Insights

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International AIDS Vaccine Initiative

VACCINE INTRODUCTION IN DEVELOPING COUNTRIES

Report on a qualitative study assessing the views of policy makers and other stakeholders

Perspectives on HPV vaccine introduction in Tamil Nadu, India

New health technologies have great potential to improve public health around the globe. Vaccines have proved to be one of the most cost-effective public health interventions, and several that prevent life-threatening infections are being licensed or are in advanced stages of clinical development. To make an impact on public health, these vaccines must reach the people who need them most. Rolling out new health technologies—including vaccines—in emerging economies poses myriad financial, socio-cultural and logistical challenges.

History reveals wide disparities in ensuring a new vaccine is accessible to those in need. Delays of more than 20 years from the time a vaccine is licensed in industrialised countries to when it is made available in developing countries have been the norm. Establishing an affordable price, promoting public education to create demand and developing health infrastructure and mechanisms to deliver the vaccine are among the issues that must be addressed.

Commitment and support from policy makers is critical to ensuring that new health technologies are quickly integrated into national health systems. Policy makers must weigh the importance of introducing a new vaccine or health technology against competing priorities, and they need specific information to make informed decisions. Thus it is imperative to understand the political, social and cultural dynamics that lead to increased attention for particular health issues at the policy level.

Recently, two highly effective prophylactic vaccines have been developed that prevent infection by the strains of *human papillomavirus* (HPV) most associated with cervical cancer. These new vaccines have the potential to avert significant illness and almost 250,000 premature deaths each year among women globally. But these vaccines pose complex challenges for policy makers, particularly because the vaccines are given to young adolescent girls and require delivery outside traditional immunisation programs that primarily serve infants and children.

To shed light on the factors that could influence policy decisions around the adoption of HPV vaccines, the International AIDS Vaccine Initiative commissioned a qualitative study to assess the views, knowledge gaps, concerns and information needs of key policy makers and other stakeholders in Tamil Nadu, India. Understanding the dynamics surrounding HPV vaccine introduction also presents an opportunity to elucidate key factors that may facilitate country-level policy decisions related to the introduction of other new vaccines and health technologies, the launching of a new vaccine into an immunisation program and the strategies for reaching an adolescent or pre-adolescent population.

IAVI hopes the findings from this study help inform those planning to introduce the HPV vaccine and other health technologies that become available in the future, particularly those targeted to adolescents in emerging economies.

Study Background

The study on which this brief is based documents the views of policy makers and influential stakeholders on the potential introduction of HPV vaccines in Tamil Nadu, India. Tamil Nadu was selected because of its high rate of cervical cancer as well as its strong public health delivery system, including a government that is receptive to new health technologies such as vaccines. Twenty-seven in-depth, face-to-face interviews were conducted in October 2008. Study participants included medical professionals and government officers, plus representatives from non-governmental organisations (NGOs), religious organisations and international development agencies. The principal investigator conducted the interviews using a guide with open-ended questions. A team of researchers translated key information from Tamil to English, and data were categorised, entered into a database and analysed by the investigator.

Participants were associated with these professions/ organisations:

- Medicine ■■■■■■ 7
- Government ■■■■■■ 7
- Religious ■■■■ 5
- NGOs ■■■■ 5
- International Development ■■■ 3

Total: 27

Study Results

Knowledge Gaps: Issues surrounding cervical cancer and HPV vaccines were generally well understood by those interviewed, but some knowledge gaps became clear. Respondents held differing views on the prevalence of cervical cancer in the region, the cause of the disease and the efficacy of the HPV vaccine. Most recognised that cervical cancer is a serious health issue in their state, and some speculated that the disease is even more prevalent than is understood because of underreporting. Others—primarily government officers—did not see cervical cancer as a serious health issue in Tamil Nadu. Some in this group also were uncertain about the nearly 100% efficacy rate of HPV vaccines.[1] One government officer stated:

"So it depends—is there a real problem, and if so, is the vaccine really effective? Have to see the epidemiology."

—GOVERNMENT OFFICER

It is well established that almost all cervical cancers are caused by the *human papillomavirus*. However, some stated that the link between HPV and cervical cancer had not been made strongly enough for the vaccine to be considered for inclusion in the national public health program. One respondent from the medical field said:

"Of all cervical cancers, what numbers are caused by non-HPV factors? We don't know this. Then we should know incidence in Tamil Nadu and India."

—MEDICAL PROFESSIONAL

Risk factors for cervical cancer were believed to be multiple childbirths at short intervals, illegal abortions, untreated sexually transmitted infections, low risk perception and a lack of personal hygiene. Although most of these factors are known to be associated with cervical cancer, there is no evidence they cause the disease.[2] Untreated HPV infection is the only known causal factor. Additional risk factors that have been identified and were not mentioned by respondents include diet, family history, multiple sex partners, use of oral contraceptives, smoking, and a compromised immune system.

[1] Efficacy is 100% for Cervarix® and 98-100% for Gardasil® against the two types of HPV that cause 70% of cervical cancer.

[2] Scientific studies that show an association between a factor and a health effect do not necessarily imply that the factor causes the health effect.

"Basically, hygiene and spacing of children are the best ways to prevent HPV. It's an infection that spreads, seems to strike the impoverished because of their lack of access to water, poor daily personal hygiene ... sharing of clothes as between mother and daughter"

—NGO REPRESENTATIVE

These knowledge gaps reflect the need for accurate information regarding cervical cancer and HPV vaccines. Especially important is the need to communicate the extent of cervical cancer disease burden to government officers, as they were least aware of the disease prevalence in Tamil Nadu. Results showed that medical professionals need clear information regarding all aspects of HPV and cervical cancer because they are likely to be influential advocates for the vaccine.

Concerns and Potential Challenges

Safety: Respondents voiced several concerns regarding the introduction of HPV vaccines. Side effects from vaccine administration were not viewed as a major obstacle, but respondents did emphasise the importance of educating the community and the vaccine recipient about possible negative reactions.[3] Some respondents representing religious groups wanted evidence that a girl's long-term reproductive health would not be affected by the vaccine.

Efficacy: Respondents indicated they need evidence that the vaccine is effective, especially over the long term. At the same time, respondents understood that it would be many years before long-term effectiveness could be demonstrated because girls would be vaccinated at a young

[3] The most common side effect of the HPV vaccine is soreness at the injection site.

age and HPV-related illness doesn't develop until years after exposure.

"We don't want something which may or may not work—where people are thinking they are protected when they are not"

—MEDICAL PROFESSIONAL

Sexual behavior: Respondents explained that the administration of a vaccine to young girls for protection against a sexually transmitted virus would be a sensitive issue, but this was not generally viewed as a barrier to community acceptance. When asked directly, respondents had some concerns that HPV vaccines could lead to an increase in sexual activity because girls might have a sense of being protected from cervical cancer. The majority of respondents did not think this was a real danger because other risks such as sexually transmitted diseases, HIV and unintended pregnancy remain. Most did not think girls would believe they were fully protected from other sexually transmitted diseases as a result of the vaccine.

Risk perception: Creating awareness about a girl's risk for HPV infection was seen as vital to creating demand at the community level. Several respondents believed it would be difficult to convey accurate risk perception to a young population. One respondent cautioned that although it is important to create awareness of risk it also is essential to avoid creating an atmosphere of fear. Establishing this balance would be necessary to gain community acceptance of the vaccine.

Priorities for Investment Cost-effectiveness of the vaccine was also a major concern. Several respondents thought that the population at risk for cervical cancer is not large enough to justify universal immunisation. Although some girls would grow

up to be at higher risk than others, respondents agreed that future risk could not be predicted at a young age. Another argument against widespread immunisation was that other health-care measures might be a higher priority for girls, such as the rubella vaccine, anemia control and improved nutrition. To balance the cost of vaccinating all girls, the vaccine would need to be highly effective, participants said.

Many respondents suggested that the government should focus on other methods of prevention, such as screening and education, rather than investing in a preventive vaccine. Some pointed to recent successful cervical cancer screening programs in Thanjavur and Villupuram districts. But beyond financing and infrastructure, participants acknowledged that a major obstacle to screening is that women in India are culturally conditioned to neglect their health. Women typically do not get medical checkups in the absence of symptoms.

"Many infections in women are not being treated at early stages. Embarrassment, financial, social reasons all apply. Plus they sacrifice for the family. They come for treatment only when [they have a] severe situation that prevents them from doing their daily work. Plus they don't discuss sex, sexual history, behavior."

—MEDICAL PROFESSIONAL

Politics: The greatest barrier by far to effective decision-making regarding the HPV vaccine in Tamil Nadu is that it lacks "political promise," according to study participants. Respondents noted the two types of health interventions most likely to be adopted: those that show quick and visible results and those that are introduced in response to strong public demand. The common view was that HPV vaccines fall short on both counts, posing a challenge to rapid adoption. The respondents who were optimistic about the eventual introduction of the vaccine believed strong community support could drive the issue to the forefront.

"The political challenge [of HPV] is that people don't see this as a public health emergency."

—International development agency

Information Needs

Respondents expressed the need for information to inform their decisions regarding HPV vaccine introduction. The majority of government officials, as well as several others, emphasised that reliable epidemiological data is needed to establish the HPV-related disease burden in Tamil Nadu. Those who worked in medicine acknowledged the slow pace of adopting new vaccines and emphasised that strong evidence of disease burden would be demanded before the government took action.

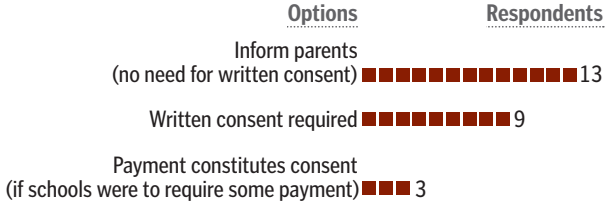
"Prevalence data should serve as an eye-opener for policy makers."

—Medical professional

Respondents also sought data on the long-term safety, efficacy and cost-effectiveness of the vaccine. They sought evidence that universal HPV immunisation would be less expensive than screening and treating those with cervical cancer. Respondents had no doubt that the government would be able to make an informed decision regarding vaccine adoption if the need could be established.

Obtaining Informed Consent for HPV Immunisations

Which of the following three options would be most appropriate for India if the HPV vaccine were delivered via schools?



Reaching Adolescents

The dynamics surrounding the delivery of a vaccine for a sexually transmitted infection to adolescents is a critical component of the decision to introduce the HPV vaccine. Two issues dominated participants' responses when asked about the best way to reach adolescents: the logistics of reaching girls and the sensitivity of discussing a vaccine for a sexually transmitted virus with a population that is not yet sexually active.

Because of high enrollment and low dropout rates in Tamil Nadu, respondents believed that most 10- to 14-year-old girls could be reached through schools. Girls who drop out of school would be more difficult to reach, but based on the success of pilot programs for the Japanese Encephalitis vaccine participants were confident it would be possible. In addition, the Tamil Nadu government has several programs in place for adolescents such as the Kishori Shakti Yojna, also known as the Adolescent Health Programme, which can help reach girls who don't attend school.

Respondents also suggested creating a culture of a second round of vaccines around age 10 to help ensure immunisation.

"[We] need to create a culture of a second round of vaccines needed at age 10-12. Currently we only think of vaccines at infancy. Once school starts they forget all about vaccinations. Creating a culture of 5th-year and 10th-year vaccinations will be easy for them to remember. Creating this is a political decision more than a professional decision"

—MEDICAL PROFESSIONAL

Study participants identified two different approaches to discussing a vaccine for a sexually transmitted infection with young girls. Some respondents indicated that providing the facts about HPV, including the method of transmission, is the best option. Others said the vaccine should be promoted with a simple message of protection against cervical cancer. Those who supported the first approach believed that although vaccination would require a discussion of sexual activity, parents would give their support because it would benefit their daughters' health. One-third of respondents said there might not be a need to communicate details regarding sexual transmission. They reasoned that because cancer is understood by the general population, positioning the vaccine as a cancer-fighting tool might be sufficient to make a compelling case for its acceptance.

"If you tell them it is for sexually transmitted problem, definitely there will be resistance. If you say it is for cancer, there will be less resistance."

—NGO

Strategies for Successful Vaccine Introduction

Details regarding the implementation and uptake of the vaccine would provide policy makers with additional information to make a decision. Respondents offered several suggestions for the launch of the HPV vaccine into Tamil Nadu's immunisation program.

Prepare data: Clear information regarding all aspects of the vaccine should be gathered well in advance of introduction. In particular, data on the following were recommended:

- HPV and cervical cancer prevalence and incidence
- Socioeconomic burden
- Vaccine safety and efficacy
- Cost-effectiveness of immunisation programs
- Examples of successful HPV vaccine programs from other countries
- Information on HPV vaccine trials, particularly in India

Ensure political relevance: To help counter the anticipated lack of political promise, demand for the vaccine should originate from the public as much as possible. To achieve this, community engagement should begin before the proposal for a vaccine program is presented to the government.

Build a buzz around the vaccine: To gain acceptance for the vaccine, relationships should be established with large organisations that work for and with young people. This means involving youth groups, sports associations and community-based organisations, as they play a key role in preparing the community for immunisation programs. Identifying a champion to communicate information also could increase the visibility of the vaccine and create trust among the general population.

Develop appropriate materials: Information, education and communication materials based on an understanding of a community's questions and concerns would need to be prepared and disseminated widely at the start of the vaccination campaign. Developing a book of data and

Implications for AIDS Vaccines

Because future AIDS vaccines are likely to have some similar characteristics to HPV vaccines (they are designed to prevent a sexually transmitted infection and might target a population that is not yet sexually active), this study can provide important lessons for future HIV vaccine introduction. A limited number of questions on HIV vaccines were included in the interviews.

Of the 23 respondents who were asked whether they would support a future AIDS vaccine, 12, or just over 50%, said they would give full support. Eight would give conditional support and three said they would not support an AIDS vaccine.

The main reason given in support of an AIDS vaccine was that adolescents are vulnerable to HIV transmission and not entirely able to protect themselves. In addition, women are more vulnerable to transmission even if they don't engage in risky behaviors. Those who would give conditional support said the vaccine must be 100% effective. Those unwilling to support an AIDS vaccine were concerned that the protection offered might encourage high-risk behavior.

The study illustrates the importance of several factors to facilitate decisions regarding introduction of future AIDS vaccines into the public sector:

- Collect and disseminate data on the safety and efficacy of the vaccine.
- Develop appropriate materials to address community concerns
- Consult with NGOs and activists
- Engage the media and ensure access to accurate information

These strategies would be crucial to informing the policy making process regarding the introduction of future AIDS vaccines.

information as a reference for health workers also was recommended.

Use the opportunity to start clinics for adolescents: Many respondents who worked with young people identified a need for guidance among youth in India. Some believed that building clinics for adolescents could serve the dual purpose of providing a place where young girls could receive vaccinations, as well as information and counseling.

"[The media's] power to convince is higher than you or me or any politician. Man in small town will say if written in Daily Thanthi then it must be right. If you are not providing them with the information, they will say it is nonsense. If you support them, they will say it is an excellent opportunity for people."

—Government officer

Engage the media: Without exception, all respondents emphasised the significant role of the media in the introduction of any vaccine. The media is influential at both the community and policy levels. Managing the media would be integral to vaccine introduction, and efforts to provide accurate information would be critical. Interviewees who have had direct experience with the media emphasised that this engagement must be a continuous process.

Consult with NGOs and activists: The majority of respondents stressed that NGOs and activists should be engaged early in the planning process.

Organise a legal and ethical committee: Some respondents thought a committee should be organised to ensure that all legal and ethical aspects of the vaccine and its delivery are carefully considered. Representatives would be available to manage any questions that might be raised by the public on legal and ethical issues related to the vaccine.

Lessons Learned

This study suggests that policy makers and other stakeholders need additional information to make an informed decision regarding HPV vaccination. This includes data on:

- The prevalence and socio-economic burden related to cervical cancer
- The safety and efficacy of the vaccine
- The link between HPV and cervical cancer
- Alternative means of preventing cervical cancer
- Details on why the vaccine would be a critical complementary method of prevention
- The effect of the vaccine on the current and future health of girls

Understanding the information needs of policy makers and other influentials is an essential component to inform decisions and develop introduction programs for new vaccines and other health technologies. This information would complement data from other studies that include views of national and state policy makers, policy decision-making processes, health systems, medical provider and community perceptions and norms, and effective strategies for reaching specific populations.

The more information policy makers have, the more prepared they will be to make an effective and efficient decision regarding the adoption of a particular health technology—a decision that could save countless lives.

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