



Strengthening cervical cancer prevention and control

Report of the GAVI–UNFPA–WHO meeting

1 December 2009, Geneva, Switzerland

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1. Introduction



Cervical cancer is a public health issue that kills at least 250 000 women every year: 80% of women who die come from low- and middle-income countries.

The huge disparity in morbidity and mortality from cervical cancer between high- and low-income populations is mainly due to poor access to, and poor quality of, cervical cancer-prevention and -control services.

The World Health Organization (WHO) and the United Nations Population Fund (UNFPA) are supporting many countries to strengthen their cervical cancer-prevention programmes. However, this strengthening of early detection of cervical cancer in low- and middle-income countries is limited by both weak health systems and lack of trained providers; therefore, universal access to screening is difficult to achieve. A new tool is now available that has the potential to improve the prevention of cervical cancer – the *Human papillomavirus* (HPV) vaccine.

In 2006, WHO and UNFPA developed a guidance note for countries on comprehensive introduction of HPV vaccines. In parallel, the European Commission, nongovernmental organizations (NGOs), and high-profile personalities have drawn attention to this new and highly effective technology that prevents infection by HPV, which is predominantly sexually transmitted and consequently may lead to the development of cervical cancer. In the autumn of 2008 the vaccine was recommended by WHO for global use in adolescent women. The Global Alliance for Vaccines and Immunization (GAVI) board also endorsed the vaccine as part of their newly adopted vaccine-investment strategy.

The opportunities and issues related to the expansion of access to the vaccine include: safety and efficacy, equity, demand, and introduction modalities.

The meeting of 1 December 2009 (see agenda and list of participants in Annex 1 and 2) was planned to update high-level decision-makers on comprehensive cervical cancer prevention and control, the current status of the vaccine, vaccine introduction, best practices and lessons learned to date, and agency plans for moving forward.

Two major outcomes have been reached:

1. *Policy commitment*: agreement from cooperating agencies and departments on the meeting report endorsing HPV vaccination as an important element of a comprehensive approach to prevention and control of cervical cancer, and a commitment to work to move this issue forward by elaborating a joint action plan;
2. *Funding strategy*: identification of the opportunities for traditional and innovative means of financing the introduction of HPV vaccine together with a comprehensive package of interventions for cervical cancer control and adolescent health; and ensuring that, at global level, cervical cancer prevention and control including HPV vaccines will be part of the discussion on innovative financing streams.

2. Overview and update

Cervical cancer is a major killer of women, especially in developing countries.

- The comprehensive approach to cancer control encompasses all the steps from primary prevention with vaccines and secondary prevention, i.e. screening for and management of precancerous lesions, to treatment and palliative care, within the context of continuum of care. HPV vaccines provide a great opportunity to decrease the incidence of cervical cancer within 20 years, but even with successful vaccination the need for screening will continue for women who have not yet been vaccinated as well as for those who have been vaccinated, as the vaccines cover only 80% of cancers. HPV vaccine introduction should be located within the context of a comprehensive approach to cancer control.
- There is a striking difference between developed and developing countries in cervical cancer prevalence and deaths, mainly due to the existence of effective cervical cancer-prevention and -control programmes in developed countries.

- The advancement in technology has made a comprehensive approach to cervical cancer control a cost-effective intervention that is suitable for wide-scale implementation in the developing world, which will increase access to and the quality of services. However, health-system strengthening will be a key element to ensure programme success.
- Due to the multifaceted nature of the interventions needed to prevent and control cervical cancer, effective partnership is required between health programmes such as immunization and vaccines, sexual and reproductive health, cancer control, child and adolescent health, health-systems strengthening, and ethics and trade.

3. HPV epidemiology and disease burden of cervical cancer

- Studies published by the International Agency for Research on Cancer (IARC) indicate vast regional variation across the world in relation to the incidence of cancer of cervix.
- There is a higher incidence of cancer of the cervix in developing countries than developed countries. Sub-Saharan Africa has the highest incidence, whereas India has the highest number of cases (20%).
- The frequency of screening and HPV infection are the strongest determinants of international differences in cervical cancer incidence. HPV prevalence varies 20-fold worldwide, but HPV infection also affects various age groups differently in different world areas. In high-income countries, for example, HPV is much more prevalent in women younger than 25 or 30 years than in older women. Conversely, in some low-income countries, middle-aged women have at least as many HPV infections as young women, mainly because of variations in the age-specific sexual behaviour of women and their partners.
- In addition, in every population, including those for which screening programmes do not exist, the risk of cervical cancer is approximately two-fold higher in poorer women than in more affluent women. Socioeconomic differences in cervical cancer risk seem to be explained not by differences in HPV prevalence but rather by factors that affect the natural history of HPV infection (e.g. early age at first sexual intercourse and childbearing, and high parity). Immune impairment due to HIV infection also leads to many-fold increases both in the burden of HPV infection and in the already existing lack of adequate screening for cervical cancer.
- Fortunately, however, there is increasing evidence that most important HPV types in cervical cancer and in severe precancerous lesions are very similar in all world regions, thus avoiding the need for region-specific HPV vaccines and HPV tests.

4. HPV vaccine

A WHO position paper published in April 2009 indicates that:

- HPV vaccine should be introduced where it is feasible and cost effective. The primary target group is girls from 9–10 years to 13 years of age (3 doses over 6 months);
- HPV vaccination cannot be a stand-alone intervention but must be part of a coordinated cervical cancer- and other HPV-related-diseases-prevention strategy;
- countries should use approaches that are compatible with their delivery infrastructure and cold chain capacity, and are affordable, cost-effective, and sustainable. Also, HPV vaccination can be an entry point to other adolescent health services, as well as to screening and treatment of precancerous lesions of the cervix in the women of reproductive age (immunize girls, screen their mothers). Twenty-two countries have included HPV vaccine in their national immunization schedule;
- there are a variety of options for delivery of HPV vaccination: school based, health-centre based, outreach in communities, and child health days. Each has been used with success in introductory studies. Choice should be context specific.

5. Economic considerations

- Currently there are only two manufactures of HVP vaccine (Merck and GlaxoSmithKline) and no newcomers are expected to enter the market in the near future.
- From the supply side, the world market of HPV vaccine seems stabilized with around US\$ 1.5 billion of sales (approximately 4.1 million young girls/women fully vaccinated) per year.
- Multinational companies have started to reduce prices for developing countries under various conditions and circumstances. However, prices remain very high. Further reductions are needed to make HPV vaccine accessible for low- and middle-income countries.
- From the demand side, the public sector in low- and middle-income countries could offer huge market opportunities for manufacturers.
- Several models of economic evaluation indicate that HPV vaccination in low- and middle-income countries where quality screening is not widespread may be cost effective if the cost per vaccinated girl (including three doses of vaccine and programme costs) is less than US\$ 10–25.
- The international community should explore a range of options and potential agreements on volumes and financing with manufacturers, for making the price of HPV vaccine affordable for low- and middle-income countries.
- Developing countries considering the introduction of HPV vaccine need to take into account costs beyond the vaccine, in order to support a comprehensive cervical cancer-prevention and -control programme. Even with vaccine, additional costs and resources are required to deliver the vaccine outside the traditional Expanded Programme on Immunization (EPI) target groups and child-immunization services.

6. GAVI approaches to HPV vaccines

- In 2008 GAVI endorsed a vaccine-investment strategy that included the introduction of HPV vaccines for routine use in girls. GAVI is working with manufactures to negotiate prices for GAVI-eligible countries. It is currently developing the application criteria for countries – which could be through either school-health or expanded-EPI programmes.
- The application criteria and guidelines for applications will be developed through the Accelerated Vaccine Introduction (AVI) platform and managed by the GAVI Secretariat, WHO, UNICEF Programme and Supply Divisions, and PATH. Key AVI activities include:
 - » strategic demand forecasts and vaccine supply;
 - » advocacy and communications;
 - » special studies.

7. Examples of countries

The Republic of Panama

- In Panama, HPV vaccine is introduced nationwide to girls aged 10 years (32 506 girls in 2009) and offered in multiple locations, including school and health facilities, through EPI.
- This programme has been taken as an opportunity to strengthen the integrated care programme for adolescents, school health programme, social security to the public and private elementary schools, and the reproductive and sexual health programme.
- Panama has paid for pneumo conjugate vaccine against *Streptococcus pneumonia* since 2008 and has introduced seven vaccines since 2005.
- Panama has invested US\$ 60 million in order to improve its health services.

- The main challenges for Panama are: (1) to sustain the budget for HPV vaccines; (2) to implement surveillance of HPV; and (3) to implement relevant research with regard to improving adolescent health.
- Panama is committed to investment in domestic resources in order to improve prevention of cervical cancer and to provide free maternity and child care.

The Republic of South Africa

- In South Africa, 85% of the population of 45 million uses public-sector health services. Private health insurance covers about 15% of the health sector. The country is faced with a weak health system and very serious TB and HIV epidemics.
- HPV vaccination is considered a priority and introduction of HPV vaccine in the private sector has put pressure on the public sector, but the feasibility remains a challenge.
- No cancer registries from South Africa are at present accepted in the IARC data base on cancer incidence in five continents. The cancer registry in South Africa was last updated in 1991.
- A cytology-based screening approach reached a number of women but not the majority. Implementation of screening is problematic. Using cytology does not seem to be appropriate given the condition of health systems in South Africa.
- South Africa is a middle-income country; therefore it is not GAVI eligible. The global funding crisis has affected the health-service provision, and there are competing priorities, for example for HIV prevention and treatment. The cost of these vaccines is the first point to be addressed before any decision on their introduction. Donation is not the solution; donation does raise concerns regarding volume and sustainability,
- Among the other points that should be considered are: (1) where to introduce the vaccine – in EPI service or schools? (2) which age group is the most appropriate? (3) should boys be included for political and equity reasons? (4) which other health interventions or education messages should be given to adolescents together with vaccine?
- A planning process to strengthen national cervical cancer prevention in South Africa is starting, focusing on:
 - » organization of the planning team with the establishment of three working groups: (1) HPV vaccine; (2) screening; and (3) treatment and care;
 - » research: (1) acceptability and feasibility of introducing HPV vaccine in four provinces; (2) messaging and packaging of services; (3) HIV/HPV interface; and (4) modelling and cost effectiveness.

The Socialist Republic of Viet Nam

- Research on HPV vaccine introduction was carried out from 2008 to 2010. It was implemented in four districts at community-based health facilities and in schools. The target population was young girls in the 6th grade at 11 years of age. The type of vaccine used was Gardasil®.
- No decision has been taken on its nationwide introduction. The decision will depend on the price, the question of sustainability, and a GAVI decision on support to countries.

PATH country introduction approaches and findings

- PATH is collaborating with many partners, including ministries of health and other government agencies, industry, and communities, to explore the most acceptable strategies for vaccinating young adolescent girls against HPV in India, Peru, Uganda, and Viet Nam.

Formative research

- Formative research was conducted to better understand the medical, policy, fiscal, and sociocultural environments and to guide the design of the vaccination and communication strategies.

- Overall, the research demonstrated low levels of knowledge and awareness regarding cervical cancer, HPV, and the HPV vaccine in all four countries. When given more information, however, most people responded positively about the HPV vaccine. Furthermore, immunization was seen as valuable and effective, and parents, extended families, and community leaders are the main influencers of the vaccination decision. Finally, the HPV link to sexual relations was not viewed as a major barrier.
- Formative research participants in all four countries supported school-based delivery of the HPV vaccine, with additional efforts to reach girls who do not attend school. In Uganda and Viet Nam, other vaccine-delivery strategies were implemented: in Uganda, utilizing Child Days Plus, which delivers an integrated package of preventive services to older children through schools, health centres, churches, and community centres; and in Viet Nam, through commune health centres.

Demonstration projects (operational research)

- Results from the formative research were used to design effective vaccine-delivery strategies, appropriate communication approaches, and targeted advocacy efforts.
- The delivery strategies were evaluated through assessing vaccine coverage and programme feasibility, acceptability, and delivery cost. Vaccine coverage in the school-based strategies exceeded 80%. Acceptability was high.
- The cost of delivering the vaccine varied by country, with the lowest estimates reported in the Child Days Plus strategy in Uganda, and the highest in Viet Nam regardless of strategy. In Peru, we learned that asking participants to sign lengthy and complex consent forms increased parental concerns and was a barrier to vaccine acceptance. In Uganda, in the Child Days Plus strategy, girls aged ten years were eligible for vaccination. This criterion was challenging, as girls and parents did not know the exact age of the girls and therefore there was no systematic way of determining those who were eligible. During the vaccine-coverage survey, it was also difficult to determine eligibility for inclusion into the survey.

8. Additional health interventions when delivering HPV vaccines to adolescents: the HPV Plus Package – characteristics of the components of the package

- HPV vaccines are indicated for young adolescent girls before sexual activity begins and they are exposed to the virus. However, adolescent health services, including sexual and reproductive health services, are minimal in many developing countries. In addition, there are a limited number of programmes with experience of delivering vaccines to this age group, as traditional vaccines have been targeted to infants and young children.
- HPV vaccination delivery could serve as an entry point for improved adolescent health services. WHO has conducted a literature review to identify which evidence-based health interventions could be delivered to adolescents together with the HPV vaccine. Based on this review, a menu of interventions has been developed, called the “HPV plus package” (Table 1).
- The HPV plus package is not “one size fits all”. It depends on the target group for the vaccine, taking into account the significant differences between 9 year olds and 13 year olds. It also depends on the epidemiology of common diseases in the country, and national priorities and capacity. Therefore, the HPV plus package needs to be tailored to a country-specific epidemiological, cultural, and school context. However, evidence is lacking about cost and feasibility.
- WHO and UNFPA are supporting operational research in a few countries to evaluate how this package could be introduced in the context of HPV vaccination and to explore the issues of cost and feasibility. It does require strengthening school health services and the links between schools and health facilities.

Table 1. Summary table of the “HPV plus package”

Intervention category	Definition	Menu of complementary interventions
Screening	Testing or screening for diseases	Vision screening Schistosomiasis screening Anaemia screening
Information	Providing information through a range of channels	HPV and cervical cancer Reproductive and sexual health Nutrition Tobacco and alcohol
Commodities	Supplementation, direct provision of commodities or increasing access to commodities	Anti-helminthic (soil transmitted) Anti-helminthic (schistosomiasis) Vitamin A/iron Bednets for malaria prevention
Vaccines	Vaccines that are currently recommended for this age group	Tetanus/diphtheria booster Hepatitis B Meningococcus Typhoid Rubella

9. Discussion



The following points were raised by the participants:

- **Strategy and interventions:** should be context specific in each country. A phased approach in national programming, i.e. to scale-up with a defined period of time, may be a better approach than a nationwide programme, especially if international resources are limited. There is a requirement to make an appropriate plan of action that will consider the cost and complexity of delivering this particular vaccine to adolescents. Any strategy that should be developed should include a menu of options of health education and services that could be delivered together with HPV vaccination. It is also important not to set unrealistic objectives and to think about a minimal package.
- **Delivery:** school attendance is limited in many places; therefore approaches that are only school based have limited usefulness, and a combined delivery strategy should be considered to ensure an acceptable coverage. It is acknowledged that there is not one single method but a variety and a combination of possible approaches to delivering HPV vaccines to adolescents. Understanding adolescent-health and service-delivery issues in countries where HPV vaccines will be introduced is of vital importance. Delivery needs to be built on what already exists. If a package on health education and services is delivered together with the vaccines, this package should be for both boys and girls.
- **A cervical cancer-prevention and -control programme:** should be strengthened when considering vaccine introduction, first in its own right, and second as delivery of HPV vaccines may increase the demand for screening as a result of population-based information for mothers of the target population for HPV vaccines.
- **With regard to messaging:** there was no strong position on whether HPV vaccine should be introduced as a vaccine for cancer or for sexually transmitted infection (STI). Probably both should be addressed, depending on how the campaign is conducted, the target population for the campaign, the context of information, and also the cultural environment of the country where it is being introduced. This aspect has to be very well discussed within countries introducing the vaccines

- **About donation:** there were many concerns; donation programmes carry the risk of not being sustainable and are influential for decision on future introduction of the donated product in countries, which does not guarantee a continuation with GAVI support. A number of countries that have received donations are unclear about the United Nations (UN) agencies position with regard to donation. Partners find it useful to have a common approach to donations, although this approach is still not clearly defined. These countries also require technical and policy support.
- **Place of cervical cancer in global health agenda:** cervical cancer is part of the comprehensive Millennium Development Goal 5 (MDG5), a reproductive health component, and hence included in the universal access target. However, given the resource requirements and existing priorities, only a substantial price reduction of the HPV vaccine will determine the inclusion of this component in the comprehensive package of prevention and control of cervical cancer. Strategy should be developed to also include cervical cancer in the Noncommunicable Diseases agenda.

In summary, HPV vaccines could be combined with: (1) the involvement of older women in screening programmes aimed towards women's health, and hopefully with the possibility of attracting funds earmarked for women's health; and (2) selected aspects of an adolescent package.

10. Elements of a joint plan of action

Positioning HPV in policy debate

The plan is to develop a joint briefing note to be endorsed by H8 at their forthcoming January 2010 meeting (H8 comprises: WHO-UNFPA-GAVI, United Nations Children's Fund (UNICEF), Bill & Melinda Gates Foundation, The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), Joint United Nations Programme on HIV/AIDS (UNAIDS), and the World Bank). The brief would acknowledge:

- cervical cancer as a public health issue that deserves attention and investment, in the light of other pressing priorities;
- the importance of agreement on price reduction strategies for the HPV vaccine;
- the use of HPV vaccines as one component of a comprehensive package of prevention and control of cervical cancer;
- the need for a comprehensive approach to adolescent health and cancer prevention;
- a focus that serves middle-income countries as well as GAVI-eligible countries;
- the consideration that needs to be given to HIV-positive individuals;
- a clear set of actions that would identify distribution of labour among partners.

Modelling at regional level to forecast country demand

This would require scenarios building with cost estimates and investment cases by region, to assess the financial affordability. It would also be important to review evidence from cost-effectiveness analysis, taking into consideration the burden of disease. These regional investment cases should focus on cervical cancer prevention and control rather than just on HPV vaccine, and should be led by WHO and WHO/IARC plus partners in GAVI and PATH.

Programme support

This entails:

- updating the technical guidelines programme development: the decision-making and introduction/ scale-up (May 2010- WHO, UNFPA, UNICEF); the WHO *Comprehensive Cervical Cancer Control: a guide to essential practice*; monitoring and evaluation "green book" (WHO/UNICEF); and case studies (WHO);

- from the clinical recommendations perspective, new knowledge on screening tools (HPV testing), which requires new recommendations and guidelines (WHO, IARC);
- knowledge sharing could also be enhanced by building on the existing community of practice groups and establishment of a hub in a programme country (WHO-UNFPA by October 2010);
- technical assistance – timely and relevant support is to be extended to interested countries/network of experts (roster/database) by May 2010. Programme planning includes Dashboard for interested countries, steps towards introduction and scale-up, monitoring, and evaluation guidance – January to August 2010 (collectively).

Procurement and supply

Forecasting will continue to be done by GAVI at global and country level, respectively. Similarly, negotiations with suppliers will continue (GAVI). In parallel, procurement-capacity development and supply-chain management will be enhanced at country level (WHO, UNICEF, UNFPA), preferably as an integrated vaccine/reproductive health commodity and supply system.

Financing

- This is the most challenging area. Leveraging resources can be done through increased efficiency, for example through integration of HPV vaccine into the Health System Strengthening (HSS) window in Joint Assessment of National Strategies (JANS), and International Health Partnership (IHP+).
- New funding can be raised by engaging new partners, e.g. foundations (Coalition for Adolescent Girls, Nike, etc.), innovative financing schemes: HSS funding platform, Millennium Foundation, International Financing Facility for Immunisation solidarity funds, individual donations, and other private/public partnerships
- It is essential to secure domestic resources including the private sector by engaging insurance companies and community groups.

Advocacy and communication

This is a key area for a successful scaling-up, policy support, and community acceptance.

11. Conclusion and deliverables

- Action plan (to be completed on 2 December 2010) and H8 paper (mid-December)
- Need to make civil society groups aware of the outcome of this meeting (circulate a summary of the report to the NGO network, UN agencies, partners)
- Need to make donor community aware of this development, including links with HIV
- Need to communicate to agency staff the partners' commitment to the issue
- UNFPA suggests working on acceptability studies/cultural issues and experience from adolescent and sexual/reproductive health.



Annex 1. Agenda

08:30-09:00	<p>Opening and Welcome</p> <p>Chair</p> <ul style="list-style-type: none"> - Introduction of participants - Objectives - outcomes of the meeting 	<p>Ala Alwan (WHO)/Purnima Mane (UNFPA)</p> <p>Helen Evans (GAVI)</p> <p>Purnima Mane (UNFPA)</p>
09:00-10:45	<p>Session I: Overview and Update</p> <p>Cervical cancer prevention and control: a comprehensive approach to improve the health of women</p> <p>HPV epidemiology and disease burden of cervical cancer</p> <p>WHO recommendations on HPV vaccine</p> <p>Analysis of supply, demand and price of HPV vaccines</p> <p>GAVI approaches to HPV vaccines</p> <p>Discussion</p>	<p>Daisy Mafubelu (WHO)</p> <p>Silvia Franceschi (IARC)</p> <p>JM Okwo-Belé (WHO)</p> <p>Claudio Politi (WHO)</p> <p>Nina Schwalbe (GAVI)</p>
11:00-12:30	<p>Session II: Regional and Country Perspectives</p> <p>Chair</p> <ul style="list-style-type: none"> - Panama - South Africa <p>Discussion</p>	<p>Ala Alwan (WHO)</p> <p>Yadira Aguilar (MoH)</p> <p>Helen Rees (SA)</p>
13:30-15:00	<p>Session II (cont.): Regional and Country Perspectives</p> <ul style="list-style-type: none"> - Country introduction, approaches and findings - Vietnam <p>Discussion on common issues: opportunities for programmes, challenges and questions to be answered</p>	<p>Aisha Jumaan (PATH)</p> <p>Nguyen Xuan Tung (MoH)</p>
15:00-17:00	<p>Session III: Towards a joint plan of action</p> <p>Chair</p> <ul style="list-style-type: none"> - Elements of a joint plan of action <p>Discussion on:</p> <ul style="list-style-type: none"> - Policy and programme support - Donation and Financing - Roles and responsibilities 	<p>Helen Evans (GAVI)</p> <p>Hedia Belhadj (UNFPA)</p> <p>GAVI - WHO - UNFPA</p>
17:00-18:00	<p>Next steps</p>	<p>Daisy Mafubelu (WHO)</p> <p>Purnima Mane (UNFPA)</p> <p>Helen Evans (GAVI)</p>

Annex 2. List of participants

World Health Organization (WHO)

Dr Fiona Jane Adshead
Director, Chronic Diseases and Health Promotion

Dr Ala Alwan
Assistant Director-General,
Noncommunicable Diseases and Mental Health

Dr Anarfi Asamoah-Baah
Deputy Director-General, Office of the Director-General

Dr Nathalie Broutet
Medical Officer, RHR/STI

Dr Vicky Camacho
Medical Officer, CAH/ADH

Dr Venkatramann Chandra-Mouli
Medical Officer, WHO/FCH/CAH

Dr Bruce Dick
Medical Officer, WHO/FCH/CAH

Dr Catherine d'Arcangues
Coordinator, WHO/FCH/RHR

Ms Tracey Goodman
Technical Officer, IVB/EPI

Ms Daisy Mafubelu
Assistant Director-General, Family and Community Health

Dr Elizabeth Mason
Director, Child and Adolescent Health and Development

Dr Michael Mbizvo
Director a.i., Reproductive Health and Research

Dr Jean-Marie Okwo-Bele
Director, Immunization, Vaccines and Biologicals

Mr Claudio Politi
Health Economist, IVB/EPI

Dr Andreas Ullrich
Medical Officer, CHP/CPM

WHO Regional Office for the Americas (AMRO)

Dr Gina Tambini (unable to attend)
Area Manager, Family and Community Health

International Agency of Research on Cancer (IARC)

Dr Silvia Franceschi
Head, Section of Infections and Cancer Epidemiology

Dr Lawrence Von Karsa
Quality Assurance Group (QAS)
Section of Early Detection and Prevention

International Atomic Energy Agency (IAEA)

Dr Rolando Camacho-Rodriguez
Cancer Control Coordinator
PACT Programme Office (PPO)

United Nations Population Fund (UNFPA)

Dr Hedia Belhadj
Executive Coordinator
Global Health Office of Executive Director

Dr Vincent Fauveau
UNFPA, Geneva

Ms Purnima Mane
Deputy Chief Executive Officer
Programme Office of Executive Director

Dr Nuriye Ortayli
Senior Advisor, Reproductive Health Technical Division

GAVI Alliance

Dr Mercy Ahun
Managing Director, Programme Delivery

Ms Helen Evans
Deputy Chief Executive Officer

Ms Nina Schwalbe
Managing Director, Policy and Performance

Dr Jon Peaman
Head, Accelerated Vaccine Introduction

UNICEF

Ms Ann Ottosen (Unable to attend)
UNICEF Supply Division
Copenhagen Office

UNAIDS

Dr Kayitesi Kayitenkore
Technical Officer, PRG/EPR

University of the Witwatersrand Johannesburg, South Africa

Professor Helen Rees
Executive Director, Reproductive Health and HIV Research Unit

Temporary Advisers

Dr Yadira Carrera Aguilar
National Coordinator, Ministry of Health
Panama

Dr Washington Lum Chong
Department of Epidemiology, Ministry of Health
Panama

Dr Nguyen Van Cuong
Expert
National Institute of Hygiene and Epidemiology
Viet Nam

Dr Nguyen Xuan Tung
Expert
Preventive Medicine Division
Ministry of Health
Viet Nam

Resource Persons

Dr Aisha Jumaan
Director, HPV Vaccine Project
PATH