BUILDING A COMMUNITY OF PRACTICE TO ASSIST HEPB BIRTH DOSE INTRODUCTION IN AFRICAN COUNTRIES

HEPB BIRTH DOSE WEBINAR SERIES

WEBINAR 1 SYNTHESIS MARCH 2021
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More than 257 million people worldwide are living with hepatitis B (HepB), with 60 million of those cases in Africa, where prevalence rates exceed 6% and more than 50% of liver cancer deaths are attributable to chronic HepB infection.

The risk of chronic HepB varies inversely with age. Children infected at birth experience the highest risk of chronicity (90%), preschool-aged children infected through horizontal transmission have a 30% risk, and individuals infected as adults have less than a 3% risk of chronicity. Globally, 16 countries account for more than 80% of chronic infections in children under 5 years old. Nine of those 16 countries are in Africa.

Hepatitis B is a vaccine-preventable disease. Preventing perinatal transmission is vitally important, in part because transmission almost always occurs at the time of birth, but also because perinatal transmission represents a growing proportion of all HepB infections, from 16% in 1990 to a projected 50% in 2030. The relative success of broader HepB immunization campaigns, which interrupt the risk of horizontal transmission, have left perinatal transmission as the single most important public health hurdle to clear in the race to eliminate hepatitis B by 2030.

The World Health Organization (WHO) recommends a universal birth dose of the HepB vaccine, ideally within 24 hours of birth, followed by at least two more doses of the vaccine as part of an immunization series. WHO elimination goals include a 90% reduction in new chronic HepB infections by 2030. Targets supporting this goal include decreasing the hepatitis surface antigen (HBsAg) prevalence among children under 5 to less than 1.0% by 2020 (achieved globally in July 2020) and to less than 0.1% by 2030. In Africa, however, the 2020 interim target has not been reached: the prevalence rate hovers at 2.5% among children under 5. Africa also is the region with the smallest proportion of countries (15 countries, or 32%) to have reached this interim target.

How can public health and other partners support African countries in introducing and scaling up the HepB birth dose vaccine (HepB-BD)? The Coalition for Global Hepatitis Elimination (CGHE), in collaboration with WHO and the Global Immunization Division of the U.S. Centers for Disease Control and Prevention (CDC), is convening stakeholders in a community of practice toward the successful introduction and scale-up of the HepB-BD for member states of the WHO African region (AFRO). Aimed at providing evidence-based strategies that can be applied locally to fit specific needs, this webinar series has four overarching objectives:

- Share products of technical assistance (TA) and operational research (OR)
- Identify and coordinate additional TA and OR priorities for health ministries and their local partners
- Prepare a toolkit to help national immunization technical advisory groups (NITAGs) develop evidence-based guidelines regarding HepB-BD vaccination
- Update the status of national HepB-BD implementation in the region underway by ministry of health, research, and TA partners.
The initial meeting (March 17-18) set the stage for the series. Participants included CGHE, CDC, WHO, Gavi, Ministry of Health Expanded Programme on Immunization (EPI) managers and Hepatitis Focal Persons, NITAG members or secretariats, and HepB researchers and technical assistance providers working in target countries that have not introduced the HepB-BD—as well as select countries that have already introduced the birth dose. CDC, WHO, and CGHE provided an update on the latest evidence for introduction of the timely HepB-BD, the status of birth dose programs globally and regionally, and current priorities for research and technical assistance. Research and technical partners also provided updates on current and upcoming projects related to the HepB-BD with Ministry of Health, research, and technical assistance partners.

**Key takeaways:**
- Evidence on disease burden data and on the efficacy of the HepB-BD is critically needed to support and persuade countries to make the birth dose a universal priority.
- The benefits of birth dose vaccination are real. Imperial College modeling data from 2015 shows that HepB-BD scale-up can have the single largest incremental impact on new chronic infections.
- While the birth dose remains foundational to HepB elimination, other strategies exist and can and should be brought to bear—testing, anti-viral prophylaxis—as part of a comprehensive strategy to eliminate mother-to-child transmission of HepB. There is a divergence between partners in the region who see the birth dose as the cornerstone of elimination and those who emphasize that the birth dose alone cannot eliminate the disease or prevent all mother-to-child transmission.
- The protective benefits of the birth dose depend both on the timeliness with which it is administered and on the infection status of the mother. Reported data shows that while the transmission risk from HBeAg+ mothers to children is 32% in sub-Saharan Africa with timely HepB-BD alone, that risk drops to 0% with timely HepB-BD where the mother is HBsAg+ but HBeAg negative.
- There is no “one size fits all” approach to birth dose introduction and scale-up in Africa. Cultural, political, anthropological, geographic, and economic factors must all be taken into consideration when framing national strategies.

**Persistent challenges to birth dose introduction and scale-up:**
- Lack of funding for vaccine introduction
- Missed opportunities for timely vaccination
- Lack of political/country buy-in and lack of national policies for the birth dose
- Stigmatization of those diagnosed with HepB
- Need for increased national immunization technical advisory group guidance in countries
- Delays and restrictions caused by COVID-19
Common operational challenges to timely HepB-BD delivery:

- Vaccine storage / cold chain limitations, especially in rural areas
- Out of facility/home births complicate introduction and rollout. Countries also lack sufficient outreach vaccination services for home births. Ensuring adherence to follow-up is also difficult.
- Inadequate coordination between maternal/newborn/child health services (MNCH) and EPI services can lead to slow timing, inadequate documentation of vaccinations, and other missed opportunities.
- Training gaps among health care workers
- Current cost of one dose of the vaccine falls below the threshold price (20 cents/dose) that Gavi asks countries to cover on their own; Gavi funding can only go to operational aspects of the BD introduction and rollout. Because of COVID-19 delays, Gavi funding for BD introduction is not yet available.
- Insufficient education and awareness among pregnant women and their families about the risk of perinatal HepB transmission
- Inadequate data systems to monitor and evaluate programs and to follow up with infants/mothers
- Differences between data reported by WHO and “real-life” data being gathered on the ground, owing in part to variations in counting “timely birth dose” (within 24 hours) versus simply “birth dose”
- Cultural practices regarding newborn vaccination and access to the newborn after delivery
- “The devil is in the details”: every country needs its own specific strategic framework that will vary depending on the situation on the ground.

Looking ahead / Next steps:

- Continue building a community of practice to support timely birth dose introduction (including advocacy and technical working groups).
- Carry out studies to generate evidence to support birth dose introduction: integrate HepB studies/serosurveys with existing country surveys, including multiple indicator cluster surveys (MICS), demographic and health surveys (DHS), and HIV impact assessments.
- Engage and continue working with existing and potential funders, including Gavi, for birth dose introduction support, currently on hold because of the COVID-19 pandemic. Advocate for stakeholder support to accelerate progress and increase country demand for donor support. Focus on political commitments, the role of NITAGs, and non-profit partnerships, as well as engagement with communities and civil society.
- For countries, continue to educate families and community members about the burden and risks of HepB and the importance of the timely birth dose, including pediatricians and healthcare professionals.
- For US CDC, support WHO/AFRO in establishing a regional verification mechanism for HepB control and elimination, including evaluating the use of HepB-BD outside the cold chain and assessing the impact of the birth dose in countries with good coverage (Namibia, Senegal).
Infant immunization is the foundation of hepatitis B prevention. Three doses of the HepB vaccine provide 95% efficacy at preventing chronic infection, and just one dose of the timely birth dose vaccine is 72% effective. The birth dose is more than 90% effective if the mother tests negative for HBeAg.

Timely birth dose is key to prevention and elimination globally, and additional strategies can be incorporated to increase its effectiveness: (1) Screening mothers for HBsAg and administering HepB immune globulin (HBIG) to infants born to HBsAg+ mothers, along with the HepB birth dose. (2) Testing HBsAg+ mothers for high viral load and giving anti-viral prophylaxis as needed. (3) Integrating HepB into triple elimination efforts for eliminating HIV and syphilis.

A community of practice to advance progress toward HepB elimination in Africa will support information sharing, peer-to-peer collaboration, technical assistance, and capacity building.
Between 2000 and 2019, the number of countries that introduced the HepB BD vaccine rose from 50 to 111, reaching a global coverage of 43%, but the Africa region falls well below this percentage. There is a global disparity between birth dose coverage and the third dose of the HepB vaccine (HepB3) coverage in infants, with HepB3 coverage much higher, at 85%. This disparity needs to be addressed moving forward.

Measurable progress has been made through routine immunization delivery, but challenges remain:
(1) 70 countries globally still need to introduce the birth dose;
(2) the coverage goal for the birth dose is challenging (at or greater than 90% within 24 hours following birth);
(3) timeliness and reporting need greater support;
(4) a high proportion of births in the WHO/AFRO region are unattended by a skilled birth attendant: globally, about 80% of babies are delivered by a skilled birth attendant, but only 50% of births in the WHO/AFRO region.

COVID-19 disruptions will require catch-up campaigns for communicable diseases, including HepB. Global elimination goals for HepB will not be reached through perinatal prevention alone – high coverage of the primary 3 dose series is also needed.

**AFRO region 2020 targets for HepB elimination include the following:**
- At least 25 countries will introduce the HepB BD.
  - Current status: 14
- At least 50% coverage with the HepB BD.
  - Current status: 6%
- At least 90% coverage with 3 doses of HepB3:
  - Current status: 73%
- Less than 2% prevalence of HBsAg among children under 5:
  - Current status: 2.53%
This percentage is 2.7 times higher than the current global prevalence of 0.94%.
HepB3 coverage improved dramatically between 2000 and 2009, though numbers have remained stagnant for the last decade. All countries have introduced the HepB3 vaccine into their infant immunization schedule (at 6,10,14 weeks or 8,12,16 weeks). But timely birth dose coverage remains low (6%). To date, just 14 out of 47 countries in the region have introduced the HepB-BD into their infant immunization schedules.

**Next steps:** Building a community of practice to support birth dose introduction; increasing advocacy; supporting the generation of evidence through studies and serosurveys; enhancing NITAG’s capacity to recommend the birth dose; supporting such recommendation sessions; and encouraging Gavi support for birth dose introduction.

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**RESULTS FROM PRE-MEETING PARTNER SURVEY ON HEPB BD ACTIVITIES**

- **DR. HENRY NJUGUNA, COALITION FOR GLOBAL HEPATITIS ELIMINATION**

Survey objectives included:
(1) Identify partners working on HepB-BD projects in Africa;
(2) describe the activities partners are undertaking;
(3) understand partner challenges and opportunities for birth dose implementation.

Fifteen partner organizations were represented in the survey. Activities included birth dose introduction planning as well as partnering with government officials and clinicians.
Partners identified key challenges to improving timely birth dose coverage:
(1) policy and planning – in particular, financing needs and lack of evidence needed to support HepB-BD introduction;
(2) programmatic needs, such as improving collaboration between maternal and child health providers and EPI programs;
(3) community and cultural barriers, ranging from the complexities posed by home births to cultural practices regarding newborn vaccination and access to the newborn;
(4) low literacy about HepB in some regions.

Partner suggestions for advancing progress included:
Sensitizing community members about the HepB-BD vaccine; addressing resistance to the HepB-BD vaccine among pediatricians and healthcare professionals who do not see it as important because the HepB vaccine is offered later to the infant as part of the 3-dose series; the need to increase country demand for Gavi and other donor support; and the importance of developing stronger collaborations with stakeholders.

Update on HepB birth dose activities from the US CDC
- DR. RANIA TOHME, US CDC/GID

The Global Immunization Division (GID) of the US CDC conducts activities to:
(1) provide evidence of disease burden to support introduction of birth dose vaccine
(2) improve coverage with timely HepB-BD through the provision of tools, assessments and other supports
(3) support HepB-BD introduction
(4) support global innovation and research

Recent disease burden surveys include Sierra Leone, which offers the pentavalent (5 in 1) vaccine but does not have the birth dose, with preliminary results showing a HepB prevalence of 1.3% in infants between 4 and 30 months of age. Over 80% of these infected infants had already received the pentavalent vaccine. The HBsAg prevalence was eight times higher in children born to HBsAg+ mothers than those born to HBsAg- mothers (5.9% vs 0.7%). A separate survey in Nigeria revealed a prevalence of 4.4% in children under age 5—a high rate in a country that has both the birth dose and the HepB3 vaccines. Coverage of the birth dose is quite low in Nigeria, less than 30%, and the HepB3-dose coverage is less than 70%.
GID also works to improve coverage with timely HepB-BD through the provision of post-introduction assessment tools and by conducting assessments (supporting work in Botswana, Namibia, Nigeria, Mauritania, Sao Tome and Principe [STP], and Senegal). Activities include a recent assessment of the cost-effectiveness of universal versus selective HepB-BD in STP: here CDC provided evidence that selective vaccination is not cost-effective and therefore a universal birth dose is recommended. An assessment in Nigeria looked at the utility of an interventions package with specific intervention components for the region, including training staff, educating pregnant women, training community health workers and volunteers, and engaging civil society.

**Additional GID activities to support birth dose introduction include:**
(a) supporting Uganda and Tanzania with generating evidence needed by NITAGs for birth dose recommendation; (b) supporting the platform for birth dose introduction in the DRC in collaboration with WHO/AFRO; and (c) supporting a HepB-BD pilot introduction in Ethiopia to help inform national scale-up efforts.

Institute Pasteur reported on the results of the NéoVac study, launched in 2015 to evaluate the feasibility and impact of the birth dose vaccine using a multidisciplinary approach in Senegal, Burkina Faso, and Madagascar. All 3 countries had a high prevalence of HBsAg (6.9 – 11.6%), and all 3 had introduced the HepB3 dose in prior years but not the birth dose.

**Study findings include the following:**
- Need to understand and respond to cultural factors that are a barrier to accessing health facilities for antenatal care and birth.
- Distance to health facilities and other accessibility issues needed to be addressed, including cold-chain requirements and vaccine availability for weekend births.
- Work is needed to determine the effectiveness of outreach home-visit strategies. In Madagascar, 62% of infants are born at home, but primary care workers are in short supply, so asking midwives to leave the facilities for home visits could be difficult. In Burkina Faso, only 12% of infants are born at home, but since the government is promoting institutional delivery, advocating for home visits could send mixed signals.
- Barriers exist to the timely administration of the birth dose both for home births and for facility births, and there is considerable variation in needs and strategies among French-speaking African countries. Even within a single country, one size does not fit all.
UPDATING ON HEPB BIRTH DOSE ACTIVITIES

- DR. PEYTON THOMPSON, UNIVERSITY OF NORTH CAROLINA
- DR. MARCEL YOTEBIENG, ALBERT EINSTEIN COLLEGE OF MEDICINE

UNC team members have been working in the Democratic Republic of Congo (DRC) since 2001, helping the government launch and advance health programs. The prevalence of HepB in children in the DRC remains high at 2.2%, even with pentavalent vaccine coverage at 61%. Health facility births are also high, with 85% of women delivering in health facilities. But challenges remain, including the timeliness of vaccinations: some facilities have refrigerators that are locked over weekend, for example, and children born on Friday have to wait until Monday to be vaccinated.

Arresting Vertical Transmission of HBV in the DRC (AVERT-HBV) is a pilot project that uses a combination of anti-viral prophylaxis and HepB-BD administration and includes (among several goals) the aim of providing a birth dose vaccine for all exposed infants. The study was integrated within existing HIV prevention infrastructures and was held at two high-volume maternity centers in Kinshasha. Results revealed an overall seropositivity rate of 2.7% among pregnant women, with 11% of these women at high risk of transmission (HBeAg+ or high viral load confirmed). Of 88 infants born during the study, 68% received a birth dose vaccine, and 77% of those doses were timely.

Seventy-three percent of infants born at one of the 2 study facilities received the timely HepB-BD, and there were no cases of vertical transmission among those who completed the study. Study authors conclude that a universal birth dose vaccine is possible in Kinshasha if the birth dose is made readily available at all facilities.

UPDATE FROM AFRICA CDC

- DR. NAFIISAH CHOTUN

Africa CDC is working to address the lack of evidence currently available to support the birth dose introduction. To this end, Africa CDC is planning two central actions: 1.) Conduct a serosurvey on the prevalence of HepB in 5 member states. This will provide baseline data on HepB in infants and mothers. 2.) Establish a viral hepatitis sentinel surveillance system in 5 member states to monitor and evaluate the HepB vaccination program and provide evidence of disease burden reduction after introduction of the birth dose.
Additional planned activities supporting the HepB-BD introduction include:
(a) Situational assessment and analysis – to improve accessibility within country plans and to assess which countries are ready to introduce the birth dose, (b) Creation of a ‘Continental action plan for elimination of hepatitis’ and technical guidelines for introducing the birth dose, (c) Capacity building to support in-country surveillance activities.

Potential future activities include genetic studies (genotyping and viral variants) and a community healthcare worker program. The latter will explore how to use community healthcare workers to raise awareness of the HepB-BD in local communities and among pregnant women.

GLOBAL AND NATIONAL MODELING TO INFORM HEPB BIRTH DOSE IMPLEMENTATION - DR. SHEVANTHI NAVAGAM, IMPERIAL COLLEGE

Imperial College modeling data shows that birth dose scale-up has the largest incremental impact on new chronic infections when compared to any other single measure. Researchers have developed country-specific models for 110 low- and middle-income countries (LMIC), calibrating country-level data to include the latest coverage of interventions and evaluating the impact of scaling timely BD vaccination to 90% starting in 2019.

The model for this projected 90% scale-up shows that globally, 770,000 deaths could be prevented with the birth dose, with 70% of these averted deaths located in the WHO AFRO region. Twenty-six percent of the global averted deaths would be in Nigeria alone. Worldwide, this 90% scale-up would lower the prevalence rate among children under 5 years nearly to 0.1%, though not by 2030 (note that this model does not include high income countries, which could improve the overall average). In Africa, at the current status quo, a 0.1% HepB prevalence in children under 5 would not be reached before 2100. By scaling up the birth dose to 90%, however, this same 0.1% prevalence could be reached just before 2060.

Scaling up the timely birth dose to 90% would have a large impact, with the greatest benefits seen in the WHO AFRO region. But the birth dose alone is not sufficient to meet WHO targets for 2030. COVID-19 disruptions could lead to a substantial number of avertable HepB infections and deaths. And while applied modeling can guide planning and inform implementation of vaccination strategies, systems need more nationally representative data – the more granular the data, the more robust the projections.
Gavi's vaccine investment strategy (VIS) assists countries with vaccine introduction and scale-up, with a focus on operations and boosting the health system and its human resources. The birth dose is one of Gavi’s newer approved vaccines, with the Gavi board voting to approve support for it in 2018, even though the birth dose poses unique challenges with co-financing and timepoint.

Because the current vaccine cost per dose does not exceed the minimum threshold payment Gavi asks countries to provide (20 cents per dose), Gavi has opted to direct financial support instead to strengthening the immunization time point, with support for broader integrated service delivery platforms. COVID-19 has had an impact on support for vaccine introductions. Gavi had planned to introduce 68 new or underutilized vaccines in 2020, but 43 of these have been delayed or have not taken place because of the pandemic. In June 2020, the board decided to pause the rollout of vaccines approved through the VIS, including delaying support for the HepB-BD. The board will reassess after the acute phase of COVID-19 has passed. Gavi leaders will meet with the board in June 2021 for an update.

The PROLIFICA program, implemented in The Gambia in 2011, is a population- and hospital-based screen-and-treat intervention for hepatitis B. Real-life results from the program indicate that only 1.1% of infants received the birth dose within 24 hours after birth, and only 5.7% of infants were vaccinated by day 7. These data differ from WHO data, which reports higher coverage. Factors associated with low birth dose coverage include low maternal education level, rural settings, and long distances from maternity centers.

The INFANT-B study, an antenatal screening intervention recently launched in The Gambia, aims to assess the HBsAg prevalence in pregnant women, collect data on mother-to-child transmission rates, and gather more information about birth dose knowledge and awareness among pregnant women. It also aims to explore the use of UnijectTM, a pre-filled, non-reusable injection device stored at room temperatures for up to one month that can be used to give the first dose of HB vaccine to newborns.

Preliminary data from INFANT-B shows that HBsAg prevalence among pregnant women in The Gambia is 6%. The majority of the women in the study did not know (>85%) that their babies should be vaccinated at birth against HepB, but 78% of these women indicated willingness to vaccinate their babies themselves using the UnijectTM system. These data need to be confirmed on a larger scale, especially in rural areas.
The Clinton Health Access Initiative (CHAI) accelerates viral hepatitis program scale-up in low-to middle-income countries through market shaping and program strengthening activities. Partner countries in Africa include Cameroon, Rwanda and Nigeria. CHAI has a growing focus on birth dose coverage and helps generate evidence on intervention efficacy.

Related activities include:

- Global support for resource mobilization, evidence generation, strategic planning, and program integration that incorporates the birth dose vaccine. CHAI provided key input on the birth dose in a case presentation to the Gavi steering committee in 2018.
- Evidence generation: with the University of Bristol, CHAI is developing a country-level model to help guide national planning for HepB programs. CHAI also supports partner countries in laying the groundwork for scaling up HepB programming and vaccine introduction strategies.
- Country-level support of HepB-BD introduction and uptake in Cameroon, Nigeria, and Rwanda. In Cameroon, CHAI supported an assessment of timeliness and coverage for the birth dose, data that subsequently informed a feasibility pilot to integrate the birth dose into the labor and delivery process. In Nigeria, CHAI facilitated an assessment to help the Nasarawa Viral Hepatitis Technical Working Group understand gaps and opportunities; CHAI also conducted a planning study to assess the timelines for the birth dose in Kano and Nasarawa. In Rwanda, CHAI will initiate support to the government for HBV elimination, including supporting a plan for introducing the birth dose.

Partners in Health has worked in Rwanda since 2005. The Rwandan Ministry of Health currently recommends the HepB-BD (single monovalent vaccination) administered to all babies within 24 hours of birth. Subsequent routine doses of HepB vaccine are co-administered with diphtheria, tetanus, whooping cough, and haemophilus influenza type B as part of the pentavalent vaccine, which is given to newborns at 6, 10, and 14 weeks.

Rwanda’s 2019 strategy to prevent mother-to-child transmission of HepB includes: (a) screening of all pregnant women; (b) following up with those who test positive and initiating treatment during pregnancy if needed;
(c) vaccinating all babies within 24 hours after birth to prevent mother-to-child transmission and early childhood infection before week 6, when infants begin receiving the pentavalent vaccine. PIH supports the government in screening for HepB (and HepC) in three districts, providing linkage to care and administering HBIG to infants born to mothers who have chronic HepB.

Current barriers to success include supply issues: the HepB vaccine is currently out of stock in the national supply chain. In addition, HBIG is expensive (approximately $80USD) and not available in the national supply chain. Linkage to care also poses a challenge and remains an ongoing issue, as does the need for different implementation approaches to HepB and HepC screening and treatment countrywide, with HepC dominant in older people, and HepB more likely to appear in younger populations.

UPDATE ON HEP BIRTH DOSE ADVOCACY ACTIVITIES FROM THE WORLD HEPATITIS ALLIANCE - DR. DANJUMA ADDA, WORLD HEPATITIS ALLIANCE

The World Hepatitis Alliance (WHA) has over 300 members, with 70 members from Africa. WHA engages in advocacy for the prevention of mother-to-child HepB transmission and sees this work as encompassing maternal health, women’s health, and children’s health. WHA gathers political and public support for action, encouraging testing of pregnant women, supporting the linkage of care for expectant mothers, and advocating for the birth dose. WHA recognizes that preventive interventions are not accessible to everyone, and the specific challenges faced by individual women and local communities vary by region. WHA seeks to combat stigma, encourage public awareness, and break down the barriers to care that women experience.

For the birth dose, WHA advocacy efforts currently include:
(1) attracting international donors;
(2) partnering with the organization of African First Ladies to drive awareness and change;
(3) engaging local communities. Civil society and individual communities are the heart of the solution to HepB. In Nigeria, for example, community-based groups are driving advocacy and demand for vaccination. Many of the barriers that pregnant women face in Africa can and should be addressed at the community level.
Dr. Njuguna presented early results from the EPI manager pre-meeting survey. Eleven countries responded to the survey invitation; of those, 4 have a birth dose policy in place: Burkino Faso (for HBsAg+ women), Mozambique (universal), Namibia (universal), and South Africa (universal).

Seven of the 11 countries plan to introduce the HepB-BD, but only three will introduce it in their comprehensive multi-year plans (cMYP). Nine countries have NITAGs in place (Chad and Namibia do not), and among these, five have discussed the birth dose introduction. Three of those five countries have implemented the birth dose. Five countries plan to or have conducted sero-surveillance among children; eight countries are aware of WHO elimination targets, and three are working with technical assistance partners.

Challenges to birth dose introduction and implementation include:
Financing/funds for vaccine introduction and a lack of comprehensive national policies. Programmatic challenges include the need for better data systems to monitor and evaluate programs. Cultural challenges include the complexities posed by home births and local practices regarding newborn vaccination and access to the newborn. COVID-19 is also posing resource and mobilization challenges.

### Hepatitis B Birth Dose Challenges

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<td><strong>Policy/Planning Challenges</strong></td>
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<tr>
<td>Financing/ funds for vaccine introduction</td>
<td>7 (64)</td>
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<tr>
<td>Lack of national policies</td>
<td>4 (36)</td>
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<tr>
<td>Lack of evidence needed to support the introduction</td>
<td>2 (18)</td>
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<td>Lack of EPI assistance to guide implementation</td>
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<tr>
<td><strong>Programmatic Challenges</strong></td>
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<tr>
<td>Data systems to monitor and evaluate programs</td>
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<td>EPI program collaborating with maternal child health providers (i.e., training clinicians)</td>
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<tr>
<td>Cold chain capacity</td>
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<td><strong>Community/Cultural Challenges</strong></td>
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<tr>
<td>Home births</td>
<td>7 (64)</td>
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<tr>
<td>Cultural practices regarding newborn vaccination/access to the newborn</td>
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<tr>
<td><strong>Other challenges</strong></td>
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<td>COVID-19</td>
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<td>Limited HR capacity</td>
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<td>Lack of support by immunization technical advisory groups</td>
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<td>Vaccine not available</td>
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Source: Slide #11 from Njuguna's presentation
DISCUSSION

- Timing of the HepB-BD: timely birth dose is different than just the birth dose. How long can one wait and still have effectiveness from the vaccine? Within minutes of delivery is more effective than within 24 hours, but there is still some effectiveness within 72 hours.

- What prevalence of pregnant women are HBeAg+ or have high viral loads, and what is the reliability of e-antigen positivity for identifying women that have high viral loads? Is e-antigen positive status less common in Africa than in Asia because of genotypical differences? The answer to this question could affect vaccine effectiveness. The birth dose is less effective in HBeAg+ mothers than in HBeAg- mothers.

- What is the efficacy of the birth dose when compared to the HepB3 vaccine series that starts at 6-8 weeks? More data are needed. One study in Africa showed the risk of transmission was 58.8% for infants who received the HepB vaccine at 6-8 weeks born to HBeAg+ mothers and 37.5% for those who received the BD vaccine born to HBeAg+ mothers.

- Hospital births versus home delivery: do countries with the highest birth dose coverage have the highest percentage of women delivering in a birthing facility versus at home? Yes. The countries with higher percentages of birth dose coverage do have more facility births. But in some countries where home births are predominant, new mothers are still coming into health facilities for post-natal care within 72 hours. Example: Senegal, which has high coverage of the birth dose.

- How long does protection last after vaccination? It is estimated that protection lasts at least 30 years.

- What screening capacities are available through HIV or TB programs? What are the issues in getting access to that technology, what are the costs for test kits, and what are the opportunities coming from COVID-19 where there’s been a large scale up of PCR testing? Integration with HIV platforms is one option, but cost is an issue. Scale up will be needed to increase volume and lower cost. Another major issue is that some women drop out when their results take too long to come back.

- Summary of other Q&A is available in the appendices
This meeting will highlight countries in AFRO to discuss ongoing work in country programs and identify the TA, research, and information/resources needed to help countries introduce a birth dose of HepB vaccine and related HBV prevention strategies. The webinar will explore the utility of a Project ECHO (Extension for Community Healthcare Outcomes) for EPI managers introducing and seeking to scale up HepB birth dose vaccination and related strategies.

This meeting will highlight evidence and information that NITAGs need to develop appropriate recommendations for HepB birth dose introduction. NITAG or EPI representatives from countries in AFRO that have implemented a birth dose of HepB vaccine will present how they made their recommendations (i.e.- the Gambia, Senegal or Botswana). A toolkit or resource packet will be developed in advance and will be presented during this webinar.

Meeting 4: Next steps (Mid-July)
- This meeting wraps up the series and finalizes plans for additional technical assistance, including support to countries in writing Gavi applications to support HepB birth dose introduction. These follow-up plans may include a Project ECHO for EPI managers introducing and scaling up HepB birth dose vaccination and related strategies. The agenda will be flexible and will be developed as the webinar series progresses.

Each webinar will have a rapporteur and meeting report. Simultaneous French translation will be provided.

### UPCOMING MEETINGS

**Meeting 2: Sharing country experiences (May 5th, 2021)**
- This meeting will highlight countries in AFRO to discuss ongoing work in country programs and identify the TA, research, and information/resources needed to help countries introduce a birth dose of HepB vaccine and related HBV prevention strategies. The webinar will explore the utility of a Project ECHO (Extension for Community Healthcare Outcomes) for EPI managers introducing and seeking to scale up HepB birth dose vaccination and related strategies.

**Meeting 3: Training for NITAGs to make a recommendation on HepB birth dose (June 17th)**
- This meeting will highlight evidence and information that NITAGs need to develop appropriate recommendations for HepB birth dose introduction. NITAG or EPI representatives from countries in AFRO that have implemented a birth dose of HepB vaccine will present how they made their recommendations (i.e.- the Gambia, Senegal or Botswana). A toolkit or resource packet will be developed in advance and will be presented during this webinar.

**Meeting 4: Next steps (Mid-July)**
- This meeting wraps up the series and finalizes plans for additional technical assistance, including support to countries in writing Gavi applications to support HepB birth dose introduction. These follow-up plans may include a Project ECHO for EPI managers introducing and scaling up HepB birth dose vaccination and related strategies. The agenda will be flexible and will be developed as the webinar series progresses.

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