information were noninteractive oral messages (47.1%) and interactive oral messages (47.1%). The most effective messages emphasized the prevention of cancer, safety of the vaccine, and national and global endorsement, while explaining clearly where and when girls could be vaccinated.

Rumours and negative publicity were best addressed quickly and comprehensively by using several communication channels, like the government media, international organizations and celebrities. Successful consent procedures were consistent with those used for routine immunization. Opt-out consent was easier in the logistic sense, while opt-in consent could generate misunderstanding and mistrust among communities.

The communication experiences of three cases national introduction of the vaccine in Bhutan, Sri Lanka and Thailand and three demonstration projects in Bangladesh, Indonesia and Nepal are available in the Region. The communication experiences of them need to be documented. Sri Lanka focused on advocacy on information on why only girls are vaccinated, why the vaccine is needed in adolescence and not at other ages, known anxiety-related adverse events following HPV vaccination, and the importance and necessity of a screening programme, despite the introduction of the vaccine. There was one clear slogan, “Stand against Cervical Cancer”, and the following five basic messages were consistently used:

1. What is the cervix and what is cervical cancer?
2. HPV causes the majority of cervical cancer.
3. A safe, effective HPV vaccine is available that prevents 70% of cervical cancer, but pap smear screening should be continued until the age of 35.
4. The HPV vaccine is given to schoolgirls in Grade 6 (10–11-year-olds), or at community-level immunization clinics if the girl is missed in school.
5. Two doses, with a six-month interval between them, are required for complete protection.
Multiple simultaneous channels, including leaflets, posters, information sheets and stickers, were developed and addressed to different audiences. Television and radio spots, programmes and discussions were dedicated to the subject, and newspaper articles published. Symposia and lectures, targeting health-care staff and professionals, were conducted.

Thailand conducted a thorough assessment of the awareness of health personnel and the public during a pilot project in one province. This included knowledge of cervical cancer, and the attitude of health-care workers, students and schoolteachers towards the pilot project, and factors related to the coverage of HPV vaccination at the school level under the pilot project. Then advocacy and communication materials were prepared for related personnel who are responsible for immunization services at all levels (doctors, nurses, public health officers, pharmacists), stakeholders (National Health Security Office, Ministry of Education, Ministry of Defence, Ministry of the Interior), teachers, parents and the target group (schoolgirls in Grade 5) and the public.

Thus, it can be seen that the countries in the Region that have introduced the HPV vaccine have made successful communication and social mobilization efforts, achieving high acceptance and coverage. However, there have been challenges in communication, including effective modes for cross-sectoral engagement, reaching out-of-school girls, rumours on the social media and crisis communication.

10. Monitoring and Evaluation

Monitoring needs to be an integral part of the introduction of the HPV vaccine. Monitoring of immunization programmes is necessary to keep track of the ongoing operational activities, keep up the drive for achieving milestones, ensure the use of resources, ensure the safety of injections, and for reprogramming and eventual evaluation. Additional considerations in favour of monitoring the HPV vaccination are that the HPV vaccine is administered to an age group not routinely served by immunization programmes, the preferred delivery system is school-based, and there is a need to link with the existing immunization monitoring/school health service monitoring.

Monitoring of the introduction of the HPV vaccine should be started prior to introduction to ensure that the desired coverage is reached. A new tool developed for this purpose is HPV introduction readiness assessment, which is intended to ensure preparedness for the introduction of the vaccine at all levels, including the national level, regional/provincial level, district level and individual level (vaccine recipient). This would create awareness and a state of preparedness among all stakeholders, like public health officials, health-care workers, education officers, school personnel and community leaders.

Estimates of vaccination coverage based on data reported in Annual WHO UNICEF Joint reporting form provide a measure of population protection against HPV infection. The choice of the age of 15 years is strategic, allowing all children vaccinated between 9–14-years to be captured to assess population coverage. Many countries use cohort measures, and all countries moving to vaccination registries will start expressing coverage for age cohorts, possibly in addition to other measures of coverage. The limitations of this method are the accuracy of age reporting, and the time interval between the vaccination year and the reporting year, particularly for single-age, early-age vaccination.
WHO recommends that countries which have introduced a new vaccine should conduct a PIE 6–12 months after the introduction of the vaccine. This will provide a systematic method for evaluating the implementation of the introduction, and its impact on the existing immunization system. Such evaluation will allow problems associated with the introduction of the vaccine to be identified early enough to be corrected and documented. Bangladesh and Nepal have conducted PIEs of HPV demonstration projects. PIEs are to be conducted by using questionnaires and checklists, and observation of practices at all levels of the health service, including cold and dry storage facilities for vaccines and other supplies and points of vaccine administration. The WHO guide for conducting an EPI review can be used with a specific focus on annexes related to HPV PIEs.

WHO recommends integrated high-precision surveys conducted periodically to evaluate HPV coverage.

11. Conclusions and follow-up actions

The following key observations and follow-up actions were agreed upon at the meeting.

➢ All countries of the Region, except DPR Korea and Timor-Leste, have analysed the disease burden of cervical cancer and have evidence that the disease is a public health problem.

➢ Bhutan, Sri Lanka and Thailand are conducting school-based HPV vaccination, through which more than 90% coverage has been achieved. The percentage of girls who are attending school is high in these countries. A demonstration project in Bangladesh showed that school-based HPV vaccination is acceptable to families, the school management and communities and more than 90% coverage with HPV vaccine has been achieved among girls in these countries through school-based vaccination Most of the remaining girls could be covered through the routine immunization centres. Hence, a joint approach using school-based immunization and vaccination through routine immunization centres seems appropriate for most countries in the Region.

➢ To date, there have been no reports of severe adverse events following immunization (AEFI) with the HPV vaccine in the Region. Mild adverse events have been reported from all countries; reporting of these events is an indicator of the sensitivity of AEFI surveillance. Globally, more than 250 million doses of HPV vaccine have been administered from 2006 to 2017. The WHO Global Advisory Committee on Vaccine Safety has stated that since the licensure of HPV vaccines, no new adverse events of concern have been found, on the basis of many very large high-quality studies.

➢ Even though the vaccine is relatively expensive, the overall costs to the health system diminish over time due to the consequent reduction in the costs of treatment of cervical cancer. Research shows that the HPV vaccine is highly cost-efficient, particularly for low-income countries. Despite the existing disease burden and recommendations from the relevant NITAGs that the HPV vaccine be introduced, policy-makers in India and Indonesia are having difficulty understanding the cost-effectiveness of the vaccination. Bangladesh and Nepal are planning to conduct cost-effectiveness studies.
Conducting an analysis of the cost-effectiveness of HPV vaccination helps with making a case for securing internal and external financial resources. Selecting the right mix of interventions to optimize the health-care budget and facilitate tender negotiations between purchasers and vaccine manufacturers.

Gavi has supported HPV vaccination since 2013. Following the recommendation of SAGE to target multiple age cohorts instead of a single age cohort, Gavi revised its guidelines in 2016 to allow countries to target multiple age cohorts. Though Gavi has approved proposals which should result in the vaccination of 25 million girls by 2020, constraints in vaccine supply will make it difficult to realize this vision. To facilitate supply planning for this costly vaccine, countries are encouraged to submit applications for funding to Gavi immediately. Doing so will ensure that the vaccine is available 18–24 months after the application has been approved.

WHO, UNICEF and the CDC need to coordinate and provide technical support to countries to help develop applications to Gavi.

There are mature school health programmes and adolescent health programmes in the countries of the Region. HPV vaccination can be integrated into these programmes. The introduction of the vaccine can be linked to augmenting cervical cancer screening programmes for women. A coordinated approach among different government departments, as well as partner agencies, is needed to introduce the HPV vaccine and control cervical cancer.

Bhutan, Sri Lanka and Thailand have developed effective communication strategies and materials for the introduction of the vaccine. All countries can use these models when introducing the vaccine.

Regular monitoring of HPV vaccination should be a part of monitoring of the national immunization programme and monitoring of school health programmes.

Bhutan conducted PIE after the national introduction of the vaccine. Countries which have introduced the HPV vaccine need to conduct PIEs and link to EPI reviews, where appropriate.

The observations of and follow-up actions recommended by the Regional meeting on the prevention of cervical cancer through HPV vaccination will be presented at the Regional Immunization Technical Advisory Group meeting, to be held in July 2018.
Annex 1

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Report of the Regional meeting on prevention of cervical cancer through HPV vaccination

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### Annex 2

**Programme**

<table>
<thead>
<tr>
<th>DAY 1: Tuesday, 5 June</th>
<th>8:00–9:00</th>
<th>Registration</th>
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<tbody>
<tr>
<td></td>
<td>9:00–09:30</td>
<td><strong>Opening session</strong></td>
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<td></td>
<td>9:00–09:30</td>
<td>- Welcome and opening address</td>
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<td></td>
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<td>- Objectives of the meeting</td>
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<td>- Introduction of participants</td>
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<td>- Administrative announcements</td>
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<td></td>
<td>9:30–10:00</td>
<td><strong>Group photograph, followed by tea/coffee break</strong></td>
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<td></td>
<td>10:00–12:00</td>
<td><strong>SESSION 1 – BACKGROUND and OVERVIEW</strong></td>
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<tr>
<td></td>
<td></td>
<td>- Cervical cancer and HPV epidemiology and Regional overview of cervical cancer control (20 mins) N Raina, WHO Regional Office for South-East Asia</td>
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<td>- SEAR Vaccine action plan: linkage to introduction of HPV vaccine (20 mins) S Bahl, WHO SEARO</td>
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<td>- Overview of HPV vaccines, global progress and technical update (30 mins) P Bloem, WHO headquarters</td>
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<td>- Discussion (20 mins)</td>
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<td>- GAVI HPV 2.0 programme (20 mins) A Sidibe, Gavi</td>
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<td>- Discussion (10 mins)</td>
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<td>12:00–12:45</td>
<td><strong>SESSION 2 – Deciding on introduction of HPV vaccine</strong></td>
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<tr>
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<td>- Session introduction (5 mins) J Liyanage, WHO SEARO</td>
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<td>- Decision-making on national introduction of HPV vaccine: country experiences (30 mins) D Gamage, Sri Lanka S. Jiamsiri, Thailand</td>
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<td>- Discussion (10 mins)</td>
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<td>12:45–13:45</td>
<td>Lunch break</td>
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<td>13:45–15:00</td>
<td><strong>Cost-effectiveness</strong></td>
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<td>Cost-effectiveness of introduction of HPV vaccine (30 mins) R Hutubessy, WHO headquarters</td>
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</tbody>
</table>
Cost considerations and budgeting for introduction of HPV vaccine: country experiences (30 mins)  
D Gamage, Sri Lanka  
S. Jiamsiri, Thailand

Discussion (15 mins)

15:00–15:30  
**Tea/coffee break**

15:30–17:30  
Overview of WHO cervical cancer prevention and control (C4P) tool (30 mins)  
Discussion (30 mins)

Decision-making and financing introduction of HPV vaccine: country experiences and challenges with financing (funding sources, scenarios for scaling up national rolling, priority-setting) (60 mins)  
**Group work**  
**Group A**: Bangladesh, Myanmar and Nepal  
**Group B**: Maldives  
**Group C**: India and Indonesia

17:30  
Close of Day 1

**DAY 2: Wednesday, 6 June**

09:00–09:40  
Presentation of Day 1 group work and discussion

09:40–10:45  
**SESSION 3 – Planning and introduction of HPV vaccination**

- Session introduction (5 mins)  
  J Liyanage, WHO Regional Office

- Vaccine delivery strategies in demonstration districts (15 mins)  
  G Tandy, Indonesia

- Planning and implementation of vaccination sessions in schools, health centres, outreach  
  P Atuhebwe, WHO Regional Office for Africa

- Logistics in districts and schools

- Lessons learned from HPV demonstration projects and national introductions (30 mins)

- Discussion (15 mins)

10:45–11:15  
**Tea/coffee break**

11:15–12:30  
Linkages with other programmes  
Opportunities for linkages – adolescent health programme (15 mins)  
R Mehta, WHO Regional Office

Country experience in integration of HPV vaccination with other adolescent health interventions (30 mins)  
K Chand, Nepal  
C Vithana, Sri Lanka

Demonstration project

- HPV and school health programme
Opportunities for linkages – maternal and reproductive health programme (15 mins)  
Discussion (15 mins)

12:30–13:00  
Social mobilization and crisis communication  
- IEC materials, communication strategies and advocacy, key messages  
- Crisis communication: preventing and responding to rumours, effective crisis plans  
O Afsar, UNICEF headquarters

13:00–14:00  
Lunch break

14:00–14:45  
Communicating for vaccine introduction  
Country experiences in communicating for introduction of HPV vaccine (15 mins)  
Summary of cross-country learning for communication strategies (15 mins)  
A Hasman, UNICEF Regional Office for South Asia

14:45–15:30  
SESSION 4 – Monitoring and evaluation  
- Readiness assessment tools for introduction of HPV and Zimbabwe’s experience (30 mins)  
- Discussion (15 mins)  
A Loharikar, CDC

15:30–16:00  
Tea/coffee break

16:00–17:45  
Monitoring tools for HPV vaccination and linking them to existing EPI tools and supportive supervision (15 mins)  
Monitoring HPV vaccination – 2010–2018, administrative coverage, coverage survey, addressing challenges (20 mins)  
Discussion (15 mins)  
Evaluating introduction of HPV and HPV programme (20 mins)  
Post-introduction evaluation of the demonstration project: country experience (20 mins)  
Discussion (15 mins)  
A Loharikar, CDC  
A Hossain, Bangladesh

17:45  
Close of Day 2

DAY 3: Thursday 7 June

09:00–10:45  
SESSION 5 – Moving forward  
- Overview of preparing application to Gavi (30 mins)  
A Sidibe, Gavi
- Discussion (15 mins)
- Utilizing experience of demonstration project to prepare the Gavi application (30 mins)  
  S Mamun  
  Bangladesh  
  A Bose  
  Nepal  
- Disease burden of cervical cancer and preparation of application to Gavi (15 mins)  
  H H Lin  
  Myanmar

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>10:45−11:15</td>
<td><strong>Tea/coffee break</strong></td>
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| 11:15−12:00 | Interactive session on integrating public health interventions for cervical cancer control  
  J Liyanage  
  WHO Regional Office |
| 12:00−1500 | Development of country-specific plans for sustaining HPV vaccination/rolling out/introduction  
  Five groups:  
  Bangladesh, Sri Lanka  
  India, Indonesia  
  Myanmar, Thailand  
  Nepal, Bhutan  
  Maldives, Timor-Leste |
| 15:00−16:00 | Country presentations on future plans                                   |
| 16:00−16:30 | **Tea/coffee break**                                                   |
| 16:30−17:00 | Follow-up actions                                                      |
| 17.00     | Closing remarks                                                        |
Annex 3

Message from the Regional Director

Representatives of the ministries of health from across the Region, distinguished participants and development partners, colleagues from WHO headquarters and country offices, ladies and gentlemen,

Welcome to this regional meeting on the prevention of cervical cancer through HPV vaccination. Although our Regional Director, Dr Poonam Khetrapal Singh, would have very much liked to attend this important meeting, she is unable to do so due to a prior commitment and, therefore, I take great pleasure in delivering this message on her behalf.

The Regional Director notes that HPV causes the most common viral infection of the reproductive tract and is responsible for a range of conditions both among females and males. These include precancerous lesions that may progress to become cancerous. Although a majority of HPV infections do not cause symptoms or disease and are resolved spontaneously, persistent infection with high-risk HPV genotypes may result in disease. A large majority of HPV cancers occur in less developed countries, where they account for almost 12% of all female cancers. This year’s World Health Assembly announced its plans to lead efforts to eliminate cervical cancer. Reflecting this drive, since 2015, the WHO Regional Office for South-East Asia has worked with 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 via its ‘Strategic framework for the comprehensive control of cancer cervix in the South-East Asia Region’.

The Regional Director notes that as per the strategic framework, countries across the Region have developed programmes for the prevention and control of cervical cancer to decrease the incidence, morbidity and mortality associated with it. These programmes include primary, secondary and tertiary prevention activities and access to palliative care. As part of the efforts to implement the strategic framework, technical units for immunization, and programmes for adolescent health, maternal and reproductive health, and noncommunicable diseases are working closely with the programmes for cervical cancer.

Notably, prior to the availability of the HPV vaccine, early detection – by screening all women in the target age group – followed by the treatment of detected precancerous lesions, was the primary strategy for preventing cervical cancers. With this in mind, in 2017, the Regional Office for South-East Asia developed a comprehensive package for cervical cancer screening for its Member States. Nevertheless, there remain large inequities in access to effective cervical cancer screening and treatment.

Distinguished representatives and partners,

The Regional Director emphasizes that three highly efficacious HPV vaccines are now available to be introduced as part of a coordinated and comprehensive strategy to prevent cervical cancer and other diseases caused by HPV. Though at present, 71 countries have introduced the HPV vaccine in national immunization programmes, most of them are in the WHO American and European regions. That said, with support from Gavi, the Vaccine
Alliance, several developing countries have either already introduced the HPV vaccine or are looking forward to its introduction.

The Regional Director takes this opportunity to thank all of you for your contributions to the South-East Asia Regional Vaccine Action Plan 2016–2020, and in doing so, remarks that one of the eight goals of the Plan pertains to the introduction of new vaccines and related technologies. The HPV vaccine is one of three new vaccines considered under this goal. Till now, Bhutan, Sri Lanka and Thailand have introduced the HPV vaccine as part of routine immunization programmes. Their experience in doing so will be of benefit to other Member States introducing the vaccine. To this end, the Regional Director is pleased that Bangladesh, India, Indonesia and Nepal have completed demonstration projects in a number of districts and are now considering the broader roll-out of HPV vaccination. She also understands that the introduction of the HPV vaccine has been recommended by the national immunization technical advisory groups of three Member States, namely India, Maldives and Myanmar, and appreciates the presence of the representatives of these countries.

The South-East Asia Region has a long history of effective partnership in immunization noting that WHO has worked closely with its Member States, and UNICEF the CDC and the other partners to improve immunization coverage.

With the establishment of Gavi in 2000, a unique public–private partnership was formed to provide new and underutilized vaccines to children living in developing countries. The Gavi Board has now approved the accelerated roll-out of the HPV vaccine programme, which will allow Gavi-supported countries to protect around 40 million girls from cervical cancer by 2020, averting an estimated 900,000 deaths.

The Regional Director requests the Member States of the Region to take advantage of this remarkable opportunity to improve adolescent and women’s health, and in doing so, to build on the Region’s remarkable achievements in immunization and accelerate progress towards universal health coverage, another of the Region’s flagship priorities.

The deliberations over the next three days will enable us to better understand the full range of issues related to the control of cervical cancer, and will help Member States develop country-specific plans to introduce the HPV vaccine using an integrated approach.

Dr Khetrapal Singh wishes you a successful meeting and a pleasant stay in New Delhi.

I echo that sentiment and look forward to coming deliberations.

Thank you.
Annex 4

Decision-making for introduction of HPV vaccine

It is important to have a systematic and transparent process for deciding on the introduction of the HPV vaccine into the national immunization programme. Ideally, the national immunization technical advisory group or an equivalent independent advisory body should be requested to undertake a rigorous review of the evidence and make an independent recommendation to the national government. The independence of the NITAG and its reliance on evidence-based decision-making reinforces the credibility of the decision, helps to resist pressure from interest groups and enhances the ability to secure government and/or donor funding for the introduction of the vaccine.

The information required

The following information is needed to decide on the introduction of the HPV vaccine.

➢ Data on the disease burden of cervical cancer and on HPV infections and types in the country are critical to convince policy-makers and medical practitioners about the introduction of the vaccine. However, this information may not be available in all countries. It can be useful to draw on the experience of other countries which have introduced the vaccine and have a similar level of development and health system capacity. The WHO position paper on HPV vaccines (May 2017) provides information on trials conducted for three types of HPV vaccine preparations, vaccine effectiveness and cross-protection.

➢ A National Cancer (or Cervical Cancer) Strategic Plan should be in existence.

➢ Information on the availability and use of other cervical cancer prevention methods (e.g. screening and treatment) is essential.

➢ It is necessary to have information on the coverage of immunization and experiences from any vaccines already being given to young adolescents.

➢ Information is required on the proposed delivery strategy (or strategies), and an analysis should be made of the proportion of girls who would be reached using the proposed strategy.

➢ Information is required on the cost, cost-effectiveness and affordability of the vaccine.

Financial sustainability of introduction of HPV vaccine

Financial sustainability is a cornerstone of the introduction of any new vaccine. The sustainability of programme administration is more than the ability to purchase the vaccine; it also includes financing any additional expenses incurred by adapting the immunization programme for the introduction or for new delivery strategies. A costing study is a particularly important assessment to be conducted before the introduction of the HPV vaccine as the target population has not previously been a part of the routine immunization programme and the delivery of the vaccine may be primarily outside health centres (at schools or other outreach locations). WHO has developed the Cervical Cancer Prevention and Control
Costing (C4P) Tool to assist countries to assess both the financial and economic five-year costs of the introduction of the HPV vaccine.

**Information on price of HPV vaccines**

Data on the price and procurement of vaccine products are essential to forecasting, budgeting and identifying sustainable financing for an HPV vaccine programme. The price of the vaccine would be an important consideration for health budgets and a major factor in deciding introduction and roll-out.

However, many countries lack access to information on vaccine prices and may be uncertain about whether they would be able to negotiate fair prices with manufacturers. Some vaccine prices are published by individual countries and by large pooled procurement groups, such as the UNICEF Supply Division and the PAHO Revolving Fund. Information on HPV vaccine prices is available on the WHO Web platform, Vaccine Product, Price and Procurement (V3P).

**Delivery strategies for HPV vaccination**

Deciding the delivery strategy is an important issue that needs to be considered carefully by each country. The pros and cons, costs, and likely success of different strategies vary according to the country-specific context.

In general, the ideal strategies should be:

- compatible with the existing vaccine-delivery infrastructure and cold chain capacity;
- affordable, cost-effective and sustainable; and
- able to achieve the highest possible coverage.

In practice, countries may need to balance strategies that maximize coverage with those considered the most feasible, affordable and sustainable.

**Integration of HPV vaccination with other public health interventions**

The introduction of the HPV vaccine may provide an impetus to health officials and policymakers to improve and strengthen other health services at the national, regional and local levels. For example, addressing structural or systems barriers that may prevent young adolescent girls from receiving the HPV vaccine may facilitate adolescent access to other health interventions. Community health worker networks can be mobilized to assist adolescents in accessing various health services, and the introduction of the vaccine may also serve as an opportunity to improve adolescent health education. Health communication, which is a key component of the successful implementation of the HPV vaccine programme, can be used to deliver a variety of other health messages as well. The HPV vaccination programme would further strengthen the existing school health programmes or initiate such programmes. Delivering HPV vaccination with other interventions may promote the sharing of resources and knowledge across programmes, optimize costs and logistics, and serve to integrate a variety of services in a more efficient, effective and sustainable way. The intervention selected must be age-appropriate and effective, and must not negatively impact HPV vaccine delivery.
Key stakeholders to be involved in the process

The successful introduction of the HPV vaccine as part of a comprehensive cervical cancer control strategy would require collaboration with a variety of stakeholders within and across programmes and sectors at different levels of the government.

Close collaborations with cancer, adolescent health, women’s health, and/or sexual and reproductive health programmes can foster supportive partnerships for the introduction of the HPV vaccine. School-based strategies may provide an opportunity to collaborate with school health programmes, and more generally, with the Ministry of Education to disseminate public health messages in schools.

Advocacy with and engagement of medical and nursing associations, national leaders, parliamentarians and other stakeholders would be essential to ensure high coverage and spread awareness of the need to strengthen cervical cancer screening.

Planning for national introduction

Once a decision has been taken to introduce HPV vaccine, a detailed planning process would need to be undertaken. The target population, delivery strategy, vaccination schedule and logistics would need to be carefully considered. The plan should outline all activities and steps required for a successful introduction by programme component, identify government departments, institutions or external partners that would be responsible for each activity, fix a timeline and make a detailed budget. It is critical to allow enough time for planning and implementation of all the specified introduction activities.

Immunization programmes without prior experience of routinely delivering vaccinations to 9–14-year-old girls may benefit by planning a phased introduction of the HPV vaccine. This would enable one to identify and resolve challenges and barriers before a national scale-up. Delivering the HPV vaccine on a small scale (e.g. 1–2 districts or states/provinces with different characteristics, such as urban/rural, high/low coverage, different levels of school attendance) allows the national immunization programme to:

1. fine tune training and communication plans;
2. evaluate how acceptable the vaccine is to the community and health professionals;
3. determine the communication and social mobilization strategies necessary to establish and sustain high coverage;
4. learn how to best access the target age group;
5. identify the human and financial resources required; and
6. consider whether the proposed delivery strategies are sustainable.

Reference