



# Shaping a Strategy to Introduce HPV Vaccines in Uganda

Formative Research Results  
from the *HPV Vaccines: Evidence  
for Impact* Project

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# Acronyms

AIDS	Acquired immunodeficiency syndrome
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
HSSP II	Health Sector Strategic Plan II
IDP	Internally displaced person
RH	Reproductive health
TT	Tetanus toxoid
UNEPI	Uganda National Expanded Program on Immunization

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# Executive summary

There is a new tool available in the global fight against what many call a “silent killer.” Cervical cancer has a devastating effect on women’s lives worldwide, killing about 270,000 women annually—the vast majority in developing countries—often because it goes undiagnosed for many years.<sup>1,2</sup> Vaccines have recently been developed to prevent infection with the human papillomavirus (HPV), the primary cause of cervical cancer.

Effort is required to prepare health systems and communities to accept and embrace any new health technology. Through our *HPV Vaccines: Evidence for Impact* project, PATH, in close collaboration with ministries of health and other partners, is piloting vaccine introduction in four countries: India, Peru, Uganda, and Vietnam. Together, we are generating evidence to help policy makers and planners in the developing world make informed decisions regarding vaccine introduction and financing. When combined with a comprehensive approach that includes screening and precancer treatment, evidence-based HPV vaccination programs could reduce developing-country cervical cancer deaths to the low levels observed in many industrialized countries.<sup>3,4</sup>

This overview summarizes results from formative research in Uganda regarding the health systems and policy context that will affect HPV vaccine introduction, as well as beliefs, values, attitudes, knowledge, and behaviors related to cervical cancer, HPV, and vaccination.

The formative research was designed to guide development of a vaccine delivery strategy, a communications strategy (for outreach to communities), and an advocacy strategy (for outreach to policymakers). As a next step, these strategies are being implemented and evaluated through a demonstration project in each country. The findings from the demonstration projects—anticipated in 2010 and 2011—can then serve as an evidence base for governments deciding when and how to incorporate HPV vaccination into a comprehensive cervical cancer prevention program.

Overall, PATH’s *HPV Vaccines: Evidence for Impact* project in Uganda found that people in diverse contexts are supportive of action to address cervical cancer, in spite of concerns and obstacles that will need to be addressed. The strategies tested in Uganda’s demonstration project will include the following elements, developed from the results of the formative research.

## Uganda’s HPV vaccine delivery strategy: key elements

- Explore two possible strategies for introduction and delivery of the HPV vaccine:
  - Offer vaccine as part of Child Days Plus (a semiannual event in Uganda designed to reach all children with a package of health services).
  - Vaccinate girls at school through a “stand-alone” strategy, with special efforts to reach out-of-school girls.
- Select targeting strategy for girls (by age or by grade in school) and generate accurate target population estimates to ensure adequate quantities of the vaccines and other supplies.
- Ensure systematic and early communication within the Ministry of Health and among it and the districts, the education sector, and key financial planning bodies.

- Address gaps in cold chain and logistics capacity, in part by involving the national immunization unit at every stage of assessment and planning.
- Monitor HPV vaccination coverage as part of Uganda’s current system for immunization tracking, and respond promptly and appropriately to adverse events following vaccination.

### **Uganda’s HPV vaccine communications strategy: key elements**

- Disseminate accurate information to address currently low levels of knowledge about cervical cancer, HPV, and the HPV vaccine, using local terms and languages.
- Develop messages that build on positive perceptions of vaccination and recent successes in reducing the burden of common childhood diseases.
- Raise awareness about vaccination safety measures, including training health workers to administer the vaccine and manage side effects at schools and other sites.
- Promote understanding that the HPV vaccine has been proven safe and effective in extensive, international clinical trials and is already being provided in many countries.
- Publicize endorsement of HPV vaccination by the Uganda Ministry of Health, health workers, education officials, and other national, district, and community leaders.
- Reach out to “decision-makers” at all levels, as everyone from children to national political leaders may play a role in deciding whether a child is vaccinated.

### **Uganda’s HPV vaccine advocacy strategy: key elements**

- Develop policy guidelines that set national standards for HPV vaccination, and integrate these into an existing policy.
- Partner with the Ministry of Health to generate momentum and leadership from other key ministries and stakeholders at the national level.
- Engage and mobilize district officials and others responsible for implementation.
- Make information available to policymakers—including through the media—on the seriousness of cervical cancer, the vaccine’s properties, usefulness, cost, and potential economic benefits.
- Explain how HPV vaccination is consistent with Uganda’s health priorities.

This research was conducted by the Child Health and Development Centre (CHDC), Faculty of Medicine, Makerere University, in collaboration with the Association of Obstetricians and Gynecologists of Uganda (AOGU), with technical and financial support from PATH.

# Introduction

“Given what you have told me about cervical cancer, I think it is a good thing that a vaccine has been developed to prevent it.\* However, whoever is planning to introduce it to the public has to be careful...There is a need for a lot of sensitization before the new vaccine is announced or even introduced, so that people are already aware of it.”

—Uganda Ministry of Health official

There is a new tool available in the global fight against what many call a “silent killer.” Vaccines have recently been developed to prevent infection with the human papillomavirus (HPV), the primary cause of cervical cancer—a disease that can become life-threatening before women even know they have it.

Globally, the HPV vaccine is considered good news for women, their families, and communities. PATH and our partners in Uganda found that people in diverse contexts are supportive of action to address cervical cancer—but that there are also questions and concerns about the HPV vaccine and potential barriers to access. Effort is required to prepare health systems and communities to accept and embrace any new health technology. Settings with weak health services and scarce resources—and where cervical cancer burdens are highest—face especially significant challenges.

That is why PATH initiated the *HPV Vaccines: Evidence for Impact* project in 2006, funded by the Bill & Melinda Gates Foundation.<sup>5</sup> By piloting vaccine introduction in four developing countries—India, Peru, Uganda, and Vietnam—the project will generate evidence to help policymakers and planners make informed decisions regarding regional and national vaccine introduction efforts and international financing plans. When combined with a comprehensive approach that includes screening and precancer treatment, evidence-based HPV vaccine programs could reduce developing country cervical cancer deaths to the very low levels currently observed in many industrialized countries.<sup>3,4</sup>

The *HPV Vaccines: Evidence for Impact* project is not a clinical trial of a new vaccine. The vaccines being used are already licensed in over 100 countries, including Uganda. Instead, the project is meant to assess and document the best possible approaches to reaching young adolescent girls with the HPV vaccine in low-resource settings.

This report shares findings from formative research in Uganda, including information on the health system and policy context that will affect HPV vaccine introduction, as well as the beliefs, values, attitudes, knowledge, and behaviors related to HPV, cervical cancer, and vaccination. The research was conducted by the Child Health and Development Centre (CHDC), Makerere University, Kampala, in collaboration with the Association of Obstetricians and Gynecologists of Uganda (AOGU), with PATH’s technical and financial support.

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\* We refer to the vaccine throughout this report as the HPV vaccine for the purpose of scientific accuracy. The strategy in Uganda and elsewhere, however, has been to refer to it as a “cervical cancer vaccine,” in order to emphasize the end goal of preventing cervical cancer.



## Cervical cancer and HPV

Cervical cancer has a devastating effect on women's lives worldwide—approximately one-half million women are newly affected each year. Of the estimated 270,000 annual cervical cancer deaths, 85 percent occur in developing countries.<sup>1,2</sup> In developed countries, screening programs (traditionally using Pap smears) are in place to spot the signs of precancer and treat them early, saving countless lives. In developing countries, however, many women cannot access screening services or do not receive necessary treatment for precancer that is identified.<sup>6,7</sup> Cervical cancer often kills women at the peak of their productive lives, meaning many years of potential life are lost.<sup>8</sup> In addition, HPV is very common: most people acquire HPV at some point in their lives, although only a small percentage of women develop cervical cancer as result.

Two vaccines—Merck's Gardasil® and GlaxoSmithKline's Cervarix™—have now been proven at least 90 percent effective in safely preventing infection with HPV types 16 and 18, which account for about 70 percent of cervical cancer cases.<sup>9-14</sup>

Because the vaccines are this effective only in girls and women with no history of HPV, and peak incidence occurs soon after the onset of sexual activity, the vaccine should be administered before sexual initiation—meaning young adolescent girls are the appropriate target group for HPV vaccination in most contexts. The potential benefit of vaccinating boys is still under investigation.<sup>15</sup>

The *HPV Vaccines: Evidence for Impact* project aims to address several of the particular challenges likely to face HPV vaccination programs. Cervical cancer, while a serious problem, is not well-known or understood in many communities. Additionally, immunization programs have traditionally been designed to reach infants and very young children. Reaching young adolescent girls, especially with information and services to prevent a sexually transmitted infection, raises a host of social and cultural issues and health systems challenges. Finally, given that cervical cancer can take decades to develop, the benefits of HPV vaccination now will not be fully apparent until many years in the future.

### Additional information on HPV and cervical cancer

RHO Cervical Cancer  
[www.rho.org](http://www.rho.org)

Alliance for Cervical Cancer Prevention  
[www.alliance-cxca.org](http://www.alliance-cxca.org)

Cervical Cancer Action  
[www.cervicalcanceraction.org](http://www.cervicalcanceraction.org)

International Agency for Research on Cancer Screening Group  
<http://screening.iarc.fr>

PATH cervical cancer prevention  
[www.path.org/cervicalcancer](http://www.path.org/cervicalcancer)

World Health Organization—cancers of the reproductive system  
[www.who.int/reproductive-health/publications/cancers.html](http://www.who.int/reproductive-health/publications/cancers.html)

World Health Organization & Institut Català d'Oncologia Information Centre on HPV and Cervical Cancer  
[www.who.int/hpvcentre/en/](http://www.who.int/hpvcentre/en/)

## Formative research and public-health planning

Formative research seeks to gather information on a target audience's beliefs, values, attitudes, knowledge, and behaviors related to a health problem of interest, as well as the context that influences and is influenced by these individual-level factors.<sup>16</sup> This exploration is an important part of planning a new public-health intervention, such as a vaccine introduction program; it provides a solid evidence base for designing a meaningful and grounded implementation approach.

In this case, PATH and our partners used formative research to explore two primary questions:

- What important factors are most likely to result in a child receiving the HPV vaccine?
- What important factors are most likely to foster institutional decisions that result in successful vaccine delivery?

Ultimately, the answers to these questions helped to develop the following outcomes in each of the four countries where the project is taking place:

- A vaccine delivery strategy.
- A communications strategy (focused on outreach to communities).
- An advocacy strategy (focused on outreach to policymakers and key stakeholders).

After the formative research is completed, the outcomes will be implemented and evaluated through a demonstration project in each country. Finally, PATH and its partners will disseminate the findings from the demonstration projects—anticipated in 2010 and 2011—to serve as an evidence base for governments that wish to develop or scale up cervical cancer prevention programs.

## Uganda: context

Uganda, located in East Africa, hosts a predominantly rural population. While English is the official language, many other local languages are also spoken.

The nearly 32 million men, women, and children in Uganda face significant threats to their health and well-being, including an AIDS epidemic and deepening poverty. Health services, and reproductive and sexual health services in particular, are insufficient to meet the needs of the population. For example, while basic requirements for cervical cancer screening and diagnosis are available in all public hospitals, screening only occurs haphazardly due to shortages in equipment and trained personnel.<sup>17,18</sup>

Given that the HPV vaccine is primarily intended for young adolescent girls, it is worth noting that half of Uganda's population is under the age of 15.<sup>19</sup> The median age at first intercourse for girls is approximately 17 years,<sup>20</sup> meaning there are many who initiate sex at even younger ages.

It is estimated that every year, approximately 40 women in every 100,000 develop cervical cancer in Uganda.<sup>21</sup> However, very little data are available regarding burden of cervical cancer overall, and the accuracy of available data is uncertain due to collection and reporting limitations in health facilities. That said, available data show that cervical



A woman and her baby in Namukanaga, Uganda.

cancer is the most common malignancy among women in Mbarara district, is the second most common in West Nile district,<sup>22</sup> and accounts for over 80 percent of female cancers in Kyaddondo County, Kampala district, where a well-established population-based cancer registry exists.

Statistics also confirm that cervical cancer is deadly for women in Uganda. According to Kyaddondo data, about half of women with cervical cancer die within three years of diagnosis,<sup>21</sup> and more than 80 percent within five years.<sup>23</sup> A records review demonstrated that 72 percent of patients diagnosed at the national referral hospital in Kampala present with late-stage disease, when it is difficult, or too late, to treat the disease effectively.

Uganda is comparable to many other African countries in terms of infrastructure and health profile, so lessons learned from Uganda may be applicable to other countries in the region with similar cultural, economic, and health contexts.

### Formative research methodology

The research team explored three principal areas related to introducing a new vaccine: vaccine delivery, social and cultural issues, and policy and advocacy.

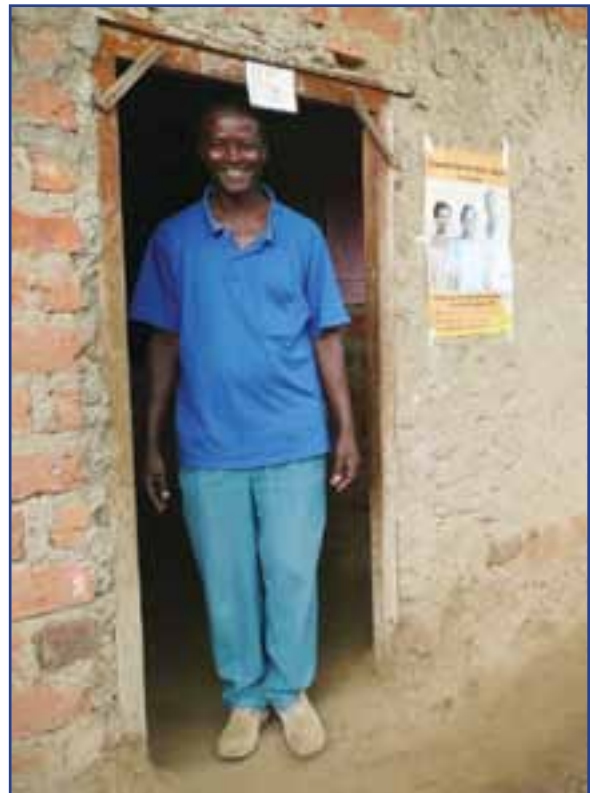
Researchers used a variety of techniques to gather information, relying particularly on focus group discussions and in-depth interviews with key informants, as well as literature and data reviews, cold chain observation, and feedback from a workshop on vaccine delivery issues. The study populations for the focus groups and interviews included:

- Girls (in and out of school) and boys (in school) aged 10 to 12.
- Parents and guardians.
- Teachers and school administrators.
- Community and religious leaders.
- Health providers and administrators.
- District and national political leaders and policymakers.

Most respondents were purposively selected based on the perception that they could influence girls' access to HPV vaccines and would enhance the diversity of experiences and knowledge reflected in the data. Only girls and boys\* in school were randomly selected.

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\* Boys were interviewed for two reasons: They may influence girls' behavior, and they may someday make decisions around HPV vaccination as parents.



The principal at Bright Model Primary School in Ibanda district, Uganda.

PATH/Robin Biellik

Before the research formally began, an exploratory study was conducted in order to identify acceptable terms and phrases that were age- and gender-appropriate, and socially and culturally acceptable. During the study, focus groups and interviews (conducted in several different languages) were tape recorded, and transcripts of the tapes were used as the primary data. The transcripts were translated into English for analysis.

The study, carried out in 2007, focused on five districts: Gulu in the north, Soroti in the east, Mbarara in the west, Masaka in the central region, and Kampala (see map). The districts were selected to include the four major regions of the country and the capital, as well as to achieve diversity in sociocultural and vaccination experiences, language, and other factors. The demonstration projects are being implemented in two different districts: Ibanda and Nakasongola.

Permission for the research was secured from relevant national and international ethical review boards. Consent for the children's participation in the study was acquired from parents/guardians and from children directly.



# Vaccine delivery strategy

In order to determine the most promising approach to delivering HPV vaccine in Uganda, the researchers talked with members of various groups regarding sites and strategies for vaccination. Officials and health-service providers also provided information on health-system capacity, infrastructure, and financing; potential obstacles; and potential impact on services and systems of introducing the HPV vaccine.

## How to reach 10- to 12-year-old Ugandan girls with the HPV vaccine

As in many countries, there are no health services in Uganda which target 10- to 12-year-old children specifically. In other words, there was no “perfect fit” in terms of adding HPV vaccination to pre-existing services for this age group.

National-level policymakers in particular strongly supported the idea of integrating the HPV vaccine into the government’s Child Days Plus program, which targets all children aged 14 and younger. During April and October each year, Child Days Plus delivers an integrated package of preventative services (e.g., catch-up immunizations, vitamin A supplementation, and deworming medicine) through schools, health units, and other outreach centers including churches, community centers, and local council offices. A 2006 review of Child Days Plus found that the program covered a wide population of children in



Primary school pupils in Ibanda.

Uganda, both in and out of school.<sup>24</sup> This strategy was endorsed by several individuals interviewed: as one district health officer in Masaka said, “I would prefer the Child Days Plus strategy because it is cheaper, less disruptive, and is held twice a year...introducing the cervical cancer vaccine in Child Days would make it a more comprehensive approach.”

Most technical and administrative health staff at the district level, some parents and teachers, and a few national policymakers were particularly supportive of delivering the vaccine separately from Child Days Plus (a “stand-alone” strategy). As one senior health planner put it, “Using the vitamin A experience [as an example] may be good...it was initially implemented separately and only handed over to [the immunization program] after it took off and stabilized.” In the end, the project team decided to compare the two strategies in terms of coverage and cost during the demonstration project. Benefits and challenges mentioned are summarized on the next page.



## How should the HPV vaccine be delivered?

### Strategy: Integrating HPV vaccination into Child Days Plus activities

#### **Benefits**

- Child Days Plus is well-established, accepted by the community, and proven successful.
- Mechanisms are in place for reaching out-of-school girls.
- There are existing resources for implementation.
- Roles and responsibilities are already well-known and understood.

#### **Challenges**

- More resources will be required to include HPV vaccination in the package of services.
- Community mobilization for Child Days Plus has previously increased demand for services beyond capacity to provide them.
- Adding the HPV vaccine could compromise the overall quality of services, especially as health workers are already overburdened by Child Days Plus.
- The HPV vaccine schedule (three doses in six months) differs from the Child Days Plus schedule (twice a year).

### Strategy: Delivering the HPV vaccine on its own (a “stand-alone” strategy)

#### **Benefits**

- Community mobilization and education will be easier if the vaccine has its own program.
- An independent budget makes a program easier and quicker to implement.
- Staff can focus attention and resources exclusively on HPV vaccination.
- A strong program will be easier to integrate into other health programs later, once it is well-established and accepted by the community.
- Any resistance to the HPV vaccine will not negatively impact other programs.

#### **Challenges**

- Costs will be greater than with a combined program, given a lack of potential cost-saving synergies.
- Ensuring the sustainability of a stand-alone program will be more difficult.

Some respondents, including many at the Uganda National Expanded Program on Immunization (UNEPI), suggested a third strategy: adding the HPV vaccine to the school-based Tetanus Toxoid (TT) Vaccine Program. Most, however, felt this was not feasible because the target group for the HPV vaccine is somewhat younger than that for the TT vaccine, making it an imperfect match. As a result, more work and resources, rather than less, would likely be required. In addition, the TT program is still quite new and is working to build acceptability and support. Either vaccination program could be compromised if integrated too early in their development.

## Where to reach 10- to 12-year-old girls with the HPV vaccine

In order to narrow options for where to test a stand-alone strategy, the advantages and disadvantages of different sites for vaccination were also considered. The majority of participants identified schools as the best place to conduct an HPV vaccination program. Girls, for example,

highlighted that they wouldn't have to walk as far to be vaccinated and would have teacher and peer support. One student noted, "There are other children also being vaccinated, so I am not afraid." Teachers echoed the idea that girls would be more comfortable in the familiar school setting. On the other hand, teachers as well as education officials expressed concern that health workers would litter while in school compounds as they had during previous health activities, and were displeased that health workers are paid for their involvement in vaccination outreach while teachers are not. Benefits and challenges mentioned are summarized in the box to the right.

Reaching girls who do not attend school is a particular challenge in Uganda. Even though school attendance has increased in recent years thanks to Universal Primary Education policies, it is still estimated that about 20 percent of children do not attend primary school, and that attendance rates are lower in the higher grades.<sup>25</sup> Community-based outreach sites, including health centers, drama clubs, and church groups, were noted as options for reaching this population, but were not perceived as feasible for all vaccinations. A school-based strategy, however, can be supplemented by targeted community-based outreach, including outreach to employers of out-of-school girls. Extra effort to ensure that private schools are included in the immunization program will also be required.

Another question raised in relation to a school-based strategy, and explored primarily with health and education officials, was whether girls will be vaccinated by age or by grade. Given that girls in school are grouped by grade, vaccinating by age was seen as more challenging logistically. Concern was also expressed that many parents do not know the exact age of their children, or might lie about their children's age so that they can receive the free HPV vaccine. On the other hand, vaccinating by grade has its own challenges. There is a fairly wide age range in grades, especially in rural areas. Some children

## Benefits and challenges of vaccinating in schools

### Benefits

- Implementing a program where the majority of the target population is together in one place is more efficient.
- A high proportion of 10- to 12-year-old girls are in school, thanks to recent progress associated with making primary school free and obligatory.
- Vaccination can happen more quickly, and students will miss less school time.
- Girls are in a familiar place with their teachers and peers for support.
- HPV vaccine systems can build on pre-existing school-based vaccination systems.
- Schools provide infrastructure and space for vaccinations, as well as teachers to help organize the students.
- School administrators and teachers can help educate parents and the community about the vaccine.
- Girls in school might be encouraged to bring friends who do not attend school.

### Challenges

- Out-of-school girls who are isolated from the public-health system will need to be reached.
- School administrators and teachers (especially those in private schools) might fear resistance from parents and communities.
- Teachers and administrators may perceive the program to be disruptive and a waste of limited time.
- Students who experience adverse events will need to be referred to a health facility.
- Parents might be more difficult to keep in the information and communication loop, as more actors are involved.
- School districts already have severely limited resources.
- Teachers will need adequate information about the vaccine and compensation (of some kind) for their time and effort.

may start school late, need to repeat years, or be accelerated. In the end, there was no easy answer to this question, and one outcome of the research was that more discussion is merited. Either way, accurate estimates of the target population will be required to determine the amount of vaccine needed.

Teachers in particular noted that it is also important to consider the timing of vaccinations in a school-based strategy. For example, scheduling a vaccination very early in the school year was seen as ill-advised, given that many children start the term late for a variety of reasons.

Some parents and children expressed a preference for health centers as vaccination sites, generally for safety reasons. This was particularly pronounced in Gulu, where the school system has broken down and most people are living in camps for internally displaced persons (IDP camps), as well as in Mbarara and Masaka. Parents in Mbarara noted that it might be easier to store the vaccines safely in health centers. In general, both groups felt that health workers are better able to deal with unanticipated side effects or mistakes (e.g., the injection needle breaking in the arm) in a health center. As one girl in Mbarara put it, “I prefer the hospital because it is usually well-equipped.” A health-center strategy was agreed to be logistically impossible, however, and strategies will be necessary to address these concerns, such as linking each school with a nearby health center.

### **Who is responsible for implementing the HPV vaccination strategy?**

HPV vaccination is linked with reproductive health, immunization, adolescent health, and cancer, raising the question of which division within the Ministry of Health should be responsible for national-level coordination of HPV vaccination. In Uganda, it was determined that the HPV vaccination program will be part of and coordinated by the immunization unit of UNEPI, with technical support from the Reproductive Health (RH) Division. Those interviewed stated that UNEPI has a relatively strong infrastructure, including facilities for vaccine storage and transport, human resources, and long-standing direct links with district leaders and health workers.

Policymakers emphasized that the RH Division, UNEPI, and the School Health Program (which was not functional at the time of the research) will all need to integrate HPV vaccination into their budgets and work plans. Additionally, they noted that the Ministry of Finance, Planning, and Economic Development will need to include HPV vaccination in Uganda’s national budget. Respondents specifically highlighted the need to ensure that an HPV vaccination strategy is part of Uganda’s medium-term expenditure framework, a key budgeting tool which enables cooperation across ministries and planning over a longer period than just one fiscal year.



PATH/Robin Brielik

A health worker at Ibanda Kikyenkye Health Centre prepares for school-based vaccinations as part of PATH’s HPV vaccine demonstration project.



Finally, many respondents at the policy level underscored the point that good coordination and communication from the national level to districts, and between the health and education sectors, must be systematic and begin early enough to allow adequate planning for logistics and training.

### **Ensuring that vaccines can be stored and transported safely**

HPV and other vaccines must be kept cold in order to maintain their potency. The system of storing and transporting vaccines at recommended temperatures is known as the “cold chain.” A review, including direct observation, of the cold chain system revealed that Uganda has a strong cold chain management system in place, including dedicated cold chain staff in four of the five districts to manage safe vaccine storage and transport. Vaccines are first stored in a “cold room” at the national level, and then are transported to refrigerators at the district level. The temperature of the storage facilities is checked twice daily. The vaccines which go into storage earliest are used first.

A number of gaps were identified which need to be addressed, however. For example, there is inadequate capacity to store HPV vaccines at both national and some district levels. Even in districts where sufficient refrigerator space exists, some equipment is broken and requires repair. Additionally, at the district level, gas cylinders are often required to run the refrigerators during frequent power outages, and shortages of the cylinders were noted. There is also inadequate freezer capacity for the ice packs required to transport the vaccines from district health centers to schools and community locations, and Kampala district does not have a dedicated vehicle for such transport. Funding shortages for health at the national level have previously presented obstacles to vaccine storage and delivery in the districts, including by causing stockouts or delays in Child Days Plus activities. Such challenges have been exacerbated by the fact that the number of districts in Uganda has increased from 50 to 80 since 2004.



Members of the HPV vaccination team transporting the vaccines to schools in Ibanda.

In order to identify and address these issues early in the planning process, the review found that coordination with the body that oversees public vaccine delivery—in this case, UNEPI—is essential. For example, timing shipments of the HPV vaccine within Uganda when other vaccines are at lower levels of inventory can help maximize valuable storage capacity. At the same time, the schedule for HPV vaccine shipments and distribution from the national to district levels will also need to be timed to meet target dates for service delivery. Assigning one key staff member to serve as the focal point for the HPV vaccine at UNEPI could also help to address logistical concerns. Additionally, a positive finding was that decentralization has given the districts greater flexibility and decision-making authority in terms of applying program resources and developing strategies for service delivery.

## Monitoring vaccine administration and adverse events

Another critical element of vaccine program planning is to ensure careful tracking of which girls are vaccinated and when, and other aspects of system performance. In general, policymakers and officials at national level perceived that it was preferable to add HPV vaccination to Uganda's current system for tracking and monitoring vaccinations, in order to avoid creating new systems and more administrative burden. These respondents did note that it will be necessary to develop new indicators specific to HPV vaccination. These might, for example, track health-worker response to adverse events or changes in people's attitudes regarding HPV vaccination.

The importance of monitoring safety and responding promptly and appropriately to reports of severe adverse events was highlighted repeatedly in interviews, especially given that the HPV vaccine is new to the country and that such events have the potential to generate negative publicity. A past incident was cited in which a woman in Masaka misattributed the death of her child to an immunization. The incident was widely covered by the media and negatively impacted immunization rates, even though it was ultimately established that the death of the child was in no way related to immunization.



PATH/Robin Bieilik

Members of the HPV vaccination team monitor vaccination at Nyamiyaga Primary School in Ibanda.

### Uganda's vaccine delivery strategy: key elements

- Explore two possible strategies for introduction and delivery of the HPV vaccine:
  - Offer vaccine as part of Child Days Plus.
  - Vaccinate girls at school through a "stand-alone" strategy, with special efforts to reach out-of-school girls.
- Select targeting strategy for girls (by age or by grade in school) and generate accurate target population estimates to ensure adequate quantities of the vaccines and other supplies.
- Ensure systematic and early communication within the Ministry of Health and among it and the districts, the education sector, and key financial planning bodies.
- Address gaps in cold chain and logistics capacity, in part by involving the national immunization unit at every stage of assessment and planning.
- Monitor HPV vaccination coverage as part of Uganda's current system for immunization tracking, and respond promptly and appropriately to adverse events following vaccination.

# Communications strategy

A communications strategy for HPV vaccine introduction involves ensuring that community members are equipped with the information they need to make informed decisions and/or give informed advice about cervical cancer prevention, including HPV vaccination. Researchers explored how members of various groups perceive cervical cancer, vaccination, and the HPV vaccine specifically.

## Cervical cancer: overall knowledge and awareness

“We mostly know about cancer of the uterus and cancer of the breasts that disturbs women a lot. We have not heard about cervical cancer.”

–Mother, Mbarara

While cancer is widely understood as a serious and often fatal disease, knowledge and awareness of cervical cancer are limited, even among health workers. Although approximately half of all adult respondents said they had heard of cervical cancer when asked directly what it was, almost none could provide more information when encouraged to elaborate further.

The majority of adults and many girls, especially those in school, know that some cancers affect only women, and many referred to cancer of the uterus or womb. A wide variety of terms exist in local languages to refer to the uterus or womb, but there is no specific terminology to refer to the cervix. As a result, uterine cancer and cervical cancer were often confused in interviews. As one mother in Masaka said, “Cancer of the cervix? We thought it was the same as that of the uterus. In both cases the uterus is affected.” Some health workers reported attempting to explain the difference to patients by referring to the cervix as the “mouth of the womb.” Most study participants, however, did not readily recognize this terminology when asked. It ultimately became clear that most people other than health workers identify cervical cancer by its symptoms and not by its specific anatomical location (see next page). Once a common understanding of the terminology was established between researchers and study participants, most people said that cervical cancer is a serious problem, and many cited instances of family members or acquaintances being affected. This included health workers, who perceived the condition as serious in spite of the fact that very few data on burden of disease are available.



Pupils at Kyarukumba Primary School in Ibanda.

PATH/Robin Brielik

Some health workers could list common risk factors for cervical cancer, and a few knew of strategies to detect cervical cancer early. Most reported that there are inadequate facilities for screening and treatment. Overall, outside of trained health staff, there was little or no awareness of the ability to detect cervical cancer early through screening.

### **Cervical cancer: perceived symptoms**

“My mother died of it...she used to bleed in an abnormal way, and she also used to get a discharge.”

*–Father, Soroti*

As noted previously, relatively more people recognized the symptoms of cervical cancer than the name of the condition itself; the symptoms seem to have more resonance as a concept than the actual term “cervical cancer.” Individuals at the community level who were able spontaneously to list symptoms primarily cited three: foul smelling vaginal discharge, sores or wounds that do not heal, and continuous, heavy vaginal bleeding. Different terms and phrases were used to describe these symptoms in different areas and languages, including “foul watery discharge,” “pus discharge,” “wounds in the opening of the womb that do not heal,” “wounds that hide in the stomach,” and “blood disease.”

There was some confusion around the fact that the same symptoms are also associated with other sexually transmitted infections (STIs) and side effects of some modern family planning methods. As one female parent in Kampala said, “When some women use family planning injections and the coil [intrauterine device], the bleeding goes on and on and on...Now what is the difference between that bleeding and that of cancer? Is it not the same? Is it not coming from the same place?”

### **Cervical cancer: perceived causes and risk factors**

“Unlike other cancers, cervical cancer is believed to be a disease that is a result of having sex with someone who has it and who then passes it on to their partners.”

*–Male gynecologist, Kampala*

There is a general perception that cervical cancer is sexually related. In all five districts, respondents correctly noted that early sexual debut and presence of an STI might increase the risk of developing cervical cancer. However, almost no one in the study mentioned HPV as the primary cause of cervical cancer, leading to widespread speculation as to how women become sick with this disease.

In Mbarara, traditional healers mentioned “obushambani” as a cause of cervical cancer, which translates to “promiscuity.” In Soroti, traditional healers speculated that women with syphilis or gonorrhea sometimes remain silent about them, and eventually these conditions became cancer. Traditional birth attendants in Gulu referred to cervical cancer as “God’s disease,” a category generally used for diseases whose cause and cure are not known. Traditional birth attendants in Masaka thought that having sex during menstruation could cause cervical cancer.



Poor personal hygiene and poor menstrual hygiene were often cited as risk factors. For example, women who do not shave their pubic hair or keep it clean were mentioned as being at higher risk by traditional healers in Masaka. People in four of the districts said that women who use dirty pieces of cloth during their periods instead of sanitary towels are especially vulnerable. In Kampala, it was reported that modern family planning methods which cause irregular bleeding can also cause cervical cancer by interfering with the normal flow of blood. In Gulu, eating food prepared with the cooking oil distributed in IDP camps or sharing toilets in the camps were also seen as risk factors. Other inaccurate causes and risk factors for cervical cancer mentioned include partner mismatch (e.g., older men having sex with young girls); frequent abortions (especially unsafe abortions); poor diet; delivering a baby when the cervix is not fully dilated; complications from delivery and childbirth; gases emitted by burning plastics; and witchcraft.

### **Vaccination: perceived benefits**

“Immunization builds a firewall around us and prevents us from being attacked by diseases... ever since I was vaccinated against measles I have never suffered from it.”

*–Male student, Mbarara*

Across districts, children, both in and out of school, parents, and community leaders, as well as national leaders, have a good understanding of vaccination and its benefits, perceiving it to be for disease prevention and protection. Many children described it as protective “against the six or eight killer diseases.” Boys in Soroti reported that being vaccinated made them feel “good, secure, and confident.” Out-of-school girls also valued vaccination because it “reduced disease.” Respondents in all groups reported that vaccination not only prevents disease, but also makes diseases less severe, and some also mentioned vaccines as “cures.” Whatever the mechanism, there is a clear understanding that vaccination makes people and populations less sick.

Declines in the prevalence of vaccine-preventable diseases were particularly relevant to community understanding of the benefits of vaccination. For example, many parents noted that they no longer see children suffering from polio, which they attributed to immunization. One father in Gulu noted, “These days our children do not suffer from certain diseases like measles...I think it is because they started vaccinating children early in hospitals; that is the reason the disease is disappearing.” Mothers in particular reported that since immunization came to Uganda, they do not see some of the common diseases affecting their children as often. Positive results were even noted by parents who had initially refused to have their children vaccinated.



PATH/Robin Biellik

A girl at Kyarukumba Primary School receives the HPV vaccine as part of PATH's demonstration project.

## **Vaccination: perceived risks**

“Some of these drugs are sometimes bad. The nurse may give it to the child without first reading the instructions, only to notice, too late, that the drug is expired.”

*–Out-of-school girl, Masaka*

In spite of an overall positive attitude toward vaccination, both children and adults in all districts reported fears regarding vaccination. Children in particular expressed concerns about side effects of vaccines, with an emphasis on pain, swelling, and bleeding.

A key theme which arose repeatedly was vaccine safety. Children and adult concerns included untrained staff providing the vaccinations; vaccines expiring; and spreading HIV and other diseases through the reuse of needles. Such concerns were often expressed in statements which revealed distrust of health workers. For example, girls in Masaka cited fears of nurses forgetting to read instructions, giving “overdoses,” or “forgetting” a needle had already been used. In Kampala, women and teachers noted that they did not trust immunization teams, as they feared that health workers were simply trying to use up their expired stock of vaccines. Some parents did not understand why children became sick after vaccinations, and reports of such adverse events spread quickly. People also remembered problems related to vaccines that were not properly handled by health workers in the past.

Such anxieties are sometimes exacerbated by myths, including that vaccines may cause infertility in women or are toxic. The idea that vaccines are part of a plot to control fertility or reduce the population of certain groups was especially common in districts like Gulu and Soroti, where there has been political insecurity and insurgency in the recent past. In some cases, groups opposed to vaccination for cultural, political, or religious reasons initiated radio campaigns against the practice, which reportedly discouraged some parents from allowing their children to be vaccinated.

## **HPV vaccine: perceived benefits and risks**

“To be honest, immunization has been very beneficial to us...if a vaccine can be introduced to curb the damage caused by cervical cancer, that would be great.”

*–Mother, Mbarara*

Most gynecologists interviewed were aware of the HPV vaccine and wanted more information. In every district and at the national level, however, most respondents had not heard of the HPV vaccine. When given basic background information by the researchers on the vaccine’s target age group, doses, and schedule, most participants were positive about the vaccine. The need and desire for more information was universally expressed across all groups of study subjects. In particular, they desired information on cervical cancer, the vaccine, safety, side effects, results from previous experience with the vaccine, and the reasons why girls aged 10 to 12 are targeted.

Many of the fears and concerns cited regarding HPV vaccination mirrored general fears regarding vaccination and immunization, with certain elements intensified due to the nature of this specific

vaccine. For example, concerns about fertility and long-term health effects were exacerbated by the fact that the vaccine is administered to young adolescent girls. Similarly, concerns regarding safety and side effects were intensified by the fact that the vaccine is designed to be given in three doses over six months: children and adults were concerned that it would be too much vaccine in a short period of time, making the vaccine's side effects worse or leading to "overdose." Finally, the fact that the vaccine is new led to concerns that children would be vaccinated as part of a clinical trial and that their daughters would be used as guinea pigs. People in Kampala, where HIV vaccine trials had failed, were particularly worried about this. It was widely noted that having the Ministry of Health and health workers endorse the vaccine would go far in allaying these fears—some parents, teachers, and community leaders stated directly or indirectly that the vaccine should be mandated.

### **HPV vaccination: who decides?**

"I am of the view that children need to look to their parents for guidance. For example, if a parent advised a child not to take a path because it was thorny, but rather to take a particular path because it was straight, a child would obey."

*—Father, Mbarara*

"Parents may refuse to let children go to a film, but if the children are interested they will surely escape through the windows and go out. Similarly, if children choose to be vaccinated at school, while their parents are busy attending to their farms, they will get home and refuse to entertain questions from their parents about immunization."

*—Mother, Mbarara*

"If Muslim sheikhs and Catholic bishops told the people to take their children for immunization, they would do it because they consider the involvement of these religious leaders a proof that the vaccine is genuine."

*—Father, Kampala*

As is reflected in the three quotations above, the issue of "Who decides?" whether a 10- to 12-year-old girl will be vaccinated is complex. The most common response was that parents are the primary decision-makers, with an emphasis on mothers, particularly in Kampala. However, in Kampala, Gulu, Soroti, and Masaka, it was also noted that fathers have more authority in the home and sometimes forbid their children from being immunized. One political leader in Kampala summarized such threats: "If you know that child is mine, do not take them for immunization...and if you do, do not return to my home."

Children themselves were also seen as having a role to play in decision-making. Education officials noted that children's assent is usually required. This was reiterated by an official from the National Council for Children who explained that children's assent takes precedence over their parents' consent. Many parents and teachers reported that if a child wants to be vaccinated, they

might work in various ways to convince their parents—or proceed with vaccination regardless of whether their parents agreed.

School officials, health workers, community leaders, and political leaders were also seen as potentially influencing the decisions of children and parents, whether through giving advice or publicly endorsing vaccination. It was noted that teachers in particular can help with mobilization of the girls to be vaccinated and that school administration and teachers can make parents more comfortable with vaccination by helping to inform them about the vaccine. Many key authority figures, including government and religious leaders, were conscious of their potential role and noted they would need more information before supporting vaccination. One member of Parliament elaborated on this idea: “If you give me enough information, my main role would be mobilization of the people in my constituency, but I can’t talk about technical issues. You the health workers must come and talk [about] facts when we have mobilized the population for you.”

### **Uganda’s communications strategy: key elements**

- Disseminate accurate information to address currently low levels of knowledge about cervical cancer, HPV, and the HPV vaccine, using local terms and languages.
- Develop messages that build on positive perceptions of vaccination and recent successes in reducing the burden of common childhood diseases.
- Raise awareness about vaccination safety measures, including training health workers to administer the vaccine and manage side effects at schools and other sites.
- Promote understanding that the HPV vaccine has been proven safe and effective in extensive, international clinical trials and is already being provided in many countries.
- Publicize endorsement of HPV vaccination by the Uganda Ministry of Health, health workers, education officials, and other national, district, and community leaders.
- Reach out to “decision-makers” at all levels, as everyone from children to national political leaders may play a role in deciding whether a child is vaccinated.



## Advocacy strategy

The need for an advocacy strategy to inform and mobilize policymakers was reinforced time and again in interviews. To inform this strategy, researchers talked with national, district-level, and local political and program leaders regarding the role that policy plays in the introduction of a new health technology, and what specific actions would enable policy development in the case of HPV vaccination.

### Is policy action required for HPV vaccine introduction?

“The starting point for any new intervention is a policy and strategic plan that provides a framework for the action.”

–Senior planner, Ministry of Health

There was widespread consensus that official action by policymakers is required, as noted previously. Respondents felt that such action would serve, most importantly, to convey government commitment to and endorsement of HPV vaccination throughout the country. This was perceived to be especially important for HPV vaccine introduction, given that young adolescent girls at the “beginning of their reproductive career” are the target population. As one Ministry of Health policy adviser put it, “Policy is needed to assure the public that the vaccine is good for the community.”

Others highlighted that the policy development process serves to inform relevant authorities, engage their commitment, and keep them actively involved in supporting HPV vaccine introduction. Respondents also noted that developing policy can help to guide and inform everyone involved in terms of their roles in implementation, and would facilitate addressing logistical issues early, including cost implications. One respondent reinforced this point by noting that the policy would “give clear principles and guidelines for implementation of the intervention.”

### What type of policy is needed for HPV vaccine introduction?

“The danger of coming up with a new policy is that health workers will be tired of them. At the moment I think we have over 150 policies.”

–Assistant commissioner, Ministry of Health

The need for policy action notwithstanding, it was also widely agreed that developing a completely new or separate policy runs the risk of duplicating work and contributing to “policy fatigue.” In



Students at Kanaama Primary School in Ibanda.

PAT/Robin Bellik

order to balance the need to act with the need to avoid overburdening health and education staff, it was suggested that current health policies relevant to HPV vaccination should be reviewed by the Ministry of Health, and policy guidelines should be integrated into those policies. Parliamentary approval was deemed unnecessary by most individuals interviewed, who stated it is only required in the case of mandating public actions. Mandatory vaccination is uncommon in Uganda.

### **Who will be involved in policy development?**

“Ministry of Health top management is needed...the Minister [of Health] in his policy statement can communicate the intervention to the rest of the people, including cabinet.”

*–Senior health planner*

Researchers talked with policymakers not only to identify possible champions for HPV vaccine introduction, but also to map out the roles of different individuals in the policy development process. At the national level, top officials at the Ministry of Health, including individuals in the RH Division, UNEPI, and the School Health Program, were seen as important actors to reach with an advocacy strategy. Respondents explained that ministry officials will be responsible for initiating national-level action on the HPV vaccine through drafting initial policy guidelines. This document will be debated and revised within the Ministry, first through a technical working group and then more broadly. Most respondents suggested that the RH Division should take responsibility for policy development, while others felt that RH is already too stretched and that Child Health, for example, might be the most appropriate department to “push” such a policy. Once members of the Ministry have been widely consulted, the policy guidelines will then be shared and discussed with members of other ministries, including Education and Sports; Gender, Labor, and Social Development; and Finance—meaning their support will also help move policy development and implementation forward.

Eventually, the Ministry of Health will likely present a policy proposal to the cabinet for review, a process which can take anywhere from three months to two years. It was noted that engaging the support of cabinet members, or even the president or first lady, early on will help secure cabinet approval more quickly.

Engaging officials at district and community levels will also be necessary, respondents noted, as many of them will be responsible for implementation of the program. For example, dissemination workshops are often organized in each district to launch new policies and engage district-level support. The districts, in turn, will be responsible for communicating the program to lower health units. Development partners, nongovernmental organizations, medical professional bodies, private service providers, and faith-based organizations involved in health were also cited as potentially important partners for implementation.

### **What information do policymakers need in order to prioritize HPV vaccination?**

“First thing is to give facts—begin by showing the problem and its magnitude and give information on what is known about the intervention to ensure all appreciate it.”

*–Commissioner, Ministry of Health*

Policymakers emphasized that scientific evidence on a number of factors would influence their decision whether to support HPV vaccination. In particular, they noted that the policy development process generally begins with an assessment of the disease burden, establishing the need for a health intervention. One policymaker noted that more information and education is still needed regarding cervical cancer disease burden: “People do not know enough about cervical cancer as a problem.” Those who already knew of the high number of cervical cancer-related deaths among women in Uganda felt that a policy to prevent such deaths is well within the scope of overall health priorities.

Additional information needs include the cost implications of HPV vaccination (“the cheaper the better”); vaccine effectiveness, especially against locally prevalent strains of HPV; data on safety and adverse events; an analysis of risks compared to benefits; and evidence of communities’ willingness to consider vaccination. Members of Parliament were particularly vocal about needing the “blessing” of the Ministry of Health to support this vaccination. Other policymakers emphasized the role of the media, noting that its coverage of HPV vaccination could influence not only their position but also acceptance by communities.

Policymakers also required reassurance that HPV vaccination could easily be harmonized with existing policies and local and international agreements on health, and that it would not interfere with other initiatives. Some emphasized that focusing on integrating the vaccine within pre-existing, widely approved strategies like Child Days Plus and routine vaccinations will help to address these concerns.

### **How does HPV vaccination fit with Uganda’s health priorities?**

Researchers systematically reviewed existing health policies to highlight where policy guidelines on HPV vaccination might fit, and what actions might be required to incorporate such guidelines.

The review included five policies: the Health Sector Strategic Plan II (HSSP II), developed to implement Uganda’s National Health Policy; a Strategy to Improve Reproductive Health in Uganda; National Policy Guidelines and Service Standards for Sexual and Reproductive Health and Rights; the UNEPI Policy; and the School Health Policy.

As an example, the research team found that a component of HSSP II to address non-communicable, or chronic, disease was in development, providing an opening to include cervical cancer. Other HSSP II objectives are enhancing gender equity in service provision and promoting immunization, both of which would be furthered through HPV vaccination programs. On the other hand, the sexual and reproductive health section of HSSP II is narrowly focused on emergency obstetric care,



PATH/Robin Bellik

Participants in a meeting to provide feedback on PATH’s demonstration project in Ibanda District.

and neither HPV nor cervical cancer is mentioned in the section on immunizations. In order to incorporate HPV vaccination effectively within HSSP II, policy advocates and policymakers would need to focus on broadening the sexual and reproductive health focus and listing HPV infection as a vaccine-preventable condition.

In terms of incorporating HPV vaccines into UNEPI policy, 10- to 12-year-old girls would need to be added to the list of target groups for vaccination, traditionally consisting of children under five and women of childbearing age (15 to 49 years). On the other hand, the immunization program was seen as appropriately flexible in terms of adding a “high burden” disease such as cervical cancer.

Ultimately, each policy has its own benefits and challenges for integration. The exercise revealed many opportunities for linking HPV vaccination with Uganda’s current health priorities—as well as the complex nature of policy evolution. It also confirmed respondents’ sense that incorporating HPV vaccination into existing policy, rather than creating an entirely new one, is a sensible approach.

### **Uganda’s advocacy strategy: key elements**

- Develop policy guidelines that set national standards for HPV vaccination, and integrate these into an existing policy.
- Partner with the Ministry of Health to generate momentum and leadership from other key ministries and stakeholders at the national level.
- Engage and mobilize district officials and others responsible for implementation.
- Make information available to policymakers—including through the media—on the seriousness of cervical cancer, the vaccine’s properties, usefulness, cost, and economic benefits.
- Explain how HPV vaccination is consistent with Uganda’s health priorities.

## Conclusion

The *HPV Vaccines: Evidence for Impact* project was designed to generate and disseminate evidence on the best possible strategies for HPV vaccination in four low-income countries. Formative research was the first step in this process, helping to shape three outcomes to be tested in a demonstration project: a vaccine delivery strategy, communications strategy, and advocacy strategy.

PATH and our partners are committed to HPV vaccine introduction in the context of a comprehensive response to cervical cancer that includes screening and treatment of precancerous lesions. While the vaccine can protect young adolescent girls against infection, screening is still needed for women who have already been infected with HPV, so precancerous lesions can be detected and treated before cervical cancer develops. Simple and affordable approaches to screening and treatment of precancerous disease are available and feasible to implement in developing countries.<sup>26</sup> Funding and political will are needed, however, to develop and implement comprehensive national cervical cancer programs and strategies.

Overall, the formative research in Uganda found that a wide range of respondents with diverse roles in vaccine decision-making are supportive of action to prevent cervical cancer, in spite of concerns and obstacles that will need to be addressed. This momentum provides a key opportunity for action. As Sarah Nyombi, Uganda Member of Parliament, wrote in an op-ed on International Women's Day 2008, "Every woman in the world has the right to prevention. Given the tools that are available, even one cervical cancer death is too many."<sup>27</sup>

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