

Implementing HPV Vaccination Programs

PRACTICAL EXPERIENCE FROM PATH | 2011



PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH'S work improves global health and well-being.

Headquartered in Seattle, Washington, PATH has offices in 31 cities in 22 countries.

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For more information, please contact:

PATH

MAILING ADDRESS

PO Box 900922
Seattle, WA 98109

STREET ADDRESS

2201 Westlake Avenue
Suite 200
Seattle, WA 98121

Tel: (206) 285-3500

Email: info@path.org

Web: www.path.org/cervicalcancer

RHO Cervical Cancer resource library: www.rho.org

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All photos in this document were taken at sites of demonstration projects implemented by the governments of India, Peru, Uganda, and Vietnam with technical support from PATH.

Cover photos, clockwise from upper left: PATH/Amyah Janmohamed; PATH/Aisha Jumaan; PATH/D. Scott LaMontagne; PATH/Amyah Janmohamed; PATH/Amyah Janmohamed.

INTRODUCTION TO THE CERVICAL CANCER PREVENTION: PRACTICAL EXPERIENCE SERIES

About the PATH HPV vaccination demonstration projects

From 2006 to 2011, PATH conducted HPV vaccination demonstration projects in four low- to middle-income countries—India, Peru, Uganda, and Vietnam—to provide evidence for decision-making about public-sector introduction of human papillomavirus (HPV) vaccines. The Cervical Cancer Prevention: Practical Experience Series of four units summarizes lessons learned that can help guide future cervical cancer prevention program planning, especially in low-resource settings around the globe.

In conducting the vaccination demonstration projects, PATH worked closely with ministries of health, civil society organizations, and other key stakeholders to carry out formative and operations research in each country. The studies looked at a variety of vaccine introduction questions, including how sociocultural barriers may impede acceptance of the vaccine; how the vaccine can be most effectively delivered to adolescent girls; how HPV vaccination can be integrated into (and strengthen) existing health programs; and what the cost of implementing HPV vaccinations might imply for health programs.

Each Practical Experience unit focuses on an important aspect of an HPV vaccination program:

- 1. Strategic Planning and Situation Assessment for Cervical Cancer Prevention.** The first unit helps decision-makers and program planners focus on key “big picture” questions about cervical cancer prioritization and on opportunities and challenges for improved cancer prevention in their countries.
- 2. Conducting Formative Research for HPV Vaccination.** The second unit demonstrates that preliminary formative research is a necessary component of overall planning, discusses formative research issues specific to cervical cancer, and explains how research results may be used for strategic planning in the cervical cancer context. [To be published in late 2011.]
- 3. Implementing HPV Vaccination Programs.** The third unit (this document) offers resources on general immunization topics such as how to set up an immunization site or to give a safe injection. However, the main focus is on practical issues relevant to HPV vaccination such as working in school settings and developing effective messaging about the vaccine.
- 4. Evaluating HPV Vaccination Programs.** This unit focuses on how program monitoring and evaluation can be accomplished within existing health infrastructures in an efficient manner. [To be published in 2012.]

Check the RHO Cervical Cancer Practical Experience Series page (www.rho.org/HPV-practical-experience.htm) regularly for completed units.

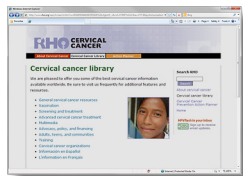
For more information about PATH's cervical cancer vaccine project, visit: www.path.org/projects/cervical_cancer_vaccine.php or contact info@path.org.

PATH resources for information on cervical cancer and HPV vaccination

The resources below are available at www.rho.org.

The following three items provide an overview of the scientific literature on cervical cancer, current evidence on methods of prevention, and information for program planning:

- The [RHO Cervical Cancer Library](#) is a comprehensive online source for detailed information about cervical cancer and how it can be prevented.
- *Outlook: [Progress in preventing cervical cancer: Updated evidence on vaccination and screening](#)* is a 12-page primer on all aspects of cervical cancer prevention, published in 2010.
- PATH's [Cervical Cancer Prevention Action Planner](#) provides a wealth of information and interactive exercises to assist with program planning.



The following documents summarize the formative research done in preparation for implementing vaccinations in each country:

- [Shaping a Strategy to Introduce HPV Vaccines in India](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Peru](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Uganda](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Vietnam](#)

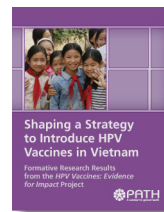
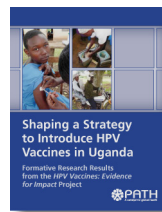
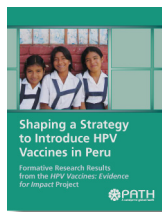
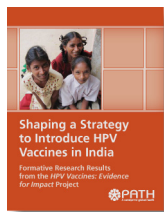


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ACRONYMS

AEFI	Adverse event following immunization
AIDS	Acquired Immune Deficiency Syndrome
EPI	Expanded Programme on Immunization
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IEC	Information, education, and communication
NGO	Nongovernmental organization
UNFPA	United Nations Population Fund
UNICEF	United Nations Children’s Fund
USAID	US Agency for International Development
WHO	World Health Organization

Introduction

This unit presents experience and lessons learned from implementing human papillomavirus (HPV) vaccination programs in low-resource settings in India, Peru, Uganda, and Vietnam. It also provides links to free resources such as training manuals, vaccination forms, educational brochures, and other publications useful to program planners and managers. Most of the resources come from the World Health Organization (WHO), the US Agency for International Development (USAID), and PATH.

The objective of the unit is to offer practical information to countries that plan to pilot, expand, or scale up HPV vaccination programs. Because circumstances in different countries will vary, the information consists of examples and suggestions that managers can consider when crafting their strategies, rather than a single design for all situations.

While many aspects of HPV immunization are similar to routine childhood vaccinations, and country Expanded Programme on Immunization (EPI) staff are familiar with these, there are some notable differences. Issues specific to cervical cancer and HPV vaccination are the focus of this document, but to provide context and continuity, it also includes some activities necessary for implementing any new immunization program.

The suggestions, techniques, and tools presented here for HPV vaccination programs were developed by country EPI programs, PATH, and other key stakeholders in the four countries in which HPV vaccination demonstration projects were carried out. A linked list of print and online resources, mostly in English, is presented at the end of the document. Links to Spanish language resources are also included. All resources are available online at www.rho.org/HPV-vaccine-implementation.htm.



PATH / Jacqueline Sherris

Primary school girls in Nakasongola, Uganda, wait to receive HPV vaccinations.

Understanding cervical cancer and HPV vaccines

HPV and cervical cancer

Research conducted over the past 30 years established that HPV is the primary cause of cervical cancer. HPV infection is very common; the majority of men and women become infected within a few years after becoming sexually active. Most infected women do not develop cervical cancer, but about 10 percent will have persistent HPV infection that can progress to precancer and cancer over 10 to 20 years. The HPV types that cause most cervical cancer cases—about 70 percent worldwide—are types 16 and 18.

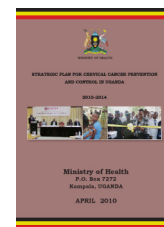
There are two ways to prevent cervical cancer: HPV vaccination to prevent infection, and cervical cancer screening and treatment to detect disease early, when it is easier to cure. While vaccination of young adolescent girls is the focus of this document, it is important to remember that current vaccines provide protection against the two HPV types that cause most cervical cancer, not against all HPV types. Because the vaccines do not protect against all types, screening is needed to prevent disease caused by other HPV types, and to protect women who have not been vaccinated.

Most experts agree that countries should consider comprehensive prevention, by offering programs for screening and treatment of adult women for precancer and cancer, as well as for vaccination of young adolescent girls. A good example of a comprehensive strategy for prevention is available in [Strategic Plan for Cervical Cancer Prevention and Control in Uganda](#).

A recent issue of PATH's publication *Outlook*, titled [Progress in Preventing Cervical Cancer: Updated Evidence on Vaccination and Screening](#), provides an overview of cervical cancer and current prevention options, including the HPV vaccines.

Vaccine efficacy

Clinical trials conducted in many countries prior to vaccine approval demonstrated that the two currently licensed vaccines against HPV work best in recipients who have not been infected with HPV and that efficacy declines once sexual activity (and likely HPV infection) begins. Most of the trials were conducted in young women between the ages of 15 and 26 years, although in studies designed to measure antibody responses, participants were as young as 9 years. No studies were done in children younger than 9 years, so the vaccines may not be given to younger children. WHO stated in [Human Papillomavirus Vaccines: WHO Position Paper](#) that the primary target population for HPV vaccination should be girls prior to onset of sexual activity, in the age range of 9 or 10 through 13 years. More information on the target population is given in the section “HPV vaccine delivery strategies” on page 6 of the current document.





PATH

Girls at a school in Gujarat, India, hold up their immunization cards after receiving their first dose of HPV vaccine.

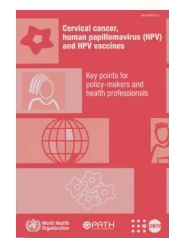
In the clinical trials, both vaccines showed high efficacy, preventing cervical infections and precancerous growths in more than 92 percent of women who were not previously infected with the HPV types against which the vaccines are designed to protect (types 16 and 18), and there was evidence of some cross-protection against a few other types. Note that it is important that women be screened for cervical cancer later in life, even when they have been vaccinated, because the vaccines will not protect against all cervical cancer.

Vaccine side effects and safety

Results from clinical trials for both HPV vaccines showed that the most common side effect was discomfort at the injection site. Other common side effects, usually of short duration, were headache, fever, nausea, dizziness, vomiting, and fainting. Serious adverse events were rare and occurred at about the same rate in the women who received the vaccine as in those who were given a placebo injection.

No reported deaths have been shown to be causally linked to HPV vaccines in clinical trials or in post-marketing reports to date. The very small number of deaths that occurred during the trials was similar in the vaccine and control groups and did not follow a particular pattern, indicating that deaths that occurred days, weeks, or months following immunization were not causally associated with the vaccine. For more information on the efficacy and safety of the two vaccines, see the package inserts for [Gardasil®](#) and for [Cervarix®](#).

The WHO/PATH/United Nations Population Fund (UNFPA) publication [Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#) provides further information about HPV infections and the safety and efficacy of the vaccines.



Planning for HPV vaccine introduction

General aspects of implementation

For any vaccination program, careful planning at the outset can ensure that the target population is reached and coverage is high. Managers who are beginning HPV vaccination programs can make use of routine EPI planning processes found in their country immunization program materials, with the addition of school-specific plans if schools will be used as vaccination sites. General immunization resources are recommended below.

The WHO publication [Vaccine Introduction Guidelines](#) covers both policy and programmatic aspects of introducing a new vaccine.

WHO also offers an online resource, the [New and Under-utilized Vaccines Implementation \(NUVI\)](#) website.

Another WHO resource, [Immunization in Practice, a Practical Resource Guide for Health Workers](#), consists of several modules that provide information on topics such as safe injections, holding an immunization session, and monitoring and using data.

PATH's online [Vaccine Resource Library](#) contains a wealth of information, especially on newer vaccines and immunization systems issues.

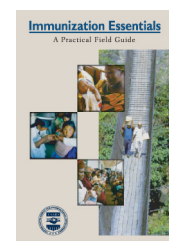
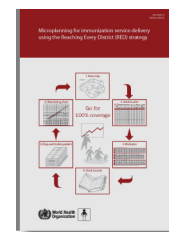
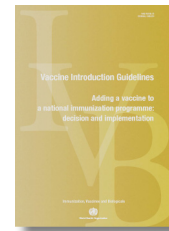
A good immunization microplanning guide is the WHO publication [Microplanning for Immunization Service Delivery Using the Reaching Every District \(RED\) Strategy](#), which covers health facility as well as district-level planning.

[Immunization Basics](#) is a website provided by USAID that covers most aspects of immunization.

The manual [Immunization Essentials](#), also from USAID, covers delivery of immunization services, cold chain and logistics, communication and dealing with rumors, and behavior change for health workers and caregivers.

Special aspects of HPV vaccination programs

When any new health technology is introduced, policymakers, managers, and health workers must prepare health systems and communities to understand and embrace the intervention. In order to ensure that the HPV vaccination projects would be successful, PATH and its country partners first gathered information on the target audience's values, attitudes, knowledge, and behaviors that could affect their response to an HPV vaccination program. Research also was undertaken to assess the policy context at national and lower levels, and to evaluate the condition of health systems. Results of this formative research were used to guide development of vaccine delivery strategies, communications strategies (for outreach to communities), and advocacy strategies (for outreach to



policymakers). While managers may not be able to carry out extensive formative research when instituting HPV vaccination programs, even simple community research can help them to avoid pitfalls and to craft appropriate strategies. See the publications of formative research results from the PATH HPV vaccine projects for details:

- [Shaping a Strategy to Introduce HPV Vaccines in India](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Peru](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Uganda](#)
- [Shaping a Strategy to Introduce HPV Vaccines in Vietnam](#)

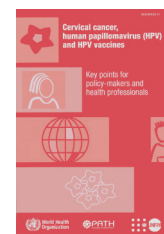
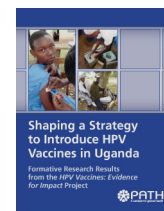
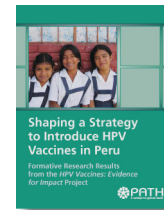
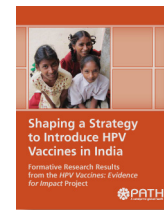
The publication [Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#) includes information on HPV vaccination-specific topics such as vaccine delivery strategies, communication and partnerships, and potential impact of vaccination programs.

The Uganda publication for an HPV vaccination program, [Bridging Phase for the Delivery of Human Papillomavirus \(HPV\) Vaccine to Prevent Cervical Cancer: A Field Guide for Health Managers and Service Providers](#), also is an excellent resource. This manual was written for a particular phase of vaccination in Uganda, known as a bridging phase, but most of the information can be applied to any HPV vaccination program.

The most prominent differences between HPV vaccination and routine immunization programs involve the target population and the venues for delivering vaccine. These differences create challenges such as how best to:

- Identify eligible girls and make sure that the correct target group is vaccinated.
- Choose the best venues for vaccinating; for example, schools or health clinics.
- Communicate the need for HPV vaccination to families and communities.
- Train health workers, community leaders, teachers, and others to implement the program.

These topics are addressed in the following sections.



HPV vaccine delivery strategies

Target population

As noted earlier, the WHO publication [Human Papillomavirus Vaccines: WHO Position Paper](#) states that the primary target population for HPV vaccination should be girls prior to onset of sexual activity, in the age range of 9 or 10 through 13 years. Most developing countries do not routinely vaccinate these older children and adolescents, so systems may need to be created or adapted to reach them. While this can be a challenge, it is also an opportunity to provide adolescents with additional health interventions and guidance.



The target population for HPV vaccination in a given country will depend on the licensing for vaccine use in that country and the country's policies. Note that the license and the country policy may differ. For example, in the United States, one of the vaccines is licensed for use in 9- through 26-year-old females and 9- through 26-year-old males, and the other for use in 10- through 25-year-old females. However, the committee that makes recommendations for vaccinations, the Advisory Committee on Immunization Practices, has recommended

vaccinating only girls and young women. Males may receive the vaccine, but there is no specific recommendation for this.

According to the World Health Organization, the primary target population for HPV vaccination should be girls prior to onset of sexual activity, in the age range of 9 or 10 through 13 years.

After deciding on the range of ages for vaccination, countries or regions must determine whether birthdate or some other indicator works best for identifying eligible girls. In cultures in which birthdates are not recorded and people do not keep track of their ages, implementing vaccination by age may not work well. PATH experience in Uganda showed generally that acceptability of HPV vaccine was high among girls,

parents, and community members. However, in the district in which an age-based vaccination strategy was implemented (vaccinating all 10-year-old girls), evaluators could not show high coverage in the target group because it was often not possible to conclusively identify those who were 10 years of age, either during vaccination or during a coverage survey afterward. In the district in which vaccinations were given in school to all girls in Primary grade 5, coverage was very high, so within this context, vaccinating by school grade was more successful.

While vaccinating by grade is logistically easier to manage than vaccinating by age, a given classroom may include girls of many different ages, so vaccinating by grade could have implications for reporting systems and evaluation of vaccination coverage, if those are age focused. Managers will need to assess the situation in their areas and craft appropriate solutions.

Each country has its own policies and procedures for how individuals agree to receive vaccinations. For example, this may be done by saturating the area with information on an upcoming program and posting immunization dates, times, and locations, or by asking for verbal assent at the time of vaccination. In the PATH demonstration projects, the goal for obtaining permission for HPV vaccination was to make the process as similar as possible to what governments were currently doing for routine immunizations. For any new vaccination program, EPI personnel should make decisions on the type of agreement or authorization needed in a manner appropriate for their country.

Schools versus clinics or health posts

The rate of school attendance among girls is improving in many low-resource areas, especially in primary schools, making school-based vaccination more feasible than ever. Each of the four PATH country demonstration projects included at least one strategy that involved immunization teams vaccinating on school premises, and compared this with an alternate strategy. If school-based programs are the main strategy in a region, managers will need to develop a complementary strategy for reaching girls who do not attend school.

A challenge in all immunization programs is reaching populations that are mobile or that live in remote areas. For these situations, special consideration must be given to planning, allowances, and logistics. Sensitization and vaccination may need to be conducted by itinerant health teams or incorporated into existing outreach programs.

For school-based programs, close coordination of efforts between education and health systems is essential, so microplanning should involve teachers and administrators as well as district and local health personnel. For example,

The rate of school attendance among girls is improving in many low-resource areas, especially in primary schools, making school-based vaccination more feasible than ever.

health workers need to work with schools to obtain names of eligible girls for vaccination rosters and to schedule vaccination days that will not fall during exams or holiday periods. Clear guidelines on the roles of teachers and health workers on vaccination days should be established.

At schools, meeting rooms or libraries often were used as vaccination rooms, temporarily disrupting some regular school activities on vaccination days, but this happened only a few days per year. Teachers and administrative staff were recruited to assist with organizing the sessions, helping with records, and watching for adverse events following immunization (AEFIs, see page 23). Most school employees felt that the time devoted to the vaccination program was a good investment in the health of their students.

In school-based programs, provisions had to be made for missed doses, since some girls were absent on the school vaccination day. In the Peru project, for example, three doses of HPV vaccine were administered in school by a team from the nearest health facility. Girls who missed a vaccination in school were reminded to obtain it at the nearest health center. This was more efficient than sending vaccinators back to schools for follow-up.

Strategies whose primary purpose was to “bundle” HPV vaccination within an existing health outreach program (such as the Child Days Plus program in Uganda) sometimes used a school as the vaccination venue because the existing program already operated there. In some cases, these community outreach programs may be underfunded or inefficient, so additional funding from the HPV vaccination program may be necessary for personnel and transport costs.

For vaccination programs that use health centers or clinics rather than schools, age-based census data can provide information for estimating the total number of girls in the community who may be eligible for vaccination.

In Vietnam, the project compared vaccinations at schools with those given at health centers in three geographical settings: rural, mountainous, and urban. Coverage was high for both strategies in all settings, and was nearly identical for the two strategies in the rural and mountainous settings. In urban areas, the health center strategy attained a slightly higher coverage, but it was noted that health centers tended to be very near to schools, making it easy for girls to get to the clinics.

The project in India used a strategy different from those in the other three project countries. In one district, a “pulsed campaign” approach was used, with the first, second, and third vaccine doses given once over a seven-month period. In the second district, a “routine monthly immunization” approach was used, with vaccinations provided every month over an eight-month period, as for the routine EPI schedule. Both approaches targeted girls aged 10 to 14 years for an initial “catch-up” round, although a regular strategy would more likely focus on a single age cohort.

In summary, by assessing a variety of strategies, the PATH projects found that high coverage could be achieved through programs based in schools, health centers, or existing outreach programs. Since all of these produced reasonable results, the choice of strategy can be based on local conditions and number of eligible girls, in order to optimize the use of available resources.

Table 1 shows the vaccination strategies used in the four country projects.

Table 1. Vaccine delivery strategies by country.

COUNTRY	STRATEGY	ELIGIBLE POPULATION/ INDICATORS FOR VACCINATION	LOCATION AND METHOD OF DELIVERY
India	“Pulsed campaign” (vaccination offered only once for each dose in a year, as is done in other vaccination campaigns)	All 10- to 14-year-old girls	Schools for school-going girls; community centers for out-of-school girls
	“Routine monthly” (vaccination offered on fixed days each month, in accordance with the routine EPI schedule)	All 10- to 14-year-old girls	Schools for school-going girls; community centers for out-of-school girls
Peru	School-based	Primary grade 5 girls at least 9 years old	Schools and outreach for doses 2 and 3
Uganda	School-based	Primary grade 5 girls at least 10 years old	Schools and routine outreach to out-of-school 10-year-old girls
	Child Days Plus-based or integrated outreach (visits to schools every 6 months)	All 10-year-old girls	Child Days Plus program at schools for doses 1 and 3 and outreach for dose 2
Vietnam	School-based	Primary grade 6 girls at least 9 years old	Schools and community outreach for 11-year-old girls in other grades or out of school
	Health center-based	All 11-year-old girls	Health center and community outreach

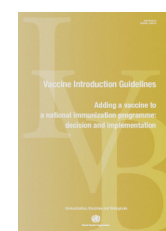
Vaccination logistics

As they do for routine immunizations in an EPI program, managers must be sure that an adequate supply of vaccine and vaccination materials are on hand, storage facilities are adequate, sufficient numbers of health workers are available, and

A good strategy for conserving resources is to arrange delivery of HPV vaccine to coincide with scheduled delivery of other vaccines.

supplies and personnel can be transported to vaccination sites. While adding HPV vaccinations to a country program can increase workloads, it also provides the opportunity to assess and improve the overall vaccine delivery system, including the cold chain, the transport and supply system, and health center staffing. Such assessments should be used to ensure that health systems are strengthened and essential services are not disrupted during HPV

vaccination sessions. The WHO [Vaccine Introduction Guidelines](#) and country EPI manuals are good sources of information on these topics.



Supply, storage, transport, and cold chain management

USAID's [Immunization Essentials](#) has a chapter on calculating how much vaccine to order to meet demand and avoid wastage. PATH project countries found that single-dose vials resulted in low wastage, on the order of less than 1 percent. Because it is important to avoid running out of vaccine, managers can start with a projected wastage of 5 percent and then adjust subsequent requests based on their experience. Managers must also ensure adequate storage space for the vials. To assist with this, a [Vaccine Volume Calculator](#) is available from WHO.

Adequate space must be available for ancillary supplies such as syringes, waste collection materials, and ice packs for vaccine carriers for transport to vaccination sites. In order to avoid overloading the cold chain storage space at health facilities, health workers should request their vaccine supply close to the dates of vaccination so the vials will be stored for only a short period of time.

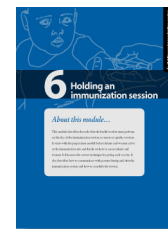
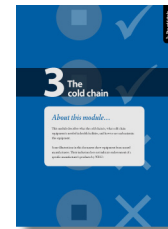
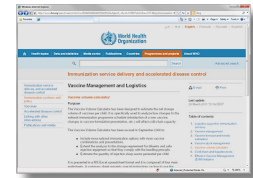
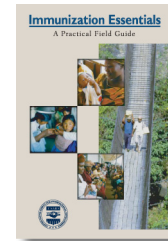
A good strategy for conserving resources is to arrange delivery of HPV vaccine to coincide with scheduled delivery of other vaccines from the national to the district level as well as from district to local health posts, provided that storage space is available. Funds must be available to transport supplies and health workers to immunization sites, since this may require hiring motorbikes, bicycles, or other vehicles and making sure that adequate staff are available.

HPV vaccines must be stored at +2 to +8 degrees Celsius and are very sensitive to temperatures below +2 degrees Celsius; once HPV vaccine freezes, it loses potency and should not be used. To determine whether vaccine has been frozen, see the WHO guide [Immunization in Practice Module 3: The Cold Chain](#). This manual also illustrates how to store vaccine in refrigerators to avoid freezing.

The vaccination session

Because HPV vaccination programs may be held at schools rather than health centers, some aspects of logistics on and before vaccination days may differ from standard procedures. For example, managers may need to contact teachers or administrators for lists of eligible girls, schools will need to provide rooms for vaccinations, and the schedule must be confirmed with the school administration. The Uganda publication, [Bridging Phase for the Delivery of Human Papillomavirus \(HPV\) Vaccine to Prevent Cervical Cancer: A Field Guide for Health Managers and Service Providers](#) includes details on the roles and responsibilities of staff on immunization days. It also includes instructions on how to administer an HPV injection and on monitoring AEFIs.

The WHO publication [Immunization in Practice Module 6: Holding an Immunization Session](#) is a manual for administering routine immunizations that is also useful for HPV vaccinations, with information such as how to prepare a vaccine carrier and how to set up a room for immunizations.

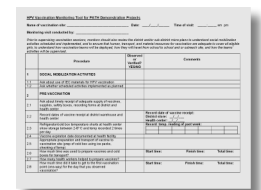




PATH/Jenny Winkler

A health worker immunizes a girl at a primary school in Piura, Peru.

[Sample vaccination cards and registers](#) are available from HPV vaccination programs in India, Uganda, and Vietnam. This resource also includes an example of an integrated register (i.e., a register with space for several types of vaccinations). A monitoring tool used in the four PATH country projects, [HPV Vaccination Monitoring Tool](#), contains a comprehensive checklist for HPV vaccination activities.



In some cases, HPV vaccination may become part of an existing outreach program to schools or communities. While this can be an efficient mode of intervention, staff responsibilities will increase, so managers need to make sure that the workload remains reasonable. As mentioned earlier, existing programs may be underfunded, so additional funds may be needed for personnel and transport costs and should be included as part of the total cost of delivering HPV vaccine. The timing of the three HPV doses may not coincide exactly with existing outreach program visits to schools, so additional planning may be needed.

HPV vaccinations can impact routine activities at health centers, whether staff leave clinics to vaccinate at schools or girls travel to clinics for vaccination. During vaccination sessions in the PATH projects, staff were not always able to attend to their other activities but were usually able to continue emergency services. To address these challenges, on immunization days, centers can mobilize additional staff from district or provincial offices or from civil society organizations. According to staff, the impact was minor, since HPV vaccination sessions were typically held just three times during the year.

When managers are planning the schedule for the three doses of vaccine, they will need to check current vaccine manufacturer recommendations, as requirements for the time between doses may change in the future.

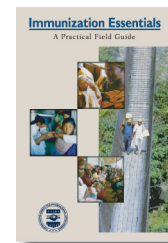
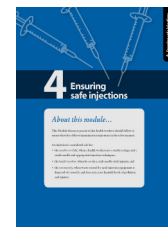
Immunization safety

A safe injection is one that does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in waste that is dangerous to the community. Unsafe injection practices can lead to transmission of bloodborne pathogens, with their associated burden of disease. For detailed information on all aspects of immunization safety, see the WHO manuals [Best Practices for Injections and Related Procedures Toolkit](#) and [Immunization in Practice Module 4: Ensuring Safe Injections](#).

HPV vaccines can be administered with autodisable syringes, a practice recommended for immunizations in general by WHO, the United Nations Children’s Fund (UNICEF), and UNFPA.

Waste management

Sharps waste can cause serious health and environmental problems, and leaving used syringes and needles in the open or on the ground puts the community at risk. Safe management of waste requires that injection equipment be discarded immediately after one use, so all used injection equipment should be placed in a safety box that is within arm’s reach for the vaccinator, immediately after use. The USAID guide [Immunization Essentials](#) presents information on waste management.



Training master trainers, health workers, and school personnel

Because HPV vaccines target a new population for most EPI programs (older girls and young female adolescents), developing an effective training curriculum for health workers and ensuring sufficient training time are essential to the success of the program. Further, since schools may be an important part of the strategy for delivering vaccines, teachers and school administrators also benefit from training.

Master trainers, health workers, and teachers need background information on HPV infection and cervical cancer so they can explain basic facts to families and community members. In the PATH projects, managers found that sensitizing all staff, including the heads of regional and local health systems and others not directly involved in vaccinations (such as midwives), motivated them and allowed them to serve as consistent and reliable sources of information to the community.

Personnel may also need to interact with journalists and the mass media, so they should receive training on how to communicate with these groups.

Background facts on cervical cancer and HPV vaccines can be found in publications such as *Outlook*, [Progress in Preventing Cervical Cancer: Updated Evidence on Vaccination and Screening](#), and [Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#). A fact book created in Uganda for health workers, [Cancer of the Cervix and its Prevention](#), provides an example that can be adapted for other programs.

Objectives of training

As is common with other vaccination training programs, a cascade approach is recommended, with national EPI staff training master trainers who then train health workers at lower levels. For a school-based program, the master trainers and trained health workers may also train and sensitize teachers, school administrators, and mobilizers. An important skill for the latter groups is the ability to use age-appropriate approaches for discussing cervical cancer with young adolescents.

It is a good idea to complete all training approximately four weeks before the first dose of vaccine will be given. As discussed above, HPV vaccination programs have some unique requirements for training, but most issues—such as how to safely administer an injection, handle waste, and manage AEFIs—will be familiar to health workers who give routine childhood vaccinations.

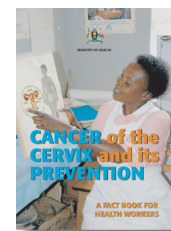
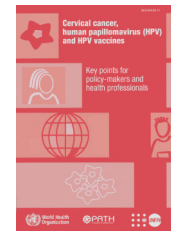
Health workers should be able to do the following:

- Describe key facts about HPV infection and cervical cancer.
- Communicate effectively with parents, girls, and other community members.
- Speak appropriately to any audience, including those without formal education.
- Administer HPV vaccine effectively and safely to the target population.
- Manage HPV vaccine supplies.
- Manage vaccination waste.
- Use the forms and processes for monitoring and supervision of HPV vaccination sessions.
- Identify, manage, and report AEFIs.

Audiences, materials, and methods

In planning the training of health workers and school personnel, vaccination program managers will want to identify or develop appropriate training and support materials, assess the time required, and secure suitable venues for training.

When conducting training for school-based vaccinations, separate sessions for health workers and for teachers seemed to work best. After initial separate

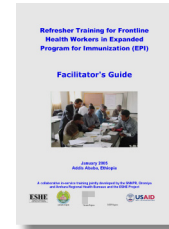


training, it was beneficial to hold a joint session aimed at coordinating roles for immunization days. Managers found that these sessions could also provide time for the combined group to do microplanning. Providing refresher training to health workers and teachers in a half-day session prior to the third dose of the vaccine was also helpful, since it comes six months after the first dose.

Interactive and participatory training methods encouraged learning, especially for skills-building. Practice sessions and role-playing helped to build skills on how health workers and teachers could communicate with parents and girls. In India, trainers found that activity-based sessions helped service providers experience what could happen in the field, for example, by role-playing an immunization session. This helped to build trainee confidence. (See: [Role-play: administering HPV vaccine safely and correctly](#).)

A USAID guide, [Refresher Training for Frontline Health Workers in Expanded Program for Immunization \(EPI\)](#), presents useful topics such as how to facilitate adult learning, health worker responsibilities for the cold chain, preparing and administering vaccines, monitoring coverage and quality of services, and communicating with caregivers.

An HPV vaccination guide, [Demonstration Project for the Introduction of HPV Vaccine in Uganda: Training of Health Managers and Service Providers: Facilitator's Guide](#), developed for the PATH demonstration project in Uganda, includes general information on conducting an HPV immunization session and collecting vaccination data, as well as sections on cervical cancer epidemiology; HPV vaccine dosing and packaging; and sensitization, mobilization, and information, education, and communication (IEC) materials for HPV vaccination. [Sample Training Agendas for Master Trainers](#) from PATH project countries are also available.



PATH/Robin Biellik

Health workers meet with community members as part of the HPV vaccination demonstration project in Can Tho province in southern Vietnam.

Community sensitization and mobilization

Successful community outreach requires consistent messages repeated in a wide variety of materials and reinforced by interpersonal contact as well as via mass and local media channels. Thus, it is crucial that managers carefully plan, implement, and adequately resource community mobilization efforts.

In sensitizing communities, trusted authorities and community members should be engaged to disseminate information and counteract rumors. Among

The PATH projects found that for general audiences, it was important to emphasize that the purpose of HPV vaccination is to prevent cervical cancer, rather than to explain that it prevents infection with HPV, a virus most people have never heard about.

these trusted individuals are teachers, who can play an important role in educating families, especially when HPV vaccinations are given at schools. Endorsement of the vaccination program by the government, indicating that the vaccine is safe and efficacious, is also critical for community acceptance. In some project countries, government officials were involved in formal launch ceremonies for the vaccination programs. This gave credibility to the programs and demonstrated that governments had made a political commitment to protect girls from cervical cancer.

Most families have had positive experiences with immunization programs, and this can be leveraged to build community support for HPV vaccination as well. The PATH projects found that for general audiences, it was important

to emphasize that the purpose of HPV vaccination is to prevent cervical cancer, rather than to explain that it prevents infection with HPV, a virus most people have never heard about. While the mode of HPV infection was clearly explained, informational messages did not over-emphasize that the vaccine prevents a sexually transmitted infection; rather, the main message always was cancer prevention. Communities in general were concerned about cancer, and they responded positively to anti-cancer messages.

It is important to tell people that there will not be an immediate impact on reducing cervical cancer rates, but that their daughters will have protection later in life against cancer caused by the HPV types that are in the vaccine. It is also important to emphasize the continuing need for screening and treatment of precancer among adult women, as well as among vaccinated girls when they are older.

Advocacy and communications programs should include plans to address possible reports of AEFIs due to the new vaccine, to deal with community concerns, and to respond promptly to rumors and other negative publicity. Managers may already have in place a crisis communications plan for situations related to other health interventions, but if not, HPV vaccination program planning provides a good opportunity to pull together a team experienced in communicating with stakeholders, the media, and the community.

The WHO manual [Immunization in Practice Module 8: Building Community Support for Immunization](#) offers many ideas for raising awareness about immunization issues and includes a chapter on dealing with misinformation and rumors. The publication [Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#) discusses the benefits and limitations of the vaccines and ways to address the concerns of different stakeholders.

Audiences, educational materials, and methods

Immunization managers will want to organize IEC activities to reach the target population of young adolescent girls and their families. This will require a different approach from that used for routine childhood vaccinations, and these efforts should include providing information and materials to schools. The broader community also should be engaged; community leaders, village elders, town council members, women’s groups, youth organizations, and religious leaders are some of the groups that can influence people to support HPV vaccination. If vaccinations will be carried out at schools, teachers and administrators must be informed of the benefits of vaccination, committed to the program, and involved in planning the vaccination sessions.

When communicating with families, community members, and community leaders, it is important to identify key messages and to decide on appropriate types of materials for different audiences. For parents, extended families, and the general community, leaflets, posters, radio messages, informational meetings,



Posters from the PATH HPV demonstration projects in Peru (left) and India (right).

public announcements, and articles in the local media all work well. Providing some details to parents about the testing of the vaccines in clinical trials and their excellent safety records will encourage them to make sure that their daughters receive the vaccine. For community leaders, fact books about cervical cancer and HPV vaccines are useful in helping them to respond to questions from their constituents.

While mass media and printed materials can be very useful, it is important to remember that interpersonal communication is the most common, and often the most effective, communication channel, particularly in addressing community needs, doubts, and concerns.

Members of medical societies, local health experts, and practicing physicians play an important role in informing families about health matters, so it is also important to engage these audiences. Messages to these groups may be presented in training manuals or meetings, and can consist of detailed information on HPV infection, the epidemiology of cervical cancer, current practice in screening and treatment for cervical cancer, and HPV vaccination.

School administrators will need facts about vaccination logistics—for example, about the three-dose schedule, which they will need to add to the school calendar. When they understand and accept basic messages about cervical cancer and its prevention, they often become advocates for the vaccinations at their schools. Teachers will need to learn age-appropriate approaches for discussing cervical cancer with young adolescents, so they should receive leaflets or brochures for this purpose.

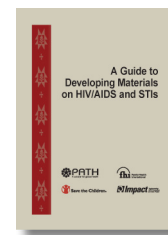
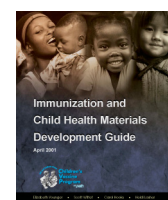
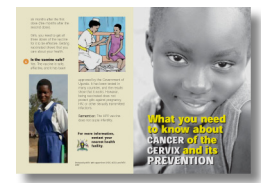
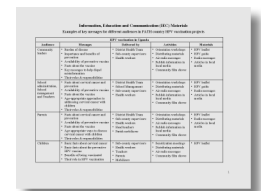
Because the mass media can have a major role in promoting either a positive or negative view of the vaccine, getting accurate, easy-to-understand messages to journalists is a good idea before beginning a program. One-to-one outreach to journalists or group discussions with media personnel may be helpful. Cervical cancer “press kits” can be distributed at these sessions.

For examples of key messages and types of materials for specific audiences from some of the PATH project countries, see [examples of key messages](#). Sample [community education materials](#) are also available, such as leaflets, posters, and fact sheets. Materials should be ready for dissemination in the community at least one month before vaccination sessions, and should be in the local language.

PATH has produced two other resources on creating communications materials and strategies that can be adapted for HPV vaccination programs: the [Immunization and Child Health Materials Development Guide](#) and [A Guide to Developing Materials on HIV/AIDS and STIs](#).

Frequency and intensity of communication

Some types of communication will be carried out only once, such as giving leaflets to girls on their first vaccination day, while others will be repeated a number of times, such as airing radio spots that promote cervical cancer



awareness, or announcing HPV vaccination sessions prior to each dose. After the first year of vaccinations, when the vaccine is better known, the intensity of education efforts can decline. However, each new location added in a scaling-up process will need intensive community education at least for the first year.

Table 2 gives suggestions for the timing of messages about vaccination sessions from the HPV vaccination project in Vietnam.

Table 2. Scheduling HPV vaccination messages in Vietnam.

TIMING	ACTIVITY	FREQUENCY
At least two weeks prior to vaccinations	Billboards/posters placed at the district center and in each community	Posters can be put up when HPV vaccinations are starting, and should remain until the third dose is complete
	Messages broadcast on the district radio station	Messages should be broadcast on the district radio station for two to three weeks prior to each dose
	Messages broadcast on the community radio station	Messages should be broadcast on the local radio station at least two weeks before vaccination, and two or three times per week for two weeks in each community prior to each dose
At least one week prior to vaccinations	Parent meetings held at the school or in the community	One parent meeting should be held in each community at least one week before first dose
	Girls' meetings or information sessions held at the school or in the community	One group discussion or meeting can be held in each school or health facility at least one week before first dose
	Messages broadcast on the radio	Messages should be broadcast on the radio twice a day during the week before each dose (local, district, and national radio stations can be utilized)
	Banners and posters placed at the school and the health facility	Banners and posters should be put up at identified places in each school or health facility at least one week before each dose
Day of vaccinations	Provincial or regional meeting held to launch vaccination	A provincial or regional launch meeting can be held on the day of vaccination, attended by provincial/regional and district staff
	District meeting held to launch vaccination	A district launch meeting can be held at the district health center, district education department, district authority, or district IEC center, attended by heads of community health centers
	Leaflets and counseling provided at vaccination sites on vaccination and active follow-up days (finishing missed doses)	Girls and parents should be counseled on vaccination and active follow-up days (for each dose)
	Current information on vaccination progress broadcast on the community loudspeaker	Updated information should be broadcast twice in each community (on and after vaccination day) at the start of a new HPV vaccination program

High-level stakeholders and other partners

A stakeholder for an HPV vaccination program is anyone who has an interest in the program, from international organizations to district health departments to local civil society groups. All key stakeholders need to be informed and educated about the HPV vaccination program so they will become engaged and ensure the success of the program.

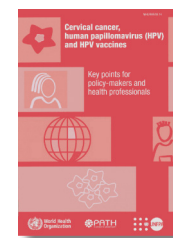
Examples of stakeholders in HPV vaccination programs are the following:

- Global level
 - WHO and regional divisions (e.g., Pan American Health Organization)
 - GAVI Alliance
 - Industry (vaccine manufacturers)
 - International nongovernmental organizations (NGOs)
- National level
 - Ministry of Health
 - National EPI coordinator
 - National Cancer Institute director
 - Department of Reproductive Health
 - Ministry of Education
 - National medical and nursing associations
 - National NGOs
 - Scientific experts and university researchers
- Regional/local levels
 - Cancer treatment center personnel
 - State or district health departments
 - Civil society organizations
 - Women's/mothers' groups
 - Youth groups
 - Child health organizations

In some settings, delivery of HPV vaccines may provide opportunities for new partnerships and innovative programming, such as “bundling” adolescent health education and services with an HPV vaccination program. According to the publication [Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#), national immunization programs may wish to consider coordinating or partnering with sexual and reproductive health services, as well as adolescent health, cancer control, and HIV/AIDS programs.

Close working links might also be developed with education services, family support groups, and women's groups; these include civil society organizations, community-based health and welfare initiatives, and the private sector.

While it is essential for HPV immunization managers to consult and work with individual stakeholders for the success of a vaccination program, it is also



important for the stakeholders to collaborate with each other. In Vietnam, for example, program administrators encouraged discussion among community-based groups such as the Women’s Union, Youth Union, teachers, and People’s Health Care Committees.

Table 3 presents an analysis of stakeholder roles and responsibilities from the HPV vaccination program in Uganda, as an example of how to engage people at all levels.

Table 3. Roles and responsibilities of HPV vaccination program stakeholders, Uganda experience.

STAKEHOLDERS	ROLES AND RESPONSIBILITIES
District and municipality/town council leaders	<ul style="list-style-type: none"> • Advocate for and promote HPV vaccination in the district. • Mobilize and allocate resources for cervical cancer prevention and HPV vaccination. • Provide information about cervical cancer screening options. • Emphasize the importance of completing all three doses. • Mobilize all eligible girls in the target population for HPV vaccination.
District health management teams	<ul style="list-style-type: none"> • Plan, budget, and implement the HPV vaccination demonstration project. • Implement the HPV vaccination communications strategy (including adaptation of communications materials). • Disseminate messages and materials on cervical cancer prevention. • Monitor and supervise the vaccination program. • Emphasize the importance of completing all three doses. • Mobilize all eligible girls in the target population for HPV vaccination. • Provide information about cervical cancer screening options.
Health workers in health facilities	<ul style="list-style-type: none"> • Provide information and distribute materials about the HPV vaccine and about cervical cancer prevention programs. • Vaccinate all eligible girls and provide counseling support. • Collaborate with schools in their catchment areas in order to mobilize eligible girls for vaccination. • Emphasize the importance of completing all three doses. • Mobilize all eligible girls in the target population for HPV vaccination. • Provide information about cervical cancer screening options.
Religious/cultural/civic/village/parish leaders	<ul style="list-style-type: none"> • Advocate for and promote HPV vaccination in the community. • Educate communities about the importance of preventing cervical cancer using HPV vaccine. • Mobilize parents/guardians to take their eligible daughters to receive HPV vaccination and complete the three doses. • Emphasize the importance of completing all three doses. • Mobilize all eligible girls in the target population for HPV vaccination. • Provide information about cervical cancer screening options.

Monitoring and supervision

Monitoring

A good microplan includes procedures for monitoring and supervision, to ensure that regular visits are made to immunization sites to quickly identify and correct problems. Work plan and monitoring forms for routine immunizations in the WHO publication [Microplanning for Immunization Service Delivery Using the Reaching Every District \(RED\) Strategy](#) can be adapted for HPV vaccination programs.

[Vaccine Introduction Guidelines](#) from WHO includes an annex entitled “Checklist for post-introduction evaluation,” which offers suggestions for reviewing records and forms, vaccination coverage, and vaccine wastage through routine reporting systems. It also provides advice for supervisors when they make field visits, such as monitoring the use of syringe safety boxes, making sure that safe injection practices are followed, and assessing community acceptance of vaccination.

WHO recommends a more formalized evaluation of new vaccine introduction programs and recently published a tool for this purpose, the [New Vaccine Post-Introduction Evaluation \(PIE\) Tool](#). Its purpose is to assist immunization managers in countries that have introduced a new vaccine by providing a systematic method for evaluating the implementation of the introduction and its impact on the existing immunization system in the country.

Another source of information and sample forms for monitoring is [Immunization in Practice Module 7: Monitoring and Using Your Data](#) from WHO.

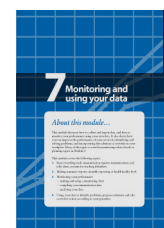
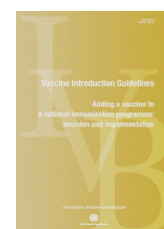
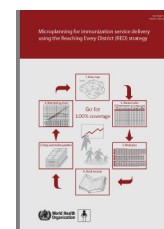
Supportive supervision

A comprehensive monitoring and supportive supervision plan should be developed (ideally during training and microplanning activities) and implemented under the direction of the district health authorities. Monitoring

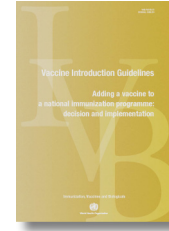
A cornerstone of supportive supervision is working with health staff to establish goals, monitor performance, identify and correct problems, and proactively improve the quality of service.

and supportive supervision strengthens the capacities of health workers and improves performance; visits can be used to provide feedback, update health staff on HPV and other vaccinations, enhance motivation, and identify training needs.

According to the [Guidelines for Implementing Supportive Supervision](#) (developed by PATH with information from WHO, UNICEF, the Pan American Health Organization, and USAID), “A cornerstone of supportive supervision is working with health staff to establish goals,



monitor performance, identify and correct problems, and proactively improve the quality of service. Together, the supervisor and health workers identify and address weaknesses on the spot, thus preventing poor practices from becoming routine. Supervisory visits are also an opportunity to recognize good practices and help health workers to maintain their high level of performance.” Managers can refer to this document, national EPI guidelines, and WHO’s [Vaccine Introduction Guidelines](#) to develop effective supervisory programs.

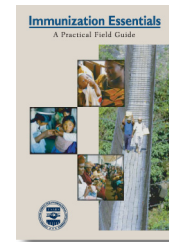


Records, data collection, and reports

When HPV immunization is added to a country program, the eventual goal is to integrate the vaccination records into existing EPI program records at all levels, from local health facilities to the national level. This integration may take time because of the need to update forms, so in the meantime, it may be necessary to keep separate records. The reporting systems should be designed to minimize health worker burden and confusion.



Good basic recording tools are available in WHO guides such as [Immunization in Practice Module 7: Monitoring and Using Your Data](#), as well as in country EPI manuals. Another excellent resource is USAID’s [Immunization Essentials](#), which includes information on using forms such as patient registers, maps, vaccination cards, tickler files, tally sheets, and immunization monitoring charts.



After immunization data are collected on various forms, they should be consolidated into summaries for transmission from the health facility to the district and higher levels. When data are summarized, the information can be used not only for official recordkeeping purposes, but also for identifying problems and taking corrective actions.



Examples of forms from PATH HPV vaccine demonstration project countries are available in [sample vaccination cards and registers](#), while Annex 3 in the [Bridging Phase for the Delivery of Human Papillomavirus \(HPV\) Vaccine to Prevent Cervical Cancer: A Field Guide for Health Managers and Service Providers](#) includes examples of health unit, sub-county, and district monthly vaccination summary sheets for the three doses of HPV vaccine.



Adverse events following immunization

There are no live or attenuated biological components in HPV vaccines, thus reducing the potential for serious adverse events. It is not possible for anyone to become infected with HPV because of vaccination.

AEFIs are events or reactions that are observed sometime after immunization—they may occur immediately, or weeks or months later. Some of these may



PATH/Robin Biellik

A health worker fills in a vaccination logbook with information from immunization cards at Kyarukumba Primary School in Ibanda, Uganda.

be caused by the vaccine or by error in administering the vaccine, while others may have causes that are not vaccine-related but occurred coincidentally following vaccination.

The WHO publication [Immunization Safety Surveillance](#) presents a review of the five categories of AEFIs and strategies that health workers can employ to prevent or manage them. The manual includes definitions of AEFIs that must be reported and their treatments, with a separate annex that deals with recognizing and treating anaphylaxis. Keeping an emergency kit in the

Managing adverse events promptly and effectively is critical to maintaining public confidence in immunization.

vaccination area will ensure that health workers can respond to an AEFI; the WHO manual reminds managers that emergency kits must contain adrenalin in case of an anaphylactic reaction. Health workers who participate in HPV vaccination and emergency teams at district hospitals should be trained on monitoring and management of AEFIs.

The WHO document [Adverse Events Following Immunization \(AEFI\): Causality Assessment](#) is also available, and country EPI materials offer further information. A general [AEFI reporting form](#) can be adapted for HPV vaccinations.

As noted in the section on basic information about cervical cancer and HPV vaccines, reports from clinical trials for the two currently available HPV vaccines showed that the most common side effect was discomfort at the injection site



(pain, swelling), and that other common side effects were headache, fever, nausea, dizziness, vomiting, and fainting. Most side effects were of short duration (from several hours up to a few days).

No deaths that occurred during the clinical trials or that were reported after licensing were shown to be causally linked to HPV vaccines. For summaries of adverse events reported during the clinical trials of the HPV vaccines, see the vaccine package inserts for [Cervarix®](#) and for [Gardasil®](#).

Despite the excellent safety record of the HPV vaccines to date, people are often suspicious of new vaccines, and reports of adverse events are more common with these. Identifying and managing adverse events promptly and effectively is critical to maintaining public confidence in immunization, so it is important to include this in training for health workers and education for community leaders.



Conclusion

HPV vaccines can help to reduce the worldwide burden of cervical cancer, which is carried disproportionately by women in low-resource countries. In order to do this most effectively, the vaccines should be given to young adolescent girls before they are exposed to HPV through sexual activity. Reaching this population poses challenges—in educating communities, training health workers, finding the most efficient and cost-effective strategies for delivering vaccines, and attaining high coverage.

In the PATH demonstration project countries, establishing vaccination programs at schools was effective in all settings, and early coordination between health and education sectors at district as well as local levels was crucial to success. Clinic-based services also yielded high vaccine coverage. In some countries, it may work best to offer vaccination at different venues for different situations, for example, using schools in urban settings (in which schools are near the clinics where vaccinators are based and therefore relatively inexpensive to visit) and using clinic-based services in rural areas in which clinics are far from schools.

Evaluation of PATH project results showed that acceptability of HPV vaccination was high and that the desire of families to avoid cancer and their generally positive view of vaccination were good building blocks for successful programs. Introducing HPV vaccination can stimulate improvements in the infrastructure of health programs, from the cold chain to staffing to recordkeeping. New programs need not cause major disruption to the health and education sectors of communities when these groups work together to define roles and responsibilities and to develop practical strategies.

Resources

All resources can be accessed online at www.rho.org/HPV-vaccine-implementation.htm.

Print resources



[Adverse Events Following Immunization \(AEFI\): Causality Assessment](#)

World Health Organization, 2005



[Cervical Cancer, Human Papillomavirus \(HPV\) and HPV Vaccines: Key Points for Policy-Makers and Health Professionals](#)

World Health Organization, 2007



[AEFI Reporting Form](#)

PATH, 2008



[Community Education Materials](#)

PATH, 2008-2009



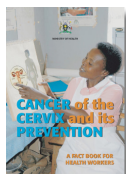
[Bridging Phase for the Delivery of Human Papillomavirus \(HPV\) Vaccine to Prevent Cervical Cancer: A Field Guide for Health Managers and Service Providers](#)

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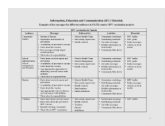
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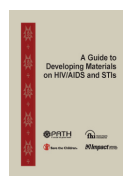
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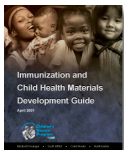
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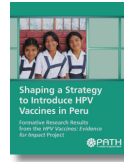
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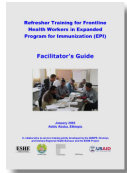
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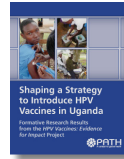
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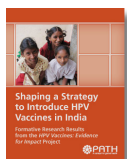
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