



Introducing HPV Vaccines in Developing Countries: Overcoming the Challenges

Despite the remarkable promise of the current prophylactic human papillomavirus (HPV) vaccines, their introduction into developing countries will present unique and considerable challenges. While vaccine developers recognize that making the vaccines available where the burden of disease is highest is a priority, global, regional, and national demand for the vaccines and requirements for their introduction are unclear, raising an array of programmatic and sociocultural issues. PATH and its partners are working on ways to identify and overcome these challenges.

Awareness of HPV and other factors influencing demand for HPV vaccines

The causative role of HPV in the development of cervical cancer has been clarified only relatively recently, and awareness of this connection is still low among health care providers and policymakers in many parts of the developing world. In some places, there is confusion between HPV, HBV, HSV, and HIV, and so a potential HPV vaccine provokes misunderstanding. Awareness of HPV is further hindered by the lack of national data on type-specific HPV incidence and prevalence and on cervical cancer mortality in many parts of the world. Studies that provide this type of data are needed to help clarify country-specific demand for HPV vaccines and may be necessary in many countries for approval of national HPV vaccine introduction policies. Individual country requirements in terms of type, size, and/or location of such studies will vary, and mechanisms for clarifying and meeting these requirements will need to be established.

The demand for HPV vaccines in developing countries will also be influenced greatly by vaccine affordability. Industry negotiations and partnerships with global vaccine distribution or financing agencies are potential mechanisms to make HPV vaccines globally available at an affordable price.

HPV vaccine implementation issues

Published studies have focused on HPV vaccines administered in three doses to women aged 15 to 25, but the vaccines have also been administered to

girls as young as 9 or 10 years—the ages for which Merck & Co., Inc. and GlaxoSmithKline (GSK) plan to register the vaccines to help ensure that individuals are vaccinated prior to sexual debut. Because of the unique target age for vaccination and the need for multiple doses, assessments will be necessary to understand how this age group can best be reached with an HPV vaccine. Preferably this will occur through existing health service-delivery systems, although country-specific strategies may vary. National regulatory authorities will need standardized tools and high-quality clinical and epidemiological data to license, recommend, and monitor HPV vaccine deployment in the field.

Current vaccine candidates are being developed to protect against HPV types 16 and 18, the two oncogenic types that are believed to be responsible for approximately 70 percent of cervical cancer cases globally. However, 30 to 40 percent of cancers are caused by other oncogenic HPV types, and their prevalence varies throughout the world, with some being proportionally more common in developing regions. For this reason, even if the vaccines are completely effective in protecting against infection with HPV 16 and 18, women can still develop cervical cancer by becoming infected with other oncogenic HPV types. Therefore, new vaccines will need to be introduced in conjunction with other cervical cancer prevention strategies. In many developing countries where cervical cancer prevention programs or health service-delivery systems in general are weak or nonexistent, this will raise an added challenge to vaccine introduction programs.

Sociocultural issues related to HPV vaccines

In general, public awareness that HPV is a sexually transmitted infection (STI) that causes cervical cancer is low. An ongoing challenge is understanding how best to explain that an HPV vaccine prevents cervical cancer by preventing the STI that causes it. This challenge, combined with the fact that pre-sexual girls—and potentially boys—as young as 9 years old may be the preferred target population for HPV vaccines suggests that vaccine introduction and awareness-raising activities will need to be

sensitive to issues of social acceptability and cultural suitability. The prospect of vaccinating young people against an STI may create opposition among parents, communities, and policymakers. Several acceptability studies in developed and developing countries have found that parents (and mothers in particular) generally would agree to have their daughters vaccinated against a sexually transmitted virus that causes cervical cancer,¹⁻³ but this may not be true everywhere or among all stakeholders. If a girls-only vaccination strategy is adopted, parents, health care providers, and policymakers may question why an “STI vaccine” is not also targeted to young men. This could potentially result in misunderstanding or mistrust that the vaccine is an effort to control girls’ fertility. It will be important to present the vaccine in such a way as to provide complete information about its purpose without also offering an overload of complex information.

Overcoming the challenges

To overcome these challenges, PATH, Harvard University, the International Agency for Research on Cancer, and the World Health Organization (WHO) are undertaking activities focused on preparing for HPV vaccine introduction in developing countries. These activities, funded by the Bill & Melinda Gates Foundation, represent a multifaceted, coordinated strategy for making HPV vaccines available, acceptable, and affordable to those most in need. Each organization’s goals related to HPV vaccine introduction are outlined below.

Harvard University

- Conduct comprehensive policy analyses using models adapted to different epidemiologic settings to estimate the population impact and cost-effectiveness of various HPV vaccination strategies in an array of low-resource conditions, and to identify potential synergies between vaccination and screening efforts.

International Agency for Research on Cancer

- Fill relevant gaps in epidemiological knowledge on cervical cancer and HPV infection, including country-specific distribution of HPV types and the age at which women acquire HPV infection.

PATH

- Negotiate partnerships with one or both HPV vaccine manufacturers that specify how,

where, and under what conditions PATH and manufacturers will work together to accelerate access to HPV vaccine in developing countries.

- Evaluate the investment case for financing by potential funders (for example, the Global Alliance for Vaccines & Immunization, bilateral donors, and countries) to purchase HPV vaccine for developing countries’ public-sector programs.
- Develop selection criteria for and identify a short list of HPV vaccine early-introducer countries.
- Synthesize information from four developing countries regarding sociocultural, logistic, policy, and clinical needs related to HPV vaccine introduction.
- Identify available information on HPV vaccine and key information needs in target developing countries.

World Health Organization

- Harmonize and standardize laboratory procedures and create a global HPV Laboratory Network to facilitate vaccine licensure and monitoring in developing countries.
- Generate an enabling environment for HPV vaccine introduction by creating an international multidisciplinary policy platform and setting a global agenda for future HPV vaccine introduction in consultation with regions and countries.
- Create a WHO Information Centre on HPV and Cervical Cancer to facilitate global, regional, and country-specific decisions on current and novel options for cervical cancer prevention.

References

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