

Summary of Bill & Melinda Gates Foundation-supported HPV Vaccine Partner Activities

Harvard University, the International Agency for Research on Cancer (IARC), PATH, 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. Summaries of each organization's goals related to HPV vaccine introduction and key milestones are outlined below.

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 (based at the Institut Catala d'Oncologia in Barcelona) to facilitate global, regional, and country-specific decisions on current and novel options for cervical cancer prevention.

Milestones

- Disseminate WHO Guidelines to Assure the Quality, Safety, and Efficacy of HPV vaccines in 2007.
- Support access to international standard reagents and operating procedures for HPV laboratory processes from 2007-2010.
- Establish global HPV laboratory network and support training on WHO standards in 2006 and 2007.
- Support decision making of National Regulatory Authorities to evaluate HPV vaccines in early adopter countries from 2006-2010.
- Disseminate policy and technical information on HPV vaccine introduction for policy makers and health care professionals from 2006-2010.
- Organize meetings in all WHO regions to explore HPV vaccine introduction in 2007 and 2008.
- Present data on HPV vaccine to WHO vaccine policy bodies (Strategic Advisory Group of Experts and Global Advisory Committee on Vaccine Safety) in 2007 and 2008.
- With ICO WHO Information Centre, post HPV and cervical cancer data on WHO website in 2007 and disseminate country-specific data on cervical cancer and HPV from 2006-2010.

International Agency for Research on Cancer

- Collate published data on HPV type distribution in cervical cancer around the globe and co-ordinate new studies in regions where such data is missing, with special reference to populations where HIV is common and may interfere with the natural history of HPV.
- Conduct surveys to determine the age-specific and genotype-specific prevalence of HPV in populations where very little, or no knowledge is available.

Milestones

- Meta-analyses of HPV type distribution in >5000 women infected with HIV, >14,000 women with invasive cervical cancer and >7,000 women with high-grade cervical lesions completed prior to 2007.
- Nine HPV surveys in China (Shanxi, Shenyang and Shenzhen), Mongolia, Nepal, Guinea, Poland, Pakistan and Algeria to be completed by end of 2008.
- Further studies to fill relevant epidemiological gaps, 2008-10.
- A comprehensive set of materials (maps, reports, etc.) produced showing the geographical distribution of HPV types worldwide, both in the general population and in cervical cancer cases, 2010.

PATH

- Organize HPV vaccination operational research projects in four countries (India, Peru, Uganda, and Vietnam) to generate experience addressing the sociocultural, logistic, policy, and clinical needs related to HPV vaccine introduction.
- Support complementary activities in up to 8 additional countries with carefully-targeted small grants.
- Negotiate partnerships with 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, including in the four demonstration projects.
- Work with partners to develop an investment case for public-sector HPV vaccine financing by potential funders (the GAVI Alliance, bilateral donors, and countries).
- Broadly disseminate research project results and other educational and advocacy messages to global, regional, and national audiences in a timely manner.

Milestones

- Advocacy and information dissemination 2006-2011.
- Country studies initiated in 2007. “Small grant” studies, 2007-2010.
- Preliminary formative research results in 2007 and 2008.
- Investment case and demand modeling in 2007 and 2008.
- Demonstration project results in 2010.
- National cervical cancer prevention policies in 2011.

Harvard University

- Develop regional and country-specific models representing different epidemiologic settings using empiric data from multiple study sites on cancer incidence, type-specific HPV prevalence and distribution across the disease spectrum, and key cofactors.
- Conduct comprehensive policy analyses to estimate the avertable burden of disease and cost-effectiveness of various HPV vaccination strategies, identify potential synergies between vaccination and screening, and the most influential factors on the sustainability and affordability of different policy alternatives.
- To develop a Core Modeling Center in order to analytically support Partner activities (e.g., PATH operational research in four countries), assist with or conduct cost-effectiveness analyses for different stakeholders in the HPV vaccine initiative (e.g., analyses to support GAVI investment case), and to inform country decision making with analyses that reflect local costs and regional priorities.

Milestones

- Complete first set of detailed country-specific vaccine impact analyses, 2007.
- Analyses of GAVI-eligible countries for investment case, 2007.
- Country-specific analyses in Asia/Pacific and Latin America, 2008.
- Complete second set of country-specific vaccine impact analyses, 2008.
- Develop predictive model to estimate incidence of cervical cancer in countries without registries, 2008.
- Conduct cost-effectiveness analyses of strategies using primary data from PATH operational research in four countries, 2009-2011.
- Dissemination of results and key messages for different decision makers in a variety of media including reports on the WHO/ICO Information Center website and other cervical cancer websites, peer-reviewed manuscripts, the planned PATH/Harvard interactive advocacy tool, and regional/country-specific reports contextualized for settings and scenarios.