# Strengthening timely hepatitis B birth dose vaccination in Ethiopia

**Hepatitis B birth dose learning agenda**

## Country context

Ethiopia's Ministry of Health (MOH) launched universal hepatitis B birth-dose vaccination in November 2025, backed by national recommendations and with support from Gavi, the Vaccine Alliance. The country has set ambitious targets which include ensuring that 70% of newborns receive the vaccine within 24 hours of birth. Evidence from a 2021–2022 pilot demonstrated successful birth-dose integration into routine immunization for facility births, but revealed challenges reaching newborns delivered at home, which account for nearly half of all births. Early discharge from health facilities also hindered timely vaccination.

To address these gaps, the MOH is advancing scalable, community-driven strategies to ensure every newborn receives the birth dose. To identify practical strategies for improving timely birth-dose vaccination, PATH collaborated with the MOH to assess learning questions on the feasibility, acceptability, market access, and cost of innovative strategies to improve coverage for babies born at home or in health facilities.

## Study design

The study included multiple methods, including a literature review, key informant interviews, focus groups, human-centered design workshops, and cost modeling of single versus multidose vial presentations.

Data were collected in Afar (pastoralist) and Sidama (agrarian) regions—chosen for their high hepatitis B burden and out-of-facility births—through interviews with national policymakers and technical experts (n=8), woreda health administrators (n=6), and facility staff (n=12). Fifteen community focus groups with caregivers and community actors (n=120) also provided important insights. UNICEF's *Journey to Health and Immunization* framework covering the caregiver and provider journey informed thematic analysis of barriers, facilitators, and implementation processes.

Three workshops (n=88 participants) included caregivers, community leaders, HEWs, immunization teams, primary health care unit directors, and woreda maternal and newborn health coordinators. Workshop participants developed and refined prototypes for improving vaccine uptake, identifying priority strategies for implementation.

## Findings

### Current implementation strategies

Ethiopia's hepatitis B birth-dose vaccination strategy prioritizes facility-based deliveries and postnatal care, while also leveraging community health platforms including health extension workers (HEWs) and women's development groups to reach home births within 24 hours. A new training manual aims to strengthen coordination across health system levels to ensure timely birth-dose delivery in both facility and home settings.

### Barriers and facilitators

National stakeholders reflected on both health system and community-level barriers and facilitators to birth-dose delivery. Health system barriers included weak tracking of home births, staff shortages, cold chain limitations, and vaccine wastage, alongside community-level challenges such as low awareness, cultural practices, and transportation difficulties. Service gaps persist in facilities due to restricted vaccine availability and misconceptions about timing, while home births rely on community members whose roles vary by region. Community health leaders are emerging as trusted facilitators, highlighting the need for stronger coordination and training across levels.

### Co-creation workshop insights

Following co-creation workshop activities and prototype refinement, participants identified priority implementation strategies for facility and out-of-facility settings. Participants recommended community-wide awareness

### About the hepatitis B birth dose learning agenda

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 timely hepatitis B birth-dose coverage for babies, whether born at home or in health facilities. By exploring innovative delivery strategies, assessing the role of community health systems, and understanding stakeholder perspectives, the project aims to identify scalable solutions. Evidence and insights from this initiative will help inform countries introducing the birth dose as well as those seeking new strategies to increase both coverage rates and timely administration.

This brief is a summary of the full case study available at www.path.org/who-we-are/programs/primary-health-care/hepb-birthdose.

raising by integrating birth-dose counseling into antenatal care and leveraging existing community structures to improve engagement, address misconceptions, and promote male involvement.

For home births, workshop participants recommended home vaccination alongside other essential newborn services or facilitating immediate transfer of the newborn and caregiver to a facility—with a strong preference for home vaccination rather than facility transfers. To improve coverage, participants suggested strengthening pregnancy and birth tracking through closer community collaboration to ensure rapid notification of HEWs.

For facility births, participants advocated for birth-dose vaccination in the delivery ward, immediately after birth. To enable this, participants emphasized the importance of vaccine availability in the wards, training midwives to administer doses, and establishing a data-sharing platform between maternity and immunization teams for better coordination and monitoring.

## Operational feasibility considerations

### Supply chain

Ethiopia's vaccine supply chain relies on fixed, outreach, and mobile delivery models, yet persistent gaps in cold-chain capacity, transportation, and coordination—especially between immunization and maternity units—undermine the timely administration of the hepatitis B birth dose. Because HEWs deliver most services through outreach and the birth dose is recommended for administration within 24 hours, policymakers must strengthen cold chain infrastructure, ensure reliable vaccine availability in delivery wards, and improve communication between service units.

### Controlled temperature chain

Controlled temperature chain (CTC) prequalification for the birth-dose vaccine represents a promising opportunity to expand timely newborn vaccination, especially for infants born outside health facilities. Most respondents in Ethiopia (95%, n=22) indicated a CTC-qualified hepatitis B birth-dose vaccine would be beneficial, emphasizing its potential to improve 24-hour coverage, extend reach in remote areas, reduce wastage, and ease cold chain constraints—provided that policy updates, staff training, and system integration are prioritized. To achieve the maximum benefit of CTC, an 6- to 14-day stability window was viewed as most practical. National stakeholders (n=3) indicated willingness to pay slightly more for a CTC-qualified birth-dose vaccine.

### Product presentation

Cost modeling based on vaccine procurement and delivery costs in Ethiopia confirm that one-dose vials have better value for money for home-based delivery, given the significantly lower wastage rate compared to current policies for discarding remaining open-vial doses used during 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, with one-dose vials providing better value for money in facilities with fewer than five births per month. Most respondents agreed that offering multiple product presentations—particularly one-dose vials—would improve delivery by reducing wastage, improving efficiency, and increasing acceptability in low-volume or out-of-facility settings.

BOX 1

### Recommended strategies for increasing timely hepatitis B birth dose coverage in Ethiopia

#### Policy and systems

- ☑ Update and disseminate national guidelines, tools, and job aids (e.g., monitoring charts, registers, and materials on social and behavioral change).
- ☑ Ensure policy emphasis on facility-based vaccination in maternity care, empowering midwives to administer hepatitis B birth dose.

#### Knowledge and awareness

- ☑ Promote awareness on the benefits of facility deliveries and early vaccination by integrating hepatitis B birth-dose counseling into antenatal care, conducting outreach in remote areas, engaging trusted public figures and leaders, strengthening male engagement, and mobilizing existing community health (e.g., traditional birth attendants, community health workers) and traditional structures.

#### Service delivery

- ☑ Strengthen health system and routine immunization functions to improve birth-dose readiness and delivery, including improved cold chain capacity and uninterrupted power supply in delivery wards.
- ☑ Improve coordination between delivery wards and EPI units, including during weekends/nights, to ensure trained staff are available to administer birth-doses prior to discharge.
- ☑ Consider using multiple hepatitis B vaccine presentations (one- and ten-dose vials, depending on setting) and CTC-approved vaccines (once available) to minimize wastage and maximize value for money.
- ☑ Implement a community-based platform, including digital tools for real-time notification, to track and refer births, supporting community and facility linkages.
- ☑ Test implementation strategy to include hepatitis B birth-dose vaccination as part of integrated home-based early postnatal care provision.
- ☑ Provide transportation support for both caregivers (to support access to birth dose at facilities) and health workers (to facilitate outreach for home-based birth-dose vaccination in remote areas).
- ☑ Monitor timely hepatitis B birth-dose coverage (within 24 hours) to assess performance, provide targeted support, and learn and improve.
- ☑ Plan for further local adaptation of hepatitis B birth-dose implementation strategies.

Prioritizing flexible, single-dose presentations, combined with strategic planning for diverse settings, can help expand equitable access to the birth dose.

## Policy and program recommendations

The synthesis derived from the scoping review, primary qualitative data collection, and co-creation workshops provides an evidence-based foundation for distinct implementation strategies designed to optimize the timely administration of the Hep B birth-dose vaccine (Box 1). The prototypes targeting both out-of-facility births and facility births were shaped by diverse participant input and validated by the national Expanded Programme on Immunization (EPI) task force on critical dimensions of feasibility, including implementation cost, policy alignment, and equity. The findings mandate an approach for effective Hep B birth-dose delivery, grounded in a commitment to iterative refinement and strategic policy alignment.

### Implementation research and iterative scale-up

The immediate policy implication is the need for an intensive, evidence-driven testing phase using an implementation science framework (Box 2). Successful national scale-up of the co-designed strategies hinges on evaluating their effectiveness under real-world conditions. This should support learning across diverse contexts and enable continuous refinement before moving to national scale up, ensuring that policies remain feasible, acceptable, effective, and sustainable over time.

### Dual strategy for vertical elimination

The government's continued efforts toward achieving universal institutional delivery remain a paramount policy objective. However, the persistence of home births in specific regions of Ethiopia necessitates a pragmatic, time-bound programmatic strategy. Policy authorization and funding support are recommended for the immediate implementation of the two prototypes designed for out-of-facility deliveries as a high-priority, interim measure to urgently eliminate the vertical transmission of hepatitis B. This dual strategy (promoting facility births while actively reaching home births) is essential to meet immediate public health goals. Furthermore, the long-term policy framework must incorporate a built-in sunset clause, dictating that the complex strategies for out-of-facility births will be systematically phased out as institutional delivery rates achieve universal coverage, allowing program focus and resources to transition entirely to the facility-based prototype. Until that universal goal is met, sustained implementation with continuous learning is critical.

BOX 2

### Opportunities for continued learning through implementation research

- **Conduct implementation research** to evaluate the proposed strategies under real-world conditions, considering feasibility across contexts, caregiver and provider acceptability, fidelity, appropriateness, effectiveness and cost-effectiveness (including for different vaccine presentations and outreach vs. facility-based strategies), and sustainability.
- **Evaluate facility-based vaccination after home birth,** noting that while rapid referral of newborns to a facility after home delivery is recognized by the MOH, it shifts travel and cost burdens to families and is not preferred by communities. This strategy warrants further testing to compare its feasibility and cost effectiveness with home-based vaccination.
- **Assess the optimal use of mixed (one- and ten-dose) vaccine presentations** for specific delivery contexts, quantifying settings where CTC adds the most value and evaluating CTC-approved vaccines' impact on timely coverage. Future studies could also explore feasibility and acceptability of microarray patch administration by CHWs.

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