Shaping a Strategy to Introduce HPV Vaccines in India: Formative Research Results from the HPV Vaccines: Evidence for Impact Project

PATH

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Formative Research Results from the *HPV Vaccines: Evidence for Impact* Project
PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, we help provide appropriate health technologies and vital strategies that change the way people think and act. Our work improves global health and well-being.

Headquartered in Seattle, Washington, PATH works in more than 70 countries.

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**Acronyms**

<table>
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<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>ANM</td>
<td>Auxiliary nurse midwife</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>HPV</td>
<td>Human papillomavirus</td>
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<td>ICMR</td>
<td>Indian Council for Medical Research</td>
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<td>NARI</td>
<td>National AIDS Research Institute</td>
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<td>NCRP</td>
<td>National Cancer Registry Program</td>
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<td>NGO</td>
<td>Nongovernmental organization</td>
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<td>NRHM</td>
<td>National Rural Health Mission</td>
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<tr>
<td>NTAGI</td>
<td>National Technical Advisory Group on Immunization</td>
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<td>TT</td>
<td>Tetanus toxoid</td>
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<td>UIP</td>
<td>Universal Immunization Program</td>
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Executive summary

Globally, nearly half a million women are newly affected by cancer of the cervix each year.1 The majority of these women live in developing countries, including more than 100,000 in India alone.2 New vaccines to prevent infection with the human papillomavirus (HPV), the primary cause of cancer of the cervix, have the potential to protect new generations of adolescent girls.

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 low-resource settings 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.3,4

This overview summarizes results from formative research in two states of India—Andhra Pradesh and Gujarat—regarding the health systems and policy context that will affect HPV vaccine introduction, as well as beliefs, values, attitudes, knowledge, and behaviors related to cancer of the cervix, 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.

In India, formative research by PATH and the National AIDS Research Institute of the Indian Council for Medical Research found that, in general, policymakers, health care providers, parents, and adolescents in both states would likely accept vaccination against cancer of the cervix, as long as it is safe, effective, affordable, and accessible. The findings from India also helped to provide insight into the complexities of vaccine introduction in a country with a population of more than one billion people. The strategies tested in India's demonstration project will be developed based on the following key findings from the formative research.

India’s HPV vaccine delivery strategy: key findings

- Explore introducing the HPV vaccine as part of India’s current immunization program, either through routine monthly services or a special campaign approach.

- Consider applying the two-step approach to vaccination developed during the Japanese encephalitis campaign in Andhra Pradesh: in the first year, vaccinate all girls in Standards 6–10 (i.e., grades 6–10) and aged 10–14, and only girls in Standard 6 and aged 10 in the second year.

- Use both schools and government-sponsored mother- and child-care health centers (anganwadi centers) as delivery sites, in order to reach the large numbers of out-of-school girls.
■ Ensure coordination within and among the national government, the states, and the districts, as well as between the health and education sectors.

■ Support auxiliary nurse midwives to deliver and monitor vaccination by providing training on the new vaccine and effective delivery.

■ Explore a potential role for the private sector in providing HPV vaccine, including possible impacts on affordability.

■ Strengthen systems for ensuring injection safety, monitoring immunization, and tracking and responding to adverse events in both states.

**India’s HPV vaccine communications strategy: key findings**

■ Disseminate information to address currently low levels of knowledge regarding cancer of the cervix, HPV, and the HPV vaccine.

■ Develop messages that build on positive perceptions of vaccination and community desire to prevent illnesses, including cancer.

■ Reassure parents and other groups that the HPV vaccine has been shown to be safe and effective.

■ Reach out to communities, including religious leaders, before introducing the new vaccine, in order to address questions and concerns (e.g., fear of side effects).

■ Use mass media, local media, and direct communication to educate and raise awareness of parents, girls, and potential decision influencers.

■ Publicize endorsement of HPV vaccination by the Indian government, professional associations, and community leaders.

**India’s HPV vaccine advocacy strategy: key findings**

■ Carefully navigate the complex policy process and be sure to reach the many individuals, departments, and agencies involved in policy development and implementation at national and state levels.

■ Generate momentum and leadership from key ministries and expert committees at the national level, at state health departments, and among district implementers.

■ Make information available to policymakers on cervical cancer disease burden, safety and efficacy of the HPV vaccine, cost and potential financing options, experience with the vaccine in other countries, and the programmatic requirements for HPV vaccine introduction.

■ Develop compelling visual aids and use human interest stories to demonstrate impacts of cancer of the cervix on women’s lives and livelihoods at the community level.

■ Explain how HPV vaccination is consistent with India’s health priorities to prevent cancer of the cervix, to promote immunization, and to protect women’s and adolescents’ health.

The formative research was carried out by the National AIDS Research Institute of the Indian Council for Medical Research, with technical and financial support from PATH.
Introduction

“Our granddaughters’ generation should be a generation without cancer.”

– Grandmother, rural area of Andhra Pradesh

Globally, nearly half a million women are newly affected by cancer of the cervix each year. The majority of these women live in developing countries, including more than 100,000 in India alone. Most did not have access to effective early detection and treatment programs that could have halted or slowed progression of the disease. New vaccines to prevent infection with the human papillomavirus (HPV), the primary cause of cancer of the cervix, have the potential to protect new generations of girls from ultimately experiencing the same fate.

Many countries have achieved good vaccine coverage for infants and very young children, but it is rare for developing world immunization programs to have strong systems for reaching young adolescents—the target population for this vaccine. That is why PATH initiated the HPV Vaccines: Evidence for Impact project in 2006, funded by the Bill & Melinda Gates Foundation. By piloting vaccine introduction in four countries—India, Peru, Uganda, and Vietnam—the project will assess and document the best possible approaches to reaching young adolescent girls with the HPV vaccine in low-resource settings.

The HPV Vaccines: Evidence for Impact project is meant to generate evidence to help policymakers and planners worldwide make informed decisions regarding regional and national vaccine introduction efforts and international financing plans. It is not a clinical trial of a new vaccine. The vaccines being used are already licensed in more than 100 countries, including India.

This report shares findings from the formative research in India, which was carried out by PATH and the National AIDS Research Institute (NARI) of the Indian Council for Medical Research (ICMR) in two states—Andhra Pradesh and Gujarat—to explore approaches to vaccine introduction. The results from India provide insight into the complexities of vaccine introduction in a country with a population of more than one billion people. In general, we found that policymakers, health care providers, parents, and adolescents in both states would accept vaccination against cancer of the cervix, as long as it is safe, effective, affordable, and accessible.

Cancer of the cervix and HPV

Of the estimated 270,000 cervical cancer deaths that occur each year, 85 percent occur in developing countries, including approximately 75,000 in India. In developed countries, incidence and mortality rates of cancer of the cervix have gradually decreased, thanks largely to screening programs (traditionally using Pap smears) that can spot the signs of precancer and treat them early. In developing countries, however, many women cannot access screening services or do not receive necessary treatment for precancer. If current global trends continue, by the year 2050, there will be more than one million new cases of cancer of the cervix each year.

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. One study from New Delhi and Hyderabad found...
that HPV types 16 and 18 were prevalent in more than 80 percent of invasive cancer of the cervix cases.\textsuperscript{15,16} Because the vaccines are 90 percent 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. The optimal target age for vaccination in girls has been shown to be between 10 and 14 years.\textsuperscript{17} The potential benefit of vaccinating boys is still under investigation.\textsuperscript{18}

The \textit{HPV Vaccines: Evidence for Impact} project aims to address several of the challenges likely to face HPV vaccination programs. Cancer of the cervix, while a serious problem, is not well known or understood in many places. 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 issues. Finally, given that cancer of the cervix can take decades to develop, the benefits of HPV vaccination will not be fully apparent until many years in the future. India also represents an especially challenging setting for vaccine introduction, given its enormous population and the many actors involved in developing and implementing policy at both national and state levels.

**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.\textsuperscript{19} 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).

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.

India: context

With a population of more than one billion people, India is a complex mosaic of diverse ethnicities, languages, regions, and cultures. Men and women in India face a variety of threats to their sexual and reproductive health. For example, more than 2.5 million people in India are living with HIV, and many are unaware of their status.20 More than 500 women die in childbirth each year for every 100,000 women who experience live births.21

About a third of India’s population is younger than the age of 15.21 Many young adolescent girls in India, especially those in rural areas, have little or no education: nearly 13 percent of 10- to 14-year-old girls have never attended school, and more than 30 percent have less than five years of schooling.22 Adolescent girls in India also face frequent under-nutrition, anemia, and infectious diseases, due in part to poor environmental sanitation. Given that the HPV vaccine is primarily intended for young adolescent girls prior to sexual initiation, it is worth noting that the median age at first marriage for women is approximately 17 years of age. Nineteen percent of the country’s total fertility rate is represented by births to young women between 15 and 19 years of age.22 There is also growing evidence of premarital onset of sexual activity.23

In raw numbers, India has the largest burden of cancer of the cervix of any country worldwide. Data from hospital-based cancer registries show that about one-third of the women admitted to hospitals with a cancer diagnosis each year are suffering from cancer of the cervix.24 Ninety percent of these cases are diagnosed at a late stage.24 Additionally, it is estimated that the population prevalence of HPV in India is about 7 percent, although unpublished reports have found rates as high as 19 percent.25 A large study conducted among women aged 16–59 in the Dindigul district of southern India reported a 12.5 percent prevalence of high-risk HPV.26
**Formative research methodology**

The research team in India 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 individuals from the following groups:

- Adolescent girls aged 10–14 years.
- Parents, guardians, and other relatives (e.g., grandmothers and aunts) of adolescent girls.
- Community and religious leaders.
- Teachers and education officials.
- Health providers, including community health workers, auxiliary nurse midwives (ANMs), anganwadi workers, registered nurses, pharmacists, medical officers, private practitioners, and cold chain technicians.
- Immunization experts.
- Policymakers.
- Policy “influencers,” including program and project implementers, nongovernmental organization (NGO) representatives, and members of professional associations.

All groups were sampled purposively, meaning individuals were selected using specific criteria to determine who would be most likely to have insights into the research topics. The focus groups and in-depth interviews included a number of participatory exercises, including drawing pictures of how a woman with cancer would look and mapping out the process of immunization in a locality.

Other research methods included a desk review of health statistics, school attendance data, existing health policies, and vaccine delivery information; field observations of immunization services, including exit interviews with clients and health facility record reviews; and consultative workshops with leading immunization experts at both national and state levels.

The study was conducted between July 2007 and March 2008 in the states of Andhra Pradesh and Gujarat.
Pradesh and Gujarat. The states were selected based on cervical cancer disease burden, immunization coverage, experience with new vaccine introduction, commitment to adolescent health and cervical cancer prevention, and willingness to participate in the project, as well as a number of other factors. The aim was to select states in the middle range for certain variables (e.g., immunization coverage). Additional statistics, including literacy rates, percentage of girls married before age 18, percentage of young children who are fully vaccinated, percentage of women visited by health workers, and percentage of children who left school during grades 1–5, were used to select one district in each state. Within each district, efforts were then made to reach tribal, rural, and urban groups.

Study sites were chosen in consultation with a national project advisory committee composed of multi-disciplinary experts in immunization and cancer of the cervix, including representatives from the Ministry of Health and Family Welfare, the state governments, ICMR, NARI, and the World Health Organization (WHO). This committee provided a number of additional strategic inputs into project implementation, as did state advisory committees consisting of government officials, medical experts, and representatives from professional organizations and NGOs.

The formative study protocol was reviewed and approved by NARI’s Ethics Committee and Scientific Advisory Committee, and by India’s Health Ministry’s Screening Committee. Approvals were also obtained from relevant state authorities to initiate the study. Oral or written informed consent was secured from all participants in accordance with local requirements.
Vaccine delivery strategy

In order to determine the most promising approach to delivering HPV vaccine in two states of India, the formative study researchers talked with members of all the study groups regarding sites and strategies for vaccination. Policymakers and health service providers also provided input on how introducing the HPV vaccine would impact current services and systems, which supplemented the document review and field observations.

How to reach young adolescent girls with the HPV vaccine

Most participants agreed that it makes sense to deliver the HPV vaccine through existing immunization services, either using routine outreach or a campaign approach. Policymakers and service providers in both states, as well as community members in Gujarat, recommended routine outreach. India’s routine immunization program currently provides six vaccines through health facilities, outreach centers, and schools. Villages generally receive services once a month, and tetanus toxoid (TT) boosters are scheduled to be delivered annually to girls and boys aged 10 and 16. Policymakers and service providers in both states felt that adding the HPV vaccine to routine service delivery at health facilities and outreach centers would not overburden the system. However, some policy influencers and other service providers expressed concerns that the HPV vaccine would add to the workload of the ANMs responsible for routine immunization.

Delivering the HPV vaccine through a campaign approach was also recommended by some respondents in both states, especially policy influencers, service providers, and community members in Andhra Pradesh. One drawback noted by a respondent in Andhra Pradesh was that those girls who miss the first dose during a campaign will miss out on vaccination altogether. Immunization experts, however, noted that this can be addressed by scheduling vaccination drives at regular and frequent intervals. Also in Andhra Pradesh, several policy influencers and service providers suggested focusing an HPV vaccine campaign only on girls in one age group (e.g., just 10-year-olds or girls in Standard/grade 6). One policymaker suggested an alternative two-step approach that was used in the recent Japanese encephalitis vaccine campaign: in the first year, vaccinating all 10- to 14-year-olds or girls in Standards 6–10, followed by only 10-year-olds or girls in Standard 6 in subsequent years.

A few respondents in both states and at the national level suggested pairing the HPV vaccine with cervical cancer screening services for older women, which could potentially result in a greater impact on cervical cancer disease burden. This was framed as consistent with the Indian government’s commitment to a continuum of care approach from infancy through adulthood. In Andhra Pradesh in particular, respondents framed this as a mother-daughter package of health
services. However, as screening services are limited in both states, the research found that the benefits to be gained by such an approach would also come with considerable challenges.

Other respondents, including some policy influencers and policymakers in both states, raised the possibility of adding the HPV vaccine to existing adolescent health services. As in many other countries, very few adolescents in India access the health system for preventive care. Additionally, few policies or programs have focused on this age group, although the Indian Academy of Pediatrics recently set up adolescent-friendly clinics where young people can seek advice on issues like mental health and puberty. An important drawback of integration with adolescent health services is that little information is available on the reach and impact of these services. Although the Government of India has expressed a commitment to adolescent health, delivery structures are still in the process of being developed and implemented. Some service providers and officials in Andhra Pradesh said that adolescent girls, particularly those aged 10–14, have limited access to health services and facilities.

Where to reach young adolescent girls with the HPV vaccine

Several respondents recommended delivering the HPV vaccine to girls in school, with additional services in health facilities or anganwadi centers (government-sponsored child-care and mother-care centers) to reach out-of-school girls. Policy influencers and service providers in Gujarat estimated that the number of girls not in school in that state could be as high as 30 percent, and the situation in Andhra Pradesh is similar. Participants also discussed a number of specific mechanisms within schools for reaching girls with the HPV vaccine. Many emphasized that school-based delivery of the HPV vaccine could use the platform provided by the TT booster, and also help to strengthen TT booster services. A few respondents worried that co-administration of these vaccines could reduce uptake due to potential increases in pain from vaccination and adverse events. A few policy influencers in Gujarat suggested that incorporating the HPV vaccine into the school health program might work, but an immunization expert there pointed out that the school program involves activities only once a year, and the HPV vaccine requires three doses in a six-month period. However, it was noted that the school health program could provide an opportunity to educate girls about the vaccine and identify girls eligible for vaccination.

Who is responsible for implementing the HPV vaccination strategy?

Most immunization in India takes place under the jurisdiction of the Universal Immunization Program (UIP) at the national level, but the states have a considerable amount of authority regarding implementation of vaccination. The national government generally procures vaccines for the country’s routine immunization program, but states may also procure vaccines directly from
manufacturers. Additionally, the national government releases UIP funds to the states, which then direct money to the districts for logistics, cold chain maintenance, injection safety, and salaries. States also fund some salaries directly, as well as electricity for immunization sites and transport of the vaccines. Vaccination policy and practice can vary significantly among the states. For example, the hepatitis B vaccine was formally introduced in Andhra Pradesh in 2002, and officials there noted that they have good experience with new vaccine introduction as a result.

In Gujarat, hepatitis B vaccine is available only in a few urban areas. Several policymakers and health workers noted that coordination among policymakers at different levels and in different departments of the government would be crucial for successful implementation. For example, respondents in Andhra Pradesh emphasized that coordination between the health and education departments would be particularly important for a school-based vaccination program.

At the point of delivery in villages, ANMs administer vaccines and monitor immunization coverage. ANM responsibilities include maintaining data on immunization, writing monthly immunization status reports, and transporting vaccines from health centers to immunization sites, as well as a number of tasks related to other health issues (e.g., birth and death reporting). Service providers and policymakers in Gujarat noted that many ANM positions are currently vacant. As a result, the current ANMs are overburdened, and in some cases, are conducting extra immunization sessions to cover the vacant posts. A policy implementer in Andhra Pradesh expressed concern that introducing the HPV vaccine would entail more work for ANMs and other support staff in terms of both vaccine administration and record maintenance requirements. This was echoed by the ANMs in that state, who highlighted that new staff, additional funding, and new infrastructure would be required. Information needs highlighted by service providers included cervical cancer disease burden in India and each state, the role of the HPV vaccine in preventing the disease, age at vaccine administration, dose schedule, guidelines for managing adverse events, and messages to be communicated to the community.

There may also be a role for the private sector to play in delivering HPV vaccine in India, as it currently provides 10–15 percent of immunization services. Interest in private-sector involvement was particularly strong in Gujarat. Some participants in Gujarat suggested that the HPV vaccine could be provided through the state's effective, well-accepted public-private partnership, involving possibly the Rajiv Gandhi Urban Health Mission. In Andhra Pradesh, the Rajiv Aarogyasri Community Health Insurance Scheme was mentioned as a means of making the vaccine available to families below the poverty line. Although the insurance scheme does not address immunization, it does include a focus on cancer. Overall, however, community
participants felt that vaccination should be provided through the government rather than private services, citing concerns about vaccine cost and quality of services. One health worker in an urban area of Andhra Pradesh noted that “for immunization, people come to the government service because facilities for immunization in the private sector are not good.” A mother in a rural area of Andhra Pradesh opined that “the government must deliver the vaccines through government hospitals, as people find it difficult to afford a vaccine in private hospitals.” An adolescent girl in rural Gujarat asked a question along similar lines: “If we are looking here and there for food and doing hard labor in the field, how can we pay money [for vaccines]?"

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 system and conversations with key informants confirmed that cold storage is available at the regional, state, and district levels for HPV vaccines, and that the distribution process and reporting systems in India are strong.

In Andhra Pradesh, for example, vaccines at the state and regional levels are stored in a walk-in cooler, and at the district and primary health clinic levels, in an ice-lined refrigerator. Vaccines are distributed in vaccine carriers on vaccination days to those transporting the vaccines, and all vaccines are placed in pouches in order that the labels remain intact and legible. A similar process is used in Gujarat. Throughout Gujarat, there are five walk-in coolers and one walk-in freezer, and most of the coolers serve between three and six districts. All of the coolers are more than 15 years old, and a few replacements are due to be installed within the year. On one occasion in the last five years, there was a shortage of government storage space in Gujarat. The problem was solved by using private cold storage.

Monitoring vaccine administration and safety

Injection safety practices were observed by formative study researchers in both states. In Andhra Pradesh, researchers found that government guidelines on injection safety were translated and distributed at the field level, as were guidelines on waste disposal. Recapping of used syringes occurred only a few times. Health workers stored used needles correctly, pointed down in puncture-proof containers. Study participants noted that since these practices were formally introduced throughout the state, the number of needle stick injuries had declined considerably. In Gujarat, appropriate auto-disable syringes were used for all injections. Moving forward, priorities for both states will include ensuring that all staff are consistently trained and retrained on injection safety, including proper needle disposal and maintaining a safe and clean workspace.
Although India does have a system in place for tracking and responding to adverse events following immunization, the researchers found that improvements are needed in both states. This was confirmed by a policy influencer in Andhra Pradesh, who noted that “to pre-empt problems with the introduction of the HPV vaccine, we would need to install an effective adverse events monitoring system.” In that state, although guidelines on adverse event follow-up are available, researchers observed that adherence by health workers could be improved. For example, some respondents noted that during the Japanese encephalitis campaign, adverse events monitoring was implemented effectively due to updated guidelines and having special teams in place. District-level officials in Gujarat echoed that adverse events reporting needs strengthening there as well, and one individual noted that such events can negatively impact vaccine uptake if not managed immediately, especially during new vaccine introduction.

An electronic system for tracking vaccination, called the Routine Immunization Monitoring System, has recently been implemented in India. Researchers confirmed that the system is used throughout Gujarat and has been installed in Andhra Pradesh. Study participants in Andhra Pradesh were knowledgeable about monitoring systems for vaccination, quality assurance, and maintaining the cold chain. Vaccine logistics forms were maintained in a complete, correct, and consistent manner. In Gujarat, although immunization is regularly monitored, the procedures for monitoring could be more effectively and widely disseminated. It was observed that vaccinators did complete immunization cards at all sites, although parents did not always remember to bring their children’s records. Participants had a variety of suggestions for improving monitoring of vaccination, including electronic systems like smart cards and enlisting the help of mothers and community members. In Gujarat, it was noted that tracking migrants is an especially important challenge in monitoring vaccination.

**India’s vaccine delivery strategy: key findings**

- Explore introducing the HPV vaccine as part of India’s current immunization program, either through routine monthly services or a special campaign approach.
- Consider applying the two-step approach to vaccination developed during the Japanese encephalitis campaign in Andhra Pradesh: in the first year, vaccinate all girls in Standards 6–10 (i.e., grades 6–10) and aged 10–14, and only girls in Standard 6 and aged 10 in the second year.
- Use both schools and government-sponsored mother- and child-care health centers (anganwadi centers) as delivery sites, in order to reach the large numbers of out-of-school girls.
- Ensure coordination within and among the national government, the states, and the districts, as well as between the health and education sectors.
- Support auxiliary nurse midwives to deliver and monitor vaccination by providing training on the new vaccine and effective delivery.
- Explore a potential role for the private sector in providing HPV vaccine, including possible impacts on affordability.
- Strengthen systems for ensuring injection safety, monitoring immunization, and tracking and responding to adverse events in both states.
Communications strategy

Members of communities where vaccination occurs need to be equipped with the background and knowledge to make informed decisions and/or give informed advice about cancer of the cervix prevention, including HPV vaccination. The formative study researchers explored how members of various groups perceive cancer of the cervix, vaccination, the HPV vaccine, and decision-making regarding adolescent girls’ health.

Cancer of the cervix: overall knowledge and awareness

“There is no treatment or cure for cancer, especially in the advanced stages.”

–Father, rural area of Andhra Pradesh

In both states, there was limited knowledge among respondents of specifics about cancer, especially cancer of the cervix. Few people in either state reported knowing anyone personally who had been affected by cancer, and there was no real sense of how frequently it occurred. On the other hand, in Andhra Pradesh, there was a strong perception that cancer is fatal and incurable. As one community member in a rural area said, “If I get cancer, I cannot survive.” In Gujarat, participants also noted that a cancer patient cannot generally be saved. One mother in rural Gujarat explained that “cancer means cancel.”

Some individuals in Gujarat mentioned hearing about a woman who had had her uterus removed as a result of some kind of women’s cancer. Few respondents in Andhra Pradesh were aware of women’s cancer, and participants there tended to mention lung, blood, breast, or stomach cancer, often citing mass media as their source of information. Those in both states who were aware of women’s cancer did not make any distinction between uterine cancer, cancer of the cervix, and “cancer of the womb.” Some teachers in Gujarat did have relatively more knowledge of cervical cancer symptoms.

Respondents in all groups conveyed an understanding of the fact that cancer can have negative impacts on families. For example, some mentioned the financial impacts of cancer, including a mother in a tribal area of Andhra Pradesh who said, “It ultimately leaves the person and family in debt.” Others emphasized cancer’s emotional impacts on the family, especially as it affects women. One teacher in rural Andhra Pradesh noted that “The mother is the heart of the family. If she got sick, the whole family would go into a depression.” Parents, girls, teachers, community leaders, and health workers also emphasized that women

Field workers review notes after formative research activities in Gujarat.
with cancer of the cervix are isolated or shunned by the community. A mother in a tribal area of Andhra Pradesh explained that “food items that are touched by those affected are not allowed to be given to others.” An adolescent girl in a tribal area of Gujarat said, “People will hate to be with her, will not sit with her for a meal, will keep her utensils and clothes separate, will not talk to her…” In Andhra Pradesh, teachers and community leaders explained that this isolation occurs either because of physical effects of the disease (e.g., foul-smelling vaginal discharge) or because of a perception that “cancer of the womb” is a consequence of bad habits or past sins.

Cancer of the cervix: perceived causes and risk factors

“Private parts of the body should be kept clean.”

–Mother, rural area of Gujarat

A few individuals in the study had heard of HPV, including some national and state policymakers, senior representatives of professional associations, and service providers. In both states, most respondents in all groups cited poor genital hygiene as the primary cause of cancer of the cervix. Some kind of sexual cause was often noted, including multiple sexual partners, unsafe sex, sex at a young age, sexually transmitted infections, multiple pregnancies or abortions, and menstrual disorders. In Gujarat, a few community members and policymakers also mentioned heredity and alcohol or tobacco use as possible causes, and participants from all groups mentioned improper nutrition. In Andhra Pradesh, home-based childbirth was suggested as a possible cause by people in the community and by health service providers, and policymakers mentioned oral contraceptive pills.

Most respondents were also not aware that cancer of the cervix is preventable, with the exception of a few health professionals in Gujarat who had heard of the HPV vaccine. Many health providers did not know about the vaccine or screening and treatment for pre-cancer.

Vaccination: perceived benefits and risks

“Prevention is better than cure.”

–Teacher, tribal area of Andhra Pradesh

In general, respondents in all groups demonstrated positive attitudes toward vaccination. Many parents and girls emphasized that preventing diseases is better than having to resort to treatment, as is reflected in the above quotation. A number of parents were also well aware of common childhood vaccinations and their positive impacts, citing reductions in diseases like polio and tetanus. One mother in urban Gujarat said, “Vaccines help to prevent disease and get rid of polio.” Adolescent girls also expressed support for immunization; as one girl in a tribal area of Andhra Pradesh put it, “We need to get all of our childhood vaccines.”

Several participants also stated that community awareness of childhood vaccines is strong and acceptance is high. For example, one father in urban Gujarat described a receptive environment when he said, “People are aware of vaccination and prioritize it even above work.” A rural
Shaping a Strategy to Introduce HPV Vaccines in India

A teacher in Andhra Pradesh reinforced this, indicating that “nowadays, people do not have many negative conceptions about vaccination.” Parents’ groups in Andhra Pradesh reported that superstitions and religious objections to vaccines are no longer a problem. One mother in a tribal area of Andhra Pradesh explained that this was due in part to the high quality of health services: “If there are any side effects or reactions, the health workers take care of them and medicines are given if children suffer with fever after vaccination.”

Not all respondents were unconditionally positive. Rural respondents in Andhra Pradesh felt that lack of awareness regarding vaccination is still a problem, which results in low attendance at vaccination programs. Teachers in Gujarat noted that non-acceptance of vaccines still occurs due to anxieties around getting infections, fevers, and paralysis. One health worker in Gujarat expressed concern that parents still do not completely understand the after-effects of vaccination. Even though they are told that slight pain or swelling at the vaccination site or fevers can occur and are not dangerous, these are still interpreted as adverse. Some children do not receive subsequent vaccinations as a result. A specific challenge for vaccinating adolescents was that most parents see vaccines as being for younger children. One teacher in urban Andhra Pradesh explained that “after children turn five, their parents have no interest in vaccination.” Specific concerns regarding the HPV vaccine, including among religious communities, are highlighted below.

HPV vaccine: perceived benefits and risks

“We will accept the new vaccine when we know its advantages.”

—Mother, urban area of Gujarat

Most participants felt that the HPV vaccine would be beneficial in India. Some participants explicitly linked this perception with support of immunization generally, including one respondent in a tribal area of Andhra Pradesh: “Owing to the positive and non-adverse effects of vaccines in the past, new vaccines would be welcome.” Other respondents in Andhra Pradesh emphasized the specific benefits of a vaccine to prevent cancer. As one adolescent girl from a rural area put it, “Since there is no medicine for cancer, it is better to have a vaccine to prevent it.” A rural health worker asserted, “If this vaccine is introduced, it will be accepted more by the people as they consider cancer more dangerous than polio.” Fathers in a tribal area of Andhra Pradesh also mentioned that the vaccines would help protect their daughters against uncertain sexual safety in marriage: “After marriage, you never know what may be caused due to intercourse and other activities, so in considering the good health of the girl-child, one should participate...”
in such a vaccine program.” Respondents across groups predicted that the vaccine would be well accepted if it were free, with limited or no side effects, and if information on its advantages and disadvantages were made widely available.

Formative study researchers found frequent concerns among community members and health care providers regarding potential side effects of the vaccine. One mother in a tribal area of Gujarat warned that “if girls get side effects after the first dose, then they will not take the second dose.” Another wondered, “Who will take responsibility if anything goes wrong after giving the vaccine?” Participants in Gujarat emphasized that tribal communities in particular are wary of vaccines due to fear of side effects. A teacher in a tribal area echoed this: “People will not really accept the new vaccine because of their perceptions that they will get infected by boils, fever, paralysis, and other things.” Some community members were worried about the vaccine’s effects on girls’ fertility; one community member in rural Andhra Pradesh asked, “Is the vaccine given to reduce population?”

Participants had a range of opinions as to whether there would be religious opposition to the new vaccine. Many individuals from different Hindu, Muslim, and Christian communities felt that there would be no opposition if the vaccine is shown to be beneficial to girls. Some community members in Andhra Pradesh did anticipate that there would be reservations connected to religion, however. On the other hand, religious leaders were generally encouraging about the vaccine when asked directly, as they see immunization positively. Like others, they desired reassurance regarding side effects. Participants in both states emphasized that communicating with religious leaders and communities ahead of time would probably help to head off potential resistance.

HPV vaccination: who decides?

“If a vaccine is introduced, it is necessary to educate parents first.”

–Teacher, urban area of Andhra Pradesh

In both states, parents emerged as the primary decision-makers regarding whether a girl would receive the HPV vaccine, with the role of mothers or fathers highlighted due to specific factors. Overall, it was reported that decisions are made jointly by both parents. For example, a teacher in rural Andhra Pradesh explained that “both the mother and father make decisions in family matters.” In rural Gujarat, a community member described it similarly: “The mother informs the father, and they make the decision together.” A father in a tribal area of Gujarat also emphasized the crucial role that parents play when he said, “Parents are just as responsible as nurses for vaccination.”

Some felt that mothers would be the primary decision-makers, as the decision involves an adolescent girl’s health. As one health worker in urban Andhra Pradesh explained, “Both parents are approached for general health issues, but when it comes to menstruation and other women’s health complaints, the mother is approached…a girl cannot share everything with her father.” Another participant in rural Gujarat stated that “The decision to give the vaccine to the child is made by the mother. The father does not understand this matter.”
Somewhat less commonly, respondents indicated that fathers would have the upper hand in the decision, particularly if finances are involved. A grandmother in rural Andhra Pradesh explained that “the decision-maker would obviously be the father because of the economic link, and because he decides family matters like where to go and what to do.” A father in rural Andhra Pradesh also noted that “fathers, who are usually more worldly and a bit more educated than their wives, decide about health issues.”

A range of additional groups and individuals were seen as having a potential influence on parents’ decisions, including community leaders, health workers (including anganwadi workers), and teachers. Other family members were also highlighted. For example, an adolescent girl in urban Andhra Pradesh reported that the “responsibility for adolescent girls’ health rests with parents and grandparents,” and a mother in a rural area noted that “maternal grandmothers also have great influence on the girls, as they are more attached to them.” In Gujarat, “aunties” were explicitly mentioned, including their roles as individuals who accompany girls to health services. While some noted that religious leaders play a role, they confirmed that parents still have the final word; as a religious leader in a tribal area of Gujarat put it, “If the religious leaders do not give permission, then it is up to the family to give permission or not.” Additionally, endorsement by the government, professional associations like the Indian Academy of Pediatrics, and community leaders were perceived as vital for HPV vaccine acceptance.

**Health information and education**

“It all depends on the way we raise awareness among the people and convey the message.”

–Religious leader, tribal community of Andhra Pradesh

Participants at all levels emphasized that education and outreach regarding the HPV vaccine would facilitate its acceptance. They highlighted the need to provide information about cancer of the cervix and its causes, as well as the benefits of the vaccine and possible side effects. For example, respondents in Andhra Pradesh suggested emphasizing that cancer of the cervix and HPV are both very common, reporting how many people in India have died of cancer of the cervix, and sharing any experiences with the vaccine from other countries. Respondents’ ideas tended to center on
addressing the specific interests and concerns noted above with regard to vaccination and the HPV vaccine. Specific slogans suggested by participants in Andhra Pradesh included:

“Protect your female children from cervical cancer.”

“The vaccine does not have any health hazards.”

Respondents recommended reaching parents, adolescent girls, and other community members with both mass media and more direct communications, including group meetings, street plays, and one-on-one interpersonal communication by trained community health workers and peer educators. Respondents in Gujarat also suggested meeting with community leaders and political leaders first, then following that up with information in the mass media and advertisements in communities. In Andhra Pradesh, participants noted that television would be a particularly effective medium, as it reaches 70 percent of villages. There was also an emphasis on ensuring consistency among government officials and politicians in order to make the message more effective.

**India’s communications strategy: key findings**

- Disseminate information to address currently low levels of knowledge regarding cervical cancer, HPV, and the HPV vaccine.
- Develop messages that build on positive perceptions of vaccination and community desire to prevent illnesses, including cancer.
- Reassure parents and other groups that the HPV vaccine has been shown to be safe and effective.
- Reach out to communities, including religious leaders, before introducing the new vaccine, in order to address questions and concerns (e.g., fear of side effects).
- Use mass media, local media, and direct communication to educate and raise awareness of parents, girls, and potential decision influencers.
- Publicize endorsement of HPV vaccination by the Indian government, professional associations, and community leaders.
Advocacy strategy

In order to guide an advocacy strategy to inform and mobilize policymakers, formative study researchers reviewed relevant documents and talked with officials about the policy formulation and implementation process in India, as well as in Andhra Pradesh and Gujarat specifically.

What type of policy is needed?

The nature of the policy needed for HPV vaccine introduction will vary depending on the vaccine delivery strategy selected. For example, if the vaccine is to be included in India’s routine immunization program, it will be necessary to review current policy at both national and state levels, and add the HPV vaccine to the immunization schedule. If, however, the vaccine is to be bundled with TT boosters or delivered through other adolescent health services, the adolescent health policy will need to be expanded, and the school health program involved. Regardless of the specific strategy chosen, policy implementers in Gujarat expressed a desire to start with existing health policies and build on them, rather than creating a completely new policy from scratch.

Who is involved in policy development or adaptation?

Although policy development is a complex process in any country, respondents in India made a special note that the number of groups and stakeholders involved will add to the complexity of vaccine introduction, and sensitivity to the dynamics among different individuals, departments, and agencies will be required. Additionally, the increasing autonomy of state governments in India means that each has its own unique policy structure, initiatives, and relationship with the national government.

According to policymakers, India’s Ministry of Health and Family Welfare and the state health departments would be key shapers of HPV vaccine introduction policy. A central-level policy body that respondents highlighted as playing a major role in new vaccine introduction is the National Technical Advisory Group on Immunization (NTAGI), which would advise the national government regarding the feasibility of introducing the HPV vaccine in India. If NTAGI recommends introduction, approval is also required by the cabinet, and bureaucrats and technocrats in various government ministries would draft implementation guidelines, including a monitoring and evaluation component. At the state and district levels, health departments would ultimately be responsible for implementing these guidelines. All of these actors represent important advocacy targets.

Respondents also noted that a number of ministries would be involved in policy development for this vaccine. For example, many participants highlighted the Ministries of Health and Family Welfare, Education, and Women and Child Development, and noted that coordination within and among these departments is crucial. National immunization experts also indicated that officials in Youth Affairs would need to be involved, given the target population of adolescent girls. Officials in different states also mentioned additional policy players. For example, in Andhra Pradesh, participants mentioned the Department of Social Welfare, and in Gujarat, Integrated Child Development Services was suggested.
Key decision-makers, including religious and other community leaders, should be targeted to activate a broad, multi-sectoral influence. The study also revealed the need for women’s advocates, champions from professional associations (like the Indian Academy of Pediatrics), and media to influence parliamentarians and bureaucrats at both the national and state levels regarding public introduction of the HPV vaccine. Although for the most part India finances its national immunization program through internal government resources, technical and financial support from major organizations such as WHO, the United Nations Children’s Fund, and the GAVI Alliance would also help facilitate policymaking for vaccine introduction.

**What are some key steps in policy development?**

In addition to review by NTAGI and development of an implementation plan by the relevant ministries and departments, a number of other steps are involved in introducing a new vaccine in the public sector. For example, respondents highlighted that various approvals would be needed for HPV vaccine introduction, including clearance from the National Drug Authority and licensure by the Drug Controller General of India. On the other hand, one state policymaker in Gujarat pointed out that even without national approval, the state could move forward with introduction itself as long as it had approval by the appropriate ethics committees. In Andhra Pradesh in recent years, both hepatitis B and Japanese encephalitis vaccines were introduced independently of the national immunization program. In this case, the state has to bear the costs of introduction, including initiating and receiving approvals at the national level and getting money disbursed from the relevant finance departments. As one state-level policymaker in Gujarat said, “It is easier if it becomes a national program before it becomes a state program; otherwise, it would require special effort.”

In Gujarat, several policymakers and influencers felt that it might be advisable to take the additional step of introducing the HPV vaccine first in the private sector. If uptake in the community was found to be high, then the vaccine could be introduced in the public sector. This approach has been applied in the past in Gujarat with the hepatitis B and measles, mumps, and rubella vaccines. Policymakers noted that the private sector is strong and often has access to new vaccines earlier, which can create pressure for public-sector introduction. Initial private-sector introduction would need to be carefully considered, however, given people’s misgivings about paying for the vaccine (see “Vaccine delivery strategy” section).
What information do policymakers need in order to prioritize HPV vaccination?

The policy review found clear prerequisites for deciding whether to introduce a new vaccine. According to UIP documents and consultation with immunization experts, a vaccine can be released for public use when:

- The vaccine is confirmed to be safe and effective.
- The disease burden is sufficient to warrant introduction of the vaccine into the national program.
- Cost of the vaccine is reasonable.
- Financial sustainability is evaluated.

National policymakers requested information on a number of factors related to these considerations, including locally relevant information on disease burden, safety and efficacy data, evidence from other countries on the use of the vaccine (especially those with a disease profile similar to India), cost and cost-effectiveness calculations, and overviews of health systems architecture developed by countries that have already successfully introduced the vaccine. Immunization experts in Andhra Pradesh also asked for more information on price and financing options; the programmatic impact of the vaccine on other health programs; surveillance and quality control; and supply security issues, given past challenges there with Japanese encephalitis vaccines. Some felt that the current high price of the vaccine could be a barrier to its introduction. Others pointed out, however, that government officials at the national and state levels would also need to consider savings on treatment expenditures as a result of the vaccine. Policymakers and influencers in Gujarat highlighted the need for different costing scenarios for different groups within the community. Participants there also suggested that a robust database with information on prevalence, incidence, and other epidemiological information on cancer of the cervix be created in preparation for policymaking. Additionally, they requested information on human resource requirements, training requirements, and needs in terms of developing an adverse events monitoring system.

Some national policymakers also noted that cancer of the cervix differs from other vaccine-preventable diseases like Japanese encephalitis, in that it is not eye-catching, visible, acute, or seasonal. These individuals recommended developing a compelling picture of the disease's impacts in terms of lives and livelihoods as part of an advocacy strategy.

How does HPV vaccine introduction fit with India’s health priorities?

The Government of India recently launched the National Rural Health Mission (NRHM) to coordinate delivery of all public health activities, and in recognition of the importance of health in the process of economic and social development.

Policymakers and policy implementers demonstrated a clear interest in developing comprehensive cervical cancer prevention programs that include HPV vaccination. In Gujarat, for example, policymakers expressed a preference for carrying out cervical cancer screening and HPV vaccine introduction in parallel. A few others, however, expressed that while cancer of the cervix is prevalent in India, it is not as common as in African countries, and that other health concerns,
Respondents noted that introduction of the HPV vaccine is consistent with India’s strong commitment to immunization. Since 2000, for example, India has prioritized immunization as a means of achieving the Millennium Development Goals. The goal of India’s UIP is to provide high-quality services to all communities in order to prevent mortality, morbidity, and disability from diseases that are preventable through currently available vaccines, as well as vaccines being developed for future use. As one policymaker noted, “There are a number of vaccines in the pipeline for introduction.” The guiding principles of the UIP are maximal reach, equity, quality and safety, sustainability, and management excellence.

In Andhra Pradesh, some respondents noted that the HPV vaccine is also appealing because it can facilitate greater attention to adolescent health. Currently, HIV/AIDS and family planning programs are the primary services available for adolescents. On the other hand, some policymakers noted that anemia should be given priority over cervical cancer prevention, as it is a more immediate problem. In Gujarat, the political leadership’s focus on women’s health has created a supportive environment for action to address cancer of the cervix.

India’s advocacy strategy: key findings

- Carefully navigate the complex policy process and be sure to reach the many individuals, departments, and agencies involved in policy development and implementation at national and state levels.
- Generate momentum and leadership from key ministries and expert committees at the national level, at state health departments, and among district implementers.
- Make information available to policymakers on cervical cancer disease burden, safety and efficacy of the HPV vaccine, cost and potential financing options, experience with the vaccine in other countries, and the programmatic requirements for HPV vaccine introduction.
- Develop compelling visual aids and use human interest stories to demonstrate cervical cancer’s impacts on women’s lives and livelihoods at the community level.
- Explain how HPV vaccination is consistent with India’s health priorities to prevent cervical cancer, to promote immunization, and to protect women’s and adolescents’ health.
Conclusion

Statistics show that, if nothing changes, by 2020 more than 200,000 women in India will be newly diagnosed with cancer of the cervix each year—double the current rate. Currently, apart from initiatives in a few states, screening for cancer of the cervix in India is mainly opportunistic. On the other hand, a clear consensus emerged from this research, calling for HPV vaccine introduction to occur within the context of a comprehensive approach to preventing cancer of the cervix. Many respondents noted that increasing cancer awareness as part of HPV vaccine outreach could create an opportunity to build a robust cervical cancer screening program for adult women.

In India, PATH and NARI conducted formative research to explore possible approaches to vaccine introduction in that setting—and found that, in general, policymakers, health care providers, parents, and adolescents would accept vaccination against cancer of the cervix, as long as it is safe, effective, affordable, and accessible. In addition to shaping strategies that will be tested in the demonstration projects, our results also helped to improve understanding of the complex environment of new vaccine introduction in a large country from the perspective of children, parents, health workers, policymakers, and a wide array of community members.
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This document is a synthesis of the research report:


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