PATH

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Moving the Needle

News from PATH on vaccine development

Recent study finds novel oral polio vaccine candidates safe and immunogenic

Next-generation novel oral polio vaccines (nOPVs) are designed to be less likely than existing OPVs to revert to a disease-causing form. Following the licensure and World Health Organization (WHO) prequalification of type 2 novel oral polio vaccine (nOPV2), which has been demonstrated to be effective against circulating type 2 virus, PATH and partners are advancing the development of nOPVs targeting types 1 and 3. Results from a first-in-human study in healthy adults found both candidates to be safe, well tolerated, and immunogenic. This paves the way for additional research to evaluate the vaccine candidates in younger populations, representing those at greatest risk of disease. As with nOPV2, these studies are building the evidence base for licensure and subsequent WHO prequalification.

R&D experts to create playbooks that map immune markers in deadly diseases

CEPI and PATH are joining forces to create pivotal playbooks that will map all available research into specific immune markers that indicate protection against target viruses with epidemic or pandemic potential. These research and development (R&D) manuals could

hold important insights for scientists, vaccine developers, and regulators to more quickly and easily determine whether a vaccine candidate will generate protective immunity against certain deadly pathogens.

Specific immune markers may signal protection against infection or disease and may reliably predict the level of a vaccine's effectiveness. These markers may be used to advance the approval of vaccine candidates when large-scale efficacy trials are not possible because there are too few cases of a disease or because outbreaks are too explosive or sporadic. While there is a growing body of research identifying potential immune markers for different epidemic diseases, scientists lack alignment when it comes to the tools and approaches used to measure these markers, making it difficult to compare findings and define or discover a biomarker predictive of a vaccine's efficacy. The first playbook will be published online in 2026 and will be freely available to all.

New global collaboration aims to accelerate RNA vaccine development

The RNA Cooperative, a new initiative supporting vaccine manufacturing in low- and middle-income countries (LMICs), began work in June 2025. It brings together emerging-market vaccine manufacturers and global nonprofit organizations to strengthen RNA vaccine development and manufacturing capacity from early research through technology transfer, workforce development, quality systems, and Good Manufacturing Practice scale-up—building clinical and production capabilities over time. The group, managed by PATH and funded by the Gates Foundation, will equip LMIC manufacturers with hands-on manufacturing experience through shared knowledge and collective learning. The Cooperative currently includes a small "core" membership of three vaccine manufacturers and may be expanded in the future.

RNA vaccine technology is flexible and can rapidly generate safe and efficacious vaccines at large scale but has largely been inaccessible to LMIC manufacturers. During the COVID-19 pandemic, mRNA vaccine development mostly occurred in higher-income countries, leading to delayed vaccine access and trailing vaccination rates in LMICs. While initial investments in LMIC RNA vaccine manufacturing have since been made, no vaccines have yet entered the clinic. By prioritizing foundational capabilities—process and analytical development, quality and regulatory documentation, supply chain, and production operations—the Cooperative aims to position manufacturers to progressively assume end-to-end ownership and help ensure sustainable, equitable vaccine access in underserved regions.

Evolving quality control assay procedures for polio vaccines

Earlier this month in Bangkok, Thailand, PATH organized an international meeting for manufacturers and regulatory testing laboratories to share evolving guidance on quality control assays for polio vaccines. This included the dissemination of results from a recent collaborative study supporting the replacement of animal models with high-throughput sequencing (HTS) for routine lot release. Other topics included the harmonization of laboratory reagents and standards with international guidance for Sabin inactivated polio vaccine development, as well as the potential of next-generation products that can be developed without biocontainment requirements. PATH will organize additional trainings on technical aspects of HTS implementation in the coming months to build manufacturer capacity for implementing these evolving approaches.

INTERVIEW

Q & A with Cynthia Lee

As malaria vaccines are rolled out in Africa, research is ongoing to improve understanding about their efficacy. Dr. Cynthia Lee, Project Director in CVIA's Bacterial & Parasitic Diseases Area, discusses recently published results from a study of the RTS,S/AS01 malaria vaccine in Kenyan adults.

Q: What was the goal of the study?

A: Our study sought to examine whether the current malaria vaccines (which target the *Plasmodium falciparum* parasite) are efficacious enough in African adults to have a role in malaria elimination campaigns and whether using antimalarial drugs to clear pre-existing malaria infections can improve vaccine efficacy. PATH conducted the study in collaboration with the Kenya Medical Research Institute, Walter Reed Army Institute of Research, and GSK.

Q: What were the results?

A: The results were unexpected and puzzling. While the administration of antimalarial drugs in adults with pre-existing *P. falciparum* infections didn't improve vaccine efficacy to

the levels achieved in an earlier and smaller study in the same population, no vaccine efficacy was achieved in adults who were free of *P. falciparum* infection at the study start and also treated with antimalarial drugs.

Q: What are the implications of these results?

A: The results emphasize the importance of conducting future vaccine testing in malaria-endemic regions. The study further provides valuable blood samples that we're using for additional laboratory tests to better understand these surprising results. Importantly, the findings do not diminish the proven efficacy of the current malaria vaccines in children and their continued implementation in Africa.

CLINICAL UPDATES

September 2025

- A first-in-human Phase 1/2 trial (NCT06611371) evaluating the safety, tolerability, and performance of a single dose of a six-valent group B *Streptococcus* conjugate vaccine candidate completed enrollment of healthy, non-pregnant women between 18 and 49 years of age from three clinical sites. The first site, located in New York, USA, began enrolling participants in November 2024; the other two sites are in Johannesburg, South Africa, and began enrolling participants in May 2025. The vaccine candidate is designed for use in pregnancy to protect infants from invasive GBS disease beginning at birth.

RESOURCES AND OPPORTUNITIES

New and updated resources

GBS vaccine clinical trial tracker

GBS vaccine snapshot

Joy's healthier future—and a lifesaving vaccine web article

On the verge of RSV disease prevention: A communications toolkit

RSV clinical trial tracker

RSV vaccine and mAb snapshot

Turning trust into coverage: Youth-led efforts raise malaria vaccine uptake web article

CVIA at upcoming events

International Rotavirus Symposium
September 30 to October 2
Cape Town, South Africa

Coalition to Strengthen the HPV Immunization Community (CHIC) Symposium
October 1 to 3
Nairobi, Kenya

World Vaccine Congress Europe
October 13 to 16
Amsterdam, Netherlands

37th Annual Conference of the International Papillomavirus Society
October 23 to 26
Bangkok, Thailand

American Society of Tropical Medicine & Hygiene Annual Meeting
November 9 to 13
Toronto, Canada

New scientific publications

Assessing commutability of the first WHO International Standard for antiserum to respiratory syncytial virus

Efficacy of RTS,S/AS01E only seen in baseline parasitemic and not baseline aparasitemic *Plasmodium falciparum*-exposed, drug-treated Kenyan adults

Plasmodium falciparum parasitemia does not diminish neutralizing antibody responses after mRNA COVID-19 booster vaccination in HIV-infected adults

Potential for a combined oral inactivated whole-cell vaccine against ETEC and *Shigella*: Preclinical studies supporting feasibility

Priming or boosting *Plasmodium falciparum* transmission-blocking responses with recombinant vaccines or gametocyte extract

Safety and immunogenicity of a recombinant double-mutant heat-labile toxin derived from enterotoxigenic *Escherichia coli* in healthy Bangladeshi adults delivered by three different routes

Sustained efficacy of the RTS,S/AS01E malaria vaccine over 50 months of follow-up when used in full-dose or fractional dose regimens in young children in Ghana and Kenya: Final results from an open-label, phase 2b, randomised controlled trial

Valuing combination vaccines: An incomplete picture

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