

Moving the Needle

News from PATH on vaccine development



First-in-human study of Group B *Streptococcus* vaccine candidate begins

Group B *Streptococcus* (GBS) is a common bacterial infection that is generally harmless in adults but can be deadly in young infants—sometimes affecting babies just a few hours old. Nearly 20 percent of women worldwide have the GBS bacterium, which live in the gastrointestinal tract and the vagina, and can be passed to a baby during birth. Currently, no GBS vaccine exists for this deadly disease that can also lead to problems during pregnancy including miscarriage, premature delivery, and stillbirth.

A [Phase 1/2, first-in-human study](#) of Inventprise Inc.'s conjugate GBS vaccine candidate began in November 2024 at New York University's Langone Health Vaccine Center. Since 2016, PATH and Inventprise have been developing a vaccine against GBS that can be delivered during pregnancy, thus allowing protective antibodies to pass from the pregnant parent to the baby in utero. PATH is supporting the [clinical study](#), which is examining safety, tolerability, and performance of the six-valent vaccine candidate in healthy, non-pregnant women between 18 and 49 years of age. Additional sites in South Africa will join the study in early 2025.

PATH and partners evaluating a new pentavalent meningococcal meningitis vaccine candidate

PATH is [supporting a Phase 2/3 study](#) of EuBiologics Co.'s pentavalent meningococcal conjugate vaccine candidate. The vaccine candidate is designed to protect against serogroups A, C, W, Y, and X—the five predominant causes of meningococcal meningitis in the African meningitis belt. The study began in Mali in September 2024 and a second site in The Gambia will begin enrolling participants in early 2025. Between the two sites, the study will enroll about 4,200 people between 9 months and 29 years of age and will examine the vaccine candidate's safety, immunogenicity, and performance when compared to a licensed vaccine.

The meningococcal meningitis prevention landscape has transformed in the last 15 years with the introduction of affordable, effective vaccines with increasingly broad serogroup coverage to the African meningitis belt—but additional vaccines are needed to ensure sustainable access and supply. Developing new, affordable meningococcal meningitis vaccines is a key tenet of the World Health Organization's (WHO's) [Defeating Meningitis by 2030](#) initiative.

New grant focuses on valuing and prioritizing novel combination vaccines

While the range and breadth of diseases that vaccines can prevent continue to expand, global immunization programs are struggling to accommodate the increasing number of vaccines given during health care visits. One potential solution is [increasing the development and use of novel combination vaccines](#). New thinking is needed to best optimize the development, policy, and regulatory pathways to more effectively and rapidly advance new combination vaccines.

PATH, with financial support from the Gates Foundation, is co-leading work to create a robust and transparent process for the identification, evaluation, and prioritization of novel combination vaccine candidates to help guide future vaccine development efforts and investments. In collaboration with the WHO's Immunization, Vaccines, and Biologicals department, PATH will: support the development of novel metrics to assess the health

impact and economic value of combination vaccines; develop frameworks to evaluate and prioritize potential combinations with feedback and input from WHO Regional Immunization Technical Advisory Groups; and work with WHO to convene regulators to sensitize them to the combination vaccine space and gather input on how to optimize the regulatory process for these vaccines.

PATH and partners recognized for work on novel oral polio vaccine type 2

In December, the novel oral polio vaccine type 2 (nOPV2) project partnership was recognized with the [2024 Innovating for Impact Partnership Award](#). Presented annually by the [Global Health Technologies Coalition](#) and selected by an independent panel of global health experts, the award recognizes breakthrough scientific research that results in lifesaving technologies for unmet global health needs. To help address the challenge of vaccine-derived poliovirus outbreaks, [researchers modified key regions](#) of the vaccine virus, making nOPV2 less likely than its predecessor to revert and regain its ability to cause disease.

Since becoming the [first vaccine to receive an Emergency Use Listing](#) from the WHO in 2020, more than a billion doses have been delivered and are successfully stopping the spread of circulating vaccine-derived polio. The recognition comes one year after [WHO prequalified nOPV2](#) to ensure broad, long-term accessibility. [Watch this video](#) to learn more about the nOPV2 partnership.

INTERVIEW

Q & A with Melanie Saville

In early 2024, [Dr. Melanie Saville](#) joined PATH as Chief Scientific Officer. As part of this role, she leads PATH's Product Development Division, which covers end-to-end work on diagnostics, health technologies, and vaccines. Dr. Saville recently shared some reflections about her first year on the job.



Q: What's unique about PATH's Product Development portfolio?

A: When I joined PATH, I was excited by the breadth and depth of the team’s technical expertise and product portfolio, which addresses the most critical health issues affecting low-resource settings. I also thought our country-centered approach and many years of working alongside national partners was a unique value-add. Our substantial experience and longstanding presence in many of these countries ensures that the products we develop are fit-for-purpose, while also facilitating rapid uptake of these innovations.

Q: How do you ensure global access to new products?

A: Before engaging with new partners, we confirm that the products we plan to develop will be available at sufficient volume to have the intended global health impact. We also want to ensure the products will be affordable, which could include supporting partners to develop efficient manufacturing processes with low cost of goods, price ceilings, referential pricing, or a cost-plus margin. Finally, we aim to balance the importance of intellectual property to the private sector while also meeting our global health goals.

Q: What’s next for the Product Development team?

A: Our near-term priorities include supporting and expanding localized manufacturing, preparing to meet the [100 Days Mission](#) when addressing emerging health threats, appropriately integrating artificial intelligence into product development, and ensuring that women’s health is a central focus of our work.

CLINICAL UPDATES

November 2024

- A first-in-human Phase 1/2 trial ([NCT06611371](#)) evaluating the safety, tolerability, and performance of a single dose of a six-valent GBS conjugate vaccine candidate began enrollment in New York, USA, of healthy, non-pregnant women between 18 and 49 years of age. This is the first of three clinical sites (the additional two, located in South Africa, will begin enrolling participants in early 2025), and 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

[Advancing vaccine affordability to save lives from pneumonia](#) op-ed

[Bangladesh embraces HPV vaccination](#) web article

[Breathing life into infant respiratory health](#) web article

[How health economics supports vaccine introduction decision-making](#) web article

[On the verge of RSV disease prevention: A communications toolkit](#)

[Preventing typhoid with vaccines in Burkina Faso](#) web article

[Zero malaria deaths are possible — if we leverage this trio](#) op-ed

CVIA at upcoming events

[WHO RSV Roadshow](#)

January 2025 to March 2025

Monthly virtual webinars

[13th International RSV Symposium](#)

March 12 to 15

Iguazu Falls, Brazil

[World Vaccine Congress](#)

April 22 to 24

Washington, DC, USA

New scientific publications

[An assessment of Ghana's pilot of the RTS,S malaria vaccine implementation programme; 2019–2021: A retrospective study](#)

[Cost effectiveness analysis of rotavirus vaccination in Indonesia](#)

[Cost of delivering childhood RSV prevention interventions to the health system in Kenya: A prospective analysis](#)

[Cost of the typhoid conjugate vaccine introduction through an integrated campaign and follow-on routine immunization in Malawi](#)

[Evaluating potential program cost savings with a single-dose HPV vaccination schedule: A modeling study](#)

[The evidence base for rotavirus vaccination in India: Current status, future needs](#)

[Gathering information on maternal immunization readiness in Bangladesh, Ghana, Kenya, Mozambique, and Nepal: Applying a WHO checklist](#)

[Has Ghana's rotavirus vaccine switch met programmatic expectations? An analysis of national surveillance data; 2018–2022](#)

[Human papillomavirus prophylactic vaccines: Update on new vaccine development and implications for single-dose policy](#)

[Measles–rubella microarray patches Phase 3 clinical trial framework: Proposal and considerations](#)

[Safety and immunogenicity in humans of enterotoxigenic *Escherichia coli* double mutant heat-labile toxin administered intradermally](#)

[What will introducing and delivering new maternal vaccines cost in Ghana and Mozambique? A prospective analysis](#)

[What will it take? Perspectives from five low- and middle-income countries on opportunities and challenges of introducing new maternal vaccines](#)

CVIA job opportunities

[Director, Statistics and Data Management](#) (Belgium, Switzerland, UK, or USA)

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

[View this email as a web page](#)

PATH is committed to respecting your privacy. Please read our [privacy notice](#) to understand how we use your personal information, and how we keep it safe.

Connect with PATH



PATH

2201 Westlake Avenue, Suite 200

Seattle, WA 98121

206.285.3500

path.org | info@path.org