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

PATH

Chronic hepatitis B: a preventable disease

The World Health Organization (WHO) estimates that approximately 254 million people worldwide live with chronic hepatitis B infection, which can lead to serious health issues.[1] The burden is particularly high in low- and middle-income countries, including the African Region, where an estimated 65 million people are infected.[1] Chronic hepatitis B infection is commonly a result of the virus being passed from mother to baby at birth (known as vertical transmission), giving infants a 90 percent risk of developing chronic hepatitis B.[2] 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.[2]

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 95 percent of vertical transmissions.[3] 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.[4]

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 percent of births occur at home.[5] While 63 percent of new hepatitis B infections are in the WHO African Region, only 18 percent of newborns receive the hepatitis B birth dose. Only 15 of 47 countries in the region offer hepatitis B vaccine as part of their routine immunization programs.[6]

Project overview

With funding from Gavi, the Vaccine Alliance, PATH has employed 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 facility settings. By exploring vaccine delivery strategies, assessing the role of community health systems, and understanding stakeholder perspectives, the project aimed to identify effective models for increasing hepatitis B birth dose coverage. Evidence and insights from this initiative can be used by 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.

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 immunization delivery strategies.
2. *Desk review of country-specific policy documents and peer-reviewed literature* to inform data collection tools and provide contextual grounding for the country case studies on hepatitis B birth dose delivery, including successes, 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 dose, opportunities or strategies to improve coverage, and health system readiness considerations.
4. *Market research* about vaccine presentation and implementing a controlled temperature chain (CTC) strategy based on desk review and interviews with policymakers, regulators, supply chain experts, and manufacturers.
5. *Demand 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 wastage rates and delivery costs associated with using one-dose versus ten-dose vials in facility and out-of-facility delivery settings.
7. *Human-centered design sprints* to develop prototypes for in-facility and out-of-facility delivery strategies.

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

Project countries

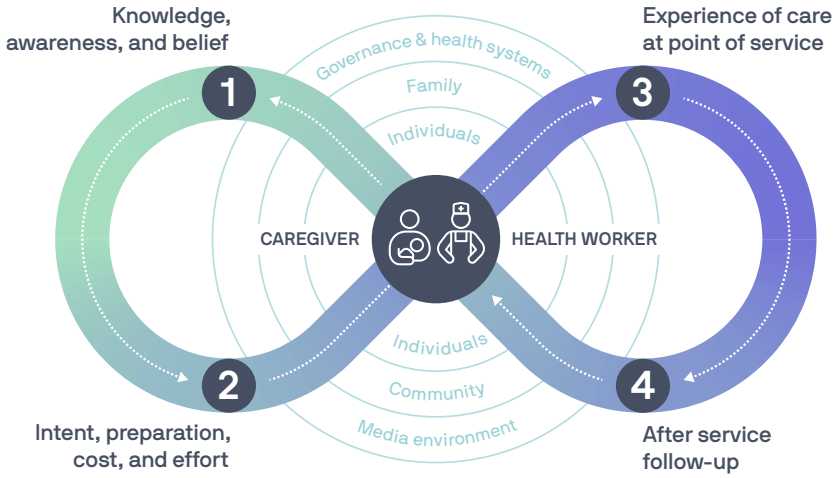
The project was implemented in four African countries—Ethiopia, The Gambia, Nigeria, and Uganda—selected based on indicators related to hepatitis B burden and vaccination rates as well as PATH's longstanding collaboration with their ministries of health. The Gambia and Nigeria are among the earliest adopters of the hepatitis B birth dose in sub-Saharan Africa, whereas Ethiopia and Uganda have recently introduced the birth dose vaccine.

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.

Abbreviations: CHEW, Community Health Extension Worker; CHO, Community Health Organizer; HEW, Health Extension Worker; N/A, not applicable; VHL, village health leader; VHT, Village Health Team; WDG, Women's Development Group.

Barriers and facilitators to timely hepatitis B birth dose delivery

The project identified key barriers and facilitators to timely hepatitis B birth dose vaccination at the community and facility levels that were common across all four countries. Barriers and facilitators were identified through desk review and interviews and are organized by four stages of the immunization journey, based on a modified version of UNICEF's Journey to Health and Immunization framework.[13] Factors at each stage influence timely birth dose delivery for both caregivers and health providers.



1 Knowledge, awareness, belief and intent

Facilitators	Barriers
• (+) 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.	• (-) 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
• (+) 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.	• (-) 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.

> "[Reporting home delivery] is the responsibility of everyone."
> (Community Leader, Ethiopia)

> "Long distances from the community to the facility make it hard for mothers to access the vaccine. When it rains, the roads are impassable, hindering mothers from reaching the facilities."
> (Community Leader, Uganda)

❸ Experience of care at point of service

Facilitators	Barriers
● (+) 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.	● (-) 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.

> **"Training midwives to vaccinate at birth is important [and creates] a big difference in our facility."**
> (Health provider, Ethiopia)

> **"Mothers fear taking their children to the facility because they have given birth in the community, and it is sometimes because of the fear of being abused by health workers."**
> (Community Leader, Uganda)

❹ After service follow-up

Facilitators	Barriers
● (+) 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.	● (-) 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.

> "The digital approach to improve vaccinations—the tools could be GIS enabled. Line listing of pregnant women and eligible children is done on that tool. The health workers are then made to see those line listed and where they are, including their vaccination status, and know those to follow up with for vaccination. The approach was done in Niger, and over 25 percent of the zero-dose children were identified and vaccinated."
> (National respondent, Nigeria).

> "My child was vaccinated, but I don't know whether my child was vaccinated with hepatitis B birth dose."
> (Mother, Uganda)

Across the framework stages, common factors emerged that shape whether caregivers and providers act in ways that support timely birth dose vaccination:

- **Caregivers' connection to the health system** – particularly through community health workers (CHWs) – contributes to their knowledge and preparation during pregnancy, influences decisions about place of delivery, and affects whether home births are identified and followed up after delivery.
- **Overstretched health workers and weak communication between communities and health workers** limit caregivers' access to early counseling, support during delivery and immediately after birth, and follow-up care.
- **Mothers' service experience at health facilities** influences their decisions about where to deliver and whether to seek postnatal care. Lack of respectful maternity care discourages facility-based deliveries and may deter mothers who deliver in out-of-facility settings from seeking newborn vaccination due to fear of reprimand.

Product and service delivery adaptations

The project evaluated how different vaccine presentations and cold chain strategies could address current barriers to improve timely hepatitis B birth dose delivery, particularly for out-of-facility births. The assessment considered operational feasibility, user preferences, and implications for service delivery.

Product preferences

Across countries there is a strong preference for one-dose vials of hepatitis B vaccine for out-of-facility birth administration compared to the current ten-dose vials. Respondents noted that the one-dose vial 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, the presentation that provides better value for money depends on the number of births in the facility's catchment area (Table 1).

Table 1. Comparison of value for money for one-dose versus ten-dose vials by delivery setting

	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

Most respondents felt it would be feasible to manage both one-dose and ten-dose vials (multiple presentations) within the immunization program, noting the value of having different options for different settings to help reduce wastage.

Looking ahead, there is clear enthusiasm for product innovations like microarray patches and prefilled syringes

that could be used to enable new service delivery models like CHW administration to support timely birth dose vaccination in out-of-facility settings. Stakeholders across countries see these as opportunities to "move the needle" on birth dose coverage.

Controlled temperature chain

A controlled temperature chain (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 help alleviate operational challenges. They agreed that using a CTC approach could address cold chain gaps, power interruptions, and the difficulty of reaching newborns delivered in out-of-facility settings.

"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)

Only in Uganda did stakeholders raise concerns about using a CTC for hepatitis B birth dose, with 33 percent of national respondents indicating that they did not believe it would benefit the immunization program. They noted the current cold chain is sufficient and expressed concerns about health worker confusion, extreme temperatures, or added operational complexity. Stakeholder views on the potential benefits and challenges of implementing CTC for hepatitis B birth dose are summarized in Table 2.

Despite recognition that CTC-approved vaccines could increase coverage, budget is a key constraint, with limited scope for marginal price increases without external support. Most respondents across The Gambia, Nigeria, and Uganda (but not in Ethiopia) were not willing to pay higher prices for a CTC-approved vaccine. Overall, half of the respondents across the four countries were not willing to pay more for a CTC-approved vaccine for either the ten-dose or the one-dose presentation. Thirty-five percent of respondents would pay marginally more ($0.10–0.20) for ten-dose vials, and 29 percent for one-dose vials with a CTC-approved label.

TABLE 2. **Stakeholder views on implementing a CTC approach for hepatitis B birth dose.**

Anticipated benefits of CTC	Anticipated CTC risks and challenges
• 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	• 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

Abbreviation: CTC, controlled temperature chain.

Vaccines indicated for CTC use require regulatory approval and WHO prequalification is also required for vaccines procured through global health mechanisms like Gavi. Manufacturers shared that the WHO process is seen as resource-, time-, and cost-intensive and provides limited return on investment in a hepatitis B birth dose market that is already characterized by low profitability and limited demand. Most manufacturers reported having sufficient data demonstrating vaccine stability at temperatures outside of the cold chain; however, they are unwilling to conduct additional studies required by the WHO prequalification process. Despite these constraints, there is one supplier currently undergoing WHO prequalification review which could expand future availability of CTC-labeled hepatitis B birth dose vaccines.

Human-centered design to co-create implementation strategies

PATH implemented human-centered design (HCD) co-creation workshops in Ethiopia and Uganda to validate the key barriers to timely hepatitis B birth dose vaccination and prototype potential strategies. The workshops were conducted over four days and brought together caregivers, community representatives, CHWs, facility-based health workers, and district-level managers. The workshop participants proposed strategies that cut across the caregiver and provider journey of care.

Community and home-birth strategies

In both countries, delays after home births are driven by low awareness of the hepatitis B birth dose, late identification of home births, and weak coordination between communities, CHWs, and health facilities. Strategies therefore focus on improving early birth notification, strengthening community trust, and reducing delays in linking newborns born at home to vaccination services. Specific co-designed strategies include:

Community-wide awareness and preparation strategies

- **Uganda:** A Village Health Team (VHT) / Community Health Extension Worker (CHEW)-led community sensitization strategy linked to antenatal care counseling and reinforced through community meetings, male engagement, and local leaders, aimed at improving early recognition of labor signs, delivery planning, and transportation for timely hepatitis B birth dose vaccination.
- **Ethiopia:** Awareness raising recommendations focused on three areas – service integration (hepatitis B birth dose counseling in antenatal care), community engagement (using public figures to build trust and address beliefs), and mobilization leveraging existing community health and traditional structures.

CHW-led birth identification, notification, and referral

- **Uganda:** Strengthening coordination and communication among VHTs and CHEWs to identify home births and rapidly notify facilities, and in the process strengthening referral and follow-up loops with traditional birth attendants and maternity wards to ensure timely vaccination at facilities.
- **Ethiopia:** A referral strategy for home births that prioritizes timely transport of newborns to health facilities for vaccination. Health Extension Workers (HEWs) coordinate early birth notification, arrange transport where needed, and follow up with facilities to ensure vaccination occurs promptly after arrival.

Home-based vaccination

- **Ethiopia:** A complementary home-based vaccination strategy in which HEWs administer the hepatitis B birth dose at home where feasible. The strategy relies on HEWs coordinating pregnancy and birth tracking through community structures and integrating vaccination into early postnatal home visits to reach newborns within the recommended time window.

Facility-level strategies

Across both countries, participants identified the maternity ward as the most reliable opportunity to ensure timely birth dose vaccination. Specific strategies focused on:

Vaccination embedded into routine delivery and postnatal workflows

- **Uganda:** An integrated facility strategy that positions birth dose vaccination as a shared responsibility between maternity and Expanded Programme on Immunization (EPI) teams. The strategy expands which cadres can vaccinate newborns, ensures vaccines are accessible in maternity wards, and strengthens mentorship, data sharing, and shared accountability to enable vaccination at all hours.
- **Ethiopia:** A facility readiness strategy focused on immediate post-delivery vaccination. The strategy emphasizes consistent vaccine availability in maternity wards, strengthening midwives' immunization skills, clarifying open-vial and wastage policies, and improving coordination and data flow between delivery units and EPI teams.

Crosscutting systems strengthening strategies

Participants identified that the success of both community- and facility-level birth strategies depends on strengthening core health system functions and designed crosscutting system-strengthening strategies tailored to each country context.

- **Uganda:** Strategies focused on CHW performance management and improved vaccine stock tracking, forecasting, and redistribution of extra stock.
- **Ethiopia:** Strategies focused on birth tracking, HEW and volunteer capacity, strengthening last-mile vaccine supply chains, male engagement, and implementing digital and referral tools linking community- and facility-level reporting on hepatitis B birth dose.

Next steps

Countries are adapting these prototypes at district and national levels, with additional adaptations planned. Moving forward, efforts will focus on integrating hepatitis B birth dose into existing integrated service delivery strategies at health facilities (alongside newborn care and prevention of mother-to-child transmission of HIV) and strengthening core health system functions, including cold chain, refrigeration, and vaccine supply tracking.

Recommendations

This project combined global market research, demand forecasting, cost modeling, country-level qualitative research, HCD co-creation, and cross-country synthesis to build a comprehensive understanding of hepatitis B birth dose delivery. The evidence generated identifies effective models for increasing timely birth dose coverage—particularly for out-of-facility births—and informs the following recommendations for key stakeholders.

Country stakeholders who are considering introducing hepatitis B birth dose or strengthening its timely administration should:

- **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.
- **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.
- **Plan for local adaptation of hepatitis B birth dose delivery strategies.** Different settings require different messengers and delivery approaches within a shared strategy. An HCD sprint can be an effective approach to develop localized, sustainable strategies to improve timeliness and coverage of hepatitis B birth dose.
- **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).

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

- **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.

Continued learning and evidence generation

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:

Service delivery strategies	• 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 postnatal checks). • Learning from successful private-sector integration into EPI systems to support timely birth dose administration in private facilities.
Product adaptations	• 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).

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Acknowledgements

PATH would like to thank the stakeholders in Ethiopia, The Gambia, Nigeria and Uganda who are working to advance hepatitis B birth-dose delivery and who generously gave their time to participate in this learning agenda. This report was made possible by funding from Gavi, the Vaccine Alliance.

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Date Published
December 2025