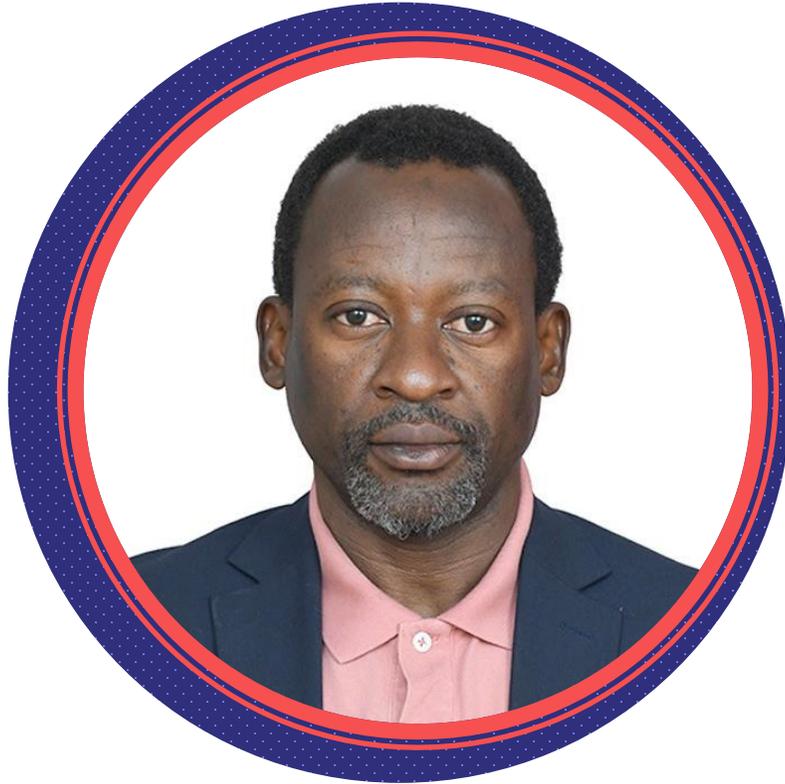


Learning agenda on hepatitis B birth dose vaccine delivery in Africa

Insights and recommendations to improve timely administration



Welcome!



Dr. Albert Komba
Project Director, SAFEStart+
PATH

Today's agenda

| | |
|--|--|
| Welcome | Dr. Albert Komba, PATH |
| Eliminating vertical transmission and the SAFEStart+ platform | Kelsey Barrett, Unitaid |
| Global progress on scaling hepatitis B birth dose | Dr. Stephen Sosler, Gavi, the Vaccine Alliance |
| Hepatitis B birth dose learning agenda: Insights from a cross-country synthesis | Dr. Katharine Shelley, PATH |
| Expert panel: Reflections on learning agenda insights to inform coverage of Hep B Birth Dose, including for out-of-facility settings | Dr. Simbarashe Mabaya, Gavi, the Vaccine Alliance <i>Moderator</i> |
| Interactive Q&A | Dr. Katharine Shelley, PATH <i>Moderator</i> |
| Closing remarks | Dr. Stephen Sosler, Gavi, the Vaccine Alliance |

Eliminating vertical transmission and the SAFEStart+ platform



Kelsey Barrett

Technical Manager

Maternal & Newborn Health Strategy

Unitaid

Global progress on scaling the hepatitis B birth-dose vaccine



Dr. Stephen Sosler

Head of Vaccine Programmes

First Year of Life Platform

Gavi, The Vaccine Alliance

Hepatitis B birth dose learning agenda: Insights from a cross-country synthesis



Insights from a cross-country synthesis



Dr. Katharine Shelley

Deputy Director

Primary Health Care

PATH

Hepatitis B birth dose learning agenda objectives

Background: Since 2009, WHO has recommended that all infants receive the first vaccine dose as soon as possible after birth. However, administering the vaccine within 24 hours of birth is challenging, particularly in contexts where births take place outside of health facilities.

Objectives: By exploring innovative delivery strategies, assessing the role of community health systems, and understanding stakeholder perspectives, the primary objectives of this project include:

- (1) Identifying promising models for increasing hepatitis B (Hep B) birth dose coverage.
- (2) Disseminating the evidence and learnings that can be used for global and country-level advocacy on delivery innovation for out-of-facility Hep B birth dose in Africa.



PATH/Khalid Alli

Hepatitis B birth dose learning agenda focus countries

| Indicator | The Gambia | Nigeria | Ethiopia | Uganda |
|---|--|---|--|---|
| Hepatitis B prevalence | 2.3% (2022) ⁷ | 6.6% (2022) ⁷ | 6.2% (2022) ⁷ | 2.4% (2022) ⁷ |
| Year hepatitis B birth dose introduced | 1990 | 2004 | 2025 | 2022 |
| Hepatitis B birth dose coverage | 98.9% (2020) ⁸ | 58.1% (2024) ⁹ | N/A | 36% (2024) ¹⁰ |
| Timely hepatitis B birth dose coverage | 37% (2024) ¹¹ | 17.4% (2024) ⁹ | N/A | N/A |
| Births outside health facilities | 13.2% (2020) ⁸ | 56.7% (2024) ⁸ | 46.1% (2019) ⁸ | 13% (2022) ¹² |
| Government strategies | Facility-only hepatitis B birth dose vaccine delivery. | Facility and outreach. | Facility-level hepatitis B birth dose administration (though pilot documented some out-of-facility vaccine administration by HEWs) | Facility-only hepatitis B birth dose vaccine delivery. |
| Community health cadres' roles in birth dose delivery | Mobilizing communities and building awareness. | CHEWs and CHOs administer vaccines at primary health care facilities. | HEWs vary in ability to administer injections. WDGs and VHLs identify home births and mobilize the community. | CHEWs administer vaccines during outreach. VHTs identify defaulters and mobilize community. |

Methods



Literature review

Rapid scoping review of global out-of-facility immunization delivery strategies.

Desk review of country-specific policy documents and peer-reviewed literature.



Qualitative—interviews and focus groups

Policymakers, immunization managers, maternal and newborn experts, supply chain officers, health providers, community members, and caregivers at national and subnational levels.



Human-centered design

Design sprints to prototype in-facility and out-of-facility implementation strategies with caregivers, CHWs, facility staff, and district managers.

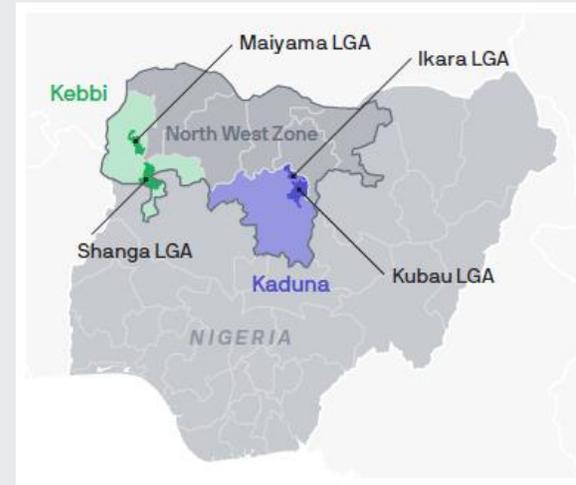
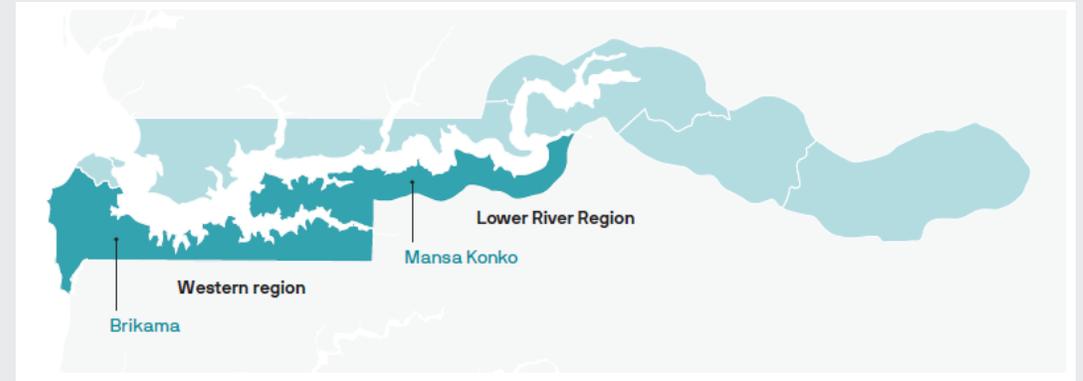


Market analysis

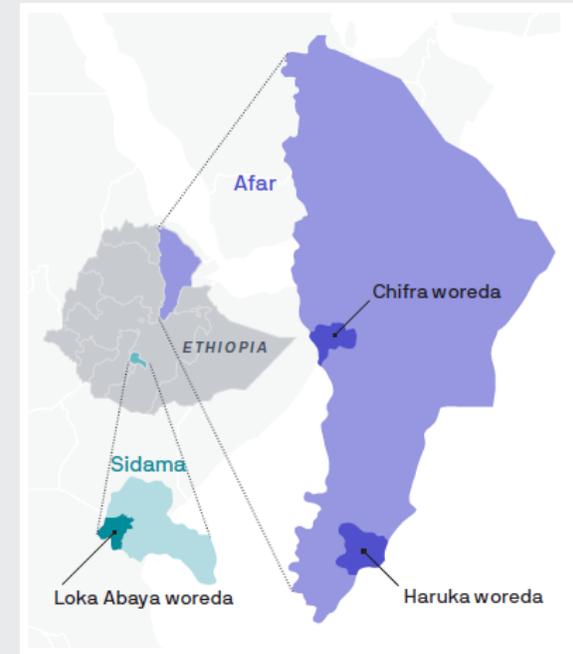
Market research on vaccine presentation and controlled temperature chain (CTC) operational feasibility.

Cost modeling of one-dose vs. ten-dose vials across delivery settings.

Evidence generated across four complementary workstreams and synthesized across four countries

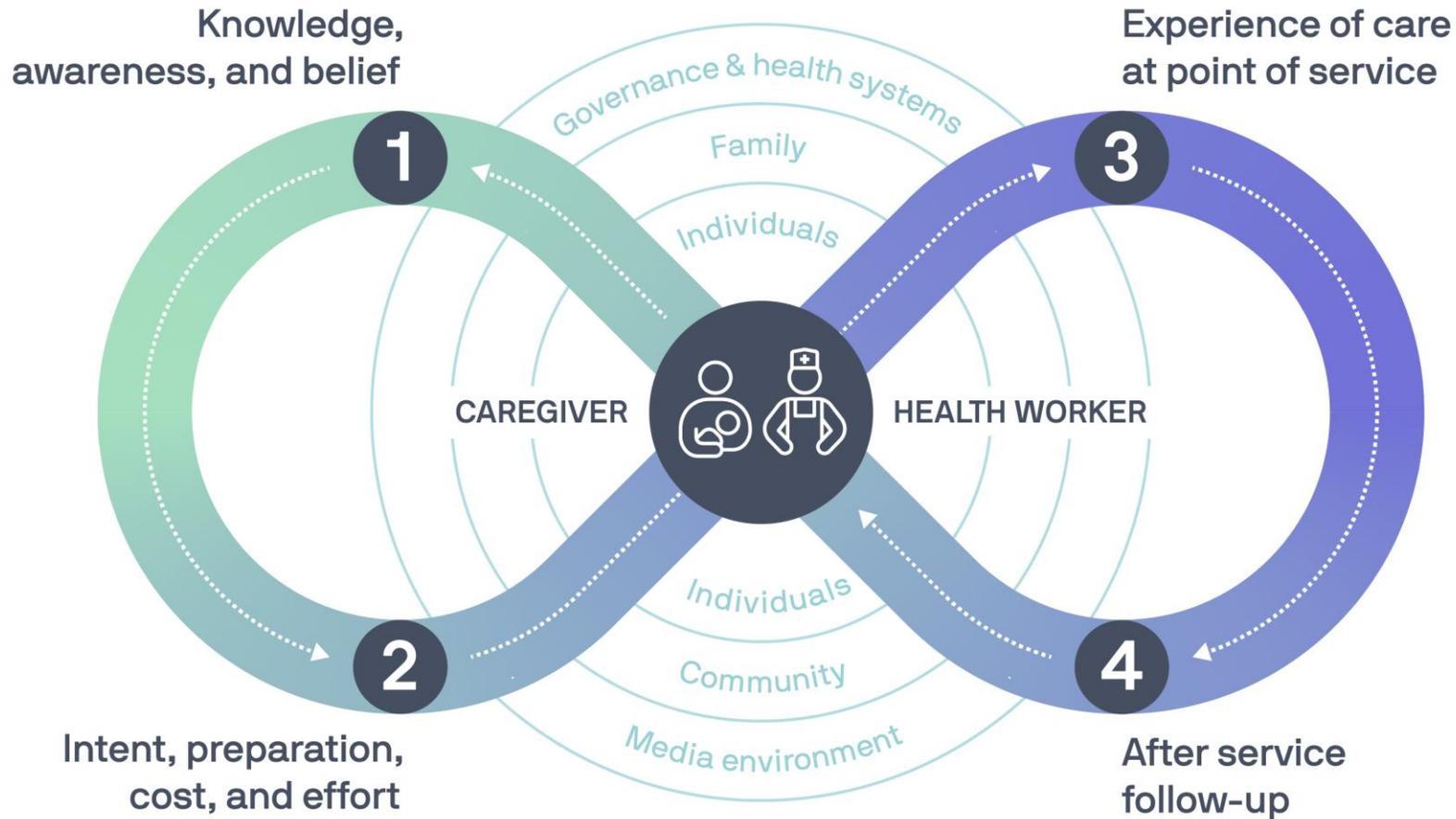


PROJECT GEOGRAPHIES



Analytical framework

Conceptual framework to understand the barriers, pain points, and potential opportunities to leverage at each stage of the journey to vaccination from both the caregiver and provider perspectives.



Facilitators and barriers to birth dose coverage identified from desk review, interviews, and focus groups were analyzed and synthesized by stage of the framework, helping to identify where along the journey to scale interventions are most needed.

Facilitators and barriers to timely hepatitis B birth dose across four countries



1 Knowledge, awareness, belief and intent

| Facilitators | Barriers |
|--|---|
| <ul style="list-style-type: none">● (+) Trusted community leaders and health cadres, along with strong acceptance in established programs, encourage timely postnatal care-seeking and support consistent birth dose delivery.● (+) Strong community networks that help identify home births, combined with providers' role as trusted sources of information, support timely birth dose delivery.● (+) Community support for facility delivery and evidence that facility births lead to more timely birth dose administration increase the likelihood that newborns receive the vaccine on time. | <ul style="list-style-type: none">● (-) Limited caregiver knowledge, cultural and religious norms, and hesitancy toward newly introduced vaccines reduce timely care seeking after delivery.● (-) Irregular training and dependence on limited EPI staff reduce providers' confidence and capacity to give the birth dose reliably and on time.● (-) Cultural preferences for home-based practices, overcrowded and less private facilities, low acceptance of hospital births, and limited vaccine capacity in private facilities all reduce caregivers' willingness to deliver in settings equipped to provide timely birth dose vaccination. |

“ They [CHWs] are playing a great role. These are the entry points to the communities. We use them to get communities to buy into our programs. To increase Hep B birth dose, it has to be through them.”
(Regional Health Directorate, The Gambia)

“ Mothers who deliver at home are often restricted from going out during the first weeks due to fears that the ‘evil eye’ could harm both mother and newborn.”
(Health provider, Ethiopia)

2 Preparation, cost, and effort

| Facilitators | Barriers |
|---|--|
| <ul style="list-style-type: none">● (+) Leveraging established community structures strengthens ownership and support for tracking and notifying home births and linkage to health facilities for opportunities to receive birth dose vaccines. | <ul style="list-style-type: none">● (-) High transportation costs, long distances, poor roads, safety concerns, and unreliable ambulance access make it difficult for caregivers to reach facilities quickly, limiting timely birth dose vaccination.● (-) Weak cold chain capacity and unreliable electricity limit consistent vaccine availability at health facilities, reducing facilities' ability to administer the birth dose on time.● (-) Informal, inconsistently defined community-based home birth tracking systems—and too few community health workers to manage them—lead to missed or delayed identification of home births, limiting timely birth dose vaccination.● (-) Community health cadres lack training, and in some cases, literacy, to be able to provide more support for birth dose delivery beyond educating and mobilizing the community. |

3 Experience of care at point of service

Facilitators

- (+) With adequate training and access, nurses and midwives are willing and able to administer the birth dose, strengthening timely delivery in facilities.
- (+) Support from community health workers and family members can bridge gaps in prioritizing mothers' recovery after delivery by bringing newborns to the facility to receive timely vaccination.
- (+) Respectful, supportive interactions with health workers encourage facility use and increase the likelihood of timely birth dose administration.

Barriers

- (-) Staff shortages, stockouts, limited service hours, and restricted access to vaccines—combined with fear of wastage from multidose vials—result in inconsistent birth dose service delivery.
- (-) When families feel well after a home birth and face heavy household responsibilities, they deprioritize facility visits and postpartum contacts, reducing their exposure to health education and opportunities for timely birth dose vaccination.
- (-) Fear of judgement, poor communication, and negative interactions with health providers discourage caregivers from seeking facility care, reducing timely birth dose vaccination.
- (-) High workloads, limited staffing, and reliance on designated vaccinators lead providers to deprioritize newborn vaccination, reducing both outreach and timely birth dose delivery.

4 After service follow-up

Facilitators

- (+) Digitized registries and structured immunization tracking systems support timely identification, follow-up, and vaccination of newborns who have interacted with the health system previously, improving vaccination coverage.

Barriers

- (-) Delayed recording of home births keeps newborns disconnected from the health system, and overburdened facility staff lack time to communicate vaccination schedules and follow-up, resulting in missed or delayed birth dose vaccination.
- (-) In some countries, private facilities do not consistently record or report vaccinations, leading to gaps in tracking and follow-up that contribute to missed or delayed birth dose administration.
- (-) Poor communication from health providers about which vaccines have been given—combined with inconsistent provision of vaccine cards—leaves caregivers unsure of their child's immunization status and next steps, increasing the risk of missed or delayed birth dose vaccination.

Human-centered design

Prioritized implementation strategies

Ethiopia and Uganda



Community-level implementation strategies in Ethiopia

Administering Hep B birth dose at health facility after home birth

- **HEW coordination and follow-up**, including notifying facilities of home deliveries and helping arrange transport.
- **Ambulance availability for rapid transport** of newborns and caregivers following home birth for birth dose and essential newborn services.
- Key functions like **birth tracking, community demand generation, male engagement, and addressing traditional beliefs** must continue, regardless of where vaccination occurs

Home-based vaccine administration by community health workers

- **Community-based birth tracking using multistakeholder community platforms**, tailored to agrarian and pastoralist settings
- **Integration with early home-based postnatal care**, pairing vaccination with postpartum health checks for mothers and newborns.
- **Expanded transport support**, particularly motorbikes, to reduce HEW travel time and allow quicker access to remote households.
- **Crosscutting strategies**, such as debunking traditional beliefs, engaging men, strengthening CHW skills, and ensuring consistent supply chain
- **Supportive mechanisms**, such as birth notification tools, referral slips, incentives for volunteer CHWs, and stronger linkages between health posts and health centers.

Community-level implementation strategies in Uganda

Strengthen community sensitization paired with respectful, consistent ANC counseling

- **Whole-of-community sensitization** on birth dose vaccines, prevention of mother-to-child transmission, labor signs, facility delivery, and advance preparation for transport and costs.
- **Consistent, clear messages** delivered via VHTs, CHEWs, influencers (male champions, religious/cultural leaders), radio, community gatherings, and local-language channels.
- **Engagement of men and families** to support decision-making and transport readiness.
- **Strengthened ANC counseling**, ensuring respectful communication on birth dose vaccines, labor recognition, and transport planning.
- **Reinforcement that no newborn should be turned away** after the initial 24-hour window, as newborns can be vaccinated up to six weeks, per national guidelines.

Strengthen trust, coordination, and referral linkages with facilities

- **Strengthening VHT presence**, building trust, and reinforcing respectful communication about vaccine safety and value.
- **Timely notification from TBAs about home births**, alert facilities when home births occur, and assist with referrals of newborns.
- **Facilities record VHT/CHEW contact information** on ANC and immunization cards to help women contact VHTs when labor begins and allow real-time follow-up.
- **Coordinated messaging** among CHEWs, VHTs, and facilities to ensure consistent guidance and supportive care for mothers.
- **Community cross-checking by VHTs/CHEWs** to verify newborns delivered at home received the birth dose and appropriate newborn care.
- **Stronger system coordination** through regular review meetings among CHEWs, VHTs, facilities; use of eCHIS for tracking births and follow-ups.

Facility-level implementation strategies

Ethiopia: Strengthen facility readiness to vaccinate immediately post-delivery

- **Consistent vaccine availability:** Maternity wards receive regular resupply via carriers or dedicated refrigerators to ensure vaccines are accessible at the point of birth.
- **Expanded midwife capacity:** Midwives receive targeted training on birth dose administration, documentation, and safe vaccine handling.
- **Improved coordination and data flow:** Delivery and EPI teams share data routinely to support follow-up and monitor timely administration

Uganda: Position birth dose as a shared responsibility across maternity and EPI teams

- **Shared responsibility:** Midwives, nurses, and EPI staff jointly ensure vaccination within 24 hr. **24/7 vaccine access:** Vaccines are stored in or near maternity wards for ease of access
- **Capacity-building:** Midwives receive training and mentorship to confidently vaccinate and document newborn vaccinations
- **No discharge without vaccination:** Hep B birth dose included in discharge checklists and routine newborn services.
- **Clear workflow and monitoring:** Protocols ensure timely vaccination and time-of-vaccination recorded.
- **Streamlined data systems:** Maternity and EPI registers aligned; routine review meetings held to track missed opportunities

Operational feasibility

Hepatitis B birth dose product presentation
and cold chain considerations



Product presentation: 1-dose versus 10-dose vials

Across countries, there is a **strong preference for one-dose vials** of hepatitis B vaccine for out-of-facility birth administration.

Respondents noted one-dose vials can maximize operational efficiency, reduce wastage, increase acceptance, and reduce missed opportunities for vaccination due to low client volume.

Cost modeling results based on vaccine procurement and delivery costs from Ethiopia and Uganda confirm that **one-dose vials have better value for money for home-based delivery**, given the significantly lower wastage rate compared to the current policy that discards remaining doses in open vials taken for outreach. For facility-based delivery, value for money depends on the number of births in the facility's catchment area: 5+ births per month → 10-dose vials.

| | 1-dose vials | 10-dose vials |
|--|------------------------|------------------------|
| Home-based delivery | Better value for money | Worse value for money |
| Low-volume facility-based delivery (1–4 births during a typical month) | Better value for money | Worse value for money |
| High-volume facility-based delivery (5+ births during a typical month) | Worse value for money | Better value for money |

Stakeholder perspectives on controlled temperature chain qualification for hepatitis B birth dose

CTC is an approach that allows certain vaccines to be stored outside the cold chain for a limited time under monitored temperature conditions.

Most stakeholders across countries and health system levels were enthusiastic about using a CTC-qualified hepatitis B birth dose to alleviate operational challenges.

Half of the respondents across countries were not willing to pay more for a CTC-approved vaccine for either the ten-dose or the one-dose presentation; a third would pay marginally more (\$0.10–0.20) for ten-dose vials, and 29 percent for one-dose vials with a CTC-approved label.

“CTC prevents wastage. It improves vaccine access to very remote areas. It is very ideal to penetrate hard-to-reach and remote areas, thus improving access.”

—National stakeholder, Nigeria

Anticipated benefits of CTC

- Enables vaccination access in rural/remote areas
- Enables vaccination in areas of low infrastructure
- Potential for greater coverage of timely vaccine administration following home births
- Reduces the need for refrigeration and/or ice
- Potential for cost savings

Anticipated CTC risks and challenges

- Requires policy change to allow CTC usage
- Need for additional supplies (threshold indicators for monitoring temperature exposure)
- Need for training (and retraining) of health care workers
- Potential confusion among health workers
- Potential for increased vaccine wastage

Recommendations



Global development partners, multilaterals, implementing partners, and donors who support countries to implement the hepatitis B birth dose consider:

- ❑ **Continue to update the hepatitis B birth dose demand forecast to inform global supply needs and improve demand visibility for manufacturers.** This project developed demand forecast scenarios that can continue to be updated based on changes in out-of-facility delivery strategies, vaccine presentation preferences, and CTC policy decisions.
- ❑ **Streamline the WHO CTC pre-qualification process to encourage manufacturers to pursue CTC approval.** Vaccine manufacturers shared that the current process is time and cost intensive with limited return on investment. A streamlined process combined with a more informative demand forecast can motivate manufacturers to pursue CTC approval to meet country demand for a CTC pre-qualified hepatitis B birth dose vaccine.
- ❑ **Offer countries the option to use Gavi support to procure and introduce one-dose vials of hepatitis B birth dose for community-based strategies and low-volume facilities.** Country stakeholders shared their preference for one-dose vials, and cost modeling results from Ethiopia and Uganda support the value for money of this approach.
- ❑ **Create channels for decision-makers, implementers, and partners to share insights, evidence, and promising practices to improve timely hepatitis B birth dose coverage.** This could build on the quarterly partners' meeting convened by Gavi by expanding it to include country representatives (e.g., EPI teams) supporting hepatitis B birth dose vaccination programs.

Country stakeholders considering hepatitis B birth dose introduction (1 of 2):

- ❑ **Strengthen core health system and routine immunization functions to improve readiness for and delivery of the hepatitis B birth dose.** Effective birth dose delivery depends on well-functioning systems for vaccine supply, workforce supervision, pregnancy and birth tracking, financing, and routine data use across community and facility levels.
- ❑ **Develop or implement policies to embed facility-based vaccination in maternity care, empowering midwives to administer hepatitis B birth dose.** Placing vaccines in maternity wards (with 24/7 access) and empowering maternity staff to vaccinate is central to reducing missed opportunities. Many countries have policies that support this; however, these policies are not consistently implemented at the facility level. One promising approach is to use a pre-discharge checklist to confirm birth-dose vaccination prior to discharge.
- ❑ **Consider using multiple hepatitis B vaccine presentations (one-dose and ten-dose vials) to minimize wastage and maximize value for money.** One-dose vials can reduce vaccine procurement costs for community-based delivery strategies and low-volume facilities. Countries should consider the implications of managing multiple vaccine presentations for health care worker training, procurement planning and stock management, data systems, and cold chain management.
- ❑ **Plan for local adaptation of hepatitis B birth dose delivery strategies.** Different settings require different messengers and delivery approaches within a shared strategy. A HCD sprint can be an effective approach to develop localized, sustainable strategies to improve timeliness and coverage of hepatitis B birth dose.

Country stakeholders considering hepatitis B birth dose introduction (2 of 2):

- ❑ **Strengthen CHW platforms to support linkages between communities and facilities.** CHWs are an essential link to provide education, referrals, and follow-up for community members, regardless of whether they are promoting a facility-based or community-based hepatitis B birth dose delivery strategy. The HCD co-creation workshop participants emphasized the importance of community cadres to identify and reach newborns delivered at home for home-based vaccination or rapid referral to a facility.
- ❑ **Consider expanding the responsibilities of CHWs to include birth dose vaccination as part of home-based early postnatal care provision.** This may be a particularly effective strategy in districts with high home-birth rates (e.g., >50 percent). This approach would require training, mentorship, and supportive supervision for CHWs to address respondents' concerns about CHWs' skills and ability to administer vaccines.
- ❑ **Monitor timely hepatitis B birth dose coverage (within 24 hours) to assess performance, provide targeted support, and learn and improve.** Consider incorporating timeliness indicators—potentially disaggregated by place of birth (facility vs. home birth)—in routine reporting and country health management information systems (e.g., DHIS2).

Continued learning and evidence generation needs

This project identified several priority areas for continued evidence generation, learning, and implementation research related to product and service delivery adaptations. Future studies could focus on the following.

| Type | Learning area |
|-----------------------------|---|
| Service delivery strategies | <ul style="list-style-type: none">• Evaluating the implementation of the HCD strategies including the effectiveness of models for rapid home birth identification (e.g., digital tools, CHW incentives, community surveillance) or task-shifting arrangements for service delivery.• Identify promising practices to improve the effectiveness and value for money of integrating hepatitis B birth dose service delivery with other essential services, particularly for home births (e.g., early PNC checks).• Learning from successful private-sector integration into EPI systems to support timely birth dose administration in private facilities. |
| Product adaptations | <ul style="list-style-type: none">• Evaluating country experiences using mixed hepatitis B vaccine presentations (one-dose and ten-dose vials), considering costs, open vial wastage rates, and health provider experiences.• Quantifying the cold chain gaps where CTC might be more valuable, including facilities that provide labor and delivery service but do not have cold chain, as well as communities with frequent home births.• Evaluating the experience of using a hepatitis B vaccine with CTC (once a WHO prequalified vaccine is available) and specifically the impact on timely hepatitis B birth dose coverage.• Testing and assessing the feasibility and acceptability of CHW administration of microarray patches (once available). |

Expert panel



Today's panelists



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Gavi, The Vaccine Alliance



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Foundation, Nigeria



Dr. Ponsiano Ocama
Associate Professor, Makerere
University College of Health
Sciences, Uganda

Audience Q&A



Hepatitis B birth dose learning agenda—new resources!

Insights and recommendations to improve timely hepatitis B birth dose vaccine delivery in Africa

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Chronic hepatitis B: a preventable disease

The World Health Organization (WHO) estimates that approximately 264 million people worldwide live with chronic hepatitis B infection, which can lead to cirrhosis, liver cancer, and liver failure. The burden is particularly high in low- and middle-income countries, including in Africa. In high-income countries, hepatitis B infection is commonly a result of the virus being passed from mother to baby at birth, however, an ethical transmission, giving infants a 90 percent risk of developing chronic hepatitis B. The second-most common cause of chronic hepatitis B is transmission during early childhood, with a 30 percent risk among children who are infected between 1 and 5 years of age.

Vaccination is critical to prevent hepatitis B infection. When administered within 24 hours of birth, the hepatitis B vaccine birth dose can prevent 75 to 90 percent of vertical transmission. Since 2009, WHO has recommended that all infants receive the first vaccine dose as soon as possible after birth, followed by two or three subsequent doses to complete the infant hepatitis B vaccine series.

However, administering the vaccine within 24 hours of birth is challenging, particularly in countries where birth take place outside of health facilities. In many African countries, more than 40 percent of births occur at home. While a 2 percent of new hepatitis B infections occur in Africa, only 10 percent of newborns receive the hepatitis B birth dose. Only 10% of countries in the region have hepatitis B vaccine as part of their routine immunization program.

Project overview

With funding from Gavi, the Vaccine Alliance, PATH has engaged 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 outside of health facilities. To maximize practice delivery strategies, assessing the role of community health systems, and understanding translational approaches, the project aimed to identify effective models for increasing

Methods

The study used a mixed methods design combining a suite of complementary approaches, including:

1. Rapid scoping review of global literature on out-of-facility vaccine delivery strategies.
2. Deep research of country policy documents and peer-reviewed literature to inform data collection tools and provide context for findings for the country case studies on hepatitis B birth dose delivery, including success, challenges, and lessons learned.
3. Interviews and focus group discussions with policymakers, immunization managers, supply chain officers, health-care providers, community members, caregivers, and other stakeholders at national and subnational levels in the four countries to gain insight into challenges to timely administration of hepatitis B birth doses, opportunities or strategies to improve coverage, and health system readiness considerations.
4. Mixed methods to assess vaccine presentation and implementation a controlled temperature chain (CTC) network based on desk review and interviews with policymakers, regulators, supply chain experts, and manufacturers.
5. Detailed forecasting to model the number of hepatitis B birth doses required for low- and middle-income countries across multiple scenarios.
6. Cost modeling to understand the vaccine coverage rates and cost associated with using one dose versus two doses in facility and out-of-facility delivery settings.
7. Human-centered design (HCD) to develop prototypes for in-facility and out-of-facility delivery strategies.

Results were analyzed by country to answer the project learning questions and design prototypes across the four countries to identify common themes.

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

Summary report | Human-centered design findings comparing implementation strategies developed in Ethiopia and Uganda

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

A case study from Ethiopia

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

A case study from The Gambia

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

A case study from Nigeria

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

A case study from Uganda

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Strengthening timely hepatitis B birth dose vaccination in Ethiopia

Hepatitis B birth dose learning agenda

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Strengthening timely hepatitis B birth dose vaccination in The Gambia

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Strengthening timely hepatitis B birth dose vaccination in Nigeria

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Strengthening timely hepatitis B birth dose vaccination in Uganda

Hepatitis B birth dose learning agenda

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Synthesis brief

Human-centered design summary

Country case studies

Country policy briefs



Visit: www.path.org/who-we-are/programs/primary-health-care/hepb-birthdose/



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Visit: www.path.org/who-we-are/programs/primary-health-care/hepb-birthdose/

**Thank
you!**

PATH
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