

SECTION 05



Expanding
Access to the
Human Papillomavirus
(HPV) Vaccine

EXPANDING ACCESS TO THE HUMAN PAPILLOMA- VIRUS (HPV) VACCINE

The proposed goal is to prevent cervical cancer by achieving 50–75 percent coverage of the HPV vaccine among 9- to 14-year-old girls.¹¹³ Cervical cancer is the first cancer we are poised to eliminate.

This effort would seek to fully immunize 40 million adolescent girls at a cost of \$843 million between 2017 and 2021. The U.S. share, we propose, should come from multiple sources and amount to approximately 50 percent of the total costs to achieve this goal.

The HPV vaccine, a highly effective means to prevent cervical cancer, is a long-term strategic investment in the future health of young women. Global deaths from cervical cancer are on the rise, and have surpassed 266,000 annually; if these trends continue, cervical cancer deaths are likely to surpass maternal deaths in the coming years.¹¹⁴

The projected impact of this initiative would be 235,000 lives saved, and nearly 650,000 cases of cervical cancer averted. By definition, these extraordinary benefits will only be realized years later, when these women—as cancer-free adults at the peak of their productive lives—are able to realize their full potential as mothers, members of their communities, and contributors to the economy.

National HPV vaccine programs also generate an important early, concrete benefit: the establishment of a new service delivery platform that reaches both in- and out-of-school adolescent girls, often for the first time since childhood. That platform can be potentially used to bring other important health services to this difficult-to-reach population (e.g., de-worming; nutritional services; sexual education, including instruction on gender-based violence prevention and response; and testing and counseling for HIV).¹¹⁵

There are powerful equity gains to national HPV vaccine programs: they bring a major health benefit to young adolescent girls, a population that is often overlooked. And that gain is even more pronounced whenever there are concerted efforts to reach the poorest, most disadvantaged young women in the 13 target countries.

OPERATIONALIZATION

What is proposed is a historic push to expand access to this cancer-preventing vaccine in 13 low-income countries that are of interest to the United States and have demonstrated need, interest, and capacity to deliver the HPV vaccine.

Essential U.S. Leadership

Success requires high-level, sustained U.S. diplomatic leadership. This will be essential to win the active buy-in, budgetary support and partnership of the 13 national governments (many of which will approach the launch of a national HPV program with caution, given the cost involved).

Further, high-level leadership will help to significantly expand the lead role played by Gavi. The recent commitments made by the Gavi Alliance Board to reboot its HPV vaccine strategy represent a fresh decision that should be actively complemented and expanded upon (see Gavi's HPV Vaccine Reboot).

Continuous diplomatic engagement with vaccine manufacturers, partner governments, Gavi, foundations, and others will lower the cost of the HPV vaccine and create a long-term pathway to fiscal sustainability.

It will also help to raise the political and financial commitment of donors, foundations, industry, and others. The United States currently accounts for 12 percent of Gavi's aggregate budget, the balance covered by a small nucleus of the UK, the Bill & Melinda Gates Foundation, Norway, and others.¹¹⁶ Expanded U.S. support to Gavi can catalyze significant additional funding from other important sources. Pink Ribbon Red Ribbon, launched by the George W. Bush Institute, PEPFAR, Susan G. Komen, and UNAIDS, has succeeded in building bipartisan support for these efforts.

Senior levels of the administration will need to position USAID, working alongside the U.S. Centers for Disease Control and Prevention (CDC) and other parts of U.S. Department of Health and Human Services such as the National Vaccine Program and the National Institutes of Health, as a critically important source of U.S. technical expertise and financial support. They can work to address both the policy and institutional requirements of launching national plans, and to support civil society and independent groups including Pink Ribbon Red Ribbon in their programs. USAID's Maternal and Child Survival Program has helped 13 Gavi-eligible countries prepare for the introduction of 24 vaccines, assisting with Gavi

applications, multiyear plans, vaccine introduction strategies, launches, and monitoring and evaluation.¹¹⁷ As national plans advance in the 13 target countries, demand will increase sharply for this form of U.S. government external support.

Last, but arguably most important, high-level leadership is required to build bipartisan support in Congress and among interest groups.

The Ultimate Power of Partner Countries

Scale-up of the HPV vaccine is ultimately the decision and responsibility of the partner country. Introduction of a new vaccine to an adolescent population departs from traditional immunization programming, which typically serves children under five years old. That decision requires national political will, careful financial planning and budgetary commitments, and sufficient health infrastructure. A frequent impediment to HPV demonstration projects has been the lack of coordination across government ministries, which is essential to reach adolescent girls through several channels: schools, clinics, community centers, and immunization campaigns. Success rests on intensified engagement, communication, and planning across the Ministries of Health, Education, and Finance.

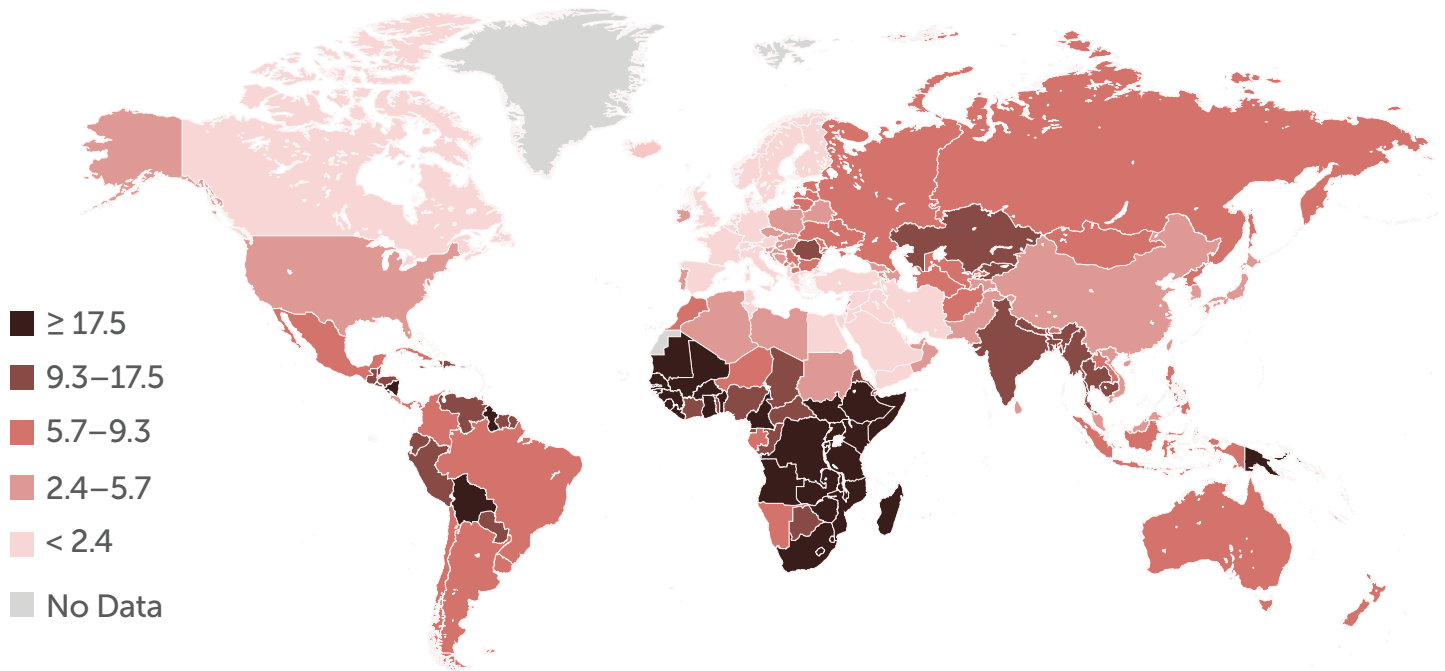


JULIE GERBERDING

"Cervical cancer affects nearly 530,000 women around the world every year, robbing them, their families, and their communities of their most productive years. More than a quarter million women die annually—730 each and every day—nearly all of them in less developed nations. We can eliminate cervical cancer just as we eliminated smallpox and polio. America can lead the way to realize this achievable goal by committing to HPV immunization for girls and screening and treatment for women."

CERVICAL CANCER WORLDWIDE

Estimated Deaths per 100,000



Source: International Agency for Research on Cancer, WHO, "Cancer Today," http://gco.iarc.fr/today/online-analysis-map?mode=cancer&mode_population=continents&population=900&sex=0&cancer=29&type=0&statistic=0&prevalence=0&color_palette=default&projection=natural-earth.

GAVI'S HPV VACCINE REBOOT: In 2013, Gavi embraced an ambitious aim of reaching 30 million girls in low-income countries with the HPV vaccine by 2020. Since then, it has helped to fund and oversee demonstration projects in 23 countries, and has successfully vaccinated 1 million girls. It has also recently launched a \$10 million partnership with Girl Effect to address negative social norms and unlock demand for the vaccine. However, countries have been slow to establish national programs. To better incentivize national governments to institute and sustain national programs, Gavi's Board recently approved two major programmatic changes with strong consensus at its December 7–8 meeting. The first will encourage countries to move rapidly and directly to national programs, bypassing an often-lengthy demonstration phase. The second will encourage

vaccination of multiple cohorts of adolescent girls ages 9 to 14 in the first year of the program, in line with the decision taken in October at the Strategic Advisory Group of Experts (SAGE) on Immunization meeting in Geneva. As a result, Gavi's projected HPV-vaccine related costs over the next four years will rise from \$350 million to \$422 million.

The Centrality of Gavi

Gavi is well-positioned to accelerate national programs. It already has in place a global strategy to expand HPV vaccine access and has provided HPV-related support to all of the target countries.¹¹⁸ Expanded U.S. support to Gavi (and its primary implementing partners CDC, UNICEF, and WHO)¹¹⁹ would be the natural multilateral channel by which the United States can expedite support to target countries in the scale-up of vaccine purchase, distribution, and delivery, as well as related costs associated with national introduction.¹²⁰



REP. DANIEL M. DONOVAN JR. (R-NY-11)

"The greatest influence the United States has is its capacity to save lives. With a continued focus on ending preventable child and maternal deaths, we can capitalize on the successes made by past administrations and pave the way for even bigger victories that reinforce our place on the global stage. My daughter was lucky: she was born in the United States with access to infant care and vaccinations. I consider it an obligation to work toward providing mothers and children all over the world with similar care."

NGOs Fill Critical Gaps

Public-private partnerships like Pink Ribbon Red Ribbon can mobilize parents and communities to demand vaccination for their girls against cervical cancer, assist with the planning and logistics of vaccination, introduce media and communication strategies to overcome barriers to vaccine uptake, and link adolescent girls to related services, including for HIV prevention.

RATIONALE

The moment is ripe to press for expanded access to the HPV vaccine in low-income countries.

First, the vaccine has become a viable global tool since its introduction in 2006, and its impacts are profound. The WHO recommends that girls aged 9 to 13 receive two doses of the vaccine,¹²¹ while Gavi has negotiated a price of \$4.50 per dose (compared to \$130 per dose in the United States).¹²² It is projected to be one of the most-high-impact vaccines in Gavi's portfolio between 2016–2020 in terms of lives saved.¹²³

Second, the burden of HPV and cervical cancer in low-income countries is enormous. In sub-Saharan Africa, this is largely because women living with HIV/AIDS are at least five times more

likely to develop cervical cancer.¹²⁴ Even though the vaccines Gardasil and Cervarix are proven to prevent 70 percent of cases, global deaths due to cervical cancer are on the rise.¹²⁵ While nearly 120 million women were targeted through HPV immunization programs between 2006 and 2014, only 1 percent were from low-income or lower-middle-income countries, where 85 percent of deaths due to cervical cancer occur.¹²⁶ The regions with the highest incidence of HPV and the largest burden of cervical cancer—sub-Saharan Africa followed by South and Southeast Asia—remain largely unreached by the vaccine.¹²⁷

Though the number of low-income countries that have taken the vaccine to national scale is still limited, there have been numerous demonstration projects and a growing body of literature detailing lessons learned.^{128, 129} PATH and the London School of Hygiene and Tropical Medicine (LSHTM) reviewed delivery experiences across 46 low- and middle-income countries, finding that "HPV vaccine delivery is feasible and can be delivered with high coverage."¹³⁰

Seriously expanding access to the HPV vaccine in low-income countries can build on burgeoning programmatic engagement, partnerships, and interest among organizations and national

governments. All of the 13 target countries are eligible for support from Gavi, and all but Nigeria have already successfully delivered the vaccine through demonstration projects.¹³¹ Two, Rwanda and Uganda, have introduced the vaccine through a national program. It is anticipated that eight of the target countries will soon submit applications to Gavi requesting support to roll out the vaccine nation-wide.¹³²

A coalition of interests is increasingly promoting expanded access to the vaccine, including the American Cancer Society, the Bill & Melinda Gates Foundation, Gavi, Pink Ribbon Red Ribbon, and vaccine manufacturers. PATH, the National Cancer Institute, UNICEF, and WHO have all become important voices.

Cost remains one of the biggest barriers in scaling up access in both Gavi-eligible and non-Gavi-eligible countries, where introducing the HPV vaccine and sustaining national programs can be prohibitively expensive in the face of competing interests.¹³³ Costs could decline if there is a concerted international effort dedicated to expanding the volume of vaccines, eventually bringing forward generic versions, and even perhaps expediting a single-dose regimen.¹³⁴

A platform to deliver the HPV vaccine can also provide adolescent girls, both in and out of school, with critical health interventions. HPV vaccination is often the first time girls are in contact with health-related activities since early childhood. It can be combined with other vital health promotion activities including nutrition supplementation, menstrual hygiene education, and gender-based violence prevention and response.

KEY CONSIDERATIONS

There are a number of serious constraints—limited finances, policy and regulatory issues, competing priorities, lack of experience with wide-scale delivery of the vaccine to adolescent girls, and implementation complexities—that explain many countries' hesitation to commit to scaling up HPV vaccination programs.

Gavi support to several successful school-based HPV vaccine demonstration projects has generated important lessons. It has been well established that reaching adolescent girls with the HPV vaccine is different than reaching children under five: it requires targeted social mobilization and high-level political will, new operational investments, and considerable patience



FORMER REP. RICHARD HANNA (R-NY-22)

"Women's rights are challenged daily around the globe. From the mother who wants access to family planning services to the adolescent girl who needs to be educated

about cervical cancer, this report identifies several key health interventions that the United States can undertake to improve its foreign aid and generate returns on its investment. The United States has long led the way to improve the lives of women and children around the world. Let's accelerate the momentum."

in transitioning from demonstration to national scale-up. Success flows from strong country ownership, either within the routine immunization program or other national programs, and a clear linkage to cancer prevention.¹³⁷

It is also vital to effectively engage communities so they understand the significant benefits of the HPV vaccine and to dispel any misconceptions. As HPV is a sexually transmitted infection, programs to educate and immunize girls ages 9–14, prior to the start of sexual activity, have faced resistance from some communities in the United States and globally that associate the vaccine with promoting promiscuity. Providing accurate information about the vaccine and addressing cultural sensitivities are important aspects of introduction to ensure necessary support from communities, providers, and national governments.

METHODS

The Task Force benefited enormously from the generous assistance provided by several organizations that are deeply involved with efforts to expand HPV vaccine access in low-income countries, including the American Cancer Society, the Bill & Melinda Gates Foundation, CDC, Gavi, LSHTM, the National Cancer Institute, PATH, Pink Ribbon Red Ribbon, and UNICEF.

The target of 50 to 75 percent coverage is ambitious but feasible, and is based on the premise that high coverage levels should be achieved on an accelerated basis.¹³⁶ Gavi only funds national scale-up of programs for countries that have adequate vaccine-delivery infrastructure and experience. Its renewed approach is based on considerable recent experience.¹³⁷

The projected numbers of young women to be vaccinated reflect the recommendation put forth at the October SAGE meeting to immunize multiple cohorts of 9- to 14-year-old girls during national introduction of the HPV vaccine, which was recently adopted by Gavi at its Board meeting on December 7–8, 2016.¹³⁸

This initiative is projected to cost approximately \$843 million between 2017 and 2021. We anticipated that a “fair share” of the U.S. contributions to this effort would represent approximately 50 percent of the total costs. Base cost projections and health impacts were provided by Stephen Resch from the Harvard T.H. Chan School of Public Health, stemming from a recent study commissioned by the American Cancer Society. These assumed an average commodity cost of \$9.71 (for two doses) and average vaccine delivery cost of \$4.51 per girl. These figures further reflected average introduction costs of \$3.13 and operational costs of \$4.23 per girl.¹³⁹ Special consideration was given to introduction and operational costs, which tend to be higher when compared to under-5 vaccines, but are critical in funding necessary technical assistance, reaching communities with information prior to launch, and delivering the vaccine through a number of channels.¹⁴⁰