PATH

July 2026

Moving the Needle

News from PATH on vaccine development

New study to assess meningococcal vaccine in pregnant and breastfeeding women

PATH is sponsoring a Phase 3 clinical study of MenFive®, the first conjugate vaccine to protect against the five predominant causes of meningococcal meningitis in Africa, in pregnant and lactating women (PLW). The study, which began in May 2026 in Bamako, Mali, aims to expand access to MenFive for all people at significant risk of suffering severe disease outcomes, and it represents a crucial prioritization of the health needs of pregnant and breastfeeding women—a group that has historically been left out of vaccine clinical trials. While there are many potential reasons for their omission, the consequence is that regulators have limited information with which to evaluate risk-benefit balance, meaning women are put in the position to either forgo a lifesaving vaccine or receive one without fully understanding the possible outcomes. For these reasons, PATH supports vaccine research and access for pregnant and breastfeeding women.

MenFive, developed by PATH and the Serum Institute of India Pvt. Ltd. with funding from the United Kingdom (UK) government's Foreign, Commonwealth & Development Office, targets meningococcal serogroups A, C, W, Y, and X. It is the world's first vaccine to protect against serogroup X and is approved for use in people aged 9 months to 85 years.

Improving the economic evaluation and licensure pathway for combination vaccines

While new combination vaccines could be highly valuable to pediatric immunization programs worldwide, traditional economic evaluations often fail to capture the full array of their benefits and challenges. This hinders decision-makers from considering their full value, potentially limiting their development and prioritization in immunization strategies. As part of a broader effort to identify high-potential new routine combination vaccines for children, PATH and the World Health Organization (WHO) researched new approaches to measuring the full economic value of combination vaccines. They developed a checklist tool, recently published in *Vaccine*, to provide analysts with a way to more clearly, consistently, and comprehensively evaluate these vaccines.

PATH and WHO are also exploring how current regulatory strategies could be updated to facilitate the licensure pathway for new combination vaccines. Another recent publication in *Vaccine* reports on key takeaways from an expert convening where regulators and developers discussed the challenging regulatory landscape for combination vaccines, in which regulatory requirements were designed for single-antigen vaccines. Regulators are open to building on existing guidelines and experience to identify ways to streamline the assessment of new combination vaccines, representing a first step toward optimizing the regulatory approval process for these vaccines.

WHO International Reference Reagents established to improve polio vaccine

The WHO Expert Committee on Biological Standardization recently recommended the establishment of new International Reference Reagents for polio vaccine testing using next-generation high-throughput sequencing (NGS) technology. The announcement marks an important milestone toward harmonizing and strengthening polio vaccine quality control as part of global polio eradication efforts. The new International Reference Reagents will enable vaccine manufacturers and researchers around the world to standardize the use of NGS for testing oral vaccines for poliovirus types 1 and 3. The NGS assay is a highly sensitive testing method that allows researchers to quickly map the population of poliovirus genomes to monitor the consistency of vaccine production. It is an alternate non-animal-based method to assess neurovirulence markers of vaccine lots. The establishment of the NGS technology as applied to live, oral polio vaccine manufacturing

lots testing is an outcome of a WHO collaborative study led by the UK Medicines and Healthcare products Regulatory Agency in collaboration with PATH and other partners. PATH contributed technical assistance and served as a convening organizer for the collaboration.

Report highlights outbreak research preparedness in East and Central Africa

A new report, available in English and French, shares a comprehensive summary of a December 2025 workshop on the Research Preparedness Program for East and Central Africa (RPECA). The bilingual technical workshop, held in Nairobi, Kenya, brought together approximately 80 stakeholders from 20 countries in East and Central Africa. RPECA is a multi-region, multi-country initiative led by PATH as the initial Technical Coordinating Partner, in collaboration with The Coalition for Epidemic Preparedness Innovations (CEPI), Africa Centers for Disease Control and Prevention, and other regional stakeholders. It aims to strengthen the rapid generation of high-quality evidence during infectious disease outbreaks. In support of this aim, the workshop participants discussed how to identify and prioritize research preparedness gaps, potential solutions, and criteria for regional coordination, as well as considerations for inclusive partnerships and engaging with stakeholders. This laid the groundwork for RPECA, including the subsequent development of workplans supporting preparedness for effective and timely outbreak research.

CEPI seeks partners to support access to biospecimens during future outbreaks

CEPI announced a Call for Technical Partners for the Biospecimen Sourcing Initiative, seeking organizations to support rapid, ethical, and coordinated access to high-quality biospecimens during outbreaks and public health emergencies. PATH is helping CEPI establish the Initiative and is managing the procedural aspects of this Call, which is seeking both biospecimen collection partners and developers of reference standards and antibodies. The Initiative aims to make outbreak material ready to develop assays and standards in a matter of weeks, compared to the six months or more it typically takes today, thereby making a vital contribution toward the goal to create a safe and effective vaccine against a virus with pandemic potential in as little as 100 days. Applications are due by 23:59 GMT on Wednesday, August 12, 2026.

INTERVIEW

Q&A with Roberto Amato

New artificial intelligence (AI) tools are transforming the landscape of vaccine research and development. Dr. Roberto Amato, PATH's Deputy Director of AI4Science, discusses his team's work exploring how AI can help speed up the process of bringing new lifesaving vaccines to market.

Q: How is PATH leveraging AI for vaccine development?

A: We're using an AI "co-scientist," which is an AI tool designed for hypothesis generation and research tasks, to identify potential immune biomarkers that indicate protection against specific diseases. These biomarkers, which are often referred to as correlates of protection, can help researchers reliably determine whether a vaccine candidate will be effective, but they're often difficult and time-consuming to identify. That's where the co-scientist comes in.

Q: What does the AI co-scientist do?

A: The co-scientist can analyze large volumes of scientific literature and generate new hypotheses based on a specific research goal. Our team then reviews these hypotheses and determines which—if any—to test in the lab. This step is critical since the tool can produce outputs that are compelling but rest on incorrect assumptions, so expert scrutiny isn't optional.

Q: Can you share any updates on the work so far?

A: Right now, we're evaluating the co-scientist's output on potential correlates of protection for rotavirus. We've identified a set of candidate hypotheses that our rotavirus experts consider worth pursuing. PATH is now leveraging our stored clinical trial samples, lab partnerships, and in-house disease expertise to take these ideas from AI into the real world to determine if there's any substance behind them.

CLINICAL UPDATE

May 2026

- A Phase 3 trial (PACTR202602775567145) evaluating the safety and immunogenicity of a single dose of Serum Institute of India's pentavalent meningococcal conjugate vaccine, MenFive, in pregnant and breastfeeding women and their infants began enrollment in Bamako, Mali. Participants will be vaccinated during pregnancy with either the study vaccine or a placebo, and in a cross-over design during breastfeeding with whichever they did not receive previously. In July, the study completed enrollment of 200 women between 14 and 32 weeks of pregnancy and will follow participants until their infants reach six months of age.

RESOURCES AND OPPORTUNITIES

New and updated resources

Advancing a vaccine against Group B *Streptococcus* fact sheet

China expands HPV vaccination web article

Community health workers on the front line of malaria vaccination in the DRC web article

Economic evaluation of combination vaccines: A checklist for assessing their benefits and challenges brief

Enhancing vaccine efficacy: Unlocking the power of adjuvants in global development webinar

Evidence to inform decision-making on single-dose HPV vaccination policy brief

Expanding the reach of RSV disease prevention: A communications toolkit

Frequently asked questions about single-dose HPV vaccination brief

Going the distance: House-to-house mobilizers sustain progress on malaria vaccine rollout in Nigeria web article

New tools to help middle-income countries make vaccination decisions web article

Nontraditional partners drive malaria vaccine uptake in the DRC web article

Presentations on single-dose HPV vaccination

Research Preparedness Program in East and Central Africa (RPECA) Initial Foundational Technical Workshop Report

Uganda's malaria vaccine rollout shows strong progress after one year web article

Using artificial intelligence to accelerate vaccine development fact sheet

CVIA at upcoming events

3rd Annual mRNA Conference Europe 2026
July 22 to 23
Frankfurt, Germany

World Cancer Congress
September 24 to 26
Hong Kong

World Vaccine Congress Europe
October 19 to 21
Amsterdam, Netherlands

38th Annual Conference of the International Papillomavirus Society
October 22 to 25
Athens, Greece

New scientific publications

Anti-microbial resistance vaccines: Communicating their true value

Economic evaluation of combination vaccines: Enabling a more comprehensive assessment of their benefits and challenges

Impact of introducing RTS,S/AS01E malaria vaccine on mortality in young children in Ghana, Kenya, and Malawi: An observational evaluation of a cluster-randomised implementation programme

Timing and frequency of antenatal care visits in relation to maternal respiratory syncytial virus vaccine opportunities in four Latin American countries

CVIA job opportunity

Field Officer, Kebbi Routine Immunization (Nigeria)

PATH's **Center for Vaccine Innovation and Access** brings together our expertise across every stage of the long and complex process of vaccine research, development, and delivery to make lifesaving vaccines widely available to children and communities across the world.

SUBSCRIBE

Moving the Needle provides updates on vaccine development.

Immunization Matters provides updates on vaccine uptake and access.

Banner photo: PATH/Patrick McKern

Connect with PATH

PATH
437 N 34th Street
Seattle, WA 98103
206.285.3500
path.org | info@path.org