PRIMARY HEALTH CARE

Implementing a learning agenda on hepatitis B birth dose vaccine delivery in Africa

Chronic hepatitis B: A preventable disease

The World Health Organization (WHO) estimates that approximately 254 million people worldwide live with chronic hepatitis B virus (HBV) infection, which can lead to serious health issues.[1] This burden is particularly high in low- and middle-income countries, including the Africa region, where an estimated 65 million people are infected.

Chronic HBV is commonly the result of vertical transmission of HBV. Babies who are infected before they are one year old have a 90% risk of developing chronic hepatitis. The second most common cause of chronic HBV is transmission during early childhood, with a 30% risk among children who are infected between one to five years old.[1]

When administered within 24 hours of birth, the hepatitis B birth dose vaccine can prevent 75% to 95% of vertical transmission.[2] Since 2009, this vaccine has been endorsed by the WHO, which recommends that all infants receive the first dose as soon as possible after birth, followed by two or three subsequent doses.[2,3]

However, administering the vaccine within 24 hours of birth is challenging, particularly in contexts where births take place outside of health facilities. In many African countries, more than 40% of births occur at home.[4] While 63% of new HBV infections are in the WHO African Region, only 18% of newborns receive the hepatitis B birth dose with only 15 of 47 countries in the region offering it as part of their routine immunization programs.[1,5]

Assessing lessons learned from innovative out-of-facility vaccination strategies is critical to advancing sustainable models of hepatitis B birth dose vaccine delivery.

Project overview

Through an innovative approach to pool resources, Gavi, Unitaid, and PATH have partnered to lead research into some of the complex challenges that restrict access to timely birth-dose vaccination.

With funding from Gavi, the Vaccine Alliance, PATH is employing a mixed methods approach to assess learning questions on the feasibility, acceptability, cost, market access, and impact of innovative strategies to improve the reach of timely hepatitis B birth dose for babies born both within and out-of-facility settings.

By exploring innovative delivery strategies, assessing the role of community health systems, and understanding stakeholder perspectives, the project's primary objective is to identify effective models for increasing hepatitis B birth dose coverage.

Evidence and insights from this initiative will be applicable to countries planning for hepatitis B birth dose vaccine introduction as well as those seeking to deploy new strategies to increase coverage rates and timely administration within 24 hours of birth.

A health extension worker provides mobile outreach for postnatal care and vaccinations in Ethiopia. Photo: PATH/Berihun Ali

Project countries

The project is being implemented in four countries: The Gambia, Nigeria, Ethiopia, and Uganda. The Gambia and Nigeria are among the earliest adopters of the hepatitis B birth dose in Sub-Saharan Africa and already have important lessons to document and synthesize, as well as considerations for reaching the last mile. Ethiopia and Uganda are planning to introduce the hepatitis B birth dose vaccine in 2025.

These countries were selected based on several criteria including a high HBV burden, moderate or high rates of home births, moderate or high birth dose rates for oral polio virus vaccine (demonstrating success with another type of birth dose), and an enabling environment for

community health providers to administer vaccines. PATH also has a strong presence in these countries through long-standing collaborative relationships with their ministry of health divisions for Expanded Programme on Immunization; Maternal, Newborn, and Child Health; and Community Health.

Learning agenda evaluation objectives

The learning agenda is organized around several interrelated evaluation objectives:

- **Understand barriers and facilitators** to timely hepatitis B birth dose vaccination.
- **Develop and pilot implementation strategies** to enable timely administration of hepatitis B birth dose for both facility and out-of-facility births.
- **Explore operational feasibility** of implementing a controlled temperature chain (CTC) strategy for out-of-facility vaccination, including roadblocks for manufacturers seeking CTC qualification.
- **Assess cost, user preferences, feasibility, and impact** for alternative vaccine product presentations (1-dose versus 10-dose) considering implementation strategies in both facility and out-of-facility birth settings.

The evaluation areas are being addressed through a phased approach, with insights from each phase informing the next. Phase 1 includes start-up and co-design with Gavi and each country's MOH as well as a rapid scoping review of immunization strategies for out-of-facility births and learning agenda protocol development. Phase 2 will include formative research, including human centered design prototyping of implementation strategies, market analyses, demand forecast modeling, and project country case studies. The final Phase 3 will include implementation research in Ethiopia and Uganda to test new implementation strategies for increasing timely hepatitis B birth dose administration, including an assessment of impact and cost-effectiveness.

The project also prioritizes gender and equity in its delivery strategies and evaluation activities. Engagement with civil society organizations and community members is critical to inform program design, including women living with chronic HBV, caregivers with recent postnatal care experiences accessing newborn vaccinations, and community health providers and skilled birth attendants who provide care at the household level.

Anticipated impacts

Project activities are expected to help shape delivery strategies for increasing timely administration of hepatitis B birth dose, ultimately contributing to improved coverage rates in pilot implementation sites. Beyond the project period, learnings may also inform strategies and decision-making in other countries planning for hepatitis B birth dose vaccine introduction or seeking to improve coverage of timely administration.

In addition, through leveraging the SAFEStart+ platform—a new partnership supported by Unitaid to accelerate demand and adoption of evidence-based approaches and integrated delivery strategies to eliminate vertical transmission of HIV, syphilis, hepatitis B, and Chagas disease—PATH will pilot prototypes of community-led vaccine delivery models for hepatitis B birth dose and investigate methods to improve efficiency and cost-effectiveness.

This evidence will also help inform organizations such as Gavi, WHO, and the Africa Centers for Disease Control and Prevention as they develop guidance and offer country support with vaccine introduction, including for CTC. In addition, the project's demand forecasting and market research will offer valuable insights to manufacturers to pursue CTC qualification for their products.

1. World Health Organization (WHO). 2024. Global hepatitis report 2024: Action for access in low- and middle-income countries. Geneva: WHO.
2. United States Centers for Disease Control and Prevention (CDC). 2022. Introduction of Hepatitis B Birth Dose Vaccination in Africa: A Toolkit for National Immunization Technical Advisory Groups. Atlanta, GA: CDC.
3. WHO. Hepatitis B vaccines: WHO position paper--recommendations. *Vaccine*. 2010;28(3):589–590.
4. Hernández-Vásquez A, Chacón-Torrico H, Bendezu-Quispe G. Prevalence of home birth among 880,345 women in 67 low- and middle-income countries: A meta-analysis of Demographic and Health Surveys. *SSM - Population Health*. 2021;16:100955.
5. CDC. Partnering to Increase Hepatitis B Birth Dose Vaccination in Africa. Accessed July 16, 2025.

About PATH
PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. www.path.org

About Gavi, the Vaccine Alliance
Gavi, the Vaccine Alliance helps vaccinate more than half the world's children against deadly and debilitating infectious diseases. www.gavi.org

About Unitaid
Unitaid saves lives by making new health products affordable and available in low- and middle-income countries. Unitaid is a hosted partnership of the World Health Organization. www.unitaid.org

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