

Shaping a Strategy to Introduce HPV Vaccines in Vietnam

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



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- PATH. Formative Research Results Informing the Introduction of HPV Vaccine in *Vietnam*. Hanoi, Vietnam: PATH; 2008.
- National Institute of Epidemiology and Hygiene (NIHE) and PATH. *Evaluation of the Health System and School Health Program for HPV Vaccine Introduction in Vietnam*. Hanoi, Vietnam: NIHE and PATH; 2008.
- PATH and NIHE. *Sociocultural Research Report for HPV Vaccine Introduction in Vietnam*. Hanoi, Vietnam: PATH and NIHE; 2008.
- PATH and NIHE. *Report on the Policy Environment for HPV Vaccine Introduction in Vietnam*. Hanoi, Vietnam: PATH and NIHE; 2008.
- PATH. Rapid Assessment of Financing Opportunities and Challenges of the Introduction of the HPV Vaccine in Vietnam. Hanoi, Vietnam: PATH; 2007.

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Executive summary

Cervical cancer is the second most common cancer in women worldwide and the most common cancer among women in the developing world.¹ Incidence and mortality rates of cervical cancer remain disproportionately higher in poor countries due to a lack of effective prevention strategies in those settings. New vaccines to prevent human papillomavirus (HPV), the virus that causes cervical cancer, therefore represent a potentially life-saving intervention for millions of women.

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 policymakers 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.^{2,3}

This overview summarizes results from formative research in Vietnam 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 comprehensive cervical cancer prevention programs.

In Vietnam, PATH and our partners conducted formative research to explore possible approaches to vaccine introduction in that setting—and we found overall support for the vaccine, as well as possible obstacles to effective HPV vaccine delivery. The strategies tested in Vietnam's demonstration project will include the following elements, developed from the results of the formative research.

Vietnam's HPV vaccine delivery strategy: key elements

- Explore two possible strategies for introduction and delivery of the HPV vaccine: through schools and through commune health centers.
- Integrate HPV vaccine into work by the national immunization program in order to capitalize on the human resources, infrastructure, and public awareness already in place.
- Train health workers on cervical cancer, the vaccine's benefits, and communication with the target population, and update their general immunization skills and knowledge.
- Coordinate among the relevant agencies across sectors and levels of government, including by harmonizing activity-specific plans at the commune level with annual plans at higher levels.
- Fortify the cold chain to accommodate a new vaccine, including by accounting for the cost of electricity at the commune level and other expenses related to maintenance.

• Support health workers, particularly at the commune level, to effectively monitor vaccination, report any adverse events following immunization, and safely dispose of used needles.

Vietnam's HPV vaccine communications strategy: key elements

- Publicize endorsements of HPV vaccination by the Vietnam Ministry of Health, the national immunization program, People's Committees, Women's Unions, and other prominent groups and individuals.
- Disseminate clear and accurate information on cervical cancer and the HPV vaccine, including on effectiveness, safety, and side effects.
- Clearly communicate that the HPV vaccine has already been extensively tested in international clinical trials, is licensed in Vietnam, and is currently being provided to girls in many developed countries.
- Tailor messages and materials for different audiences; for example, make materials for girls and parents more accessible, and those for teachers and health workers more scientific.
- Use a variety of communication strategies to reach decision-makers, including outreach through Women's Unions, People's Committees, health workers, and teachers.

Vietnam's HPV vaccine advocacy strategy: key elements

- Partner with the national immunization program and the Ministry of Health to generate momentum and leadership from other key ministries and diverse stakeholders at the national level, including the Ministry of Finance.
- Consider engaging global agencies, including the World Health Organization and the GAVI Alliance, along with regional and local implementers in the policy development process.
- Make information available to policymakers on cervical cancer disease burden in Vietnam, effectiveness of the HPV vaccine, and potential financing sources, as well as safety, side effects, and cost-effectiveness (when available).
- Convene workshops with policymakers to promote awareness and interest regarding the HPV vaccine.
- Explain how HPV vaccination is consistent with Vietnam's health priorities to prevent cancer and to promote immunization.

The formative research was carried out by the National Institute of Hygiene and Epidemiology of Vietnam, with technical and financial support from PATH.

Introduction

"I have participated in a hospital program on cervical cancer management and realize that people are interested in this issue. Overall, I think that people will support a cervical cancer vaccine;* however, their support may also be affected by many factors, including its cost and what information they receive about it."

-Health education official, Hanoi

Cervical cancer is the second most common cancer in women worldwide and the most common cancer among women in the developing world.¹ Incidence and mortality rates of cervical cancer remain disproportionately higher in poor countries due to a lack of effective prevention strategies in those settings. New vaccines to prevent human papillomavirus (HPV), the virus that causes cervical cancer, therefore represent a potentially life-saving intervention for millions of women.

It can take decades before poor countries have access to new health technologies, despite the fact that these countries often have a significant need for them. Delays may occur for financial, political, and cultural reasons. An improved understanding of factors that will influence vaccine availability and acceptability—including potential vaccine delivery mechanisms, impacts on overburdened health systems, and policy facilitators or barriers—has the potential to speed up the process. The overall success of an eventual vaccine program will depend on the support of individuals and groups at multiple levels, well-organized and well-resourced delivery, and favorable policies.⁴

That is why PATH initiated the *HPV Vaccines: Evidence for Impact* project in 2006, funded by the Bill & Melinda Gates Foundation.⁵ By piloting vaccine introduction in four developing countries—India, Peru, Uganda, and Vietnam—the project will generate critical evidence to help policymakers and planners worldwide make informed decisions regarding regional and national vaccine introduction efforts and international financing plans.

The *HPV Vaccines: Evidence for Impact* project is not a clinical trial of a new vaccine. The vaccines being used are already licensed in more than 100 countries, including Vietnam. 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.

In Vietnam, PATH and our partners conducted formative research to explore possible approaches to vaccine introduction—and we found overall support for the vaccine, due in part to a strong immunization program and a national commitment to addressing cancer. However, the research also revealed possible obstacles to effective HPV vaccine delivery. This report shares findings from the formative research in Vietnam, which was carried out by the National Institute of Hygiene and Epidemiology (NIHE) of Vietnam, with technical and financial support from PATH.

^{*} We refer to the vaccine throughout this report as the HPV vaccine for the purpose of scientific accuracy. The strategy in Vietnam 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

Approximately half a million women are newly affected by cervical cancer each year.¹ Of the estimated 270,000 annual cervical cancer deaths, about 85 percent occur in developing countries.¹ In developed countries, incidence and mortality rates of cervical cancer have gradually decreased thanks largely to screening programs (traditionally using Pap smears) that can detect the signs

of precancer and treat them early. In developing countries, however, many women cannot access screening services or do not receive necessary treatment.^{6,7} If current global trends continue, by the year 2050, there will be more than one million new cases of cervical cancer every year.⁸

Two vaccines—Merck's Gardasil[®] and GlaxoSmithKline's Cervarix[™]—have 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.⁹⁻¹⁴ 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.¹⁵

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 places. Additionally,

Additional information on HPV and cervical cancer

RHO Cervical Cancer www.rho.org

Alliance for Cervical Cancer Prevention www.alliance-cxca.org

Cervical Cancer Action www.cervicalcanceraction.org

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

PATH cervical cancer prevention www.path.org/cervicalcancer

World Health Organization—cancers of the reproductive system 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/

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, may raise 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 will not be fully apparent until many years in the future.

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.¹⁶ 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 an effective and evidence-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).

The next step after the formative research is to implement and evaluate the three strategies 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.

Vietnam: context

Vietnam, the easternmost country on the Indochina Peninsula of Southeast Asia, has a population of more than 85 million people.¹⁷ More than two-thirds of the population lives in rural areas, many of which are characterized by hills or densely forested mountains. The northern part of the country consists mainly of highlands and the more densely populated Red

River Delta area. The southern part of the country is made up primarily of mountains and coastal lowlands, in addition to the Mekong River Delta area.

Although adolescents in Vietnam have typically reported relatively low rates of sexual activity, that picture may be changing. For example, more than 20 percent of male respondents and 13 percent of female respondents reported engaging in sexual touching in a survey of Vietnamese adolescents.¹⁸ Other data show that while only 7.1 percent of young men and 1.2 percent



A girl rides through traffic in Hanoi, Vietnam.

of young women between the ages of 15 and 24 report they have ever had sex, 27 percent of adolescents in another survey say that their close friends have.¹⁹ At the same time, adolescent

reproductive health services are not widely available and are not prioritized by the health sector or policymakers.

Cervical cancer is the most common cancer of women in Vietnam.²⁰ There is a shortage of national data and statistics on cancer, however, and the data that do exist are often contradictory. Research has mainly been conducted in big cities or provinces, and the National Cancer Registry relies on passive surveillance from five provinces. Many studies have confirmed that cervical cancer rates are higher in the south of Vietnam than in the north. For example, reported incidence rates in the northern city of Hanoi are 6.8 per 100,000 women,²¹ compared with 26 per 100,000 women in the southern city of Ho Chi Minh.²²

Currently, there is no national cervical cancer screening program in Vietnam, and screening only occurs opportunistically. Even where services to address cervical cancer do exist, health clinics are often overburdened, and people do not feel that services at commune or district levels are of high quality. In many cases, lack of appropriate diagnostic equipment means that women have to be re-tested after they are referred to higher levels of the health system. People seeking cancer treatment are often forced to move to cities for the treatment, along with their caregivers. Having cervical cancer can therefore lead to severe socioeconomic consequences. In addition, even in the big cities, there is a shortage of qualified personnel to diagnose and treat precancer.

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 quantitative and qualitative techniques to gather information, relying particularly on a Knowledge, Attitudes, and Practices (KAP) survey, focus group discussions, and in-depth interviews with key informants, as well as literature, data, and policy reviews, and health facility audits. The KAP survey, which contained questions about knowledge of cervical cancer, decision-making for young girls, and access to health information, was administered to randomly

selected 11- to 14-year-old girls and their parents. The study populations for the focus groups and interviews included:

- Young adolescent girls.
- Parents of young adolescent girls or of children less than one year of age (targets of current or future immunization programs).
- Teachers.
- Health workers.
- Community leaders and civil society representatives.



Health workers in Hoa Binh, Vietnam.*

^{*} Hoa Binh was not a site for the formative research. Photos from Hoa Binh are from a separate clinical study by PATH and NIHE to evaluate different schedules for administering the three required HPV vaccine doses.

Policymakers at national and subnational levels.

Focus groups and interviews were tape-recorded. Transcripts were developed from the tapes and used as the primary data for analysis. The team used electronic management software to further organize, sort, and synthesize transcript data for analysis and interpretation. The KAP survey was analyzed using statistical software.

The research, carried out in 2007 and 2008, focused on three provinces representing the geographical regions of Vietnam, as well as the two most urbanized and populated cities in the country: Thai Binh province in the north, Nghe An province in the central region, Dong Thap province in the south, and Hanoi and Ho Chi Minh City.

One district was selected from each city, and two from each of the three provinces, for a total of eight districts in the study. The districts were chosen to achieve diversity in economic status, ethnicity, immunization coverage, and secondary school



attendance rate, as well as factors such as the willingness of authorities in that area to participate in the research and an adequate recordkeeping system to provide necessary data.

Permission for the research was secured from relevant national and international institutions. Oral or written consent was secured from all participants in accordance with local requirements, including parental consent for the participation of young adolescents.

Vaccine delivery strategy

In order to determine the most promising approach to delivering HPV vaccine in Vietnam, the researchers talked with members of the various study groups regarding sites and strategies for vaccination. Policymakers and health service providers also supplied information on health system capacity and infrastructure, potential obstacles, and potential impact of introducing the HPV vaccine on services and systems. These conversations were supplemented by policy document review and field observations.

Where and how to reach young adolescent girls with the HPV vaccine

Most respondents preferred schools as the venue for reaching young adolescent girls with HPV vaccine. Community leaders and health workers, for example, preferred schools because of the high coverage rates that they believed would result. However, parents and girls preferred health center-based delivery of vaccination due to safety concerns (see next page).

School-based strategy: Policymakers and community leaders preferred a school-based strategy because the majority of 11- to 14-year-old girls are enrolled in school. As one member of the Women's Union said, "The number of pupils in the school is very stable. All pupils go along with any official activities at school." Other aspects of the school environment were seen as conducive to girls' participation, including encouragement by teachers and school administrators, and the effect of seeing their peers participating. Another justification offered for a school-based strategy was that vaccines have been successfully provided in schools before, including those

for typhoid, polio, measles, and tetanus. In those programs, vaccination was organized according to school schedules, and teachers listed the eligible students and helped to mobilize students and their parents-systems on which the HPV vaccination program could easily build. Most of those interviewed agreed that this partnership has worked well in the past. As one leader at the Hanoi health department said, "There are some advantages if the vaccines are introduced at school. For example, it is easy to localize and manage. The collaboration between the health sector and the education sector is very good."



School girls in Hoa Binh, Vietnam.

Some community members, especially those unfamiliar with school-based immunization, did express concerns about this strategy. It became clear that some interviewees misunderstood school-based immunization to mean that school staff, rather than trained workers from the health center, would be vaccinating children. Those individuals were worried about the shortage of health professionals at schools. This misperception could also occur in actual community outreach for a school-based vaccination campaign. In addition, participants from the health sector, as well as some parents, cited maintaining the cold chain or dealing with adverse events following immunization as challenges in a school environment. One vaccinator in Dong Thap said, "The cold chain must be transferred to the school, the health staff must go there, and so must the vaccine. How will we ensure injection safety?" Another vaccinator in Thai Binh worried that "we cannot take all of the equipment for handling emergencies to the school." Another perceived disadvantage of a school-based strategy is that out-of-school girls have not been consistently covered by previous campaigns, meaning there would be a need for follow-up to reach them in communities. An education official in Nghe An felt confident this would be possible, however, noting, "We can reach out-of-school children through local authorities and commune health station staff; they will help us to introduce the vaccines to each village."

Health center-based strategy:

Advantages cited by those respondents who preferred health centers as a vaccine delivery site were the capacity to ensure safe injections, quality of care, and efficient vaccine supply transport and management. In particular, the ability to deal with adverse events and side effects in a health center was emphasized by many. As one vaccinator in Thai Binh said, "It is easier to monitor patients and treat them if any complication occurs after immunization." Overall, community members expressed a great deal of confidence in commune health centers, which seemed to account partly for their preference. One mother explained that



A health worker and school girls discuss the HPV vaccine at a school in Hoa Binh.

"in the commune health station, the health staff is very professional and patient...the commune health station is very clean and hygienic." A mother in Nghe An remarked that "the health staff at the commune health station is very kind; they visit our homes, encourage us to take our children to be immunized, and provide much useful information."

Those who explicitly opposed vaccinations in commune health centers mainly cited reasons of convenience. One mother in Dong Thap worried that "if a parent is busy, there is no one to take the child to the commune health station." A health worker in Dong Thap said that "pupils find access to the commune health station difficult. They would not come." Additionally, the health systems assessment found that 293 communes in Vietnam do not have a commune health station, meaning an alternate plan would need to be developed for those areas. Others noted that the equipment at the health centers is old and needs to be updated, which can impede the quality of care at such facilities.

Who is responsible for implementing the HPV vaccination strategy?

Vaccines in Vietnam are provided to the population by the National Expanded Program on Immunization (NEPI). NEPI is managed by the Ministry of Health and implemented through NIHE, four Regional Institutes of Hygiene and Epidemiology, 64 provincial preventive medicine centers, more than 700 district preventive medicine centers, and more than 10,000 commune health centers or stations. The system is responsible for planning, management, implementation, monitoring, and evaluation of immunization at central, provincial, district, and commune levels. National and regional steering committees develop and organize action plans, and monitor and supervise activities at different levels.

The NEPI budget is used for purchasing vaccines and injection supplies; information, education, and communication activities; disease surveillance; and vaccination campaigns. The budget does not cover provincial-, district-, or commune-level salaries, allowances, or other expenses, such as for transportation, buildings, electricity, and so forth. Overall, NEPI has been proven to be highly cost-effective. The cost of US\$4.81 per fully vaccinated child is

much lower than the figure of US\$15 that is generally accepted as the threshold for costeffectiveness of immunization programs in developing countries.²³ The government has pledged to increase the total budget for NEPI by 10 percent annually. Currently, through its routine infant vaccination program, NEPI provides essential childhood vaccines to prevent polio, tuberculosis, diphtheria, pertussis, tetanus, and measles, and recently added vaccines against hepatitis B and Japanese encephalitis. NEPI also conducts periodic special campaigns to target older groups.



Lab technicians at a health center in Hoa Binh.

Traditionally, NEPI has achieved high coverage rates, reaching more than 90 percent of all children younger than the age of one since 1999. Many health workers have strong experience with and commitment to immunization. As one health worker said, "We are very familiar with immunization work. When new vaccines are introduced, our work might be harder, but we are here for the people's health care and protection." This attitude was widely reflected: although introducing HPV vaccines might add to an already heavy workload, providing new vaccines is part of the role of health workers. As the head of a commune health center in Nghe An put it, "Is [receiving the HPV vaccine] the right of the people? Then we should do it now." This was even expressed in spite of the fact that many health workers participate in other activities in addition to immunization; for example, one provincial-level report found that staff responsible for immunization actually spend only between one-third and one-half of their time on NEPI activities. Some health workers did request improved working conditions and incentives for taking on additional work as part of new vaccine introduction efforts.

Many health workers also pointed out that introducing a new vaccine provides a good opportunity for training and re-training. Commune health workers, for example, are generally trained only when they are initially hired. As one health worker said, "Since working in immunization, I've been trained only once. In my opinion, commune health workers should be regularly trained because there is always new information that we wouldn't know unless we were trained." Health workers emphasized that the training should focus on practical skills. National leaders indicated a willingness to spend a good part of a future HPV vaccination budget on training, as well as communication activities. Many noted that it will be necessary to adapt the national or regional plan for new vaccine introduction to district- and commune-level realities particularly in terms of required staff assignments, organization of immunization sessions, and budget plans for each activity. One health worker described that often "the actual implementation is different from the original plan for many reasons, including budget and time constraints."

The health sector also collaborates closely with the education sector in order to implement schoolbased immunization programs. Traditionally, the two sectors have developed and signed a joint action plan that formalizes responsibilities. A leader in the Hanoi health department went so far as to say that "this collaboration has always been smooth," in part thanks to these intersectoral plans. At the commune level, actors involved in implementing HPV vaccine introduction would include People's Committees, Women's Unions, and Culture and Information Officers. For example, the People's Committee not only helps to coordinate activities across sectors at the commune level, but also helps with community mobilization for vaccination. One health worker in Dong Thap noted, "The most important thing is to have support and leadership of People's Committees and government agencies."

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 of the cold chain system and conversations with policymakers and health staff confirmed that Vietnam has a well-equipped cold chain system. For example, all refrigerators at the provincial level have FreezeWatch[™] installed, which helps to detect and alert staff in case of freezing.

Overall, it was agreed that while the national and regional cold chain system would be sufficient for PATH's HPV vaccine demonstration project, the provincial, district, and commune cold chain systems would require some improvements. Some reported that refrigeration systems at the district and commune levels are out of date or insufficient. The assessment of the health system found



Transporting supplies for a vaccination program.

that at least 6,000 of nearly 11,000 communes throughout the country lack sufficient refrigerator storage. Ice boxes for vaccine transport are often used to keep the vaccines cold when there is insufficient refrigerator space. As a health worker at the provincial level in Thai Binh described, "Basically, the cold chain at commune level meets the requirements of vaccine preservation... However, some limitations remain. Vaccine carriers must be used in place of insufficient refrigerators. Most refrigerators are out of date or broken." Even some communes that have a refrigerator are using household models not designed for vaccine storage. Household refrigerators were particularly common in the province of Dong Thap in the south. Going forward, there is a plan funded by the government of Luxembourg to supply all provinces and districts with refrigerators by 2010. Also, staff at the national level had plans for maintaining cold temperatures in case of power cuts, but that was less frequently the case at the provincial or district level. In terms of personnel, those at the national and regional levels were found to be sufficiently trained in maintaining the cold chain, but frequent mistakes were observed among workers at the district and commune levels, including discrepancies and gaps in recordkeeping.

An additional challenge is that a fairly small percentage of the national budget for immunization is devoted to cold chain maintenance. For example, the national program budget of NEPI does not cover electricity at the commune health centers, so some communes do not run their refrigerators throughout the month, leading to inconsistent refrigeration. As one health worker in Dong Thap asked, "How do we pay for the monthly electricity fee? Cash is always the big problem." Additionally, monthly vaccine pick-up or meeting attendance by health workers is not covered by the budget and is often paid for out-of-pocket by staff themselves. If HPV vaccination is scheduled to occur at a time that is not concurrent with routine immunization sessions, commune health staff will have to make an extra trip to obtain the vaccines, and therefore, incur extra personal expenses.

Monitoring vaccine administration and safety

While there is an established nationwide system in place for reporting adverse events following immunization, Vietnam is in the process of improving its monitoring and reporting system from the commune level to the central level. Provincial and district health workers are already trained on reporting, and commune health workers are in the process of being trained. Most commune health workers interviewed did have forms for reporting adverse events, but some confusion persisted at this level over what post-immunization monitoring meant. One health worker, for example, defined it as "informing young mothers about unusual responses and advising them to give children a cool

drink, anti-fever medicine, or apply a cold compress to the child's injection site." That said, after commune and village health workers in Thai Binh and Dong Thap received training on monitoring postimmunization responses, recording and reporting adverse events was noted to have improved.

In terms of waste disposal, according to Vietnamese guidelines, used needles and syringes are to be deposited in safety boxes and destroyed in incinerators at the commune level. Improvements are



A health worker reviews vaccination records at a school in Hoa Binh.

clearly needed in this area, as field observations found that most safety boxes were full to the point of overflowing, and many syringes and needles were buried rather than incinerated. One health worker in Dong Thap described the correct practice: "After injecting, we don't re-cap the needle and we put them into those yellow boxes. When the boxes are full, we incinerate the needles." However, the health worker also added that the "communal incinerator doesn't meet the standards of the Ministry of Health, but 'half a loaf is better than no bread.'"

Another critical element of vaccine program planning is to ensure careful tracking of which girls are vaccinated. Commune health staff are responsible for listing the number of children who need vaccinations and then reporting on immunization coverage to districts. Observation of immunizations revealed that some cases of vaccination were not recorded, which can lead to incorrect

Vietnam's vaccine delivery strategy: key elements

- Explore two possible strategies for introduction and delivery of the HPV vaccine: through schools and through commune health centers.
- Integrate HPV vaccine into NEPI's work in order to capitalize on the human resources, infrastructure, and public awareness already in place.
- Train health workers on cervical cancer, the vaccine's benefits, and communication with the target population, and update their general immunization skills and knowledge.
- Coordinate among the relevant agencies across sectors and levels of government, including by harmonizing activity-specific plans at the commune level with annual plans at higher levels.
- Fortify the cold chain to accommodate a new vaccine, including by accounting for the cost of electricity at the commune level and other expenses related to maintenance.
- Support health workers, particularly at the commune level, to effectively monitor vaccination, report any adverse events following immunization, and safely dispose of used needles.

coverage calculations and estimates for vaccine demand planning. The commune health staff mentioned that paperwork related to documenting immunization activities can be burdensome, especially as they are responsible for a number of other health activities.

Communications strategy

Community members and leaders need to be equipped with the knowledge to make informed decisions and/or give informed advice about cervical cancer prevention, including HPV vaccination. Through focus groups, individual interviews, and a community survey, researchers explored how members of various groups perceive cervical cancer, vaccination, and the HPV vaccine specifically, as well as who makes decisions regarding vaccination.

Cervical cancer: overall knowledge and awareness

"Women who suffer from white vaginal discharge or prolonged menstruation and don't have timely treatment may develop cancer."

-Women's Union member, Dong Thap

Nearly all focus group and interview participants believed that cancer in general is a very serious disease that cannot be treated. Many equated cancer to a "death sentence," for example. There was some awareness, including among a few mothers, that people can live longer if cancer is detected and treated early.

In the survey results, ambiguity emerged as to familiarity with cervical cancer specifically. For example, 77 percent of parents and 39 percent of girls reported that they had heard of cervical cancer, yet only 50 percent of parents and 18 percent of girls could mention one correct symptom. In terms of specific symptoms, less than 25 percent of parents knew about abnormal bleeding or vaginal discharge. Nearly all of those who had heard of the condition perceived that it is severe or very severe, likely because that is their perception of cancer in general. Knowledge levels regarding cervical cancer, including causes and symptoms, were higher in the northern part of the country than in the center or the south, despite the fact that reported incidence and prevalence of cervical cancer are higher in the south. There were also signs that knowledge varies by education level, age, and income; for example, girls whose parents have higher incomes are more likely to know about cervical cancer, as well as HPV.

Some focus group and interview participants expressed that there was a lack of awareness of cervical cancer among the community. For example, one Preventive Medicine Center authority in Dong Thap said, "Mothers do not understand much about this disease. If they understand, they will allow their children to have vaccination. But it is very difficult if parents do not understand."

Cervical cancer: perceived causes and risk factors

"This is the first time I've heard of [HPV]; nobody told me about it before, so I had no idea."

-Father, Dong Thap

No parents or girls who were interviewed for this study had ever heard of HPV (as opposed to cervical cancer or cancer), and only two health workers had heard of it. A few people did note in interviews or focus group discussions that they had heard through mass media about a virus that

causes cancer. As one father in Hanoi said, "I've heard of a virus causing cancer on TV at least twice. But I can't say that I know much about it, and different channels provide different information. I've heard that cancer can be caused by things like chemicals or heredity." The survey results showed that almost 25 percent of parents and around 13 percent of girls had heard of HPV. However, about onethird of parents believed that other issues related to genital hygiene or sexual behavior cause cervical cancer, including poor hygiene, HIV/AIDS infection, early onset of sexual activity, and promiscuity.

The two health workers interviewed who had heard of HPV did not have a fully accurate understanding of what it is or how it is transmitted. For example, one health worker in Dong Thap, who knew that HPV is also associated with genital warts, thought that "anyone, either woman or man, can contract this virus due to hygiene problems…a man who doesn't adopt proper hygiene practices will acquire it." The other individual was unclear as to whether men could acquire HPV, and also believed it could be transmitted through polluted water. Indeed, it was commonly perceived that cervical cancer is a waterborne illness, perhaps because it is more common in the south, where there is heavy flooding and rice farmers spend a good deal of time immersed in water. Further, many thought that this water was polluted and contained harmful chemicals from farming that caused the illness. As one teacher in Dong Thap said, "In Thap Muoi region, women have to soak themselves all day in watery fields, so reproductive tract infections are very common. Some infections may lead to cancer, so it can be concluded that polluted water is the main cause." Other environmental mechanisms were also cited, including eating fish from polluted water.

Vaccination: perceived benefits and risks

"Nowadays, parents bring their children to us for vaccination, not like in the past when they would run away if we tried to visit them at home. However, after [recent] immunization troubles, people have their doubts again."

-Health worker, Dong Thap

Overall, parents and children expressed favorable views toward vaccination and the national immunization program. Many parents felt that vaccines are important for their children's health.

As one father in Thai Binh said, "I had my eldest child get the hepatitis A vaccine this year, at age 13. I worry for my children...I try to afford all their vaccinations." A member of the Communal People's Committee in Thai Binh echoed that "people accept any vaccine for their children under six...almost 100 percent of parents have their children vaccinated." Some attributed the positive perceptions of vaccination to the communications and outreach by NEPI and its partners, although many also reported that the quality of care received at the health center and the good attitudes of the health staff (noted in a previous section) made most parents even more willing to accept vaccination.



ATH/ Amynah Janmohamec

In early 2007, however, a few infant deaths temporally associated with doses of hepatitis B vaccine were highly publicized in the mass media, leading to a quarantine of some vaccines and subsequent shortage of vaccine supply. Although the deaths were investigated and found not to be attributed to the immunizations, awareness of vaccine safety issues was heightened in the community. It was found in interviews and focus groups that more people were aware of the initial controversy than of the outcome of the investigation. Additionally, rumors and reports of vaccine side effects were associated with other vaccines. One member of the Communal People's Committee in Dong Thap reported that "There have been cases of anaphylactic shock after tetanus toxoid vaccination, so people have become scared of it. Some dogs which received a rabies vaccine have become infertile. That also makes people scared." Policymakers also noted that parents today are more empowered and expect more out of their health services as Vietnam has become more developed, and that mothers are actively seeking more information about side effects and safety of health interventions.

HPV vaccine: perceived benefits and risks

"It's quite good if this vaccine can help eliminate the risk of contracting cervical cancer. What we need to consider is whether it causes any side effects and how it affects our health and our reproductive health."

-District People's Committee member, Hanoi

When given basic information, study participants overall (including parents, girls, teachers, health workers, and community leaders) were very positive about a vaccine to prevent cervical cancer and perceived that it would be acceptable to most communities in Vietnam. Many girls interviewed said that they would want the vaccine for themselves if it were available, and many parents said they would want their children to receive it, particularly once they were reassured regarding the vaccine's effectiveness. For example, as one member of the Women's Union in Dong

Thap expressed, "It is very good to learn that another disease is preventable. My daughter is at the age of this vaccination, and if a vaccine is available...that's great!" She went on to express that she believed the Women's Union would be eager to coordinate with the health sector around communications and advocacy work.

Most interviewees attributed their positive feelings to the fact that the vaccine prevents a very serious health problem with a high mortality rate. As a representative of the District Preventive Medicine Center in Dong Thap said, "In general, people are scared of cancers, as they are incurable. If we have a vaccine against cancer, people will accept it." Additionally, many cited the benefit of vaccines in general and their ability to prevent health problems and save trouble in the future; as one father in Thai Binh explained, "We only have two children. There are many diseases these days, and I'd rather pay money for prevention than treatment."



A mother accompanies her daughter at a school-based vaccination session.

However, many statements of benefit were followed by clear statements of concern and the need for reassurances related to side effects and potential long-term effects of the vaccine on girls' fertility. Informants clearly expressed the desire to be reassured that the vaccine is safe. As one teacher in Thai Binh explained, "We are anxious, having heard so much information about recent incidents related to children's vaccinations on TV. We'll need full and correct information about this vaccine; otherwise, we'll be very scared of it."

An additional concern was that the girls receiving the vaccine would actually be part of a clinical trial. This was intensified by the fact that the vaccines were perceived to come from richer countries. As a member of the finance department in Hanoi said, "Pharmaceutical firms in the developed countries often bring their products to the developing countries for pilot experiments." Policymakers in particular also worried about how long the vaccine would last, and what would happen once its effect wore off. As one hospital representative said, "At a certain seminar, it was said that the vaccines have been proven to last for five years. What will happen after that? If children then suffer from cancer, who will be responsible for this and how will we deal with it?"

Interestingly, several parents expressed that they would be willing to obtain this vaccine for their children, no matter the cost. As one mother in Dong Thap said, "If the government introduces this program, we should follow the guidelines and have our children fully vaccinated so that they will be protected from disease. No matter how much it costs, we'll pay for it." Another mother in Hanoi expressed, "I know there are several types of vaccines that are not produced in Vietnam and must be imported, so they are costly. I'm therefore not concerned about the cost. The issue of most concern is the quality of the vaccine." This was not, of course, universal; for example, one mother in Thai Binh expressed concern that not everyone would be able to afford the vaccine if it were not provided by the government.

HPV vaccination: who decides?

"Generally, it's the mother who decides whether their children get vaccinations, because the father is busy at work."

-Mother, Nghe An

In general, most people interviewed, including parents, girls, teachers, health workers, and community leaders, felt that mothers are the key decision-makers regarding whether their daughters will receive the HPV vaccine. Among those who participated in the KAP survey, 60 percent of mothers and 45 percent of girls said it was the mother's decision. Mainly, people expressed that this is because cervical cancer is a women's health issue to be discussed by mothers and daughters. The decision was often considered outside the realm of fathers—whether because they are less involved with health decision-making for their daughters, or because vaccinations are often free. For example, one representative from the Preventive Medical Center in Dong Thap said, "I think it's mothers, not fathers, who make the decision. Mothers more often take care of their daughters, especially when she reaches the age of puberty. Mothers can persuade the girls to have vaccinations...fathers just deal with money."

In focus groups and interviews, some participants did explain that the issue merited more discussion within the family, whether between both parents or including the girl as well. Those

who felt this way often focused on concerns about potential negative impacts on a girl's health, given that this is a new vaccine. For example, one father in Dong Thap said, "The husband alone can't make the decision. This is an important issue that may affect the next generation, and an infertile girl is worth nothing, so that must be considered. The husband and wife should reach an agreement...it would also be unacceptable to say, 'I am a woman, I know better.' There must be a discussion." A few parents noted a role for the girl. One father in Ho Chi Minh City said, "I used to make the decision, but now I think my daughter has grown up, so we have to listen to her. First, we should ask her to express her opinion; second, we should explain to her the advantages and disadvantages of the vaccine." On the other hand, few girls who participated in the KAP survey saw a role for themselves: 98 percent said that it was a decision for one or both parents.

Health information and education

"This is a new vaccine, so the preparation of a communication strategy is very important; for example, any positive and negative information about the vaccine should be made widely available. In addition, we should prepare logistical aspects well to ensure effective implementation."

-Ministry of Health official

Vietnam has a strong history of community mobilization for vaccination through information and education, so many individuals felt that this would be a critical part of a vaccination strategy. Although unions and other community groups still play an important role in outreach and education, in recent years, they have become somewhat less involved as vaccination has been more widely accepted by the community. As one health official in Thai Binh said, "Previously, when awareness of people was low, the role of unions was very important. Broadcasting, television stations, and unions were involved in monitoring, stimulating, and reminding the population about immunization. Since the awareness of the population has improved...the participation of unions in immunization has decreased." Others noted that communication around immunization today is often limited to mass media, rather than direct communication, due to budget constraints.

On the other hand, mothers expressed a clear preference for learning about immunization and new vaccines through health workers and through the Women's Union. Generally, health

workers give advance notice to parents about upcoming immunization campaigns, and they remind mothers about upcoming vaccinations. The Women's Union has the capacity and infrastructure to provide direct communication to women, especially rural women, through network meetings, courses, and workshops. Most respondents noted that this kind of outreach should be supplemented by posters, leaflets, videos, and even quiz contests. As a member of the Women's Union in Hanoi put it, "We should provide information to mothers so that they can understand the importance of vaccination



Girls in Thanh Hoa province review educational materials about HPV and cervical cancer.

against this disease...The Women's Union has a network of collaborators and peer educators at the ward and commune level, so the communication is very effective." Teachers, many of whom are Women's Union members, also saw themselves as working with health workers to carry out health-education and social-mobilization activities. They noted the desirability of printed materials to reinforce what they learn in more interactive sessions. As a school health officer in Dong Thap said, "I need two hours to prepare well for a 45-minute session. Therefore, I need a manual, not just a lecture."

Vietnam's communications strategy: key elements

- Publicize endorsements of HPV vaccination by the Vietnam Ministry of Health, the national immunization program, People's Committees, Women's Unions, and other prominent groups and individuals.
- Disseminate clear and accurate information on cervical cancer and the HPV vaccine, including on effectiveness, safety, and side effects.
- Clearly communicate that the HPV vaccine has already been extensively tested in international clinical trials, is licensed in Vietnam, and is currently being provided to girls in many developed countries.
- Tailor messages and materials for different audiences; for example, make materials for girls and parents more accessible, and those for teachers and health workers more scientific.
- Use a variety of communication strategies to reach decision-makers, including outreach through Women's Unions, People's Committees, health workers, and teachers.

Advocacy strategy

In order to guide an advocacy strategy to inform and mobilize policymakers around HPV vaccine introduction, researchers reviewed Vietnam's health policy structure and talked with national, regional, and local officials about the decision-making process for a new health intervention.

What are the steps in policy development and who is involved?

"It is possible to prepare a proposal justifying the urgency of the issue and presenting data on the actual situation here; comparing this vaccine with other vaccines currently available in the world; and describing how this vaccine has been scientifically evaluated. Then it should be proposed to add [this vaccine] to the list of vaccines provided in Vietnam. If NEPI's request is approved by the Ministry of Health, the Ministry of Finance shall accept it."

-Ministry of Finance official

The policy review highlighted two important components of introducing a new vaccine in Vietnam: registering the vaccine, and introducing a registered vaccine as part of NEPI's routine vaccinations. Not all new vaccines that are registered necessarily become part of NEPI's schedule, but those that do reach a much wider public.

The Ministry of Health in Vietnam oversees NEPI and is the government body responsible for managing health care, including preventive medicine. The Ministry of Health may produce its own policies or collaborate with other ministries to develop national policies related to health or medical issues. Health policies are most often created in response to new research findings or community demand and are drafted by the appropriate sector within the Ministry of Health—NEPI, in the case of new vaccine introduction. NEPI will circulate a draft policy among appropriate leaders within the Ministry of Health and other relevant ministries, including the Ministry of Planning and Investment and the Ministry of Finance in order to secure consensus on potential funding for the policy. The proposal will ultimately be submitted to the prime minister. Therefore, outreach to a wide variety of actors within government at different points along the policy pathway will be needed.

In addition to the central government level, the policy review identified other important advocacy targets as well. For example, policymakers noted that the position that international agencies such as the World Health Organization (WHO) and the GAVI Alliance take on the HPV vaccine will have important influence over the decisions made at the national level. Additionally, the Provincial health department and People's Committees may have helpful input to provide during policy development, as they will be key partners in the implementation process.

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

"For the Vietnamese people, we should ensure the following factors: safety first, then efficacy, and a reasonable price. These three factors must always go together; otherwise, it is very difficult to implement the program."

-Reproductive health official, Ministry of Health

The three key factors that are emphasized when a vaccine is considered for inclusion in NEPI are disease burden, effectiveness of the vaccine at preventing the disease, and the financing source. In addition to these fundamental elements, policymakers highlighted a desire to receive information on the side effects and cost of HPV vaccine. New data on cost-effectiveness could be helpful to policymakers in prioritization of new vaccines. Ministry of Health officials also emphasized that if the vaccine is manufactured by a well-known company with a good reputation, is licensed in developing countries, and is recommended by WHO, it will be approved for inclusion in NEPI more easily.

Researchers also talked with policymakers about the ways in which they would like to receive information. Several emphasized that written information would be most effectively reinforced through interactive workshops and direct communication. For example, a member of the Hanoi finance department suggested that "In addition to sending documents to leaders, you should meet with them directly to provide more detail...policymakers may be too busy to read documents they receive in the mail." It was also noted that these workshops would have the most credibility if they were organized by the Ministry of Health.



National and provincial immunization and communication staff at a vaccination planning workshop.

How does HPV vaccine introduction fit with Vietnam's health priorities?

"We would like to introduce the HPV vaccine very much, as an effective method of cervical cancer prevention."

-Representative, Preventive Medicine Center, Hanoi

A wide range of policies and related documents in Vietnam reflect a government commitment to cancer, cervical cancer, and introducing new vaccines. For example, cervical cancer or cancer is explicitly mentioned in several national health policies. Vietnam is beginning to experience a double burden of both communicable diseases and noncommunicable diseases. Cancers have been prioritized as a key noncommunicable cause of mortality in Vietnam. The prime minister recently ratified a program to prevent and control noncommunicable diseases, and both prevention and early detection of cancer are among the four priorities of the program. In the Strategy for Reproductive Health Care 2002–2010, a stated objective is to "reduce breast, cervix

[and other types of] cancer mortality rates by 30 percent and decrease the proportion of cancer diagnosed in advanced stages from 80 to 50 percent." In other words, cancer is a major priority which will be included by the Ministry of Health in its annual budget plan, which has the potential to be approved by the Ministry of Finance.

In addition, interviews with leaders at the national level, including the Ministry of Health, and representatives of People's Committees at various levels confirmed that they consider immunization a national health priority. Specifically, those policymakers and officials interviewed demonstrated a supportive attitude toward HPV vaccine introduction. As with the general population, many cited the benefits of vaccines as an inexpensive and effective way to prevent dangerous diseases. In fact, no policymakers expressed unsupportive views of the HPV vaccine. It was suggested, however, that conferences or press events might be held to effectively call attention to the issue.

Policymakers did express concerns about the cost of the vaccine. For example, one

Vietnam's advocacy strategy: key elements

- Partner with NEPI and the Ministry of Health to generate momentum and leadership from other key ministries and diverse stakeholders at the national level, including the Ministry of Finance.
- Consider engaging global agencies, including WHO and the GAVI Alliance, along with regional and local implementers in the policy development process.
- Make information available to policymakers on cervical cancer disease burden in Vietnam, effectiveness of the HPV vaccine, and potential financing sources, as well as safety, side effects, and cost-effectiveness (when available).
- Convene workshops with policymakers to promote awareness and interest regarding the HPV vaccine.
- Explain how HPV vaccination is consistent with Vietnam's health priorities to prevent cancer and to promote immunization.

representative of the Preventive Medicine Center in Thai Binh asked, "Can the HPV vaccine be subsidized? If the cost is high, the people, especially those living in rural areas, cannot afford it." Given that other vaccines, including Japanese encephalitis, Haemophilus influenzae type b, and rubella, have already been prioritized under the national immunization plan, the HPV vaccine will have to compete for resources.

Conclusion

Formative research in Vietnam found a strong immunization delivery system in place, as well as communities and policymakers receptive to the idea of a vaccine to prevent cervical cancer. However, the research also helped to identify possible obstacles to an effective vaccine program, including gaps in the cold chain system, parental concerns about safety and side effects, and policymakers' skepticism about the cost-effectiveness of this new intervention. These elements not only helped to inform strategies for PATH's demonstration project, but will help to guide vaccine introduction plans in Vietnam and in developing countries worldwide.

Although the formative research found support for actions to address cervical cancer, no national guidelines on cervical cancer screening currently exist in Vietnam. Isolated programs and activities have been implemented in the country, especially in Hanoi and Ho Chi Minh City, and a few well-known political leaders have personally taken up cervical cancer prevention as a cause, but much more needs to be done. PATH and our partners are committed to a cervical cancer prevention strategy that includes screening and treatment of precancerous lesions in addition to vaccination. Efforts to introduce the HPV vaccine in Vietnam can be supplemented by introduction of simple and affordable screening and treatment approaches, in order to help women who have already been infected with HPV.

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