Improving timeliness of birth dose vaccines in 15 health Facilities in Cameroon through integrating immunizations into maternity and newborn care services:
A Feasibility Assessment

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List of Abbreviations

BCG	Bacillus Calmette–Guérin vaccine
BD	Birth Dose
bOPV	Bivalent Oral Polio Vaccine
CCE	Cold Chain Equipment
CHAI	Clinton Health Access Initiative
cMYP	Comprehensive Multi-year Plan
CMA	Centre Médicalise d'Arrondissement
CNERSH	Comité National d'Éthique de la Recherche pour la Santé Humaine
COVID-19	Corona virus disease
CS	Centre de santé
DHIS	District Health Information Software
DN	Dose de naissance
EPI	Expanded Program on Immunization
HCW	Health Care workers
Hep B	Hepatitis B Virus
IRB	Institutional Review Board
NITAG	National Immunization Technical Advisory Group
OPV	Oral Polio Vaccine
PEV	Programme Elargie de vaccination
TB	Tuberculoses
VPO	Vaccin Polio orale

Executive Summary

In the Cameroon Expanded Program on Immunization (EPI), the birth dose vaccine for oral polio vaccine (OPV-0) and tuberculosis vaccine (BCG), are recommended with a third birth dose vaccine for hepatitis B (HepB-BD) being considered for introduction.

Although Cameroon introduced the HepB antigen as part of the Pentavalent vaccine into the immunization program in 2005, infants are currently unprotected until the first Penta shot at six weeks. Introduction of HepB-BD is a key priority for the Cameroon government through the National Cancer Strategy document as well as the Hepatitis Prevention and Treatment Guidelines. However, the timeliness of administration of Hepatitis B vaccine within 24 hours of birth is critical to ensure the highest efficacy and prevent transmission of the virus.

While coverage rates for BCG and OPV 0 are relatively high (91% and 78% respectively), these vaccines are often administered weeks or months after birth[1], not within the 24-hour timeframe recommended for Hepatitis B birth dose. Therefore, there are concerns from the Cameroon National Immunization Technical Advisory Group (NITAG) and other stakeholders on the feasibility of achieving high timely coverage of HepB-BD. The timeliness of administration of the birth dose vaccines within facilities relies on many system components including integrated processes between maternity and immunization units and healthcare worker awareness of birth dose administration guidelines.

The main aim of this pilot study is to assess the feasibility of immunizing newborns with BCG and OPV0 (and eventually HepB-BD) within 24 hours of birth by integrating routine immunization into maternity and immediate newborn care in 15 facilities in Cameroon.

Further, the specific objectives of this pilot study are to:

1. Integrate birth dose immunizations into maternity and immediate newborn care services
2. Measure the change in proportion of newborn receiving birth doses BCG and OPV0 within 24 hours compared to baseline data
3. Measure the change in average age of babies receiving birth doses of BCG and OPV0
4. Assess the operational feasibility and acceptability of interventions and describe any factors (barriers and enablers) that may influence further implementation of birth dose strategies

This feasibility assessment is to provide quantitative findings of an intervention integrating immunizations into maternity and newborn care across 15 health facilities in Cameroon. Overall, in 20 weeks an intervention phase will be followed by a final assessment. The approach will utilize quantitative data from healthcare worker surveys, the birth registry and immunization registry, and maternity unit reporting forms. The study findings will be used to inform strategy on HepB-BD introduction in Cameroon as well as interventions to strengthen service delivery structures for newborns.

1 Chiabi et al, Vaccination of infants aged 0 to 11 months at the Yaounde Gynaeco-obstetric and pediatric hospital in Cameroon: how complete and how timely?, BMC Pediatrics, 2017

1 Introduction

1.1 Background

In the Cameroon routine immunization program, two vaccines are recommended for administration as soon as possible after birth (oral polio vaccine/OPV0 and tuberculosis vaccine/BCG) with a third birth dose vaccine (hepatitis B birth dose/HepB-BD) being considered for introduction. These recommendations for timely administration of the birth dose vaccines are in line with the position of the World Health Organization (WHO) on birth vaccines, as summarized below:

- **BCG:** in countries or settings with a high incidence of Tuberculosis (TB) and/or high leprosy burden, a single dose of BCG vaccine should be ***given to all healthy neonates at birth***. If the BCG vaccine cannot be given at birth, it should be given at the earliest opportunity before exposure to infection[2].

- **OPV0:** in polio-endemic countries and in countries at high risk for importation and subsequent spread of poliovirus, WHO recommends a bOPV birth dose also called 'zero dose' followed by a primary series of three bOPV doses and at least one IPV dose. ***The bOPV zero dose of bOPV should be administered at birth, or as soon as possible after birth***, to maximize seroconversion rates following subsequent doses and to induce mucosal protection before enteric pathogens may interfere with the immune response.[3]

- **HepB birth dose (HepB-BD):** *All newborn (including low birth weight and premature newborn) should receive their first dose of Hepatitis B vaccine as soon as possible after birth, ideally within 24 hours to be effective against vertical transmission*. The timeliness of HepB-BD is important because the risk of developing chronic Hepatitis B virus (HBV) infection varies inversely with age: 80-90% of infants infected during their first year of life develop chronic infections, as opposed to 30-50% of children infected before the age of 6 years and 1-5% of adults[1].

Cameroon's HepB prevalence is estimated to be 11.9%, which is nearly double the African average prevalence (6.1%) and triple the global average prevalence (3.5%)[4]. Although Cameroon introduced the HepB antigen as part of the Pentavalent vaccine into the immunization program in 2005, infants are currently unprotected until the first Penta shot at six weeks. Furthermore, vertical transmission during this period tends to be particularly common in countries with high HBV prevalence[5]. The monovalent hepatitis B vaccine that can be given at birth is inexpensive, costing between $0.29 and $0.42 per dose, thus making it a small investment for a major step towards eliminating HBV completely. Further, as of 2021, Gavi will start funding HepB-BD.

[2] WHO position paper on BCG vaccines, February 2018

[3] WHO position paper on Polio vaccines, March 2016

[4] Global Hepatitis Report, 2017 & Bigna JJ, Amougou MA, Asangbeh SL, et al Seroprevalence of hepatitis B virus infection in Cameroon: a systematic review and meta-analysis BMJ Open 2017;7:e015298. doi: 10.1136/bmjopen-2016-015298

[5] Gentile I, Borgia G. Vertical transmission of hepatitis B virus: challenges and solutions. Int J Womens Health. 2014;6:605-611. Published 2014 Jun 10. doi:10.2147/IJWH.S51138

The Cameroon government previously expressed the desire to introduce HepB-BD and developed a draft HepB introduction plan in 2016 with budget provisions for two consecutive years. This Plan were suspended pending the decision from GAVI to fund HepB-BD introductions. However, this will be reviewed during the preparation of the National Immunization Strategy 2021-2025. Currently, HepB-BD is included as a key priority in the National Cancer Strategy document as well as the National Strategic Plan for the Control of Viral Hepatis.

Administrative and survey coverage data in Cameroon does not capture the timing of vaccination so coverage of birth dose vaccines within 24 hours is unknown. To better understand the current service delivery system and needs for birth vaccines in Cameroon, CHAI and EPI carried out a field study in 2019 with the objective to describe timeliness of current birth dose vaccines and the barriers and facilitating factors that influence timeliness and coverage. The study was approved by the Cameroon National Ethics Committee for Human Health Research (2019/03/4447/CE/CNERSH/SP).

This was a cross-sectional study of 30 selected sites with both an immunization and labor and delivery unit across three regions (Center, Far North, and West) within Cameroon, utilizing both qualitative and quantitative approaches. The findings from the study indicate that across the 30 sites, only 4% and 7% of newborn received BCG and OPV0, respectively, within 24 hours. The reported key barriers hindering timely birth dose administration included: (i)maternity units were not equipped functioning fridges, (ii) lack of awareness and insufficient demand by caregivers for birth dose vaccines (e.g. birth dose education at antenatal visits, (iii)vaccine hesitancy among caregivers mainly due to religious beliefs, myths and rumors. The key facilitators were (i) raising awareness among caregivers on the importance of birth dose vaccinations, (ii) improving access to functioning fridges in the maternity unit and (ii) addressing practices on multidose vial policies.

Attaining high timely coverage with birth dose vaccines is a common challenge among low- and middle-income countries. This challenge has been attributed to numerous barriers including, lack of integration into maternal and newborn health programs and protocols, lack of healthcare worker and caregiver knowledge, unavailability of cold chain storage, fear of vaccine wastage for multi-dose vials, high proportions of out of facility births, and difficulties of access and demand for target cohort.[6,7,8,9] These barriers echo those identified in 2019 in Cameroon Global best practices and lessons learned from other countries suggest that successful timely administration of the birth dose vaccines relies on many system components including integrated processes between maternity and immunization units, healthcare worker awareness of birth dose administration guidelines, and demand from mothers and community.

[6] WHO. Practices to improve coverage of the hepatitis B birth dose vaccine, January 2013.

[7] Miyahara, R., Jasseh, M., Gomez, P., Shimakawa, Y., Greenwood, B., Keita, K., Ceesay, S., D'Alessandro, U., & Roca, A. (2016). Barriers to timely administration of birth dose vaccines in The Gambia, West Africa. *Vaccine*, *34*(29), 3335–3341. https://doi.org/10.1016/j.vaccine.2016.05.017

[8] Gavi the Vaccine Alliance, Annex C: Hepatitis B Birth Dose Investment Case. October 2018.

[9] Country presentations at WHO AFRO regional workshop on Hepatitis B birth dose, June 2019.

1.2 Study Aim and Objectives

The main aim of the pilot study aim is to assess the feasibility of immunizing newborns, within selected facilities, with BCG and OPV0 within 24 hours of birth by integrating routine immunization into maternity and early newborn care. In this study only the current birth vaccines (BCG and OPV) will be assessed. The findings will inform strategies for strengthening the birth platform as well as HepB-BD introduction which is envisaged in the cMYP (2016-2021).

Further, the specific objectives of this pilot study are to:

1. Integrate birth dose immunizations into facility-based maternity services
2. Measure the change in proportion of facility births receiving birth doses BCG and OPV0 within 24 hours
3. Measure the change in average age of all babies receiving birth doses of BCG and/or OPV0 at the facility
4. Assess the operational feasibility and acceptability of interventions and describe any factors (barriers and enablers) that may influence further implementation of birth dose strategies

1.3 Justification for Pilot Study

Cameroon's national policy recommends that OPV0 and BCG be administered as soon as possible after birth. While coverage rates for BCG (84%) and OPV0 (79%)[10] are relatively high in Cameroon, it is estimated that these vaccines are often administered weeks or months after birth,[11] not within the timeframe recommended for their administration or that which will be needed for a successful HepB-BD program (<24 hours after birth).[12] Currently, most health facilities do not administer vaccines every day, but rather only on designated immunization days. With babies being born every day, this poses a challenge to reach newborns via the current immunization service delivery system. Based on the study conducted in 2019 that highlighted the barriers and facilitators of timely birth dose administration, the Ministry of Public Health with support of CHAI decided to pilot facility specific HepB BD integration programs. A component that arose from the 2019 study that was of key concern was the lack of communication and integration between the immunization and maternity wards. Thus, this pilot work proposes a facility-based approach to better integrate birth dose vaccination into the broader facility-based maternity and newborn care processes to ensure newborns born within facilities are vaccinated within the recommended timeframe. While the previous assessment and studies have identified many common barriers to timely birth dose administration, the purpose of this work is to focus on the feasibility of integrating the birth dose vaccine process into maternity practices.

[10] EPI administrative data 2018

[11] Chiabi A., Nguefack F., Njapndounke F., Kobela M, Kenfack K, Nguifack S., Mah E, Nguefac-Tsague G., Angwafo F., (2017). Vaccination of infants aged 0 to 11 months at the Yaounde Gynaeco-obstetric and pediatric hospital in Cameroon: how complete and how timely?. *BMC Pediatrics*. 2017. 17:206. DOI 10.1186/s12887-017-0954-1

[12] WHO (2015). A Guide for Introducing and Strengthening HepB-BD Vaccination. www.who.int/immunization/documents

2 Methodology

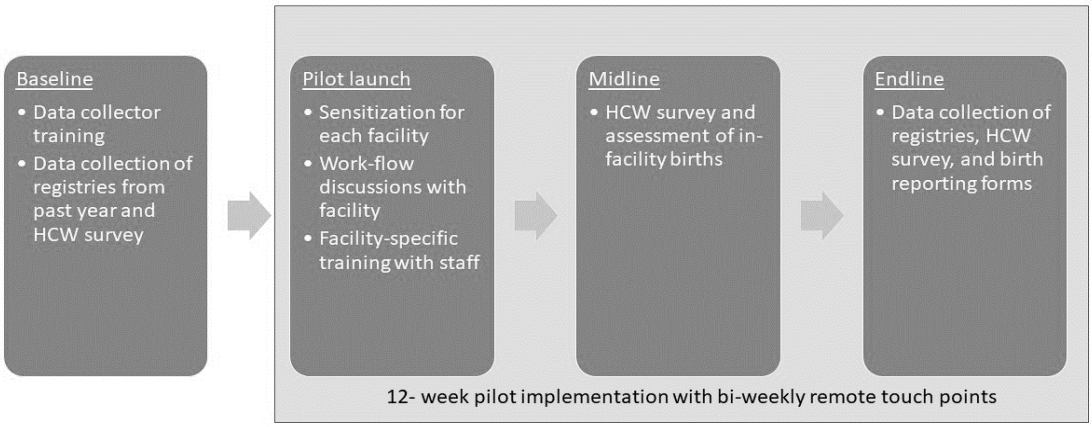
2.1 Study Design

This is a three-part intervention study; baseline, implementation and final assessment. The purpose of this feasibility assessment is to report on the quantitative findings of an intervention integrating immunizations into maternity and newborn care across 15 health facilities in Cameroon. The overall aim is to assess the feasibility of administering OPV0 and BCG birth doses within 24 hours of birth in Cameroon:

1) ***Baseline data collection*** *(4 weeks to complete)*
2) ***Intervention implementation*** including health care worker training, and ongoing monitoring of the project *(12 weeks to complete)*
3) ***Final assessment*** to gather an end line estimate of the outcomes *(4 weeks to complete)*

The figure below is a graphic representation of the study outline.

Figure 1: Outline of pilot study



This pilot study is expected to take 20 weeks (see appendix 5.1 for a detailed project timeline) not including initial preparations such as obtaining ethics approval and training of data collectors. There is a possibility for delays due to an increase in COVID-19 pandemic. The study team will ensure the proper conduct of the study while respecting strict barrier measures.

2.2 Study sites

Health facilities across Cameroon are classified under six categories namely: category one: General hospitals, category two: Central hospitals, category three: Regional hospitals, category four: district Hospital, category five: Medicalized Health centers and category six: Integrated Health centers. We purposefully selected 15 health facilities from these categories. These health facilities were also selected from three regions based on their dissimilar characteristics in geography, culture and immunization coverage. We also selected a mix of public and privately owned as well as semi-rural and urban health facilities. For the purpose of this study, we define semi-rural health facility as one serving a community that depends predominantly on agricultural activities for subsistence. For logistic reasons, more facilities were selected in the center region.
Study sites selected are as follows:

Table 1: List of study sites by region

Adamawa	Center	West
1. Hospital Protestant de Ngaoundéré 2. CMA de Mbe 3. CMA Dibi	4. Hôpital Nicolas Barre 5. HD Biyem Assi 6. HD Obala 7. Centre Medical Marie Reine Etoudi 8. HD Cite Verte 9. CS Catholique Nkoabang 10. CMA Ahala 11. CS Deo Gracia, Nkolbisson 12. CSI Urbain Mbalmayo 2	13. HD Mifi 14. HD Foumbot 15. CSI Catholique Baham

2.3 Study Period

The study is scheduled to take place for 20 weeks between January and April 2021.

2.4 Study Population

The study population will include:

- All babies received in the maternity unit, or EPI unit for OPV0 and/or BCG vaccines in the 15 study facilities, during the 1-year baseline period and the intervention period;
- HCW from the 15 facilities involved in either EPI or maternity and newborn care

2.5 Site selection criteria

The 15 health facilities will be selected based on the following inclusion and exclusion criteria while ensuring a mixture of semi-rural and urban, and large and small facilities, private and public facilities to observe feasibility and challenges across different levels of health care. Below are the proposed facilities purposefully selected through an iterative process with key stakeholders and EPI regional managers.

Table 2: Site selection criteria

Characteristics of health facilities selected	**Urban setting**	**Semi-rural district**
High volume (Above 100 average monthly deliveries)	• Hôpital Nicolas Barre • HD Biyem Assi • HD Mifi • Hospital Protestant de Ngaoundéré	• HD Obala
Medium volume (50 – 100 average monthly deliveries)	• Centre Medical Marie Reine Etoudi • HD Cite Verte	• CS Catholique Nkoabang • CMA de Mbe • HD Foumbot
Low volume (Below 50 average monthly deliveries)	• CMA Ahala • CSI Catholique Baham	• CMA Dibi • CS Deo Gracia, Nkolbisson • CSI Urbain Mbalmayo 2

Inclusion criteria:

- Facilities providing maternity and newborn services including immunization services
- Facilities with either functional cold chain equipment with reliable power sources on site OR those located within one km of the district or another facility with cold chain equipment on site for easy access

Exclusion criteria:

- Facilities participating in research or interventions that will impact the outcomes measured
- Facilities experiencing higher than normal demand of COVID-19 patients will be excluded to not overburden HCWs further and potentially impact ongoing services
- Health facilities that participated in the 2019 birth platform assessment

2.6 Facility sensitization and workflow creation and vaccine availability

Study staff will introduce the purpose of the study to the selected study sites and gain permission to conduct the study overall. Study staff will set up a time to meet with the facility to discuss the process of integration and discuss facility-specific situations. A workflow of facility-specific integration will be proposed and further refined during the intervention training.

Further, vaccines available to the EPI units will be used for this study. No vaccines or consumables will be procured separate from the usual channels. Currently, EPI has the following vaccines in stock at the central, regional, district and health facility stores.

Table 3: Details of vaccines (BCG and OPV) currently available at EPI

Vaccine	Manufacturer	Country
BCG	GreenSignal Biofarma Pvt Ltd	India
BCG	BB-NCIPD Ltd	Bulgaria
bVPO	Bharat Biotech	India
bVPO	GlaxoSmithKline	Belgium

2.7 Training Sessions

2.7.1 Intervention training

Training sessions will be held at each of the 15 facilities separately, with the same study members leading the sessions. Rather than a central training, we will conduct training at each facility, thus reducing mass gatherings during the COVID-19 pandemic. Please see the infection control section (Section 3.2) for COVID-19 related processes during training. At each individual training, all relevant and available health staff, including EPI focal points and maternity and newborn staff, will be asked to participate. In facilities where not all staff are able to attend training, we will ensure at least 1 staff member per shift is able to attend, to enable the information to be passed down to all staff members. During the touch points with the facility, staff will assess if the information was indeed passed down. The sessions will be split into two half day to prevent the facility from closing for a day and to allow for staff to be properly distanced. Moreover, training sessions will be held outside where possible. Ahead of training, a member of the study team will discuss potential training dates with the facility in-charge, ensuring dates occur when most convenient for the staff. The principal investigator will ensure that participants are comfortable throughout training and data collection. The training session will incorporate the below components.

Table 4: Summary of components included in training session

Training Component	Details
Maternity and newborn clinical protocols	Knowledge reinforcement for topics relating to birth dose immunizations including: • Immunization basics (Note: the HCW participating in the study are anticipated to be well-versed in this already, however we can leverage modules from Vaccination in Practice training to provide targeted refreshers based on the audience) • Birth dose vaccine information for OPV0 and BCG including safety information and contraindications

	• Immunization technique including vaccine handling and site of administration • Directly address hesitancy surrounding opening a multi-dose vaccine vial for only 1 baby by sharing PEV policy on opening vials for one child as well as training on practices to carry this out effectively (e.g. updating wastage rates in forecasts for ordering, calculating shelf life once opened, etc.) • Reinforce incorporating birth dose conversations into routine antenatal care visits and adding messaging into ANC talking points
Roles and responsibilities of different providers	Outline detailed roles and responsibility for each HCW involved in birth dose vaccinations. Develop and train on facility-specific work flows (see section 2.5 above) which will orient HCW to how the birth dose administration fits into maternal and newborn care in terms of sequencing of services, process for recording and reporting and collecting the vaccines (see below), and mitigation plans and reminders (e.g. to follow safe newborn checklist and best practices in terms of handling emergencies first, etc.)
Policy for birth dose administration	Provide information on updated policy for the birth dose vaccines to be administered in the maternity unit.
Cold chain storage planning	During the baseline assessment, study members will assess each maternity unit's 24/7 access to a working refrigerator for vaccine storage. Each facility will have a plan (as part of the integrated workflow) on how to access the vaccines immediately after a birth takes place and will be outlined. For facilities without cold chain equipment, a daily schedule (including weekends and holidays) will be implemented where a morning trip is made to the closest health facility or district health service with CCE to pick up vaccines and an evening trip is done to return unused vaccines to the same health facility.
Recording and reporting harmonization	To ensure birth doses vaccines are properly recorded in both facility records and for the purposes of this pilot study, two record changes will take place and will be described in detail. **Birth dose maternity reporting form** For the duration of the pilot study maternity units will be provided with a simple recording form with space to document each birth and information on birth doses given. Scenarios for accurately filling out the form will be discussed. **Updated birth registry**

	The birth registry will also be updated to include a column to check if the baby received the birth doses of BCG and OPV0 within 24 hours. At the end of each day, this paper will be brought to the EPI unit to incorporate into their record books. In addition, child health cards will need to be stored in maternity units so caregivers can acquire the book at the time of the birth dose administration, and the updated birth dose information is recorded on the health card.
Out of facility births	We will use this opportunity to brainstorm strategies to address birth dose timeliness among out of facility births for future studies.

Contingency plan:
In the event of worsening COVID-19 pandemic, the pilot study will be restricted to facilities that have already completed training sessions and the intervention for the remaining facilities will be on hold until it is safe to continue with the intended pilot study.

2.7.2 Data collectors training

Training for baseline will occur for this group approximately 1 week before data collection begins and will last for 3 days. The data collection training will cover the purpose of the study, methods in quantitative data collection, electronic data collection methods, ethics, and a thorough review of the data collection tools. The training will be didactic with role-playing scenarios and data collectors practicing the data collection tools on example registers. A refresher for end line data collection and any changes in language will be emphasized in a morning review before data collection. In addition to training required for this pilot study, training will also cover COVID-19 transmission information and the importance of avoiding touching one's face, shaking hands, and safe coughing and sneezing etiquette. For additional information on infection control, please see section 3.2. Guidelines for reporting all illnesses to study staff and refraining from working when sick will be outlined. The infection control plan for each data collection activity outlined in this protocol will also be discussed and hard copies shared with data collectors to ensure they are aware of expectations.

In the final day of training, the data collectors will pilot the data collection tools in 2 health facilities. Through the pilot, any changes or edits in data collection tools will be incorporated.

Contingency plan:
In the event of worsening COVID-19 pandemic that occurs before data collection training, the pilot study will be on hold until it is safe to continue.

2.8 Ongoing trouble-shooting touch points

To enable touch points to discuss problems during the 12-week intervention and foster a relationship between the study team and maternity staff, ongoing monitoring of the intervention will occur. Due to

COVID-19, this will be occurring remotely. Every two weeks the head of the delivery unit will take a photo of the birth dose maternity reporting forms and send it to the study team for review of progress. Once the photo is obtained a brief telephone conversation will occur to troubleshoot immediate challenges, check on the pilot study progress, and to further strengthen the relationship.

Contingency plan:
In the event of worsening COVID-19 pandemic and facilities see a large increase in case load, scheduling the phone meetings will be delayed until it is reasonable to continue.

2.9 Data Sources and Collection

2.9.1 Birth registry and immunization registry

To obtain accurate data on birth dose timeliness, the birth registry and immunization registry will be utilized (Section 5.4). At each birth maternity staff record birth details into a birth register which includes the newborn's first and last name, date of delivery, type of delivery, complications, sex, and date of discharge (however, it is common for not all sections to be fully completed). Each health facility also maintains an immunization registry containing information on each child and all vaccinations given at the facility with the corresponding date. The baseline and end line assessment of timeliness are each expected to last two weeks and will consist of data collectors visiting each facility and collecting information using electronic data collection and tablets. Two methods will be employed to capture different indicators around timing of administration for birth dose vaccines. Both will utilize registry extraction of the immunization register and birth register. Data collectors will ask permission before utilizing the registers and assure that the data collection will not disrupt ongoing facility activities.

Age of babies at time of receiving birth vaccines (BCG and OPV0) – Immunization registry extraction

<u>At baseline:</u>
Data extraction for children in the immunization register will occur by using a sampling interval to ensure children are sampled throughout the entire year. The sampling interval will be created by taking the total number of children entered into the immunization register for the previous 12 months and dividing by our required sample size (N = 30). For instance, if 90 children were entered into the register in the past 12 months, the sampling interval will be 3; if only 30 children were entered into the register in the past 12 months, the sampling interval will be 1. With the sampling interval, the data collector will count backwards from the most recent entry in the immunization register and begin gathering data. The data collector will record the name, date of birth, and record the date(s) of immunization for each of the birth vaccines in the immunization register. Using the name and date of birth, the data collector will then cross-check with the maternity registers to confirm that same child's date of birth. Records that are missing either a date of immunization or date of birth will be recorded to help determine how many children were potentially born out of the facility, or have incomplete records, but will not count towards the total desired sample size for timeliness coverage. Data collectors will continue working backwards through the registers entering data for every Xth child (according to the sampling interval) until they have successfully recorded the

date of immunization and date of birth for 30 children. If they reach the end of the year without entering complete data on 30 children, the data collector will be instructed to loop back through the year but start now on the second child registered when counting.

At end line:
The end line registry extraction will utilize the same sampling technique as baseline. The same sample size (N = 30) will be used with the sampling period being the duration of the study period.

Proportion of babies born in facilities receiving birth dose vaccines within 24 hours – Maternity registry extraction

At baseline:
The same sampling interval/methodology described above will be utilized again, only this time the data collectors will begin with the birth registers to determine their sampling interval. Then this interval will be used to pull names first from the birth register to select a sampling of babies that were born in that specific facility and then cross-checked with immunization dates for birth vaccines in the immunization registers. Records that are missing either a date of immunization or date of birth will be recorded to help determine how many children were not vaccinated at that facility or lack complete records. Data collectors will continue working backwards through the registers entering data for every Xth child (according to the sampling interval) until they have successfully recorded the date of birth and date(s) of immunization for 30 children.

At end line:
The end line registry extraction will utilize the same sampling technique as baseline. The same sample size (N = 30) will be used with the sampling period being the duration of the study period. As there will be children who may not receive their birth dose vaccines before the end line data collection, this indicator will focus on those children who did/did not receive the vaccine within 24 hours.

Contingency plan:
In the event of worsening COVID-19 transmission, facility staff will locate the relevant registry pages and will send photo records of the pages to study staff. Study staff will then continue with data extraction as outlined.

2.9.2 Birth dose reporting form

To obtain information on the specifics of the birth dose administration, the reporting forms created for this pilot study will be used (Section 5.4). After each birth, a member of the maternity unit staff will fill out the birth dose reporting form, in addition to normal recording procedures. As part of the ongoing supervisory check-in the reporting forms will be sent through email or WhatsApp to study members for brief review. While data collectors are at each facility for registry extraction at end line, they will collect the completed birth dose reporting forms.

Contingency plan:
As the hard copy forms will be gathered at the end line of the study, in the event of worsening COVID-19 transmission, data collectors will delay collecting the birth dose reporting forms until it is safe to do so.

2.9.3 HCW surveys

To obtain HCW knowledge on birth dose vaccines and corresponding policies, we will conduct HCW surveys (Section 5.4). During the baseline, midline, and end line assessment, HCW's from the 15 facilities will be asked to participate in a survey over the phone with the intention to include a minimum of 3 HCW's from each facility. The survey is expected to take 1 hour and will consist of closed and open-ended questions. The baseline survey will be updated with appropriate language and indicators for the midline and end line survey. Telephone surveys will be scheduled at a time most convenient for the HCW. During the baseline assessment and before any surveys are conducted, copies of the consent form will be left at each facility for survey participants to read through. Prior to beginning the survey, we will read through the consent form to obtain verbal consent. The data collection team will conduct the surveys and will input the participant's survey responses on electronic tablets with all data to be stored on an encrypted server and accessed only by study team members.

Contingency plan:
In the event of worsening COVID-19 transmission and HCW's see a substantial increase in workload with no available time to complete the survey during working hours, surveys outside of working hours will be arranged. If this is required HCW's will be compensated for personal cell phone minutes.

2.10 Study Outcomes

The primary outcome of this pilot study is change in proportion of newborns receiving birth doses of BCG and OPV0 within 24 hours. The key indicators from HCW surveys will be updated to include those from midline and end line surveys and will be sent for review prior to conducting those surveys.

Table 5. List of key indicators and sources

Key Indicator	Source (data collection tool)	Assessed at baseline	Assessed at midline	Assessed at end line
Average age of babies at time of receiving birth dose vaccines (BCG and OPV0)	Birth registry and immunization record	×		×
Proportion of babies born/received in facilities receiving birth dose vaccines (BCG and OPV0) within 24 hours		×		×
The reason why BCG and OPV0 birth dose vaccines were not administered within 24 hours	Birth dose reporting form		×	×
			×	×
			×	×
	HCW survey	×	×	×
Proportion of HCWs that know ideal timing for birth dose vaccines		×	×	×

		×	×	×
Reported concerns with administering birth dose vaccines within 24 hours		×	×	×
Reported barriers to administering birth dose vaccines within 24 hours		×	×	×
Reported barriers to educating caregivers on birth dose vaccines		×	×	×
Maternity unit's access to birth dose vaccines		×	×	×

2.11 Data Analysis

All outcomes will be descriptive in nature with the intent to assess preliminary impact and not statistically significant findings. For both measures of timing of birth dose vaccines, we will compare the facility-level value at baseline to end line of the intervention. Basic statistics (means and proportions) will be performed on the HCW surveys and the new birth dose reporting forms. Information and recommendations reported in open-ended questions from HCW surveys may inform final recommendations of the project but only at an aggregated level and would not be published, shared, or reported at the individual level.

To identify indications of COVID-19 impacting in-facility births, we will use the information contained in the DHIS2 over the last 2 years to compare historical yearly birth trends for the 15 included facilities, with the trends we observed during this pilot study. Due to the small sample size of health facilities and short nature of this study any potential findings of changes in time trends will be descriptive in nature. During check-ins with the facilities the team will also document other factors due to the pandemic that may impact the study such as stock outs or changes on guidance. As this data is not formally gathered, this will be documented and descriptive in nature. Please refer to study tool "Notes for touch point calls" in Section 5.4 that will gather informal information about the health facility-specific processes.

2.12 Data Quality Control Measures and Security

All surveys will be completed in an electronic format using a tablet with incorporated skip patterns to confirm the highest quality data. All data to be stored on a secure server and accessed only by the study team. To minimize data collection errors, daily supervision of data entry into the tablets will be reviewed.

2.13 Dissemination

Upon the completion of this study, the primary dissemination aim is to provide information that is valuable to the RDPH, EPI, NITAG, Department of Family Health -, and implementing partners for purposes of improving early coverage of birth dose vaccines and preparing for a potential HepB-BD introduction. The design of the evaluation, methods used to collect and analyze data, and results will be synthesized with input from the co-investigators into a technical report, which will be presented and shared with relevant stakeholders. With approval from MOPH, the key findings, lessons learned and recommendations resulting

from this feasibility assessment will also be shared more broadly with the global health community to inform the delivery of birth dose services in other countries.

2.14 Limitations

This pilot study will have several key limitations. The sample of the study will be small and purposeful in that it will only include 15 health facilities that meet a set of pre-defined criteria (see above). Therefore, this work will not be statistically precise nor be nationally representative and the participating sites will likely not experience certain challenges pertaining to birth vaccines that are undoubtedly experienced elsewhere in Cameroon as a whole (such as sites located in conflict zones, etc.). Instead, the purpose of the sample is to assess the feasibility of integration of birth dose vaccines BCG and OPV0 in maternity and newborn care services to gather lessons and formulate recommendations for the broader routine immunization and maternal and child health programs.

Data collected from registers to determine timing of vaccine administration results is a limitation in that it requires us to have both a date of birth and date of vaccination in facility registers. Therefore, babies who were born out of the facility (either at home or in a different facility) will not contribute to the aggregated figures, the same goes for babies who were born in the health facilities but receive vaccination elsewhere. Furthermore, we cannot guarantee the accuracy of the facility records. Key barriers and factors associated with the birth dose process will be descriptive in nature.

3 COVID-19 Impacts

3.1 Cameroon COVID-19 Situation

Given the changing COVID-19 situation, we will do our utmost to guarantee the safety of participating staff, implementation facilities, and communities. Prior to launching the pilot study, the in-charge of each selected facility will be briefed on the purpose of the pilot study as well as the risks and benefits of participating during the COVID-19 pandemic. The in-charge will grant permission for the pilot study to occur, or request that the facility be excluded due to the burden of COVID-19 pandemic and limited HCW staff. Such decisions to exclude facilities will also occur along with key government officials. In addition, prior to travelling for community visits, study staff will contact community leaders and key community contacts through telephone calls, where possible, to discuss the pilot study and assess the communities' willingness to have non-community members come to conduct a visit. Any formal requests for information or permission will be respected and followed.

Throughout this proposal we have outlined contingency plans for each intervention activity and data collection procedure. We will conduct weekly reviews and work from a decision framework that reviews multiple sources. The decision framework includes:

- **Review government recommendations and restrictions:** If the government has institutionalized closures or the National Ethics Committee recommends research to be suspended, we will not proceed. Instead, we will continue remote data collection where possible, but hold off on further implementation.
- **Review of Imperial model estimation of R_t:** The model currently estimates for 6-week forecasts. We will review the current transmission rate from this model listed in the weekly Imperial situation reports. If the rate reaches above 1, we will consider suspending the pilot study implementation. For comparison, we will also compare the Cameroon R_t to other African countries. If we decide to suspend activities, we may continue remote data collection where possible, but hold off on further implementation.
- **Review of the Imperial model and IHME projections**: In addition to the estimated transmission rate, we will pull the projections for future transmission from the Imperial model as well as IHME. Both models build projections under varying scenarios (e.g. reducing transmission by requiring masks) and will help us examine potential risks in the future. If there is a projected spike in virus transmission, we may decide to suspend activities until after the transmission spike.
- **While reviewing the data we will take into consideration the burden on HCWs and we will consider not conducting surveys during any spikes in COVID-19 transmission.**
- **It is important to note that the proposed contingency framework will be relying on model projections and country-reported data. All discussions and decisions will recognize the challenge of modeling for an entire country (i.e. lack of sub-national projections), COVID-19 testing, and data reporting systems.**

3.2 Infection Control Procedures

For each activity, we will implement WHO guidelines on prevention and control of infection as follows:

- Training sessions will be held outdoors whenever possible
- All participants in the training sessions will be required to wear masks and observe social distancing measures (2 meters). Masks will be provided for all study personnel and gloves for trainers to pass out tablets
- Study staff and data collectors will not attend training if they have or are presenting with flu-like symptoms. Study staff and data collectors will be screened ahead of training. We will only invite those who have not experienced COVID-19 symptoms and we will ask for them to not attend training or data collection if they do experience symptoms
- alcohol-based hand sanitizer and disinfectant will be provided to study team and health facility staff. In addition, soap and water or alcohol-based hand sanitizer will be easily accessible at study sites
- All training session attendants will be required to wash their hands with soap and water or alcohol-based hand sanitizer at the beginning of each day, at regular intervals throughout the day. Handwashing will also be required before and after any refreshments.
- Sufficient training materials and office supplies will be provided to prevent sharing among training participants
- All surfaces will be disinfected before and after each day's training or data collection
- Tablets will be disinfected before and after each use

- Data collectors will visit the site at the quietest time of day to minimize contact with facility staff and community members
- Data collectors will be required to wear masks and social distancing of 2 meters will be required when in the facility. If the facility itself does not allow for social distancing, the training and registry data extraction will occur outside where it will be possible.
- In training recommendations, we will let folks know not to come if they have symptoms. We will only invite those without symptoms and confirm they only attend if they don't have symptoms. Study staff will ask participants to opt-out if they develop symptoms. Data collectors will be sent home if they present with flu-like symptoms
- Prior to entering the facility, at regular intervals throughout, and at the days end, data collectors will be required to wash their hands with alcohol-based hand sanitizer
- For data collector's relying on public transportation to the participating facilities, alternative options will be discussed to minimize risk

4 Ethical Considerations

4.1 Informed Consent and Confidentiality

In accordance with Ethics Guidelines for Health Research Involving Human Participants in Cameroon and CHAI's Human Research Guidelines, we are seeking approval from CHAI's internal Scientific and Ethics Review Committee (SERC) and the National Ethics committee in Cameroon.

All HCW's who participate in the HCW surveys will provide informed consent. All study staff, including data collectors, will undergo ethical training sessions. In order to ensure confidentiality, all data collectors will sign a confidentiality agreement. Their activities and data safety measures will be supervised in the field by study managers.

4.2 Potential Risks for Participants

As the purpose of this work is to assess the integration of birth dose vaccination into the maternity process, there is no specific physical or psychological harm for participants. Personal information such as name will not be gathered in surveys; there is minimal risk to participants' data being identified. Child-level data from birth registries may have names of the children included but the names will be removed from the database, thus all datasets will be de-identified. The data will be kept on a secure server and only accessed by study staff using password encrypted computers.

4.3 Benefits for Participants

As the pilot include capacity building for service integration, HCW's will benefit from training and supportive supervision. Newborns born in participating health facilities during the study will benefit from immunization and protection from potential infections. In addition, the data and report will potentially benefit the

population health of Cameroon as the findings will contribute towards strengthening the service delivery of birth vaccines.

5 Study Tools

5.1 Information Notice

Participant Information Notice for Baseline

Study Title: *« Improving timeliness of birth dose vaccines in 15 health facilities in Cameroon through integrating immunizations into maternity and newborn care services: A Feasibility Assessment»***.**

Principal investigator:

Name	Ankouane Andoulo Firmin
Institution	Faculty of Medicine and Bio-Medical Sciences, University of Yaoundé I
Address	Yaoundé, Tel : 677 56 40 70
Email	Ankouane andoulo@yahoo.com

Invitation of participant in the study:

Dear participants, we solicited your participation in this study which aims to assess the feasibility of immunizing newborns with BCG and OPV0 birth doses within 24 hours of birth.

Study objective: The objective of the study is to integrate routine immunization into maternity and early newborn care in select facilities.

To this end, there are several sub-objectives:

1. Integrate birth dose immunizations into maternity and early newborn care services
2. Measure the change in proportion of births receiving birth doses BCG and OPV0 within 24 hours during the intervention period compared to during baseline
3. Measure the change in average age of babies receiving birth doses of BCG and OPV0 during the intervention period compared to during baseline
4. Assess the operational feasibility and acceptability of interventions and describe any factors (barriers and enablers) that may influence implementation of birth dose strategies

Study period and population:

Data collection for the study will take place between January and April 2021. The study population is Health care workers (HCWs) attending either maternity or immunization units within the participating facilities.

Data collection procedure with participants:

As a HCW, if you agree to participate, we will ask you to complete a short survey that will take approximately one hour. Since the interview is long, you will be asked to participate at a time and location that is most convenient for you. The purpose of the questionnaire is to obtain knowledge and perspectives of HCWs regarding the birth dose policies and administration practices. The responses will be documented by the interviewer on a tablet. No personal identifiers will be collected during the interviews. If you agree to participate, the study staff will request that you find a time to talk with the interviewer that is convenient for you and allows for privacy.

Right of withdrawal without prejudice to participation:

It is understood that your participation in this study is voluntary and you remain free to terminate it at any time. If any question makes you uncomfortable, you have the right to not answer. If you decide to opt out of the research, you can contact the researcher or study coordinator at **651050700**. It is important to note that the data gathered cannot be directly linked to you and your information will be confidential if you agree to participate.

Disadvantages, risks and advantages that may arise from this participation:

As the purpose of this work is to assess the feasibility of a process, there is no specific risk for participants. Though personal information such as name and personal health information will not be gathered in interviews, there is minimal risk to participant data being identified.

Compensation:

No compensation is provided for this study.

Full address of main researcher and other persons to contact if needed.

Study Coordinator: Delphine Kamga, MPH, Clinton Health Access Initiative, Y Building rue 1775 nouvelle route Bastos, P.O. Box 5241, Yaoundé, Email: dkamga@clintonhealthaccess.org , Tel: +237 651050700

National Ethical Committee of research for Human Health (NECRHH), Technical Secretariat, Tél: 243 67 43 39, email: cnethique_minsante@yahoo.fr .

5.2 Informed Consent Form

Do you agree to participate in the following study: *« Improving timeliness of birth dose vaccines in 15 health facilities in Cameroon through integrating immunizations into maternity and newborn care services: A feasibility assessment».*

Conducted by the following investigator: Ankouane Andoulo Firmin, Faculty of Medicine and Bio-Medical Services, University of Yaoundé I, Tel : 677 72 92 70, Email: Ankouane andoulo@yahoo.com

Do you fully understand the participant information notice concerning this study;
Or

- a copy of the participant information notice for this study has been given to me;
- the participant information notice for this study has been read and explained to me fully;
- I have fully understood the objectives of this study;
- I have received answers to all the questions I have about the study;
- The risks and benefits of participating in this study have been fully explained to me;
- I understand that I can accept or deny to participle in this study;
- I understand that I can decide to stop participating in the study at any time
- My consent to participate in the study does not disengage the researcher from his ethical obligations;
- I reserve all my rights according to the law.

I agree to voluntarily participate in this research according to the stipulations of the information notice by:

- ☐ Responding to interview questions where comfortable
- ☐ Answering a questionnaire

Done in _____Did the study participant provide verbal consent? Y N

Principal Investigator:
Ankouane Andoulo Firmin

Study Participant:

5.3 Data collection tools

HCW Questionnaire

Facility Health Care Worker Survey Questionnaire

Facility ID: _____

Instructions: Please pay close attention to the instructions of the question as not everyone is eligible for these questions. Additionally, please pay close attention to the skip patterns.

Section I: Consent			
NO.	**QUESTION**	**RESPONSE CODE**	**SKIP**
HCW -1.1	DID YOU ADDRESS ALL THE QUESTION THAT THE FACILITY HCW HAD DURING THE CONSENT PROCESS?	YES .....1 NO 2	IF NO, PLEASE GO BACK AND ANSWER QUESTIONS.
HCW -1.2	IS THE FACILITY HCW OVER THE AGE OF 18?	YES .....1 NO 2	IF NO, THANK AND END SURVEY
HCW -1.3	DID YOU OBTAIN VERBAL CONSENT FROM THE FACILITY HCW?	YES .....1 NO..... 2	IF NO, THANK AND END SURVEY
Section I: Site Information			
NO.	**QUESTION**	**RESPONSE CODE**	**SKIP**
ID1	RECORD SURVEY START TIME		
ID2	SELECT THE REGION *Select the name in Survey CTO*	REGION 1 ..... 1 REGION 2 ..... 2 REGION 3 3	
ID3	SELECT IF THE AREA IS URBAN OR SEMI-RURAL	URBAN..... 1 SEMI-RURAL..... 2	

ID4	SELECT IF THIS IS A PUBLIC OR PRIVATE FACILITY	PUBLIC ..... 1 PRIVATE FOR PROFIT ..... 2 PRIVATE FAITH-BASED 3	
ID5	PLEASE SELECT THE FACILITY LEVEL	LEVEL 1: (REGIONAL AND REFERRAL HOSPITAL) . 1 LEVEL 2: (DISTRICT, CMA SOME FAITH-BASED). 2 LEVEL 3: (IHC, HC) ..... 3 OTHER (SPECIFY)..... 4	
ID6	SELECT THE HEALTH FACILITY NAME *Select the name in Survey CTO*	FACILITY 1..... 1 FACILITY 2..... 2 FACILITY 3..... 3 FACILITY 4..... 4	
ID7	ENUMERATOR ID *Select your name*	NAME 1 ..... 1 NAME 2 ..... 2 NAME 3 ..... 3 NAME 4 ..... 4 NAME 5 ..... 5 NAME 6 6	
ID8	SUPERVISOR ID *Select your supervisor's name*	NAME 1 ..... 1 NAME 2 ..... 2 NAME 3 ..... 3 NAME 4 ..... 4 NAME 5 ..... 5 NAME 6 6	

Section 2: Facility and respondent details

NO.	QUESTION	RESPONSE CODE	SKIP
FD1	OVERALL POPULATION OF THE HEALTH AREA	[___|___|___|___|___|___|___] CATCHMENT POP DON'T KNOW..... 99999	
FD2	WHAT IS YOUR PRIMARY JOB TITLE?	FACILITY IN-CHARGE..... 1 HEAD MATRON ..... 2 NURSE ..... 3 PHYSICIAN/DOCTOR ..... 4 OTHER (SPECIFY)..... 6	

FD3	WHAT UNIT ARE YOU WORKING IN? *Read out loud and select most appropriate*	MATERNITY..... 1 IMMUNIZATION ..... 2 BOTH MATERNITY AND IMMUNIZATION..... 3 OTHER (SPECIFY)..... 6	
FD4	HOW LONG HAVE YOU BEEN WORKING IN MATERNITY AND/OR EPI UNIT? *Select most appropriate combined experience in one or both units*	LESS THAN 6 MONTHS ..... 1 6 - 12 MONTHS ..... 2 12- 24 MONTHS ..... 3 24-36 MONTHS..... 4 OVER 36 MONTHS..... 5	
FD5	HOW MANY YEARS HAVE YOU BEEN STATIONED AT THIS HEALTH FACILITY?	[____] .....NUMBER OF YEARS IF LESS THAN 1..... 0	

SECTION 3: HCWs knowledge

NO.	QUESTION	RESPONSE CODE	SKIP
B1	ACCORDING TO EPI NORMS AND STANDARDS, WHAT ARE THE VACCINES THAT ARE ADMINISTERED BEFORE THE 6 WEEK IMMUNIZATION VISIT? (DO NOT PROBE, SELECT ALL THAT APPLY)	OPV0.....A BCG .....B PENTA.....C PCV ..... D HEP B .....E OTHER (PLEASE SPECIFY:____) .....F NONE.....X DON'T KNOW .....Y	Select all that apply A→Answer B2 B→ Answer B3 C→Answer B4 D-X→B5
B2	IN AN IDEAL SITUATION, WHEN SHOULD OPV0 VACCINE SHOULD BE ADMINISTERED TO A NEWBORN INFANT, ACCORDING TO EPI NORMS AND STANDARDS? *(Read out loud and have the participant select most appropriate)*	WITHIN 24 HOURS OF BIRTH.....1 AFTER 24HRS AND WITHIN TWO WEEKS OF BIRTH ..... 2 TWO WEEKS AFTER BIRTH.....3 AFTER TWO WEEKS OF BIRTH .....4 DON'T KNOW 99	
B3	IN AN IDEAL SITUATION, WHEN SHOULD BCG VACCINE SHOULD BE ADMINISTERED TO A NEWBORN INFANT, ACCORDING TO EPI NORMS AND STANDARDS? *(Read out loud and have the participant select most appropriate)*	Within 24 hours of birth .....1 After 24 h of birth but within two weeks of birth .....2 Six weeks of birth .....3 After six weeks of birth.....4 Don't know 99	

B4	How many children need to be present for a vial of OPV to be opened?	[___|___].....No. of children Don't Know.....99	
B5	How many children need to be present for a vial of BCG to be opened?	[___|___].....No. of children Don't Know.....99	
B6	If your facility provides HepB vaccine at birth, How many children need to be present for a vial of Hep B to be opened?	[___|___].....No. of children Does not provide HepB birth dose.....98 Don't Know.....99	
B7	Is it recommended to administer BCG at birth to healthy and clinically stable low birth weight infants (<2500 grams)?	Yes .....1 No .....2 Don't Know.....99	
B8	Is it recommended to administer OPV0 at birth to healthy and clinically stable low birth weight infants (<2500 grams)?	Yes .....1 No .....2 Don't Know.....99	

SECTION 4: General Unit information on Birth Dose

NO.	QUESTION	RESPONSE CODE	SKIP
CA1	How many HCWs work on the maternity unit?	[___|___] ..... No. of HWs Don't Know.....99	
CA2	How many HCWs work on the immunization unit?	[___|___] ..... No. of HWs Don't Know.....99	
CA3	In this facility, which vaccines are administered before newborn discharge? *Read list and select all that apply*	OPV0..... A BCG.....B HepB0.....C None..... D Other (Specify) .....X Do not know.....Y	
CA4	In this facility, does the maternity unit administer birth vaccines before newborn discharge?	Yes .....1 No 2	

CA5	HOW DOES THE FACILITY INFORM MOTHERS ABOUT THE BIRTH DOSE VACCINES? *Do not read list. Select all that apply*	Pamphlet ..... A Posters.....B Talking with them when they visit .....C Talking to people out in the community ... D Other (Specify) .....X No information provided.....Y	
CA6	WHAT INFORMATION DO YOU PROVIDE TO MOTHERS ABOUT THE BIRTH DOSE VACCINES? *Do not read list. Select all that apply*	Schedule ..... A Importance.....B Side effects .....C Other ..... D No information provided.....X	
CA7	WHAT ARE THE CHALLENGES TO ADMINISTERING A BIRTH DOSE VACCINE WITHIN 24 HOURS OF BIRTH?	[Open-ended]	
CA8	WHERE ARE VACCINES STORED IN THIS FACILITY? *Read list. Select all that apply*	In Maternity..... A In EPI.....B Office of facility in charge.....C Other (Please specify) .....X Don't Know.....Y	
CA9	PLEASE SELECT HOW THE VACCINES ARE STORED FOR EACH LOCATION LISTED ABOVE *Read list. Select all that apply*	**A: In Maternity** Fridge..... A Cold Box.....B Cool Water Pack .....C Fridge tag ..... D **B: In EPI** Fridge..... A Cold Box.....B Cool Water Pack .....C Fridge tag..... D **C: Office of facility in-charge** Fridge..... A Cold Box.....B Cool Water Pack .....C Fridge Tag ..... D	
CA10	DOES THIS FACILITY KEEP THE OXYTOCIN OR VITAMIN K COLD?	**A: Oxytocin** Yes .....1 No .....2 Do not have Oxytocin.....3 Don't Know.....9 **B: Vitamin K** Yes .....1 No .....2 Do not have Vitamin K.....3 Don't Know.....9	A →1 answer CA12, CA13, CA14 B→1 Answer CA14, CA15, CA17 Otherwise, skip to CA18

CA11	WHERE IS THE OXYTOCIN STORED? *Do not read list. Select all that apply*	In Maternity..... A In EPI.....B Office of facility in charge.....C Do not have Oxytocin..... D Other (Please specify) .....X Don't Know.....Y	
CA12	HOW THE OXYTOCIN IS KEPT COLD? *Read list. Select all that apply*	Fridge..... A Cold Box.....B Cool Water Pack .....C Other (Please specify) .....X Don't Know.....Y	
CA13	WHO IS RESPONSIBLE FOR ADMINISTERING OXYTOCIN IN THIS FACILITY? *Do not read list. Select all that apply*	Doctor..... A Midwife .....B Maternity staff .....C Other (Please specify) .....X Don't Know.....Y	
CA14	WHERE IS VITAMIN K STORED IN THIS FACILITY? *Do not read list. Select all that apply*	In Maternity..... A In EPI.....B Office of facility in charge.....C Other (Please specify) .....X Don't Know.....Y	
CA15	HOW THE IS THE VITAMIN K KEPT COLD? *Do not read list. Select all that apply*	Fridge..... A Cold Box.....B Cool Water Pack .....C Do not have Vitamin K..... D Other (Please specify) .....X Don't Know.....Y	
CA16	WHO IS RESPONSIBLE FOR ADMINISTERING VITAMIN K IN THIS FACILITY? *Do not read list. Select all that apply*	Doctor..... A Midwife .....B Maternity staff .....C Other (Please specify) .....X Don't Know.....Y	
CA17	DOES THE MATERNITY UNIT STAFF HAVE 24/7 ACCESS TO VACCINES IN THE IMMUNIZATION UNIT?	Yes .....1 No.....2 Don't Know.....9	
CA18	IF A VACCINE NEEDED TO BE ACCESSED LATE AT NIGHT OR ON THE WEEKEND, COULD MATERNITY STAFF ACCESS IT?	Yes .....1 No.....2 Don't Know.....9	
CA19	WHAT DOES THE MOTHER PAY FOR VACCINATION BOOKLET/CARD?	Booklet [___|___] ..... cost Don't Know.....99	

SECTION 5: HCW perspectives			
NO.	**QUESTION**	**RESPONSE CODE**	**SKIP**

E1	WHAT CONCERNS DO YOU HAVE ABOUT ADMINISTERING OPV0 WITHIN 24 HOURS OF BIRTH? *Do not read list. Select all that apply*	Adverse events following immunization ... A Inadequate personnel training.....B Inadequate guidance (SOPs) .....C Uncertainty on contraindications..... D Multiple vaccines administered together ..E No concerns.....F Other (please specify) X	
E2	WHAT CONCERNS DO YOU HAVE ABOUT ADMINISTERING BCG WITHIN 24 HOURS OF BIRTH? *Do not read list. Select all that apply*	Adverse events following immunization ... A Inadequate personnel training.....B Inadequate guidance (SOPs) .....C Uncertainty on contraindications..... D Multiple vaccines administered together ..E No concerns.....F Other (please specify) X	
E3	WHAT BARRIERS HAVE YOU FACED WHEN EDUCATING MOTHERS ABOUT THE BIRTH DOSE VACCINES? *Do not read list. Select all that apply*	Mothers think education is a waste of timeA Custom of sequestering new-borns .....B Not enough time during visits.....C Lack of appropriate education materials for mothers ..... D No barriers.....E Other (please specify) X	

SURVEY RESULT			
NO.	**QUESTION**	**RESPONSE CODE**	**SKIP**
RESULT	Record the result of the survey.	Survey complete .....1 Survey partially complete .....2 Other (specify) 6	
	Record ending time of the survey		

DATA COLLECTOR COMMENTS			
NO.	**QUESTION**	**RESPONSE CODE**	**SKIP**

COMMENTS	*Record any comments that you have about the survey, particularly anything that may have affected the survey completion or quality of data entry or the survey*	---------- ---------- ---------- ---------- ---------- ---------- ---------- ---------- ---------- ----------	

Immunisation register extraction

Immunization register extraction

Facility ID: _____

Date: _____

Please collect data until 30 entries are complete (all dates included) using sampling interval with both date of birth AND date of administration. For sampling interval, count how many children are entered within a year of today's date. Divide this total number by 30 to get your sampling interval. For instance, if there are 300 children within the year, your sampling interval is 300/30 or 10. Therefore, you will enter every 10th child until you reach 30 children in total with both a birth date AND a date of administration.

Child number	Q1. Date of Birth	Q2. Date of OPV0 administration	Q3. Date BCG administration
1	**A - Date of birth listed.** 1 = Yes, 2 = No (If no, skip Q1.B) **B - Date listed**	**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q2.B) **B - Date listed**	**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q3.B) **B - Date listed**

Delivery register extraction

Facility ID: _____

Date: _____

Does the register have the dates or administration listed for birth dose vaccines: 1 = Yes, 2 = No.

Does the register have the dates or administration listed for birth date: 1 = Yes, 2 = No.

For sampling interval, count how many children are entered within a year of today's date. Divide this total number by 30 to get your sampling interval. For instance, if there are 300 children within the year, your sampling interval is 300/30 or 10. Therefore, you will enter every 10th child until you reach 30 children in total. For this work you will also be looking the child up in the immunization register. Please ask the in-charge and the EPI nurse to gather this information when it is not in use.

	Delivery register			Immunization register		
Child Name	Q1. Date of Birth	Q2. Date of OPV0 administered	Q3. Date BCG administered	**Q4. Were you able to find this child based on name and birth date in the register?** 1 = Yes, 2 – No (if no, skip Q5 and Q6)	Q5. Date of OPV0 administered	Q6. Date BCG administered
	A - Date of birth listed? 1 = Yes, 2 = No (If no, skip Q1.B) **B - Date listed** C – Time of Birth	**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q2.B) **B - Date listed** C – Time of vaccine administration	**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q3.B) **B - Date listed** C – Time of vaccine administration		**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q5.B) **B - Date listed** C – Time of vaccine administration	**A – Was vaccine administered?** 1 = Yes, 2 = No (If no, skip Q6.B) **B - Date listed** C – Time of vaccine administration

Newborn data tool

This form should be used to record data about each delivery during the study period. Data should be completed by a delivery nurse and shortly after the baby is discharged.

Child #:		**Facility Code:**		**Date:**	__ __ / __ __ __ / __ __

Delivery Information →			***OPV0 →***	
GENDER	Male .....1 Female 2		OPV0	Yes.....1 No.....2
DATE OF BIRTH, TIME OF BIRTH, AND BIRTH WEIGHT	__ __ / __ __ __ __ : __ __ (DD/MM HH:mm) _____Grams		DATE AND TIME THE BABY RECEIVED OPV0	__ __ / __ __ __ __ : __ __ (DD/MM hh:mm)
CIRCLE ALL SERVICES PROVIDED	EPI visit.....A Dr visit.....B PNC.....C Other.....X If other, specify:		IF NO, PLEASE CIRCLE THE PRIMARY REASON	Caregiver refused.....1 Stock out .....2 Scheduled for later.....3 EPI was not open.....4 Left before receiving the vaccine.....6 Too few children to open a vial.....7 Not eligible for clinical reasons .....8 Not enough time for vaccination .....9 Other.....10 If other, specify:
OXYTOCIN GIVEN?	Yes.....1 No.....2		***BCG →***	
DISCHARGE DATE AND TIME	__ __ / __ __ __ __ : __ __		BCG	Yes.....1 No.....2
PLEASE LIST ANY COMPLICATIONS OR COMMENTS ON THE BIRTH:			DATE AND TIME THE BABY RECEIVED BCG	__ __ / __ __ __ __ : __ __
			IF NO, PLEASE CIRCLE THE PRIMARY REASON	Caregiver refused.....1 Stock out .....2 Scheduled for later.....3 EPI was not open.....4 Left before receiving the vaccine.....6 Too few children to open a vial.....7 Not eligible for clinical reasons .....8 Not enough time for vaccination .....9 Other.....6 If other, specify:

Notes for touchpoint calls

This form should be used to record any facility-specific information about the intervention including occurrence of stock outs, cold chain equipment challenges, or any unforeseen challenges that may have been discussed that relate to the intervention.

Area	Description

5.4 Project Timeline

The study will commence after all relevant stakeholders have aligned on the project and any necessary administrative and ethical approvals for the protocol have been obtained and data collectors have been identified and trained.

Activities	Week																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Baseline Assessment																				
Facility visits to collect baseline data	x	x																		
Conduct baseline surveys with HCWs	x	x																		
Preliminary analysis to determine current timing of birth vaccines			x	x																
Intervention implementation																				
Carry out on-site training for health facility staff					x															
Support any adjustments needed to service delivery processes (e.g. adjusting cold chain storage, etc.)					x															
Carry out twice monthly mentorship meetings to monitor progress and troubleshoot as needed							x		x				x		x					
Conduct mid-point surveys with HCWs											x									
Final assessment																				
Collect final data on timing of birth dose vaccine administration																	x			
Conduct final surveys with HCWs																	x			
Data analysis																	x	x		
Technical report development																		x	x	x

5.5 References

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