

Supporting influenza vaccine production in Vietnam

Increasing vaccine supplies against a seasonal and pandemic threat

With influenza vaccine development and production resources mostly concentrated in the industrialized world, low- and middle-income countries can face great challenges in protecting their populations against seasonal and pandemic influenza—a virus that causes mild to severe respiratory distress and even death. These countries are often unable to afford or access critical vaccines that can help prevent the spread of the virus within their own communities, as well as the rest of the world.

Influenza can be seasonal in temperate regions, but may occur more year-round in the tropics. Seasonal influenza alone causes 250,000 to 500,000 deaths and 5 million cases of severe illness worldwide each year.¹ Occasionally, highly virulent strains can occur and lead to widespread outbreaks called pandemics. Public health leaders worry that a pandemic strain could lead to millions of deaths in today's highly interconnected world, mostly in countries with limited health care resources.² The most severe influenza pandemic, in 1918, infected up to 50 percent of the world's population and caused 20 to 50 million deaths worldwide.³ Widespread outbreaks—including the influenza A/H1N1 pandemic of 2009—underscore the importance of expanding real-time vaccine production to address the needs of the global population.

The rapid development, production, and distribution of influenza vaccines could potentially save millions of lives. Furthermore, the best defense against an influenza pandemic is a well-developed capability to produce seasonal influenza vaccine, which helps to maintain manufacturing capacity on an ongoing basis. Yet, current influenza vaccines are difficult to produce in large quantities and at low cost. With a gap of several billion courses between today's influenza vaccine production capacity and what is needed in real time to protect the global population in a pandemic, global health leaders recognize that the participation of many vaccine suppliers worldwide is vital to meeting pandemic demand. Vaccine manufacturers from low- and middle-income countries will play an important role to this end and are expanding their efforts to produce high-quality, life-saving influenza vaccines at a lower cost. Vietnam is one of those countries with the potential to supply influenza vaccines that can be affordable and accessible in a future influenza pandemic.



A domestic supply of high-quality influenza vaccine will help Vietnam sustainably equip itself against both seasonal and pandemic outbreaks. PATH/Patrick McKern.

ENHANCING PANDEMIC INFLUENZA PREPAREDNESS

Vietnam has a population of approximately 90 million people and no domestic supply of influenza vaccines for use during seasonal spread or pandemic outbreaks of influenza. The country has also experienced isolated cases of avian A/H5N1 influenza in humans and more widespread outbreaks in poultry. PATH is implementing a project to support the enhancement of sustainable influenza vaccine production in Vietnam in collaboration with the Biomedical Advanced Research and Development Authority (BARDA) within the US Department of Health and Human Services. The project builds upon support that BARDA has provided to the World Health Organization (WHO) to assist Vietnam, and other countries, in preparing for eventual licensure and the commercial-scale manufacture of influenza vaccines, with particular attention to achieving synergies with WHO work.

We are collaborating with several groups in Vietnam to assist in the production and clinical evaluation of high-

quality, safe, and effective vaccines for a pandemic influenza. We are supporting a state-owned vaccine developer, Institute of Vaccines and Medical Biologicals (IVAC), to advance the clinical development of an inactivated, whole-virus influenza A/H5N1 pandemic vaccine candidate and a low-cost seasonal, inactivated trivalent influenza candidate. This work builds on a previous cooperative agreement with BARDA through which PATH helped IVAC ready its production facility for the manufacture of influenza vaccines. With support from PATH, IVAC had since advanced pandemic and seasonal vaccine candidates into clinical trials. A pandemic influenza A/H5N1 vaccine candidate is currently being evaluated in a Phase 2/3 clinical study and IVAC recently completed a Phase 1 clinical study of a seasonal, split virion, inactivated influenza vaccine candidate in healthy adults, which showed the vaccine candidate to have a good safety profile and to evoke an immune response. Along with PATH support, IVAC also advanced a pandemic influenza A/H1N1 vaccine candidate into the clinic and contributed to the global response to the recent avian influenza A/H7N9 outbreak by initiating production of a monovalent, inactivated vaccine against this virus strain, which has caused severe illness and death in humans.

With support from BARDA, PATH is also supporting the production of cell-culture-based influenza vaccines at VABIOTECH, a state-owned vaccine and biological production company in Vietnam. Such vaccines could be promising options in a pandemic given their potential to be produced efficiently, at large-scale, and without reliance on egg supplies. To date, PATH has helped VABIOTECH obtain a license for two cell lines that can be used for the commercial manufacture of influenza vaccine, conducted technical training, and purchased equipment and supplies.

Over the course of the project, PATH has also worked with Vietnam's Ministry of Health to support the country's enabling environment for vaccine development. As a result, the Ministry of Health developed several guidelines for influenza vaccine clinical trials and licensure, as well as a long-term plan for influenza vaccine development and use in Vietnam.

By helping Vietnam strengthen its influenza vaccine production capacity, this project takes an important step toward increasing local and regional vaccine supplies and improving real-time response in an influenza pandemic. It

will also serve as a model for other efforts to build local production of influenza vaccines in low- and middle-resource countries.

PATH supports this work in Vietnam through a cooperative agreement funded by BARDA for approximately US\$14 million, which also supports influenza vaccine manufacturers in other countries such as Serbia, China, Brazil, and India.

REFERENCES

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