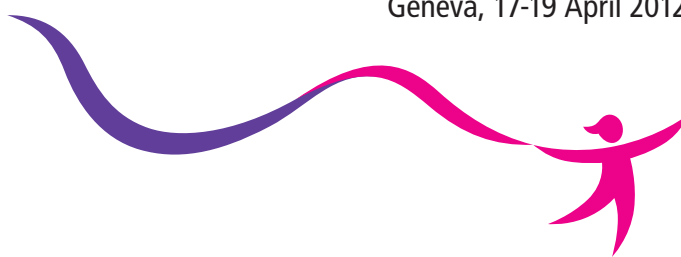




Report of the HPV Vaccine Delivery Meeting

Identifying Needs for Implementation & Research

Geneva, 17-19 April 2012



**World Health
Organization**

Department of Immunization, Vaccines and Biologicals
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1 | Introduction & Background of the meeting

Cervical cancer is the 2nd most common cancer affecting women by age-standardized rate (ASR) for incidence and more than 85% of the global disease burden is in developing countries. The availability of HPV vaccines as a new approach to successfully fight cervical cancer has generated substantial excitement and enthusiasm for introducing the vaccine.

As of the end of 2011, 40 countries had introduced HPV vaccine in their national immunization schedule. Global experience with HPV vaccine delivery to its target population of 9 – 13 year old girls remains limited, particularly in resource-poor settings. Furthermore, there are many stakeholders and partners for HPV vaccine introduction and cervical cancer prevention who are new to immunization and are not the traditional child health partners of immunization programmes, but who bring experience from the fields of reproductive health, adolescent health, school health, cancer control, HIV prevention, and women's health.

In this complex context, there is a need to optimally coordinate the energy, advocacy, and resources of the many stakeholders and partners so that critical vaccine delivery issues are addressed and so that countries can best benefit from the new opportunity that HPV vaccine can offer. This report summarizes key points from presentations and plenary discussions at the meeting. Priorities for action are outlined in section 9.

Objectives

1. To share an update on HPV vaccine introduction issues and the activities of key partners and stakeholders.
2. To determine outstanding questions that need to be addressed for optimal HPV vaccine delivery in countries.

Outcomes

1. A shared vision among public-private partners on short-, medium-, and long-term priorities for HPV activities.
2. A set of prioritized operational research issues that would facilitate HPV vaccine delivery.
3. A mapping of partner efforts and resources to support HPV vaccine introduction.

Participants at the meeting

The meeting brought together immunization, adolescent health, cancer, and education programme specialists from a range of agencies, non-governmental organizations (NGOs), and academic institutions including: UNICEF, UNESCO, UNAIDS, UNFPA, the World Bank, U. S. CDC, the Health Protection Agency, GAVI, Bill & Melinda Gates Foundation, USAID, PATH, Save the Children, Pink Ribbon Red Ribbon Initiative, Union for International Cancer Control, Pathfinder International, Barcelona Centre for International Health Research, Johns Hopkins School of Public Health, and the London School of Hygiene and Tropical Medicine, as well as from four departments within WHO Geneva and from 5 of the 6 WHO regional offices.

2 | The “State of the Science” of HPV vaccines

- Currently there are 2 prophylactic HPV vaccines with high efficacy (>90%) against a variety of vaccine-type-related outcomes: a bivalent vaccine (Cervarix) and a quadrivalent vaccine (Gardasil/Silgard).
- Both vaccines have high efficacy against cervical precancers (CIN2+) due to HPV types 16 and 18. The quadrivalent vaccine also has high efficacy against genital warts due to HPV types 6 and 11 and against anal precancers (AIN2+).
- Approximately 70% of cervical cancers in all regions of the world are due to HPV types 16 and 18; this means that 30% of cervical cancers are from HPV types not included in the 2 currently available vaccines. Cross-protection against infections caused by HPV types not currently in the vaccines and the duration of cross-protection are under study.
- There is no evidence of waning protection over time for either vaccine. Currently, there is information for a post-vaccination follow-up period of 8-9 years.
- Pre- and post-licensure safety data are very reassuring and show an excellent safety profile. HPV vaccines can be co-administered with other vaccines.
- Small studies in HIV-infected persons show that HPV vaccine is safe and immunogenic. However, antibody titers are lower and long-term immunogenicity and duration of protection are unknown. Studies are on-going. There are no contraindications to vaccinating HIV-infected persons with HPV vaccine.
- Use of quadrivalent HPV vaccine for males is recommended in 3 countries (U.S., Australia, and Canada) but publicly funded only in one (U.S.). Decision to recommend the vaccine for males depends on epidemiology of HPV disease in a country, cost-effectiveness, and affordability. For most low and middle income countries, the burden of cervical cancer far exceeds the burden of HPV-associated cancers in males.
- Two-dose vaccination schedules or schedules with longer intervals between doses may be more convenient for vaccinees, providers, and parents and could facilitate implementation and reduce costs. Data from initial, small studies appear promising but are not powered to provide adequate certainty and do not yet answer whether 2-dose schedules will provide adequate long-term protection or whether 2 doses will be sufficient for special populations, such as those who are immunocompromised.
- Substantial vaccine research is ongoing; post-licensure monitoring data and effectiveness data are becoming available. Second generation vaccines are being developed. WHO monitors the availability of new data to determine when global recommendations for vaccine use should be updated.

3 | The “State of the Art” of HPV vaccine delivery: A Work in Progress

- WHO recommends a Comprehensive Approach to Cervical Cancer Prevention and Control with attention to primary prevention (education, HPV vaccination), secondary prevention (screening for early detection and early treatment of precancerous lesions and of early cancer), and tertiary prevention (cancer treatment and palliative care).
- The WHO position paper on HPV vaccine¹ recommends that HPV vaccine be introduced into national immunization programmes where cervical cancer prevention is a public health priority, vaccine introduction is feasible and financially sustainable, and cost-effectiveness has been considered. In addition WHO recommends:
 - Prioritizing high coverage in the primary target population of girls who are 9 to 13 years old.
 - Prioritizing strategies to include populations who are likely to have less access to cervical cancer screening later in life.
 - That HPV vaccine introduction should not divert resources from effective cervical cancer screening programmes.
 - That HPV vaccine should be introduced as part of a coordinated strategy to prevent cervical cancer and other HPV-related diseases.
 - That opportunities to link vaccine delivery to other health programmes targeting young people should be sought.
- HPV vaccine introduction comes with challenges common to any new vaccine introduction: it is necessary to justify that the vaccine addresses a public health priority, to assess costs of the vaccine and of delivery, to consider timeline and coordination with other immunization programme priorities, to create a new vaccine introduction plan and incorporate it into the country's comprehensive multi-year plan (cMYP) for the national immunization programme, and to view the vaccine as part of an integrated disease control approach.
- Challenges that are unique to HPV vaccine introduction are that it needs to be delivered 3 times within 6 months to a new target population, 9-13 year old girls, who have not previously been routinely served by immunization programmes in most countries. In developing countries where this population may be receiving some services related to nutrition, de-worming, vision screening, or malaria prevention or other services, these services are different from delivering HPV vaccine since they typically do not require health workers, injections, or cold chains. Optimal vaccine delivery strategies to routinely reach girls with 3 doses in ways which are acceptable, affordable, and sustainable and which achieve high coverage are still being determined. In any given country, it is likely that combining several different vaccine delivery strategies (e.g. facility-based, school programmes, campaigns) will have to be considered.
- Opportunities with HPV vaccine include the possibility of establishing primary care for 9-13 year old children and harnessing the added energy and advocacy of new stakeholders and partners (in addition to immunization, also partners in adolescent health, school health, reproductive health, HIV prevention, cancer, and women's health) to make HPV vaccine delivery successful.
- Countries that are considering HPV vaccine donations may wish to review the 2010 WHO-UNICEF Joint Statement on Vaccine Donations to consider the recommended requirements that should be satisfied before accepting the donation.

¹ See <http://www.who.int/immunization/documents/positionpapers/en/>

Lessons learned from HPV vaccine introductions

- Global experience with successful and sustained HPV vaccine delivery to 9-13 year olds remains limited. Every country has an array of problems to solve when implementing HPV vaccine; HPV vaccine delivery is unlike anything most immunization programmes have previously done.
- Size of target population and location of target population are often revisited after the 1st and even the 2nd year of HPV vaccination. Delivery strategies are also revised after initial introduction to be able to sustain routine vaccine delivery.
- Costs for both vaccine and for vaccine delivery are significant, and may not be affordable for many developing and low income countries.
- Demonstrating successful delivery of HPV vaccine through demonstration projects using donated vaccine does not assure that HPV vaccine delivery will be sustainable or feasible on a national scale.
- Where schools are used for vaccine delivery, it is necessary to have good coordination at high levels between Ministry of Education and Ministry of Health, engagement and education of local school staff, and both high enrollment and high attendance of girls (in order to have good coverage and achieve affordability). In countries with existing infrastructure (e.g., school health coordinators or school immunization teams), these are useful for HPV vaccine delivery. But in the absence of existing infrastructure or ongoing funding support, using schools for delivery is not always sustainable due to the logistics and costs. Finally, to vaccinate girls who are least likely to access cervical cancer screening later in life, a country cannot rely solely on school-based vaccine delivery.

WHO HPV Vaccine Resources

These and more resources may be found at <http://www.who.int/nuvi/hpv/resources/en/index.html>

- **Burden of cervical cancer disease** by country may be found on the HPV Information Centre website (<http://www.who.int/hpvcentre/>)
- For **putting together a national strategy for cervical cancer prevention**, one can use the WHO WPRO November 2009 Meeting Report, Annex 4 and Annex 5, on http://www.wpro.who.int/entity/noncommunicable_diseases/documents/cervical_cancer_meeting/en
- **To estimate costs of HPV vaccine introduction**, one can use the WHO Cervical Cancer Prevention and Control Costing Tool on http://www.who.int/nuvi/hpv/cervical_cancer_costing_tool/en/index.html
- To examine cost-effectiveness, one can review the 2011 BMC Medicine article on use of **cost-effectiveness models for HPV vaccine introduction** in low- and middle-income countries.
- **To assess the readiness of a country's school and health systems to deliver school-based immunization services**, a country may use the School Vaccination Programme Readiness Assessment Tool.
- One can review requirements that should be satisfied before accepting a vaccine donation by reading the **2010 WHO-UNICEF Joint Statement on Vaccine Donations**.

- Investments in effective IEC (Information, Education, and Communication) are critical for HPV vaccine.
- Effective follow-up systems are needed in order to reach missed girls and to reach girls again in order to deliver 2nd and 3rd doses.

Monitoring and evaluation of HPV vaccine delivery

- HPV vaccine coverage monitoring by dose and by year of age is necessary for programme assessment and for vaccine impact monitoring and to allow comparison of vaccine coverage trends over time and across geographical areas.
- A critical issue for HPV vaccine coverage is that the denominator should be the total number of girls in a given geographic area by year of age. A denominator of total girls enrolled in school describes coverage for a school vaccine delivery strategy but does not describe coverage for the eligible target population.
- WHO has developed HPV Vaccine Coverage Monitoring Guidance with tally sheets for country use, as well as guidance on conducting an immunization coverage cluster survey for HPV vaccine.
- Through the annual WHO-UNICEF Joint Reporting Form that is used to collect vaccine coverage data, countries should report data on numbers of HPV vaccine doses administered.
- WHO recommends that countries conduct Post-Introduction Evaluations (PIEs) approximately 6-12 months after introducing any new vaccine in order to assess delivery of the new vaccine. A PIE is an on-site assessment of all aspects of vaccine delivery (training, supervision, communication, cold chain, access to target population, acceptability by population, etc.) with the goals of identifying programmatic gaps and of making improvements to the vaccination programme. Countries can request support for conducting a PIE through their WHO Country and Regional Offices.

4 | The “State Of The Art” of adolescent health services

- Adolescents are young people between the ages of 10-19 years. This period between childhood and adulthood is generally considered to be a healthy time of life, but also one when exposure to certain risk factors – in particular, the adoption of health risk behaviors – can result in poor health during and beyond the adolescent period.
- The WHO/UNFPA/UNICEF framework for Programming for Adolescent Health² proposes that adolescents should be provided the support and opportunities to acquire accurate information; build skills; obtain counseling (especially during crises); have access to health services, including those for sexual and reproductive health; and live in a safe and supportive environment.
- Recognition that adolescents face barriers to access health services has led to efforts to reduce those barriers and to improve quality of health services to adolescents, in order to create adolescent or youth friendly health services (AFHS or YFHS). Evidence-based research and experiences from a variety of countries have demonstrated that AFHS is associated with increased service utilization. However, improvements in adolescent health outcomes as a result of AFHS have yet to be determined.
- AFHS initiatives have tended to focus on delivering a package of evidence-based sexual and reproductive health related interventions. These initiatives have particularly reached, or in some cases specifically targeted, the older adolescent population, between 15-19 years of age. There is less experience in reaching the younger age group that comprises the HPV vaccine target population of 9-13 years.
- For younger adolescents (including 9-13 year olds), parents play an important role. Thus, parents need to be fully engaged in decision-making regarding their children’s use of health services. This may include taking them to health facilities. In addition, in most countries, parents need to provide consent or approve that their young adolescent may receive health services.
- Throughout the world there are examples of successful adolescent health programmes and projects. Many of these, however, are not implemented at national scale, and many have been time limited.

² WHO/UNFPA/UNICEF.1997. *Action for adolescent health: Towards a common agenda.*
http://www.who.int/maternal_child_adolescent/documents/frh_adh_97_9/en/

5 | The intersection of health and education sectors

- The FRESH initiative (Focusing Resources on Effective School Health) was launched at the World Education Forum in Dakar in April 2000 by UNESCO, UNICEF, the World Food Programme, WHO, the World Bank and others. The FRESH initiative (see box) suggests that the school health programme will be:
 - most equitable and cost-effective if all of these components are made available, together in all schools;
 - most effective if delivered through strategic partnerships between health and education sectors (especially teachers and health workers); schools and the community; children and other key stakeholders.

The FRESH initiative has four core components that provide the framework for implementing an effective school health and nutrition programme:

1. **Policy**: health- and nutrition-related school policies that are nondiscriminatory, protective, inclusive, and gender-sensitive;
2. **School environment**: safe and psychologically supportive; with access to safe water and separate sanitation facilities for girls, boys, and teachers;
3. **Education**: skills-based education, that addresses health, nutrition, HIV prevention, and hygiene issues and promotes positive behaviours;
4. **Services**: simple, safe, and familiar health and nutrition services that can be delivered cost-effectively in schools and increased access to youth-friendly clinics.

- The education sector has a goal of achieving good educational outcomes. Thus, the importance of school health to the education sector is to create the good health which will permit those good educational outcomes. Today, health programming is routinely considered by education development partners and they have increased their funding for school health programmes. Successful school health interventions may themselves change school populations by attracting more students, improving attendance, and reducing drop outs. Information on schools and health may be found at <http://www.schoolsandhealth.org>.
- Typically, school health services have most often consisted of nutritional interventions. Providing meals (breakfast/lunch), nutritional supplementation, distribution of food rations, and deworming have been the main health interventions in school. These have generally been delivered by the education sector staff (teachers) rather than health workers from the Ministry of Health.
- Age of compulsory school attendance varies greatly between countries. Generally compulsory education begins at ages 5-7 years; it may end as early as 9-12 years in some countries and as late as 17-18 years in other countries.

- Primary gross enrollment rates for girls are less than 70% in some countries.
- Patterns of school attendance of girls can differ by age – in some countries (e.g., post-conflict situations) attendance of girls may increase with age. In other countries, older girls tend to drop out of school, often due to pregnancy. Poorer rural girls are less likely to be in school or they drop out as they get older.
- In many countries, a large proportion of adolescents are enrolled in primary school, rather than in secondary school as might be expected based on their age. Particularly in African countries, the majority of adolescents attend primary school. The implication for vaccination programmes targeting a specific age range is that careful analysis of age structure within grades is required to develop a vaccination delivery strategy that appropriately targets a selected age group.
- The Global Partnership for Education (see www.globalpartnership.org) functions as a funding equivalent to The Global Fund for HIV/AIDs, TB and Malaria.
- Approximately 50% of countries deliver some vaccines (e.g., tetanus, measles-containing vaccine, polio, rubella) in schools. Typically, the vaccines require delivering a single dose and are delivered via campaigns.
- A 5-country study to evaluate successful school vaccination found that the following were enabling factors: high enrolment, a strong primary healthcare system, central government support, good collaboration between ministries of health and education, cooperation of school and health staff, existence of standard operating and training procedures, and community trust in the public health and education systems. Challenges with delivering vaccines in schools included: difficulties recording and reporting vaccine coverage data, vaccinating children who were not in schools or who were enrolled in private schools, obtaining parental consent, increased work load for health workers, disruption to other services provided by health workers, costs for per diems and travel.
- WHO has developed the WHO School Vaccination Programme Readiness Assessment Tool for countries to systematically review necessary elements for a school vaccination programme and from that assessment, to develop a plan to address gaps if putting a school vaccination programme in place is desired.
- WHO also supports Global School Health Policies and Practices Surveillance.

6 | Conclusions from Working Group #1 – Social mobilization and communication for HPV vaccine delivery

The success of HPV vaccine delivery will depend on communication and social mobilization to a much greater extent than for introduction of new infant vaccines where mothers are already bringing their infants for a routine schedule of infant vaccines. Because of the unique target group for HPV vaccine (girls 9-13 years) it will be necessary to design messages and strategies for both parents/caregivers and the girls themselves. The use of social media (Facebook, Tumblr, SMS, etc.) can be important for accessing young adolescents who have access to this technology, as will be “girl-to-girl” or “peer-to-peer” approaches. Anticipated communication challenges will be to strike the right balance between HPV being a cause of cancer but also a sexually transmitted infection, getting girls to return for 2nd and 3rd doses; and the continuing need for screening as the current vaccines do not protect against all HPV types. The group felt that there was good potential for integrated messages about cervical cancer screening: For example “mother & daughter messages”; when a mother brings her daughter for HPV vaccination the mother is informed about the need for cervical cancer screening. Existing communication/social mobilization methods apply to HPV vaccine introduction: develop a communication strategy prior to vaccine introduction, conduct formative research, test messages, plan proactively with the media/journalists, target decision-makers and people of influence at all levels, prepare for adverse events and misinformation or rumors, use a diversity of channels, and identify and train a MOH spokesperson. A number of partners have developed HPV vaccine communication and social mobilization materials and a request was made to have these collected together and made easily accessible in one location.

Additional notes from this working group are in Annex 3.

7 | Conclusions from Working Group #2 – Delivery of HPV vaccine primarily through schools

The working group identified various considerations and challenges related to using a school based HPV vaccine delivery strategy. To optimally make use of a school as a venue for vaccination, it is important to know levels of school attendance, drop out and absenteeism; the age distribution in grades to identify an ideal target grade; and the school year schedule so that one can properly time vaccine delivery so that it is delivered to the highest number of children without being disruptive to the school schedule. The need for school health- and health service policies, experiences and linkages between the school and health ministries were noted. Prior experience with vaccine delivery in school would be a strong asset. Financial considerations include the cost of outreach, the costs of training education sector staff about the health issue, and the potential efficiencies that could be realized if linkages with delivery of other interventions for adolescents can be made. The importance of social mobilization of both health and education staff was underscored. Campaign-like or pulsed vaccine delivery in schools was thought to simplify issues related to cold chain and storage management. It was recognized that careful planning and management would be needed to address the approach for obtaining parental authorization and to address any parent – adolescent disagreement on whether the girl should receive the HPV vaccine. At the same time, it was felt that the authorization process provides an opportunity for communication with parents. The group noted that there needs to be a good understanding of which girls are missed in a school strategy and specific efforts made to identify what strategies can be used to reach these girls.

Additional notes from this working group are in Annex 4.

8 | Conclusions from Working Group #3 – Delivery of HPV vaccine primarily through health centres and other non-school strategies

From the experiences of countries where HPV vaccine has been introduced and where schools were not used as delivery venues, it was acknowledged health facilities were a key venue and that 9-13 year old girls do not frequent health services. The group discussed building upon the possible motives for visiting health services; the motives included girls accompanying their mothers to clinics for other reasons and girls wishing to access water, nutritional supplements or other valued commodities, such as menstrual hygiene products. Given the equity concern to vaccinate girls who are least likely to access cervical cancer screening later in life, the group realized that countries could have several different vulnerable girl populations. They discussed the types of girls who were least likely to be attending schools or accessing health services; noted that it would be necessary to enumerate them – the size of the population; where they live and with whom (parents/guardians); conditions that underlie their vulnerability (e.g., the nature of their livelihood) in order to design vaccine delivery strategies. Other issues that would be important to consider include: identify follow-up mechanisms for 2nd and 3rd doses and clarifying who is responsible for vaccine delivery to these often marginalized populations. Key issues needing further exploration were the need to analyze and understand successes and gaps from the existing experiences of reaching 9-13 year old girls with health services – in particular, reaching those considered vulnerable/marginalized with health services – and developing methods to assist countries to enumerate vulnerable populations.

Additional notes from this working group are in Annex 5.

9 | Priorities for action related to HPV vaccine delivery

Immediate/Short-term priorities (before end of 2012)

1. Develop a plan and process to compile and review the evidence-base needed to develop a menu of health interventions of value for 9-13 year olds (“early adolescent health menu”).
Responsible: WHO HQ with partners
2. Organize existing information, tools and materials to guide the development of communications strategies and activities to support the introduction of HPV vaccine in countries.
Responsible: WHO HQ
3. Review and summarize best practices and various options used for obtaining consent/assent/ authorization for 9-13 year olds to receive HPV. *Responsible: WHO HQ*
4. Develop inter-programmatic and cross-sectoral collaborations to support the introduction of HPV vaccine with consideration of a comprehensive approach to cervical cancer prevention and control and of improving delivery of health services to 9-13 year olds.
Responsible: All partners and agencies

Medium-term priorities (in next 1-3 years)

1. Support ongoing monitoring and evaluation of HPV vaccine delivery in early introducer countries in order to problem-solve and identify lessons learned for programmatic challenges and financial sustainability. *Responsible: Countries, WHO Regional Offices, WHO HQ and partners*
2. Assist countries with national HPV vaccine introductions so that decision-making and implementation are optimally informed and so that issues related to comprehensive cervical cancer prevention and control, to adjunct health service delivery, to financial sustainability, and to impact on immunization programme and health system are duly considered and addressed.
Responsible: WHO Regional Offices, WHO HQ, and partners
3. Improve understanding of best approaches to accessing and delivering care to populations of 9-13 year old girls who may be at highest risk of being under- or un-vaccinated (i.e., vulnerable populations). *Responsible: WHO HQ and partners*
4. Monitor and compile the evidence pertinent to updating global recommendations for HPV vaccine use (e.g., alternative dose spacing and reduced-dose schedules, vaccination of males, etc.) for review by WHO’s Strategic Advisory Group of Experts (SAGE) for immunization for SAGE review and recommendation. *Responsible: WHO HQ*

5. Provide technical assistance to countries with designing and implementing HPV vaccine demonstration projects to evaluate feasibility (including vaccine coverage) and cost of vaccine delivery and to assess potential of jointly delivering adjunct health interventions with HPV vaccines. Document and share the learning from these projects.

Responsible: WHO, all partners and agencies

6. Build an evidence base (including information on efficacy, feasibility, impact, cost-effectiveness, affordability) for health interventions targeted for 9-13 year old children living in low and middle income countries. Build an evidence base to understand determinants for successful combination of one or more of these health interventions with HPV vaccine delivery.

Responsible: All partners and agencies

Long-term priorities (over next five years)

1. Confirm the thermal stability and feasibility of using HPV vaccine in a controlled temperature chain at temperatures higher than the traditional 2°C to 8°C range and collaborate with industry to submit their products for re-licensing (or initial licensing) and WHO prequalification with this specification.

Responsible: WHO HQ, Optimize, BMGF, HPV vaccine manufacturers, and global partners

2. Evaluate immunization schedules for HPV vaccine for younger ages than the vaccine is currently licensed. *Responsible: HPV vaccine manufacturers*

3. Develop evidence-based guidelines on selecting and implementing health interventions for 9-13 year old children in low and middle income countries. *Responsible: WHO HQ*

Annex 1 | Meeting agenda

HPV Vaccine Delivery: Identifying Needs for Implementation & Research

17-19 April 2012, Intercontinental Hotel, Bruxelles/Amsterdam Room,
7-9 Chemin du Petit-Saconnex, 1209 Geneva, Switzerland

Objectives

1. To share an update on HPV vaccine introduction issues and the activities of key partners and stakeholders.
2. To determine outstanding questions that need to be addressed for optimal HPV vaccine delivery in countries.

Outcomes

1. A shared vision among public-private partners on short-, medium-, and long-term priorities for HPV vaccine activities.
2. A set of prioritized operational research issues that would facilitate HPV vaccine delivery.
3. A mapping of partner efforts and resources to support HPV vaccine introduction.

Day 1 | Tuesday, 17 April 2012

Taking Stock of HPV vaccine in 2012

Objective: Provide an overview of the current scientific knowledge and delivery experience with HPV vaccine

Outcome: (i) Up-to-date technical briefing on HPV vaccine; (ii) Common understanding of the successes and challenges in HPV vaccine delivery to date; and (iii) Sharing of tools and materials available to support HPV vaccine introduction.

Chair: Carsten Mantel, IVB/WHO

- 13:00-13:20 Welcome and Introductions
*Elizabeth Mason, Director, Department of Maternal, Newborn,
Child and Adolescent Health MCA/WHO*
- 13:20-13:30 Overview and objectives of the meeting
Susan Wang, IVB/WHO

Session I: "State of the Science" of HPV Vaccine: What we know; what we don't yet know

- 13:30-13:45 Overview of current knowledge of HPV vaccine - A Guided Tour
Laurie Markowitz, CDC
- 13:45-14:00 Discussion

Session II: “State of the Art” of HPV Vaccine Delivery: A work in progress

- 14:00-14:15 Global update on status of HPV vaccine introduction and tools to support decision-making and delivery
Susan Wang, IVB/WHO
- 14:15-14:30 Using costing and cost-effectiveness tools to support HPV vaccine delivery
Mark Jit, Health Protection Agency
- 14:30-14:45 Discussion
- 14:45-15:45 Learning from HPV vaccine introductions (10 min presentation/5 min clarifications)
- Experience from the WHO European Region
Liudmila Mosina, WHO EURO
 - Experience from the WHO African Region
Richard Mihigo, WHO AFRO
 - Experience from the WHO Western Pacific Region
Kimberly Fox, WHO WPRO
 - Experience from the WHO Americas Region
Andrea Vicari, WHO PAHO
- 15:45-16:15 Tea/Coffee Break
- 16:15-16:30 PATH Experience with HPV vaccine demonstration projects (Uganda, Peru, Vietnam, India)
Vivien Tsu, PATH
- 16:30-17:00 Discussion – What works? What are the gaps?

Targeting Adolescents

Objective: To review the best practices and lessons learned for providing health services to adolescents.

Outcome: Shared knowledge and experience on what practices and strategies work for adolescent health service delivery.

Session III: Best Practices for Adolescent Health Service Delivery

- 17:00-17:15 WHO approach to health services for adolescents
Paul Bloem, MCA/WHO
- 17:15-17:30 Experiences in health service delivery to adolescents – progress and lessons learned from the South-East Asia region
Rajesh Mehta, WHO SEARO
- 17:30-17:45 Health system strengthening to reach adolescents with health
Matilde Maddaleno, WHO PAHO
- 17:45-18:15 Discussion – What works? What are the gaps?

Day 2 | Wednesday, 18 April 2012

Identifying Synergies

Objective: To learn about activities that could facilitate HPV vaccine delivery.

Outcome: Identification of opportunities to create synergies between on-going adolescent health activities and HPV vaccination.

Chair: Jane Ferguson, MCA/WHO

08:30-08:45 Synthesis from prior day
Bruce Dick, Johns Hopkins Bloomberg School of Public Health

Session IV: Partner Activities for HPV Vaccine & Adolescent Health Service Delivery

- 08:45-09:00 GAVI funding support for the introduction of HPV vaccine
Tania Cernuschi, GAVI Secretariat
- 09:00-09:15 Discussion
- 09:15-10:00 Opportunities for HPV vaccine delivery (10 min presentation/5 min clarifications)
- UNICEF's adolescent health activities
Susan Kasedde, UNICEF
 - UNFPA's adolescent health activities
Nuriye Ortayli, UNFPA
 - UNESCO's adolescent health activities
Kirstin Holst, UNESCO
- 10:00-10:30 Tea/Coffee Break
- 10:30-10:45 Global data on girls & education to inform school-based HPV vaccination efforts
Albert Motivans, UNESCO Institute for Statistics
- 10:45-11:00 School health service delivery
Don Bundy, Africa Region, Human Development Network, The World Bank
- 11:00-11:15 Immunization of school-aged children: Current global experience
Tracey Goodman, IVB/WHO
- 11:15-12:00 Discussion
- 12:00-12:15 Introduction to Working Groups
Tracey Goodman, IVB/WHO

Prioritizing Issues

Objective: To determine the outstanding questions and issues that need to be addressed for optimal HPV delivery in countries.

Outcomes: A set of prioritized activities and operational research issues that would facilitate HPV vaccine delivery.

Session V: Working Groups (including lunch from 12:15-13:00)

- 12:15-16:00 Concurrent Working Groups:
1. Social mobilization and communication for HPV vaccine delivery
 2. Delivery of HPV vaccine primarily through schools
 3. Delivery of HPV vaccine primarily through health centers
 and other non-school strategies
- 16:00-16:30 Tea/Coffee Break

Mapping Partners and Resources

Objective: To learn about partners and what they wish to offer or might be seeking with regards to collaboration on HPV vaccine delivery.

Outcome: A mapping of partner efforts and resources to support HPV vaccine introduction.

Session VI: Opportunities for HPV Vaccine Delivery through Partners & Partnerships ("Who can contribute what")

16:30-17:30 Partners Roundtable

- UNAIDS
- Pink Ribbon Red Ribbon Initiative
- Lalla Salma Association Against Cancer
- Save the Children
- Union for International Cancer Control (UICC)
- Centers for Disease Control & Prevention
- Bill & Melinda Gates Foundation
- USAID
- Barcelona Centre for International Health Research (CRESIB)
- Global Task Force on Expanded Access to Cancer Care & Control in Developing Countries

Day 3 | Thursday, 19 April 2012

Chair: Tracey Goodman, IVB/WHO

8:30-10:00 Report Back from Working Groups (15 min each) and Discussions (15 min each)

1. Social mobilization and communication for HPV vaccine delivery
2. Delivery of HPV vaccine primarily through schools
3. Delivery of HPV vaccine primarily through health centers and other non-school strategies

10:00-10:30 Tea/Coffee Break

Session VII: How do we monitor for success?

10:30-10:45 PATH's Monitoring & Evaluation Framework for HPV Vaccine Introduction

Emmanuel Mugisha, PATH/Uganda

10:45-11:00 Monitoring & Evaluation of HPV Vaccination Programmes:

Coverage Monitoring, Post-Introduction Evaluations and Vaccine Impact Monitoring

Susan Wang, IVB/WHO

11:00-11:15 Discussion

Next Steps

Objective: To review the key questions, priorities, research issues, and opportunities for optimal HPV vaccine delivery.

Outcome: A shared vision among public-private partners on short-, medium-, and long-term priorities for HPV vaccine activities.

Session VIII: Review and Way Forward

11:15-12:30 What next? Identifying the short-, medium-, and long-term priorities and the ways forward (with Discussion)

Bruce Dick, Johns Hopkins Bloomberg School of Public Health

Annex 2 | List of Meeting Participants

WHO Regional Representatives

AFRO

- Richard Mihigo
Regional Routine Immunization, New Vaccines Programme Area Coordinator
- Khadidiatou Mbaye
Regional Officer Responsible for Cervical Cancer Prevention, Health Promotion Cluster
- Collins Boakye-Agyemang
Communications, Advocacy and Media Programme Manager

EURO

- Liudmila Mosina
Vaccine Preventable Diseases & Immunization
- Nathalie Likhite
Communications consultant
- Valentina Baltag
Child and Adolescent Health

PAHO

- Andrea Vicari
Immunization, Comprehensive Family Immunization Regional Project
- Matilde Maddaleno
Regional Advisor, Adolescent Health

SEARO

- Rajesh Mehta
Child & Adolescent Health

WPRO

- Kimberley Fox
Vaccine Preventable Diseases
- Ornella Lincetto
WHO Representative's Office in Vietnam

World Health Organization Headquarters

Family, Women's and Children's Health (FWC)

- Islene Araujo de Carvalho

Immunization, Vaccines and Biologicals (IVB)

- Teresa Aguado
- Tracey Goodman
- Carsten Mantel
- Pem Namgyal
- Susan Wang
- Michel Zaffran

Interns

- Jennifer Heumann
- Michaela Fesenfeld

Maternal, Child & Adolescent Health (MCA)

- Paul Bloem
- Jane Ferguson
- Elizabeth Mason

Interns

- Charlotte Christiansen
- Stephanie Flash

Reproductive Health & Research (RHR)

- Nathalie Broutet
- Venkatraman Chandra-Mouli

Chronic Diseases and Health Promotion (CHP) Noncommunicable Diseases & Mental Health (NMH)

- Andreas Ullrich

Partners

UNICEF

- Jesus Lopez-Macedo
Health Section
- Susan Kasedde
Senior Specialist, HIV Prevention
- Oya Asfar
European Office

UNESCO

- Albert Motivans
Head of Section, Institute for Statistics
- Kirsten Holst
Liaison Officer, Geneva

UNAIDS

- Hedia Belhadj
Director, Partnerships Department

UNFPA

- Alanna Armitage
Director, Geneva Office
- Agathe Lawson
Geneva Office

UICC

- Lucrecia Peinado
Programme Director, Cervical Cancer Initiative
- Marguerite Cornu
Cervical Cancer Initiative

PATH

- Vivien Tsu
Associate Director, Reproductive Health
- Emmanuel Mugisha
Country Manager

Pathfinder International

- Julio Pacca

Save the Children

- Natalie Roschnik
School Health and Nutrition Advisor,
Department of Education and Child
Development

World Bank

- Don Bundy

London School of Hygiene and Tropical Medicine

- Debby Watson-Jones

Health Protection Agency

- Mark Jit

U.S. Centers for Disease Control & Prevention

Division of STD Prevention

- Susan Hariri
- Lauri Markowitz

Global Immunization Division

- Kashmira Date

Johns Hopkins School of Public Health

- Bruce Dick
- Michelle Hindin

USAID

- Susan McKinney
Senior Technical Advisor for Immunization,
Bureau for Global Health

Bill & Melinda Gates Foundation

- John Yang

GAVI

- Khin Devi Aung
- Deblina Datta
- Tania Cernuschi

Barcelona Centre for International Health Research (CRESIB)

- Azucena Bardají

Temporary Advisor

- William Wekwete

Annex 3 | Notes from Working Group #1 – Social mobilization and communication for HPV vaccine delivery

Workgroup participants: Jesus Lopez-Macedo, Nathalie Likhite, Kashmira Date, Matilde Maddaleno, Collins Boakye-Agyemang, Oya Asfar, Lucrecia Peinado, Vivien Tsu, John Yang, Deblina Datta, Tracey Goodman, Andreas Ullrich, Hedia Belhadj

Good Practices for Advocacy and Social Mobilization

- For policy-makers highlight the linkage of HPV vaccine introduction with national health priorities, such as the National Cancer Control Plan. Use data from cost-benefit analysis.
- Communicate who (e.g. MOH) is responsible for the decision to introduce HPV vaccine and the technical reasons why.
- Develop a comprehensive communication plan prior to HPV vaccine introduction.
- Work proactively with the media: identify and train a spokesperson within the MOH; develop a briefing kit for journalists with key messages and FAQs; use innovative ways to encourage news coverage (e.g. PAHO has used competitions for the best article); anticipate and be prepared to rapidly and effectively respond to any adverse events and misinformation.
- Conduct formative research to develop messages and identify target groups for communication. Recognize that there is generally low awareness among stakeholders, and that anti-vaccination groups can be very effective at spreading fear.
- Create positive social support for HPV vaccine introduction
- Identify decision-makers and influencers at community and household level
- Recognize the role of medical professionals, teachers, women's groups, religious leaders:
 - Provide tools and information to frame messages
 - Use context-specific channels
 - Women's groups in multiple settings
 - Engage role models such as sport or music celebrities (examples from Angola & Uganda)
 - Religious leaders used to convey permission from ancestors (Ghana)
 - Use of mobile technology to persuade husbands/fathers (examples from Ghana)

Key Steps for Demand Generation and Individual Behavior Change

- Identify what the individual behaviors are that we want to see (e.g., girls receiving HPV vaccination, women accessing cervical cancer screening services)
- Frame concepts and in familiar terms (symptoms, names, pictures/symbols, personal experiences)
- Use girls who are enrolled in schools as a mechanism to relay information out-of-school girls with specific information (where, when, what)
- Use social media (such as Facebook, Tumblr as outreach tools)
- Use HPV vaccination as an entry point to promote other adolescent health and reproductive services. In many countries immunization programmes have better infrastructure compared to adolescent health programmes.

Additional comments from the plenary discussion related to this workgroup

- Broaden and have integrated messages for cervical cancer screening: For example “mother & daughter messages”; when a mother brings her daughter for HPV vaccination she is informed about the need for cervical cancer screening – but this can only work also if those other services are available!
- Need to educate parents and girls of the need to return for doses 2 and 3 to decrease drop-out
- What is different about communication and social mobilization for HPV vaccine as compared to other vaccines?
- Delivery strategies for HPV vaccine depend on communication and social mobilization in a way that is not so essential for introduction of new infant vaccines where mothers are already bringing their infants for a routine schedule of infant vaccines
- There is a special role for social mobilization and communication to access at-risk girls (but vulnerable girls may not be literate so print or SMS messages or communication delivered via schools may not reach them)
- Need to communicate and educate additional audiences as compared with new infant vaccines: in addition to parents, girls, religious leaders, school staff
- May need more innovations in social mobilization such as pulsed social mobilization messages to motivate girls to come for dose 1 and then to return for doses 2 and 3

Communication materials and resources to take note of

- WHO/ICO Information Centre on HPV and Cervical Cancer website (<http://www.who.int/hpvcentre/en/> (for statistics and country disease burden data)
- PATH rapid formative research methodology (forthcoming) and other documents on communications learning from PATH demonstration projects (www.rho.org)
- CDC website <http://www.cdc.gov/hpv/>
- WHO EURO Vaccine Risk Communications Guide (forthcoming).

Outstanding questions and research areas

- What is the evidence-base for interventions for young adolescents?
- What is the optimal link between HPV vaccination and Adolescent & Reproductive Health services?
- Who are the out-of-school girls and what are the most effective communication strategies and means to reach them?
- How can social media be leveraged for HPV vaccine demand creation?
- To what extent are men involved in decision-making related to HPV vaccination?
- How can communication strategies and messages be monitored and evaluated to ensure that they are addressing vaccine acceptability issues, particularly among refusers?

Annex 4 | Notes from Working Group #2 – Delivery of HPV vaccine primarily through schools

Workgroup participants: Valentina Baltag, Kimberly Fox, Lauri Markowitz, Paul Bloem, Debby Watson-Jones, Natalie Roshnik, Don Bundy, Khin Devi Aung, Pem Namgyal, Carsten Mantel, Andrea Vicari

Considerations for HPV vaccine delivery through schools

- UNESCO's school enrollment ratio data are important resources; however, since there can be sudden local changes to enrollment, it is important to use in-country data as well as UNESCO data.
- School enrollment, attendance, drop-outs and absenteeism describe how many adolescents are in school so it is necessary to understand how and when the data for these descriptive statistics are collected.
- The school calendar of exams, special school events, and holidays is important to review. When is the best time to deliver vaccine so that it is least disruptive to the school schedule?
- Age distribution by grade is important data to target intervention; use in-country data and UNESCO data.
- Further useful information to plan vaccine delivery includes knowing the landscape of schools (public/private/boarding, etc.) and the completeness of the Ministry of Education's school listing (are faith-based or private schools also registered with MoE?).
- Having prior experience with other school-based health services can inform planning for vaccine delivery in schools. Collecting information on experience or existence of other school-based health services by grade and by age including types of services, who delivers (health workers or school staff) the service(s), and the financing of services can be useful.
- Understanding whether any school health policies exist and whether a collaborative framework between education and health sectors is in place is useful.
- WHO has developed the WHO School Vaccination Programme Readiness Assessment Tool for countries to use to systematically make an assessment of the considerations described above and from that assessment, to develop a plan to address gaps if putting a school vaccination programme in place is desired.
- As with any vaccine introduction plan, the following elements need to be understood:
 - Health system (health worker) capacity to deliver vaccine in the school
 - Financial considerations: cost of vaccine delivery in schools to the government (both for Ministry of Health and Ministry of Education)
 - Information and communication needs at various levels (national, regional, etc.) for health and education staff
 - Cold chain, volume, storage, and transportation

Challenges

- Logistics of obtaining authorization for vaccination from parents
 - Could be done as part of registration process
 - Who provides authorization and how is it obtained? Proxy permitted?
 - What to do when parents are not readily available (e.g., boarding schools, migrant or otherwise absent parents)?
- Possible differences in desire for vaccination by girls compared to parents
- Time and resources needed to train school staff

Opportunities

- Parental authorization process could be an opportunity to increase awareness about cervical cancer screening
- School delivery is consistent with the role of schools to educate and communicate with parents
- Schools have a duty of care that may help provide reassurance that this is a safe intervention
- Could use existing in-service training mechanisms for teachers

Strategies to consider reaching girls who are not vaccinated through school delivery of vaccine

- Who are the girls who may be missed in a school delivery strategy? Ethnic minorities, migrants, rural populations, those who initially refuse, private school populations
- Strategies to reach girls missed in school based delivery:
 - Communicate to inform families of non-enrolled or absent girls when vaccine is offered in schools to encourage these girls to go to schools to be vaccinated; increase communication and social mobilization
 - Offer several rounds of vaccinations, not just 3 rounds (but more expensive)
 - Provide referrals to nearby health facilities for missed vaccinations

Outstanding questions & research areas

- Determine vaccine stability outside of cold chain and if feasible, get vaccine licensed for such use
- Consider work on issues related to consent/assent/authorization for HPV vaccines such as formative research on parental attitudes and ethical issues
- What is the impact of integration of various other services with HPV vaccine? What is the impact on acceptability and coverage with combined interventions? What is the impact on delivery costs?
- Clarify the epidemiology of girls who are unvaccinated and under-vaccinated for HPV vaccine
- Do programmatic evaluation to identify predictors of high coverage
- Determine costs of delivery strategies and do cost-effectiveness analyses

Annex 5 | Notes from Working Group #3 – Delivery of HPV vaccine primarily through health centres and other non-school strategies

Workgroup participants: Jane Ferguson, Bruce Dick, Liudmila Mosina, Susan Hariri, Khadidiatou Mbaye, Rajesh Mehta, Susan Kasedde, Albert Motivans, Julio Pacca, Emmanuel Mugisha, Michelle Hindin, Susan McKinney, Tania Cernuschi, Azucena Bardaji

Delivery strategies

- Should build on existing systems in EPI, Adolescent Health, Reproductive Health, school health; as well as standard health service delivery and outreach
- Immunization strategies and venues: facility/health unit based and outreach into communities; timing can be routine/regular or occasional/campaign/sporadic
 - Examples: Macedonia used immunization mobile teams; Netherlands used fitness centers as venues for outreach vaccination, Uganda used outreach in markets or vaccination in health centers.

Why do girls use health services?

- Accompany mothers when coming for other reasons
- Coming for other service like nutrition supplementation, water
- Offer HPV vaccine in combination with other services that girls want (e.g., menstrual hygiene products)
- Peer educators provide information and refer girls to health centers
- Health worker home visits to encourage girls

Vulnerable girls are an important portion of the target population to vaccinate

- How to identify the girls? (do they live alone or not with parents or guardian?)
- How to enumerate them? What is the size/magnitude of this group?
- Where can they be found?
- How to deliver HPV vaccine to them?
- A country can have several different vulnerable girl populations
 - MoH may need more health workers to find and vaccinate vulnerable girls. Examples include: domestic workers, agriculture or market workers; disabled or chronically ill girls; migrants, forced laborers, ethnic minority or lower caste; HIV orphans; girls whose parents are too poor to afford school uniforms and supplies

Follow-up mechanisms for doses 2 and 3

- Mobile technology such as cell phones with SMS or audio messaging for the illiterate
- Vaccination cards or adolescent health record as record of vaccines given and reminder of next dose that girl will need to obtain.

Outstanding questions and research issues

- What adolescent health services are already reaching adolescent girls? Can HPV vaccine delivery be integrated with delivery of other health services?
- Why/when do 9-13 year old girls go to health facilities? What might increase their utilization of services?
- Clarify best approaches for determining the size of the population of 9-13 year old girls and the places where they could be reached with vaccination.
- Identify/map health services that could or already reach all adolescent girls; understand coverage and costs of these services.
- Identify/map health services that could or already reach vulnerable adolescent girls; understand coverage and costs of these services.
- Synthesize experiences of providing vaccines with adjunct health services to adolescents and to vulnerable girls.
- Develop rapid assessment methods or implementation research to ascertain feasibility of various approaches to reach vulnerable adolescents
- Based on evidence, develop a checklist of tasks for use in micro-planning to identify/develop strategies for vulnerable girls
- Modeling of costs, feasibility, etc. of approaches to reach vulnerable girls

Useful products to consider developing in order to support countries

- Guidance to countries on the issue of options for obtaining authorization/consent/assent for HPV vaccination
- Dissemination of experience and tools from demonstration projects and national HPV vaccine introductions



Department of Immunization, Vaccines and Biologicals
Expanded Programme on Immunization