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Study Title: Assessing the use of Mapping for Health (M4H) data for immunisation programme implementation and associated impact on coverage, equity, and cost-effectiveness in the Democratic Republic of Congo

I. Background and Rationale

Mapping for Health (M4H) in DRC aims to strengthen the equity and effectiveness of vaccination interventions in the Democratic Republic of the Congo (DRC), through the provision of accurate and improved micro-plans, and harmonized and integrated spatial demographic and health data. In combination, a set of gender and equity integration and capacity development activities aim to help relevant stakeholders address gender related and social exclusion barriers to reach zero-dose and undervaccinated children. The initiative is supported by Flowminder and the Center for International Earth Science Information Network at Columbia University (CIESIN), and in collaboration with WorldPop at the University of Southampton (UoS) and partners. The project is part of the Geo-Referenced Infrastructure and Demographic Data for Development (GRID3) program and targets nine priority provinces of DRC, namely Kinshasa, Kwilu, Kasai, Kasai Oriental, Lomami, Haut-Lomani, Haut-Katanga, Sud Kivu and Ituri.

The Mashako Plan, a unique, high-level national health initiative contributes to the advancement of health information systems in DRC by aiming to increase the effectiveness of vaccination interventions. A key strategy is the integration of geospatial demographic and health data into decision-making. M4H's innovative approach in supporting the achievement of the Mashako Plan and extension to the rest of the country could lead the way for other African countries. CIESIN and Flowminder, in collaboration with GRID3 partners, have proposed M4H in DRC to bridge demographic and health data gaps in a coordinated, holistic way.

The M4H innovation was identified through the INFUSE program at Gavi, The Vaccine Alliance and is funded by the Canadian Government. Infuse is an innovation accelerator and supports programs that are proven and ready to scale. It is also being supported by the DRC Country Team and co-led in collaboration with the M&E Team. The GRID3 Consortium is already in DRC and has done some early work modelling population and producing core geospatial data layers: settlements, health boundaries and health facilities. One of the key objectives of this project is to effectively use spatial data to improve micro-planning within the EPI program. The program's gender equity approach focuses on the Expanded Programme on Immunisation (EPI) and civil society partners to have gender capacity to collect, analyse and devise gender responsive vaccination strategies to reach those left behind.

To support this effort, Gavi has engaged HealthEnabled through the "Effective Design, Implementation, Integration, and Evaluation of Digital Health Systems to Enhance the Strategic Use of Data for Immunisation Programming" grant to assess the ability of the proposed approach to be evaluated and develop a research design to evaluate the acceptance and effective use of Mapping for Health data for microplanning and routine immunisation implementation and its impact and cost-effectiveness on immunisation outcomes.

II. Mapping for Health Study Goal, Aims, and Objectives

The overall goal of the study is **to assess the use of Mapping for Health (M4H) data for microplanning and routine immunisation programme implementation and associated impact on immunisation coverage, equity, and cost-effectiveness**. In particular, the study will test the hypothesis that the effective use of M4H geospatial data can increase immunisation coverage and equity through the identification of missed settlements (and zero dose children) and optimization of vaccination strategies and supply distribution as well as a gender-specific interventions in a sub-set of Health Zones and Health Areas in Kasai and Kinshasa. As part of Gavi's intensified strategy to address gender inequity, gender-related considerations have been included in the overall research design. These have been highlighted throughout the study aims and objectives below in blue.

The overall structure of the research study includes one province selected for inclusion of gender-specific activities in a subset of Health Zones and Health Areas, namely Kasai; another M4H province selected to assess effects of M4H interventions without gender, namely Lomami; and a control site to compare both M4H sites against, namely Kasai Central. In addition, the protocol includes prioritization and segmentation of primary research participants for the intervention strength survey and qualitative in-depth interviews (where possible engaging with equal numbers of male and female EPI managers, supervisors, and vaccinators) as well as in the secondary analyses of immunisation coverage and equity surveys (gender-disaggregated analyses of birth cohorts).

As such the proposed gender-related research question for M4H is:

In what ways does the gender intervention, gender and/or gender dynamics effect the generation and/or use of M4H data within microplanning activities and/or as part of routine immunisation programme implementation, impact, and cost-effectiveness?

Guidance on proposed approaches to gender integration into the M4H study aims and objectives have been included below in blue, along with the introduction of a specific objective to document and evaluate the impact of the gender-specific activities implemented in Kasai. The overall research approach is the same as the original protocol, but has been re-organised and simplified to facilitate the research implementation process.

Study aim 1: Conduct a process evaluation to understand the program and implementation context, and identify the mechanisms through which geospatial data use influences immunisation coverage

Objective 1.1: Conduct key informant interviews and secondary analysis of program data to assess the process through which M4H geospatial data is created.
Document where possible the engagement of individuals engaged in the generation of mapping data by gender.

Objective 1.2: Conduct direct observation and key informant interviews at the National and Provincial levels and secondary analysis of program data to assess the process through which M4H geospatial data is shared for use in microplanning processes.
Document where possible the engagement of individuals engaged in the receipt of M4H data by gender.

Objective 1.3: Conduct direct observation and key informant interviews at the National and Provincial levels and secondary analysis of program data to assess the process through which M4H geospatial data is used as part of macroplanning processes and planning for microplanning at Health Zone level.
Document where possible the engagement of individuals engaged in the use of M4H data for macroplanning and preparation for Health Zone microplanning by gender.

Objective 1.4: Conduct direct observation, intervention strength survey with qualitative questions with Health Zone EPI Managers and secondary analysis of program data to assess the process through which M4H geospatial data is used as part of microplanning processes. Document Health Zones with high acceptance and use of M4H data, moderate acceptance and use of M4H data, and/or low acceptance and use of M4H data in microplanning.
Document where possible the engagement of individuals at Health Zone level engaged in the use of M4H data for microplanning by gender. Include questions related to gender and gender dynamics related to data use in the intervention strength survey and qualitative questions.

Objective 1.5: Conduct intervention strength survey with qualitative questions and secondary analysis of program data to assess the process through which M4H geospatial data is used as part of routine immunisation programme implementation.
Document where possible the engagement of individuals at Health Area and facility levels engaged in the use of M4H data for routine immunisation programme implementation by gender. Include questions related to gender and gender dynamics related to data use in the intervention strength survey and qualitative questions.

Objective 1.6 Conduct a rapid ethnographic study to document and identify associations with acceptance and use of M4H data through the gender intervention in Kasai
Include all gender-associated Health Zones and Areas in the intervention strength survey with qualitative questions in Objectives 1.4 and 1.5.

Note: Secondary analyses of program data will document the data that is created by Health Area and Health Zones and assess the acceptance and use of M4H geospatial data on immunisation programme planning at Health Zone, Provincial and National levels and implementation considerations related to vaccination strategy – outreach or fixed (past vs. updated), Identification of previously missed settlements/ children, Target population estimate (denominator- past vs. updated) and use of mobility data to update target population estimates (to be determined based on availability of program data).

Study aim 2: Conduct a quasi-experimental design study in three provinces (two intervention- one with gender activities, one without gender activities, and one control) to determine the associated effects of the acceptance and use of M4H data by Health Zones and Health Areas on immunisation coverage and equity (especially zero-dose children).

Objective 2.1 Use data from EPI Programme immunisation coverage and equity surveys of children 12-23 months of age to determine changes in immunisation coverage and timeliness after 12 months of implementation in two intervention provinces and in one control province. **Disaggregate the number of eligible children by gender by location. If available, assess characteristics of the mother by location such as education, literacy, female-headed household, etc.**

Objective 2.2 Use intervention strength data and secondary analysis of coverage survey data to assess the impact of M4H data use as compared to the status quo on its effectiveness to increase immunisation coverage and timeliness.
Disaggregate the number of vaccinated vs. eligible children by gender by location (including sites with gender interventions vs. those without gender interventions). If available, assess characteristics of the mother by location such as education, literacy, female-headed household, etc.

Objective 2.3 Use intervention strength data and secondary analysis of coverage survey data to assess the impact of M4H data use as compared to the status quo on reaching the most marginalized children 0-23 months (girls/boys) and the main caregivers - women and adolescent girls in their reproductive years (15-49 years of age) particularly those in the poorest and poorer socioeconomic strata, and children of low-literate and innumerate caregivers (mainly female, below 25, 25 and older), etc.
Disaggregate the number of vaccinated vs. eligible children by gender by location (including sites with gender interventions vs. those without gender interventions). If available, assess characteristics of the mother by location such as education, literacy, female-headed household, etc.

Study aim 3: Determine the incremental cost-effectiveness of geospatial data use as compared to the status quo

Objective 3.1 Using an ingredients approach, estimate the economic costs of implementation for each type of M4H data, including program development, start-up, M4H data generation, and M4H data socialisation.

Objective 3.2 Use the lives saved tool to model the incremental lives saved associated with changes in immunisation coverage following 12 months of implementation in intervention and control provinces.
Disaggregate the number of vaccinated vs. eligible children by gender by location and intervention strength associations. If available, assess characteristics of the mother by location such as education, literacy, female-headed household, etc.

Objective 3.3 Estimate the incremental cost per life saved and cost per Disability Adjusted Life Year Averted of each intervention type versus status quo.
Disaggregate lives saved by gender by location. If available, assess any associated characteristics of the mother by location such as education, literacy, female-headed household, etc. with lives saved.

Objective 3.4 Estimate the incremental cost per life saved and cost per Disability Adjusted Life Year Averted of M4H implementation in calendar years 2019-20 versus status quo of 2014 (pre-implementation)
Disaggregate incremental cost per life saved by gender. If available, assess any associated characteristics of the mother by location such as education, literacy, female-headed household, etc. with cost per life saved.

Objective 3.5 Conduct probabilistic sensitivity analyses to identify key cost drivers and assess uncertainty.
Include any gender-related analyses associated with key cost drivers and uncertainty.

Where additional gender considerations may be incorporated are in the documentation of program data by tracking the gender of those engaged in mapping and/or microcensus activities and associated relevant analyses, characteristics of the mother associated with full immunization as part of the secondary analysis of coverage and equity survey data, and in the qualitative instruments in alignment with each of the relevant study aims- especially those related to use of M4H and any potential associations between gender of EPI Managers on M4H data use in microplanning and/or gender of supervisors and vaccinators on the use of M4H microplans as part of routine immunisation programme implementation.

III. Methods

Program description

A key focus for M4H is effective use of geospatial data to support microplanning and macroplanning by identifying missed communities and children and to improve immunisation

service planning and delivery to increase immunisation of zero-dose and under-immunised children. To measure effective use, it is important to first define how M4H approaches, products, and support are created, shared, and intended to be used by various user groups. In M4H the initial entry point for geospatial data for immunisation is through micro-planning. Micro-plans from health areas and health zones then feed into the macro-planning processes at provincial and national levels. In parallel, population estimates using micro-census and satellite imagery will be created and provided to inform micro and macro-planning. Subsequently, estimates derived from CDR data will be used to inform on mobility-derived changes in population density each month over time to support potential changes in micro and macro plans and coordination between departure and arrival health zones. In case of significant events mobility indicators can be provided at finer temporal frequency, and abnormal large changes will be flagged in monthly indicators to warn users.

The "intended use" and "effective use" of M4H in DRC is described as follows.

Intended Use of M4H Data

Creation of Mapping for Health Data

Health zone participatory mapping is defined as:

The process of generating administrative base maps (containing settlements, health areas boundaries, health facilities) through a collaborative process between GIS mappers (using existing data and satellite imagery) and local health teams (local knowledge of their area)

- In each health zone, two mappers work closely with representatives of each health area to identify and validate settlements, boundaries and health facilities
- The mappers then train health workers to use smartphones in order to go back to their health area and take GPS coordinates to complete the administrative base maps
- The data is gathered, verified, and consolidated by the mappers
- The data is shared to the MCZ/ ECZ for review and validation
- On average ~10 -day process per health zone

Population estimation is defined as:
An independent source of population numbers used to help improve resource allocation/plan appropriate routine immunisation strategies as part of the micro and macro-planning process.
The result is a 100m x 100m gridded population layer with uncertainty measures, with gender and age breakdown. Population estimates are then provided to users at different level (area, zone, province, etc. for micro and macro-planning (mechanism TBD).
The method used to produce the estimates is:

- A microcensus survey is conducted in select sample areas
- Microcensus survey data, sub-national boundaries, settlement data and other geospatial covariates are used as input to model the population outside of the surveyed area

Health zone and health area georeferenced documentation to support micro-plans development and use is defined as:

The core administrative data produced during participatory mapping as well as the population estimates are combined to update the core micro-plan information: a tabular list of settlements per health area, along with their estimated population number (incl. < 1 year old).

These data are also used to generate a health zone/health area thematics map to complement the georeferenced micro-plans and display the following information:

- health area boundaries
- settlements and health facilities falling within these boundaries
- gridded population estimates for the catchment area

Generation of mobility estimates from mobile phone usage data is defined as:

A system for automated routine capture of mobility estimates from CDR data will be developed for all M4H provinces. The mechanism through which this information is shared is still being confirmed with DHIS2 as one prominent option under consideration. It is recommended that discussions related to building in updates within DHIS2 be undertaken with University of Oslo and the DHIS2 in DRC. Mobility indicators include:

- Number of subscribers estimated to reside in each health zone, each month, and % changes from the previous month and from the median of the past 12 months
- Origin-Destination Matrix of home relocations for all subscribers, for each pair of health zones, each month: the number of subscribers who changed residence from health zone A in the previous month to health zone B in the current month
- The number of subscribers classified as "highly mobile" (regularly changing their health zone of residence or stay (e.g. every few months)
- Trajectories of groups of subscribers classified as "highly mobile": for each sufficiently large group (>15 subscribers), the list of their main stays in a given location each month over the last x months (e.g. the last 6 months)
- If a particular event (e.g. flood, conflict): the number of subscribers classified as 'displaced' by the event (forced change in location of residence), daily and then monthly after the mobility of the population displaced by that event has fallen below a given level
- Estimates of a number of people from a number of subscribers, for the above data products (number of people residing in each HZ, number of people migrating from HZ A to B, number of highly mobile people, number of displaced people)

Acceptance and Use of Mapping for Health Data for Routine Immunisation Planning

The core geospatial layers can be used to provide key and timely insights for health zone and provincial decision makers:

- identify hard to reach settlements or settlements likely to fall in between two health catchment areas
- estimate the population of the health areas and health zones estimate a health-care facility's catchment population
- estimate the number of vaccines needed for a health area based on its population
- assess the population coverage of current fixed vaccination strategies
- optimize outreach vaccination strategies based on population distribution
- optimize the cold chain and new fridge allocation based on population distribution

The use as intended of population estimates is defined as:

PEV central considers and/or uses population estimates for macro-planning and supports their consideration and use by provinces, health zones and health areas for micro-planning.

The use as intended of population mobility data is defined as:

At provincial and operational level (users such as Medecin Chef d'Antennes, Medecins Chef de Zone and Data Managers):

Receive data indicators (see above) on a regular basis (monthly + when large movement)
Use these indicators to:

- adapt immunisation routine each month (during implementation):
- support more regular micro-planning with monthly revised targets at health zone level (microplans can be revised every month at branch or DPS level, based on population migrations between health zones)
- justify the quantities distributed a posteriori (from the HZ to the DPS to the central level)
- support better coordination between health zones and provinces (population moving out of a health zone and relocating to another)
- provide quantified estimates of population mobility to contextualised with known population movements (recurring and unusual) to inform planning
- plan ahead the necessary quantities of vaccines and their variations according to the seasons
- emergency planning (note this may be outside the field of vaccination)

At central level (PEV):
Receive data indicators (see above) on a regular basis (monthly + when large movement)
Use these indicators to:

- support the assessment of the implementation and deviations from targets
- review of the vaccination strategy to take into account usual (seasonal mobility)
- emergency planning (note this may be outside the field of vaccination)

Effective use of spatial data including population estimates within micro- and macro-planning processes by health area, health zone, provincial, and national level staff is defined as:

All health areas in prioritised provinces using geospatial data including population estimates to develop micro-plans that can identify previously uncharted areas, determine number of vaccines needed, and assign optimal immunisation strategy and fridge location by proximity to health facilities and population distribution.

All health zones use health area micro-plans produced using geospatial data to develop health zone micro-plans and support and monitor health area immunisation planning and implementation activities. And considers and/or use mobility data to update plans and immunisation activities.

Key outputs include: Cumulative identification of at-risk population and settlements that do not fall within reach of monthly routine vaccination sessions, number of vaccines needed, and optimal immunisation strategy and fridge location by proximity to health facilities and population distribution.

M4H provinces use health zone geospatial data including population estimates within micro-plans to develop provincial macro-plans and support and monitor provincial immunisation planning and implementation activities. And considers and/or use mobility data to update plans and immunisation activities.

Key outputs include: Cumulative identification of at-risk population and settlements that do not fall within reach of monthly routine vaccination sessions, number of vaccines needed, and optimal immunisation strategy and fridge location by proximity to health facilities and population distribution.

National EPI programme uses provincial geospatial data and population estimates within macro-plans to support and monitor provincial immunisation planning and implementation activities. And consider and/or use mobility data to update plans and immunisation activities.

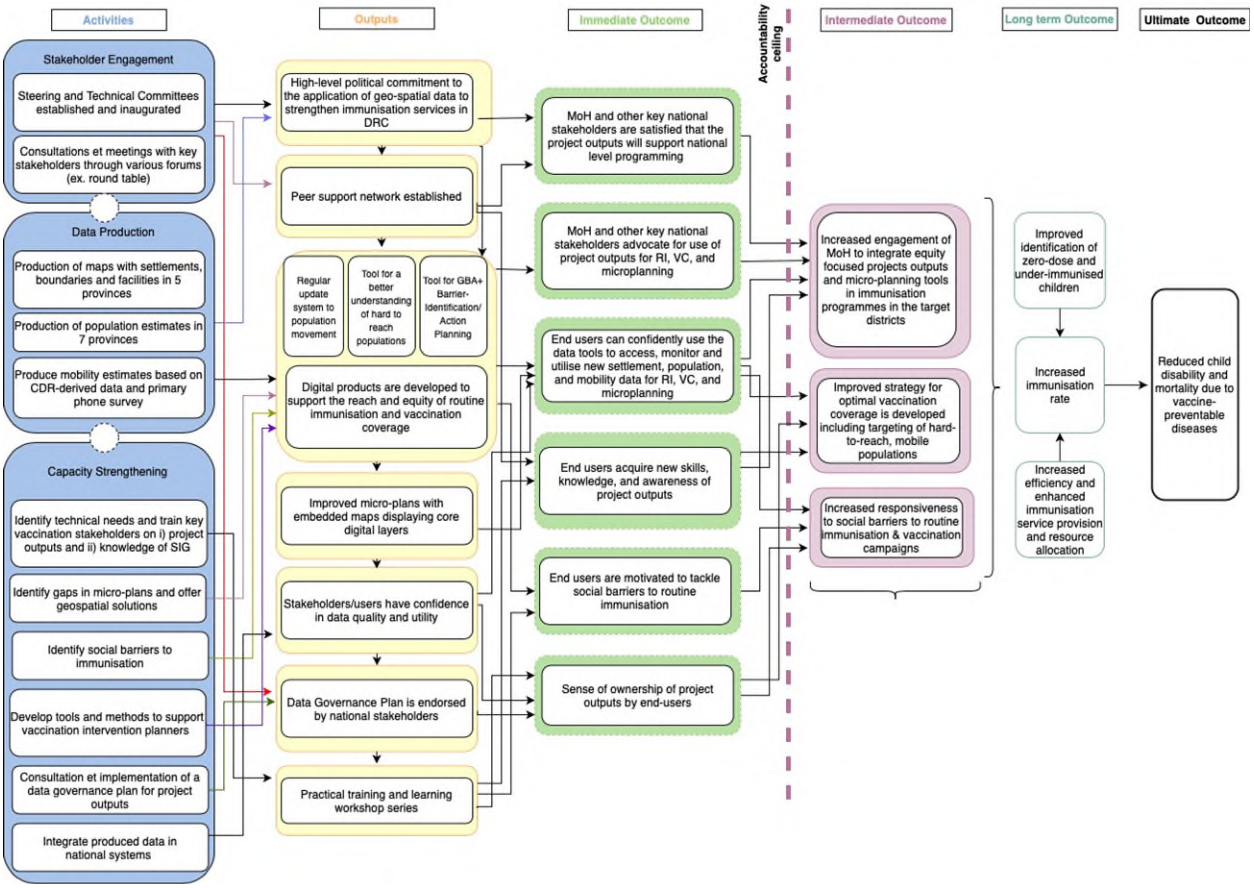
**This can be measured through a dose response of participating health areas, health zones, and provinces and observed by identifying/ documenting/ tracking consideration and use of geospatial data in micro-plan and macro-plan development processes and for EPI/ immunisation monitoring activities.

1. Specifically, we will aim to look at the effects of M4H by different levels of users on:
2. Adopting and (if possible) updating population estimates for routine immunisation planning, implementation, and monitoring
3. Setting immunisation targets
4. Identifying zero-dose children and their primary caregivers
5. Identifying under-immunised children and their primary caregivers
6. Adjusting vaccination strategy to optimize vaccine service delivery
7. Updating stock levels and distribution points
8. Identifying and adapting targets and strategies to population shifts through use of mobility estimates
9. Increasing gender considerations in immunisation service planning, implementation, and monitoring based on what the program carried out in the gender specific component of M4H and to assess how the geospatial mapping component was influenced by gender differences among data users and whether the geospatial mapping provides more accurate data from a gender and equity perspective.

Theory of change

The figure below outlines the theory of change for M4H. This will be used to inform the development of the qualitative instruments (observation and interview guides), the intervention strength survey instruments, and the secondary analyses of immunisation coverage survey data. The gender interventions will be evaluated separately using a rapid

ethnographic approach and relevant Health Zones and Health Areas will be purposefully included as sited for the intervention strength survey.



Study design

This is a mixed-methods, effectiveness study with a quasi-experimental design. Impact will be assessed using a pre/post study design which draws upon the EPI Programme Immunisation Coverage Surveys conducted with support from KSPH in 2021, which will be repeated in 2023. Efforts to assess impact will be both informed and complemented by qualitative research (direct observations and in-depth interviews), intervention strength surveys in prioritised Health Areas in intervention and control sites to assess adherence to microplans with and without M4H data, and secondary analyses of M4H programme data to document data creation, data acceptance, and data use. A targeted rapid ethnographic study will be conducted in Health Zones and Health Areas in Kasai which have been exposed to gender-specific programme activities. These sites will be purposefully included in the intervention strength survey sample.

Setting

Evaluation activities will be carried out in 3 Provinces- two intervention and one control. Provincial selection was carried out in collaboration with implementing partners and key stakeholders and prioritizes implementation in sites that have health zones that represent urban, peri-urban, remote, and conflict settings. Selected provinces are Kasai (M4H with gender), Lomami (M4H only) and Kasai Central (control site).

Data collection

The research is planned to be carried out in 2021-2023 depending on COVID-19 and feasibility of primary, in-person data collection. Secondary analyses of programme data will focus on four sources of data (1) programme data related to the creation of M4H geospatial data, (2) M4H data provided for use in microplanning – maps with optimised strategies and vaccine distribution data, population estimates, and processed CDR data; (3) Microplans developed at the Health Area and Health Zone levels; (4) Macroplans at the Health Zone, Province, and National levels; and if possible stakeholder engagement with DHIS2 dashboards (for the access to and use of mobility data). Access to these data will be facilitated by the M4H team. Additional secondary data analysis will be done at baseline and end-line to assess associated effects on immunisation coverage and equity. This will then also be used with programme cost data provided by M4H to measure cost-effectiveness. The primary data collection will then focus on the following to align with the M4H process of data generation, sharing, and use as part of the planning process and then as part of routine immunisation service delivery.

High-level Qualitative Assessment of M4H Data Development, Sharing, and Use Process will be conducted by HealthEnabled and KSPH researchers in DRC to document the process through which the geospatial data were created, shared, accepted and used in Kasai and Lomami. The following data collection tools will be developed by the research team to facilitate this process.

M4H Programme Data (Study Aims 1, 2, & 3)

1. **Programme Data Matrix** will be created and/or adapted to capture programme data to be provided by M4H and supplemented by the research team by Health Area – including, mapper demographics (sex, age, level of education), types of data generated (maps, gridded population, etc.), new settlements identified, data shared, data accepted, data used as part of Health Zone microplanning, vaccination strategy – outreach or fixed (past vs. updated), Identification of previously missed settlements/ children, Target population estimate (denominator- past vs. updated), and use of mobility data to update monthly targets and support coordination between health zones and planning (provided monthly revisions take place) or annual targets (supporting revision of strategy and annual planning). Analyses of these data will be used to define user profiles including levels of 'effective' use at different levels of the health system including zonal and facility levels. A part of the former, the proportion of health areas in the intervention arm which are shown to use M4H data for micro-planning will be used to define highly (75% or more health areas using M4H data for micro-planning), moderately (50-75% health areas using M4H data for micro-planning),

Passive (less than 50% health areas using M4H data for micro-planning) and non-users (health areas never using M4H data for micro-planning).

M4H Data Development (Objective 1.1)

2. An **M4H Data and Intervention Development/ Design Interview Guide(s)** will be created to conduct in-depth interviews with M4H programme staff at global, national, and province levels. The target sample will be up to 20 key informants, including up to 10 individuals involved in mapping activities in Kasai and Lomami and 4 individuals involved in the gender intervention design and implementation. Interviews will be conducted in English or French based on the preference of the respondent. These will then be used to inform the development of all other instruments.

Key Considerations: Intervention Development/ Design Interviews (Adapted from MAPS Toolkit)

- **Groundwork:** How were various actors involved in developing the vision for the intervention? How was this done in particular for the gender and social inclusion component of the program? What technical problems was it seeking to solve? How did DRC's specific health system context affect the design of the interventions? How did provincial and national actors experience the interventions?
- **Partnerships:** What are the various stakeholders who have been involved in the development and roll out of the interventions? In what ways have partnerships strengthened the interventions? How was this done in particular for the gender and social inclusion component of the program In what ways have partnerships been a challenge? Do other sectors, beyond health programs, use the special data? What kinds of intersectoral engagement could be beneficial?
- **Finances**: [unlikely to be directly explored in the KIs but the role of funders will be discussed under partnerships]
- **Technology and architecture:** In what ways does each intervention meet the needs of the users? In what ways does it still need to be adjusted? Who benefits from each intervention and in what ways? What do you see as the optimal future for M4H data? What is likely to happen going forward?
- **Operations:** What are some of the best things about how the intervention was implemented? What are some of the challenges faced in terms of initial roll out, use and maintenance? How do provincial and national stakeholders experience using M4H data from health zone micro- and macro-plans to develop provincial macro-plans? In what ways do provincial and national level stakeholders engage through the use of M4H data from digital micro-and/or macro-plans?
- **M&E:** What kinds of feedback do you receive about each intervention**,** including gender intervention? How is the health system able to react to feedback?

M4H Data Sharing (Objective 1.2)

3. An **M4H Data Sharing Observation & Interview Guide** will be created for use by KSPH researchers to document the process through which M4H data is presented to key stakeholder groups for use in EPI microplanning and overall perceptions and acceptance of the usefulness of the data. Meetings to present the data are planned in Kinshasa and in each of the Provinces starting in October 2021 and continuing into early 2022. Target number of observations: 3-5 observations with a minimum of one observation and 3 interviews per Province and in Kinshasa (~9 interviews).

M4H Data Use for Microplanning in Health Zones in Kasai and Lomami (Objective 1.4)

4. An **M4H Data Use Microplanning Intervention Strength Survey (with qualitative questions and section to document observations)** will be created for use by KSPH researchers to document which M4H data is accepted and used by EPI Managers at Health Zone level in the microplans with special focus on updated vaccination strategies, newly identified settlements, vaccine distribution, etc. and overall perceptions and acceptance of the usefulness of the data. Microplanning is planned for the Provinces starting in late 2021 and continuing into early 2022. Target number of surveys: 1 Survey per Health Zone in Kasai (18) and Lomami (15) with additional observations and/or in-depth interviews for microplanning activities (if feasible). A complementary approach to document the microplanning process will be designed for the control site (Kasai Central).

M4H Data Use for Macroplanning in Kasai and Lomami (Objective 1.3)

5. An **M4H Data Use Macroplanning Intervention Strength Survey (with qualitative questions and section to document observations)** will be created for use by KSPH researchers to document the which M4H data is accepted and used by EPI Managers at Province Level based on microplans created by Health Zones with special focus on updated vaccination strategies, newly identified settlements, vaccine distribution, etc. and overall perceptions and acceptance of the usefulness of the data. Macroplanning is planned for the Provinces after Health Zone microplanning to develop the overall vaccine and resource allocations. Target number of surveys: 2-3 Surveys per Province in Kasai and Lomami with additional observations and/or in-depth interviews for macroplanning activities (if feasible). A complementary approach to document the macroplanning process will be designed for the control site (Kasai Central).

M4H Data Use for Routine Immunisation Programme Implementation in Health Areas in Kasai and Lomami (Objective 1.5)

6. An **M4H Data Use for Routine Immunisation Intervention Strength Survey (with qualitative questions and section to document observations)** will be created for use by KSPH researchers to document which M4H data is accepted and used by Health Areas with special focus on adherence to microplans that use M4H data with updated vaccination strategies, newly identified settlements, vaccine distribution, etc. and overall perceptions and acceptance of the usefulness of the data. Routine immunisation programme implementation is planned for the Provinces starting in early 2022 upon completion of the microplanning and macroplanning process. In each intervention province health areas will be stratified by rural, urban, peri-urban, and conflict sites as well as connectivity and 60 health areas will be randomly selected. In the health areas, the immunisation programme administrator will be surveyed as well as a subsample of immunisation staff to assess the use of the geospatial data as part of the micro-planning processes. Where possible efforts will be made to interview even numbers of male and female respondents. Target number of surveys per province in Kasai, Lomami, and Kasai Central: ~75 surveys/ province. All Health Areas in Kasai which have been engage in targeted gender activities will be included in the routine immunisation intervention

strength survey sample. A complementary survey instrument to document the routine immunisation process will be developed for the control site (Kasai Central).

Key Considerations: Observation and Interview Guides & Intervention Strength Surveys

- **Experience with initial interventions**: How did health workers at the health zone and health area level experience the initial map creation exercise (the participatory meeting)? Are there differences by sex of provider or by seniority?
- **Micro-planning process**: How are micro-plans formed and to what extent is spatial data used at planning meetings (at various levels of the health system) to inform immunisation strategies, vaccine numbers, and fridge placement?
- **Immunisation context and zero dose children**: How do MCZ and ECZS understand their health zones and areas in terms of coverage, barriers/determinants to access, utilization and coverage; implementation monitoring; planning? Have the interventions changed this (geospatial and gender combined as well)? Why are settlements and individual children missed? To what extent does mapping and the use of spatial data affect missed settlements?
- **Dynamism and adaptation of maps**: How adaptable and easy-to-update are the maps and/or digital microplans? How well do they reflect environmental dynamism (such as migration)?
- **Support and supervision**: What is the support and supervisory context at health facilities? How does this context play out around immunisation in general and the use of digital maps specifically? (Including IT responsiveness)
- **Time allocation**: How do health actors allocate and spent their time (including vaccination outreach sessions, data entry activities, vaccine delivery and logistics)? Has the intervention changed this?

Rapid Ethnographic Case Study of Gender Intervention in Kasai (Objective 1.6)

7. **Rapid ethnographic case studies and key informant interviews:** An overview of the gender intervention will be documented as part of the initial set of qualitative data collection activities, including a stakeholder mapping of all government and CSO partners engaged in the gender intervention. This will be used to identify the target sample and create interview and observation guides for each respondent type and activity. An iterative and open-ended approach will be taken, wherein the guides are designed to cover a range of domains, but specific phrasing of questions can be adapted by the researchers to take a semi-structured approach and emphasis across the domains can shift according to emerging themes and data saturation. This part of the study will look at the longer term impacts of the gender intervention of the M4H as it was designed: gender capacity building of health staff and partners to address social barriers to vaccination uptake and coverage targeting a select number of staff at central and operational levels. These will then be linked to relevant Health Zone and Health Area intervention strength surveys and qualitative research to assess relationships between the gender intervention and acceptance and use of data for microplanning and use of data for routine immunisation programme implementation. In addition the Health Area intervention strength for those engaged in the gender intervention will undergo a sub-set secondary data analysis to identify relationships with immunisation outcomes and cost-effectiveness.

Gender Intervention & Research Considerations

The following is an outline of the gender interventions implemented by M4H as well as the sites that have been supported with these activities and specific research considerations.

Key questions: *In what ways does gender play out among health workers, their use of spatial mapping, data use, immunisation planning, and their conduct of routine immunisation? Did the gender training of certain health workers make a difference in how they interpret and use the data? Are there any unintented results from the combination of capacity building in gender and geospatial mapping for those involved health workers (by sex)?*

Gender audit [September 2020-January 2021] -> baseline to review the current state of capacity with regards to gender, equity and social inclusion. Baseline and endline reports will be used as part of the programme data analyses.

Gender-based Analysis Tool to support the integration of gender in vaccination. This tool will be used to inform the design of both qualitative instruments as well as the intervention strength surveys to be used at Health Zone and Health Area levels.

Training of Trainers in Kasai and Kinshasa: training to strengthen capacity to understand gender and social inclusion and apply the principles in programming, implementing and monitoring/evaluating vaccination interventions. All trainers who have received training will be tracked in the Programme Data Matrix and engaged in the Rapid Ethnography and intervention strength surveys. A sub-set of trainees will be included in the Rapid Ethnography and all those working in Health Areas will be purposefully sampled in the intervention strength surveys.

Sensibilisation sessions -> the newly trained trainers (ambassadors) sensitise key personnel and community leaders in their zones/areas. Review of reports will be conducted to pull in relevant information into the Rapid Ethnographic Case Studies. Key informants in various roles of participation in the sensibilization sessions will be included in the Rapid Ethnography.

Multisectoral Roundtable on Gender and integration with vaccination & Creation of networks derived from the roundtable Review of reports will be conducted to pull in relevant information into the Rapid Ethnographic Case Studies. Key informants in various roles of participation in the Roundtable on Gender sessions will be included in the Rapid Ethnography along with associated networks.

Final Gender Intervention Products: Policy brief on key steps to improve gender integration in vaccination; Finalisation of the GBA+ Tool; Development of processes (i.e. via fiche technique though method is TBC) to include gender to the micro-planning process; M&E Endline incl. endline of gender activities. Documents will be used to contribute to the Rapid Ethnography and inform the inclusion of gender in the Interview and Observation Guides for Macro and Microplanning as well as in the intervention strength surveys for Health Zones and Health Areas.

The qualitative data collection activities for the rapid ethnographic case studies will involve up to 50 interviews (see suggested breakdown below) and 10-15 observation activities at health zone, health area, and immunisation programme implementation levels per province, as well as 10-15 key informant interviews at the national and provincial levels. It will

Training of Trainers Health Zones: Banga-Lubaka and Kamonia and Health Areas: Kamonia cité, Kamako État (ll) and Biponga- conduct in-depth interviews with 10 of the 16 trainers trained and associated Gender Sensitisation Sessions with 25% or approximately 35 community and other health workers reached in subset of Health Zones and Health Areas.

- *Health zones: Kamonia, Tshikapa, Kalonda-Ouest, Banga-Lubaka*
- *Health areas: Kamonia, Kasekwe, Luangatshimo, Kamako 1 and 2, Kabangu and Lungembe, Clinique,Mennonite,Stade 1, Hôpital et Bel'air, Tshitangu and Bakuba, Kasai 1 and Tukunyema, Banga Lubaka, Banga Banneux, Lunduba, Biponga.*

Secondary Analyses of Coverage Survey Data at baseline and 12 months after routine immunisation implementation (Study Aim 2)

The study will leverage two sets of immunisation coverage surveys being implemented by the EPI Programme in collaboration with KSPH in 2020/2021 and in 2022/2023.

The guiding principle for analysis will be the Intention to Treat methodology, with the intervention variable determined by the randomized study arm. The unit of analysis will be children aged 12-23 months living in households within the Health Areas chosen for the intervention strength survey. The primary outcome will be the proportion of zero dose immunisations amongst children 12-23 months (disaggregated by sex) in the sample. Effectiveness of the intervention will be the difference in outcome between the intervention and control areas. We will additionally explore alternative models using the implementation strength of the intervention (high/medium/low use) which will allow consideration of the differential dose response of effective use and its impact on key outcomes.

The unit of randomization and intervention is expected to be the Health Area. Health Areas from each province will be randomized after stratification for characteristics known to be correlated with immunisation outcomes. Sample size estimates assume that the coefficient of variation for health area / zone size is about 0.3. We assume the conventional type I error rate of 0.05 and power of 80% to detect a difference of 5 percentage points reduction from 18% to 13% in zero dose children (using DPT 1 as marker).

The study team will coordinate with the coverage survey teams to align timelines for the second coverage survey in the intervention and control sites to be conducted after 12 months of implementation of the immunisation programme using M4H data. The end line secondary analyses will then be conducted as data is made available.

Economic evaluation (Study Aim 3)

Efforts to determine the value for money of M4H as compared to the status quo will aim to generate estimates of the incremental cost per life saved and cost per DALY averted. Economic costs incurred by implementing partners will be tracked prospectively, using an ingredients approach and drawing from project financial records. Costs will be captured over three phases: (1) Start up: data development; (2) Implementation: data sharing and use. Start-up activities are defined as one-time activities required to create M4H data, including training of trainers, facility level training of providers, community mapping, population modeling, etc. The Implementation phase includes all of the activities required to support continued implementation following start-up activities. Examples include socialization meetings to share and facilitate the use of data at the National, Province, and Health Zone levels. Once collected, all costs will be converted into 2021 base year US dollars using consumer price indices obtained from the IMF and the relevant market exchange rates. Capital costs will be annualized using local life expectancies and a 3% discount rate.

To complement cost estimates, we will additionally model incremental lives saved using the Lives Saved Tool (LiST; www.livessavedtool.org). Incremental changes in immunisation will be inputted into LiST for DRC and used to generate an estimate of the impact of M4H. Lives saved will be used to calculate Years of Live Lost and the broader composite utility measure of Disability Adjusted Life Years (DALYs). One-way and probabilistic sensitivity analyses will be carried out to identify key drivers of costs. To accommodate stakeholders interested in using

cost estimates to forecast the total costs required for budgeting purposes, we will additionally present costs incurred without adjustments for annualization.

Table 1. Summary of impact data sources and needs by study aim

	Study aims	Data source	Data needs
2	Impact on immunisation	MICS-5 2014 and MICS-6 2018-2019	Compare the proportion of children 12-23 months who were fully immunised (baseline vs. endline) Compare the proportion of children 12-23 months who did not receive DPT 1 (zero dose) (baseline vs. endline) Timeliness of full immunisations (baseline vs. endline)
2	Equity	MICS-5 2014 and MICS-6 2018-2019	Compare the estimates of zero dose immunisation, full immunization, and timeliness of immunisations between the two surveys across the wealth quintiles, by the child's gender, levels of mother's / father's education, and other sociodemographic characteristics.
3	Cost effectiveness analysis	IRD financial data Lives Saved Tool	Programme costs associated with start-up and implementation of M4H in 2020-2022 Model the incremental lives saved associated with changes in immunisation outcomes for the calendar year (at baseline and endline)

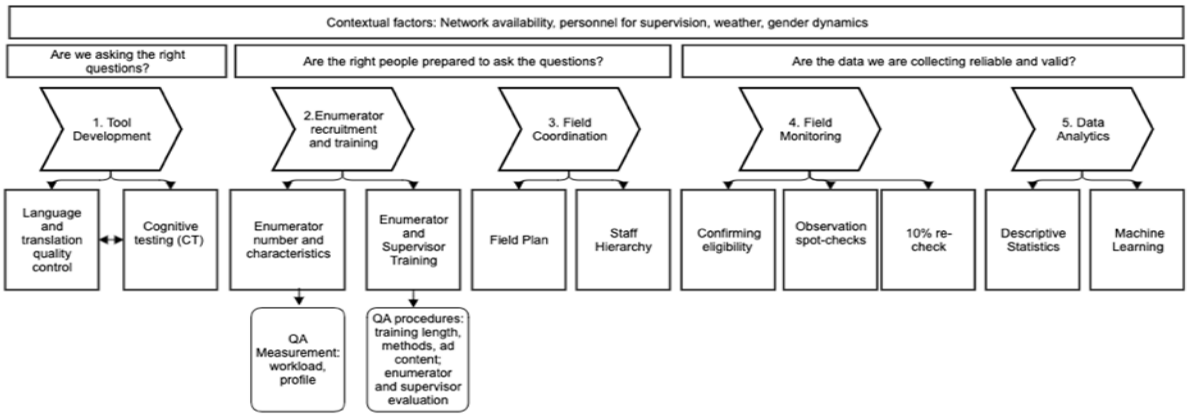
Data quality:

The research team has extensive prior experience conducting health services surveys. The approach to data quality monitoring will start from inception during tool development. Tool development will follow the following steps: 1. Survey draft based on use as intended and effective use for the routine immunisation programme, literature, and/or expert review; 2. Translation; 3. Pilot testing; and 4. Computer-assisted personal interviewing (CAPI) checking. For the provider survey, the absence of validated questions will necessitate the addition of a step on cognitive interviewing[1] (ref). Cognitive interviews aim to enhance the content and translation of questions to ensure they are understood as intended by both researchers and enumerators with varying levels of literacy, life experience, world views, etc.

[1] Kerry Scott, Dipanwita Gharai, Manjula Sharma, Namrata Choudhury, Bibha Mishra, Sara Chamberlain, Amnesty LeFevre (2020). **Yes, no, maybe so: the importance of cognitive interviewing to enhance structured surveys on respectful maternity care in northern India** *Health Policy and Planning*, Volume 35, Issue 1, February 2020, Pages 67–77, https://doi.org/10.1093/heapol/czz141

Once the survey tool is developed, the research team will work with faculty collaborators from the KSPH to identify and train survey enumerators. This training will include sensitization on gender and social inclusion analysis and gender-sensitive research methods. Senior members from the research team at HealthEnabled will attend the training and early period of implementation. This process of senior researcher engagement in the day to day training and implementation will ensure data quality and fidelity of survey implementation. During the period of training, we will additionally explore the feasibility of adding time-stamps to key survey questions. This will allow for the monitoring of enumerator survey implementation and identification of outliers ranging from questions administered too quickly or too slowly.

Figure 1. Overview of quality assurance processes



Beyond the development of the tool and enumerator selection and training, the quality of data is improved by strong field coordination. Field coordination is built on two main components: field and logistics planning as well as coordinating the monitoring of data collection through supervisors and checks. The research team will work with KSPH to develop protocols for field coordination and monitoring at five levels of field hierarchy: 1. Enumerator level; 2. Immediate field supervisors; 3. Coordinators; 4. Field-level data quality supervisor; and 5. Back-end data quality supervisor. As part of efforts to monitor survey implementation, the research team will define parameters for confirming the eligibility of respondents, and conducting observation spot-checks of survey implementation. If budget allows, we will also plan for a second stage of reliability monitoring via a 10% resample of the survey.

Apart from field level coordination and monitoring, routine data analytics will be carried out throughout field work with a focus on: 1. Descriptive analyses; and 2. Outlier analyses. Descriptive analyses will focus on the conduct of basic frequencies across all questions in the survey with the aim of ensuring that questions are not being unexpectedly skipped, and/or that there are not anomalies (e.g. incorrect unique identifiers or ineligible respondents). The outlier analysis aims to identify anomalies in the data which could indicate gaps in quality.

<u>Data analysis</u>:

Implementation strength will be assessed at the Health Area level (unit of randomization and implementation) based on Health Zone survey and secondary analyses of program data, namely Vaccination strategy – outreach or fixed (past vs. updated), Identification of previously missed settlements/ children, Target population estimate (denominator- past vs. updated) and use of mobility data to update monthly or annual targets (provided monthly revision takes place).

Qualitative data analysis will start in the field through the debriefs using a domain specific framework (domains as the rows, interviews or observations as the columns). The framework will be regularly reviewed during data collection by reading across the rows to identify areas of divergence or convergence by domain. In depth analysis will take place after data collection, wherein the interviews will be recorded, transcribed and translated, and will be coded and analyzed alongside the observation notes in NVivo 12 using Grounded Theory with a thematic framework approach.

Qualitative data collection will require a minimum team of four:

- two qualitative researchers (with gender balance)
- a research coordinator (who will also collect some data)
- research lead (not based in country the whole time)

Initial analyses of observations and in-depth interviews will occur through daily debriefings which are embedded into the schedule for data collection. Debriefings will yield preliminary findings which will be in turn, presented during a Workshop with the full research and implementation team. Debriefings will be carried out using a framework, in google sheets wherein the rows consist of the domains explored in the IDIs and the consent scripts. Each respondent will be assigned a row in the spreadsheet and notes from the interview will be used to fill out the cell related to each respondent's statements for each question/domain in the interview. This will enable daily examination of response trends, themes, and areas where revision to the interview guides are required. Audio recordings will be transcribed and translated into English. A Codebook will be developed to code the transcripts in preparation for analysis in Nvivo. The first ten interview transcripts will be coded by two separate qualitative analysts for consistency and to clarify and updates needed to the Codebook. The analysis will be conducted using Grounded Theory in Nvivo. The results will be synthesized and summarized with illustrative quotes alongside relevant study aim quantitative analyses.

Ethical clearance

This study is considered Human Subjects Research and as such we will be sure to uphold all of the ethical requirements for such research to respect the dignity, privacy, and confidentiality of research participants. The risk to participants is low. Participation in the study will be voluntary. The research participants will primarily be health administrators and officers working on the EPI program within the health system in DRC. A description of the purpose of the study will be provided and full informed consent will be obtained from participants prior to enrollment in the study. All data will be deidentified to protect the identity of respondents. All conflicts of interest will be declared. The study has been reviewed and approved by the Kinshasa School of

Public Health Internal Review Board and will be submitted for registration for an International Standard Randomised Controlled Trial Number and be registered at www.isrctn.com.

PROJECT MANAGEMENT PLAN

HealthEnabled under the leadership of Patricia Mechael and Musha Kalailizi will serve as the overall research coordinators and liaise with the Kinshasa School of Public Health (KSPH), EPI Research Unit, the intervention team for M4H, and Gavi, the Vaccine Alliance. HealthEnabled has engaged with the KSPH to co-design the study, lead the fieldwork data collection and to analyze and publish the results. KSPH has appointed a Principal Investigator (PI) at a Full Professor Level, who will be responsible for carrying out the study in accordance with the research protocol and will represent the KSPH team in stakeholder meetings. A research team of a Qualitative Researcher (Associate Professor Level), 2 Qualitative Data Collectors, a Statistician and team of survey enumerators, and a Health Economist (Associate Professor Level), will assist the PI. Kinshasa School of Public Health will hold monthly meetings with HealthEnabled and EPI Research Steering Committee to share the progress of activities. Due to a recent death of KSPH's lead health economist, we will engage with the Digital Health Evaluation Network for support and capacity building/ mentorship on the secondary analysis of coverage survey data, intervention strength survey, and the cost-effectiveness components. The study will be coordinated in collaboration with the Research Steering Committee from the EPI. The role of this steering committee in this study will be to approve the study protocol, facilitate the research team to access health zones and health areas and monitor survey implementation processes.

Timeline

Evaluation activities will be carried out from Q1-2020 to Q4-2022 or into early 2023. This timeline assumes intervention implementation can happen in 2021 and/or early 2022 and that a 12-month period of implementation is required prior to endline immunisation coverage surveys. In light of field realities with the Covid-19 pandemic and in an effort to avoid further delays, the research team will use MICS and current coverage survey data for baseline immunisation coverage rates. These data will be used with other available data to facilitate sampling and stratification required for the intervention strength survey. All other activities are outlined in the timeline below. The target will be to publish one peer-reviewed paper.

Activities	Actors	Q4 2021	Q1 2022	Q2 2022	TBD 2023 (12 months after routine immunisation)
Protocol registration	HealthEnabled				
Baseline immunisation coverage survey secondary analysis	KSPH w/ DHEN				
Draft of 1. intervention design/ development interview guide	HealthEnabled w/ KSPH				
Programme Data Matrix Development & Implementation	HealthEnabled w/ KSPH & DHEN & M4H				
Draft of Direct Observation & Key Informant Interview Guides for Sharing & Use of M44 Data	KSPHw/ HealthEnabled				
Draft of Intervention Strength Survey for Health Zones Microplanning	KSPH w/ HealthEnabled & DHEN				
Implementation of M4H for planning research components	KSPH with HealthEnabled				
Data Analyses for M4H data creation and use of M4H for planning research components	KSPH with HealthEnabled & DHEN				
Site stratification of Health Areas for intervention strength in routine immunisation based on Programme & Planning Data analyses	KSPH & DHEN/ HealthEnabled				
Intervention strength survey implementation in Health Areas for data use for routine immunisation service delivery and monitoring	KSPH w/ HealthEnabled				
Gender intervention Rapid Ethnography	KSPH w/ HealthEnabled				
Intervention strength survey & complementary qualitative data analyses and write-up	KSPH w/ HealthEnabled and DHEN				
Ppt development and presentation to key stakeholders (preliminary findings)	KSPH w/ HealthEnabled and DHEN				
Prospective tracking of program costs	Intervention teams w/KSPH				
Final program costs provided	Intervention teams w/KSPH				
Secondary analysis of coverage survey data w/ intervention strength and programme data	KSPH w/ DHEN				
Modeling of lives saved based on survey coverage data	KSPH w/ DHEN				
Ppt development and presentation to key stakeholders (complete findings- English & French)	KSPH & HealthEnabled w/ DHEN				
Report of complete findings (English & French)					
Peer review manuscript	KSPH & HealthEnabled w/ DHEN				