

Partnership for Influenza Vaccine Introduction (PIVI)



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The Partnership for Influenza Vaccine Introduction (PIVI) has a mission to help low and middle income countries reduce morbidity and mortality from influenza and enhance their pandemic preparedness through introduction of vaccine and expansion of existing vaccination programs. PIVI plays a pivotal role by supplying donated influenza vaccine and supplies to countries that lack those resources but are otherwise ready to establish or expand their influenza vaccination programs. PIVI is based at the Task Force for Global Health's Center for Vaccine Equity, which coordinates a broad partnership that includes CDC, ministries of health and a variety of private partners (BioCSL, Becton Dickinson) and public partners (Bill and Melinda Gates Foundation, Pan-American Health Organization), that donate supplies or funding for the project. PIVI operates on a model of using the donations to ensure that partners in ministries of health have available influenza vaccines and resources to protect key target populations. CDC's Influenza Division has supported PIVI because of its unique value to protect vulnerable populations in partner countries, to provide countries with experience in delivering influenza vaccines which will be useful for pandemic preparedness goals, and to catalyze the development of sustainable influenza vaccination programs. The experience gained from the vaccine campaigns delivered under PIVI also helps create the evidence base for global use of influenza vaccines, especially in high priority populations, such as pregnant women. PIVI began in 2012, and since that time has helped vaccinated more than 1 million persons in Lao PDR, Nicaragua, Armenia and Morocco. <http://pivipartners.org/>

2014 Activities

In 2014, a donation of 763,000 doses of influenza vaccine to the Lao PDR Ministry of Health allowed the existing program to expand nationwide to encompass all 38 provinces. Vaccine was provided for five target populations—pregnant women, elderly, health care workers, essential government personnel, and those with chronic disease. Nationally 36,173 pregnant women were targeted for vaccination



A healthcare worker in Tavush Marz being vaccinated for influenza during the National Immunization Campaign.

using hospitals and antenatal clinic settings. The 2014 influenza vaccine campaign launch integrated with National Immunization Day activities for children receiving EPI vaccines and other health interventions (Vitamin A and deworming). In the antenatal clinic setting, pregnant women also received tetanus toxoid vaccine.

In Nicaragua ~25,000 pregnant women were immunized in Managua, achieving 96% coverage of the target population, and closing a gap that enabled the Nicaragua Ministry of Health to immunize the full cohort of pregnant women nationwide. The vaccine was delivered through a national immunization campaign and through antenatal clinics with deployment of the tetanus toxoid vaccine. Building on the 2013 PIVI donation, Nicaragua expanded its coverage of pregnant women and assumed progressive responsibility for full country ownership of the program.

In 2014, the Partnership received a donation of >180,000 doses of vaccine from Green Cross, facilitated by PAHO, enabling the PIVI program to expand to Armenia and Morocco. In Armenia the National Immunization Program distributed 60,000 doses of donated influenza vaccine. The vaccine was distributed nationwide through existing vaccine and health programs, targeting 18-27 year old adults, health care workers in primary health care facilities,

and elderly persons and children living in residential care institutional settings. Although pregnant women were not a specific target population in 2014, vaccine was offered to interested pregnant women.

In Morocco, the National Immunization Program and DELM conducted a national 6-week campaign distributing 123,310 doses of donated influenza vaccine, targeting health personnel and health care students (medicine, nursing, pharmacy, and dentistry), diabetics through NGOs, elderly in nursing home settings, persons with chronic renal failure receiving dialysis treatment, and a sample of pregnant women. Although in Morocco the vaccine is not currently approved for use in pregnant women, this year's program provided an opportunity to hold discussions with the national agency responsible for pharmacovigilance and plan focus groups to better understand issues related to influenza vaccine hesitancy in current and future target populations.

To measure program impact, PIVI implemented an evaluation protocol in all four countries (Armenia, Lao PDR, Morocco, and Nicaragua). In Nicaragua and Lao PDR, the evaluation focused on understanding the impact of vaccine on birth outcomes among pregnant women. Results are expected in late 2015. Program evaluation reports summarizing the influenza vaccine campaigns in Armenia and Morocco have been finalized. PIVI is currently working on further developing knowledge, attitudes and practices survey protocols for use in PIVI countries and is exploring cost-effectiveness protocols and models of vaccine impact in experienced PIVI countries.

Discussions on vaccine procurement for the current year and beyond are underway with multiple vaccine manufacturers. In addition to discussions on vaccine donations, the project team is holding discussions with vaccine manufacturers and UNICEF to negotiate vaccine purchase at a reduced cost for the program and provide an opportunity to discuss supply for future sustainable country programs. PIVI also engaged Gavi in discussions on how best to use data to inform a potential 2018 vaccine information statement deliberation to consider support for influenza vaccine.

Strategic planning to raise awareness and support among donors in partner countries is ongoing. A landscape analysis of potential private sectors donors has been conducted and a strategic communications plan will be developed.

Objectives of PIVI

- Reduce morbidity and mortality from seasonal influenza by protecting at risk populations, particularly those prioritized by WHO/SAGE recommendations, such as pregnant women.
- Evaluate the programmatic aspects of seasonal influenza vaccine implementation.
- Demonstrate that the introduction of seasonal influenza vaccine can be both feasible and accepted and can strengthen future public-private partnerships for the introduction of new vaccines into the Expanded Program on Immunization.

Principles

- Vaccine donation should not interfere with current influenza vaccine program growth and should serve as a catalyst for sustainable vaccine program.
- There must be demonstrated commitment from MoH, country and regional WHO offices.
- The country must have existing influenza surveillance systems in place and/or a National Influenza Center.
- Vaccine target groups should be based on local data and be informed by WHO SAGE recommendations.
- An evaluation plan must be developed to assess the vaccine program's introduction and impact.
- A sustainability plan should be developed by the country to develop a sustainable source of seasonal influenza vaccine among priority groups.
- The program should be coordinated with WHO Global Action Plan and other partners.



The central deposit cold room in Casablanca, Morocco.



Partnership Deliverables

- Increases in vaccine coverage in vaccine target groups in partner countries.
- Successful integration of influenza vaccine in partner countries' current immunization programs.
- Reduction in influenza-associated health outcomes in immunized populations in partner countries.
- High acceptability of influenza vaccine among stakeholders in partner countries.
- Sustainability of respiratory disease surveillance, laboratory capacity and rapid response capabilities that have been developed in response to pandemic preparedness priorities.
- Develop data to support evidence-based decision making related to influenza vaccination of potential target populations.

Future Plans

The program targets the most vulnerable populations as designated by WHO's SAGE recommendations with an emphasis on maternal immunization. The program seeks to meet country partners' target requirements from PIVI supply resources. PIVI plans to engage new country partners on an annual basis. PIVI's expansion will be governed by the level of vaccine and other donations and the successful transitioning of existing partner countries to sustainable programs. Factors that will aid in successful implementation include PIVI's collaboration with WHO's Global Action Plan for Influenza Vaccines (GAP-2), incorporation as a key component of CDC's Influenza Division's International Strategic Plan, recognition of HHS/BARDA influenza vaccine development program, and cooperation with Gavi's future consideration of support for influenza vaccine in Gavi-eligible countries. Constraints to PIVI implementation may include limitations in vaccine supply, delays in regulatory time frames for approval of new vaccines, unpredictability of donations, variable timing of influenza season in partner countries paired with the available vaccines formulation, limitations in the provision of immunization supplies and challenges in the logistics and transport of vaccines and supplies.

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