STUDY PROTOCOL

"Marklate don cam: Scaling bundled health services in rural Sierra Leone"

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Implementation Partners: Ministry of Health of the Government of Sierra Leone, Concern Worldwide

Country: Sierra Leone

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Summary: This document contains the design and analysis plan of a Cluster Randomized Controlled Trial (RCT) evaluating the effect of a program implemented by the Ministry of Health and consisting of the door-to-door delivery of a bundle health products and services in remote rural communities in Sierra Leone. The bundle will be delivered by Health Outreach Teams, and it will contain of (i) routine child immunizations (including malaria), (ii) Vitamin A, IPTi and deworming, (iii) ORS/Zinc co-pack, (iv) HPV vaccine, (v) chlorination tablets for water purification. Products (i) – (iii) will be offered to children under the age of 5, product (iv) will be offered to girls age 10 – 17 years, and product (v) will be offered to households with children under the age of 5 and/or girls age 10 – 17 years. In the short term, the primary aim is to evaluate the impact and cost-effective of this model of delivery on uptake and use of health products and services amongst the rural poor in Sierra Leone. In the longer-term the objectives are: a) to evaluate the impact of increased access to healthcare across rural communities on well-being, with a focus on child health and cognitive development, accumulation of human capital, maternal health, households' wealth, and labour productivity; b) to evaluate spill-overs of well-being to siblings, other cohorts, and adults, and the general equilibrium effects in the education and labour markets over children's life cycles; and c) to develop a generalizable and scalable approach to improving health and well-being through increased access to healthcare. This document includes recruitment strategies and sampling, describes roles and responsibilities for implementation and evaluation, the defines the outcome variable definitions and analysis strategy. We note that we anticipate potentially carrying out additional analyses to assess long run impacts; this document is not intended to be comprehensive or to preclude additional analysis.

Contents

Study Overview

Title: Marklate don cam: Scaling bundled health services in rural Sierra Leone

Conditions:
Diarrhea, human papilloma virus, malaria, measles, meningitis, pneumonia, polio, rotavirus, tuberculosis, vitamin A deficiency, waterborne diseases, worm infestation, yellow fever

Intervention / treatment:
Delivery of a bundle of vaccines and health products

Other study ID numbers:
NA

1. Contacts and locations

- Sierra Leone: selected study villages in Koinadugu, Bombali, Karene, Falaba, Port Loko, Tonkolili and Kambia District
- England: University of Oxford, Oxford.
- Netherlands: Wageningen University & Research, Wageningen.
- United States: Yale University, New Haven.

2. Extended Study Summary

Background and study aims: In many poor countries, access to healthcare is severely constrained (Albarracín et al., 2024). In Sub-Saharan Africa, 150 million people are over one hour away from the nearest health centre. In more remote areas, the poor state of the infrastructure and the limited options for motorised transport, combined with endemic poverty, make access even more challenging (Falchetta et al., 2020). In Sierra Leone, one of the poorest countries in the world, it takes the equivalent of one week of income for the average person residing in remote rural communities to reach a health facility (Mobarak et al., 2022).

Fiscal constraints in many poor countries have worsened since the COVID-19 pandemic (The Economist, 2023), limiting funding to increase access through the *expansion* of healthcare infrastructure. It is thus important to develop innovative and cost-effective solutions that expand the reach of the *existing* health infrastructure.

This project assesses the impact and cost-effectiveness of a door-to-door healthcare delivery campaign by the Ministry of Health (MoH) of Sierra Leone. In 250 communities, Health Outreach Teams (HOT) deliver child immunizations, the HPV vaccine, and other health products. We

compare uptake and, ultimately, health outcomes to 200 communities randomly assigned to control status.

We build on previous work in Sierra Leone, where we demonstrated that expanding access can increase healthcare uptake at a low cost. Using a cluster-randomised controlled trial, we showed that, within two-three days, 'last-mile' delivery of health services through mobile vaccination teams resulted in a fivefold increase in vaccination rates for COVID-19 (Meriggi et al. 2024).

An immediate implication is that it would be much more cost-effective to deliver a bundle of useful health services and products simultaneously on that same trip. With MoH, we co-developed a health bundle that aims to provide large potential gains to health in rural communities. We focus on routine immunizations and HPV, for which in rural Sierra Leone vaccine rates are below WHO target rates. In addition, poor water quality and associated diseases severely affect these populations.

A key question is whether expanding the set of health products offered through outreach can yield high impacts while maintaining a high level of cost-effectiveness. In the short term, the primary aim is to develop and evaluate cost-effective solutions to increase access to health care amongst the rural poor in Sierra Leone.

In the longer-term the objectives are: a) to evaluate the impact of increased access to healthcare across rural communities on well-being, with a focus on child health and cognitive development, accumulation of human capital, maternal health, households' wealth, and labour productivity; b) to evaluate spill-overs of well-being to siblings, other cohorts, and adults, and the general equilibrium effects in the education and labour markets over children's life cycles; and c) to develop a generalisable and scalable approach to improving health and well-being through increased access to healthcare.

The current registration focusses on the short run effects. We expect to upload an additional registration for the longer run effects.

Who can participate?

The research will include households in 450 remote villages in rural Sierra Leone, across 7 districts: Koinadugu, Bombali, Karene, Falaba, Port Loko, Tonkolili and Kambia. Within these villages the program prioritizes "project households": (i) households with teenage girls (age 10-17), and (ii) households with children under 5.

What does the study involve?

Villages are randomly allocated to the treatment group or the control group. The control group receives no intervention. Villages in the treatment group receive a visit by a Health Outreach Teams (HOTs) of the Ministry of Health that will organize a community meeting and will visit each home of project households deliver a bundle of health services and products to rural communities. The bundle will include: (i) Routine child immunization (BCG, Polio, DTP-HepB-Hib, Pneumococal, Rotavirus, MR, Yellow Fever, Malaria) targeted to children under the age of 5, (ii)

Health products including deworming, Vitamin A, IPTi , ORS/Zinc targeted to households with children under the age of 5, (iii) HPV immunization targeted to girls age 10 – 17, (iv) Chlorine tablets for water purification targeted to households with children under the age of 5 and/or girls age 10 – 17. Project households will received a supply of 3 months of ORS/Zinc and Chlorine tablets. Treatment communities will be visited three times, with 3 months in between.

What are the possible benefits and risks of participating?

The potential benefits of this project are large. As part of the sensitization sessions, participants will receive information about vaccine and health product use, effectiveness and safety. This information conforms with health authority guidance. Information and increased access to the health bundle, should increase the uptake of vaccines and use of health products, and reduce the likelihood of infections, disease and increase health outcomes. Society at large benefits due to reliable causal estimates of the cost-effectiveness and benefits of the bundle, which informs public health campaigns.

Potential risks relate to privacy risks and psychological and reputational risks if members of the households' local community learn about information such as the prevalence of diseases and related symptoms in their households. There is minimal physical risk to participants from this study, except minimal risks associated with specific vaccinations and health product over use. There might be stigma attached with participants' choice to get vaccinated. The study will maintain the confidentiality of any information provided by participants. There are no anticipated risks beyond the ordinary for participants in this study.

Where is the study run from?

This study is running in 450 selected villages across 7 Districts in Sierra Leone and is coordinated by University of Oxford, Wageningen University, and Yale University, and implemented in coordination with the Ministry of Health in Sierra Leone and Concern Worldwide.

When is the study starting and how long is it expected to run for?

Short run effects are captured between November 2024 to November 2025. It is our ambition to track long run impacts for at least 10 years (subject to availability of funding).

Who is funding the study?

The study is funded by Givewell, the International Growth Centre and the Mercury Project at the Social Science Research, which received funds from the Rockefeller Foundation and the Bill & Melinda Gates Foundation.

Who is the main contact?

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3. Participation criteria

4.1. Description

Inclusion criteria

We primarily focus on households in rural communities that have either (i) least one child under 5, and/or (ii) at least one girl aged 10-17. We will refer to these households as "project households" hereafter.

A household is defined as a group of people who have usually sleep in the same dwelling and taken their meals together for at least 9 of the 12 months preceding the interview (except for infants). If there is any ambiguity (e.g. children of the household head who have been studying another district in the last year), we consider the household members are part of a single financial unit to determine whether they are part of the household.

Inclusion criteria for health intervention activities (led by the MoH and CWW). Inclusion criteria are set by MoH:

- All members of communities assigned to treatment condition in our study are eligible to receive relevant information through participation in a sensitization/information campaign implemented at the community level
- Project households:
    - Where children under 5 are eligible to receive Routine child immunization and deworming, Vitamin A, IPTi ORS/Zinc:
    - Girl age 10 – 17 are eligible for HPV vaccine
- Both types of households areeligible to receive Chlorine tablets.

Inclusion criteria for research activities (led by the research team):

- All individuals aged 18 or older residing in study communities are eligible to be interviewed in the census. Respondents must consent to the survey.
- All individuals aged 18 or above from project households are eligible to be interviewed for subsequent surveys. In addition, we include on a sample of upto 20 non-project households. Information pertaining to the vaccination status of teens and children and/or the use of health products (ORS/Zinc, IPTi, Vitamin A supplementation, chlorine and deworming) will be collected from the caregivers. Respondents must consent to the survey.

Exclusion criteria

Exclusion criteria for health intervention activities (led by the MoH and CWW). Exclusion criteria are set by MoH.

For health products:

- Project households where caregivers do not consent to receive health products.

For Vaccines

- Eligible Children whose caregivers do not consent
- Children outside the eligible age range.
- Children under 5 are not eligible to receive vaccines
- Girls aged 10-17 are not eligible to receive the HPV vaccine.
- Children in the eligible age range who may experience sever adverse effects from the vaccination due to co-morbidities or other exclusion criteria set by MoH.

Exclusion criteria for research activities (led by the research team):

- Non-consenting survey respondents.

4.3. Sexes eligible for the study

All

4. Intervention

The Sierra Leone Ministry of Health will deploy Health Outreach Teams (HOT) for a door-to-door delivery of a bundle of child immunizations, HPV vaccination for teenage girls, and health products. HOTs will visit communities three times, 3 months apart. In this section we describe the activities carried out in communities assigned to treatment. All these implementation activities are carried out by the MoH and CWW.

The campaign will be carried by a mobile HOT based at health facilities. The HOT will consist of social mobilizers , a trained nurse and a MoH-approved data-clerk. Social mobilizers are trained by the MoH to disseminate information about the health products and services. Nurses are specialized in administration of vaccines and distribution of health products and services. Data-clerks register beneficiaries and issue their vaccination cards. The team will travel to the communities from the health facility (which we estimate takes about a day), primarily using motorbikes and carrying all vaccines and health products stored in appropriately cooled containers.

The intervention will roll out as follows. Social mobilizers travel to the communities and meet with village leaders to explain the goal of the campaign. This communication strategy is complemented by an endorsement from higher authorities (such as the Paramount Chief and District Medical Officer - representing respected and well-known informal and formal institutions). They will contact village leaders to express their support for the project and request cooperation from village authorities.

After granting their support, village leaders will be calling a community meeting. During this community meeting, social mobilizers will conduct sensitization of the village population. All

residents of the community are eligible to attend this meeting. All households in the community with children under 5 and/or girls aged 10-17 (ie project households) will be specifically invited to the meeting. The objective of this meeting is to inform the community members about the door-to-door campaign. During this meeting, the social mobilizer will provide information about the vaccines and health products in the bundle (including their benefits and risks), and they will answer any questions from attendees.[1] This may include information on the importance of drinking clean water, the dangers of diarrhea (especially for children under 5), the importance of vaccines, and any address concerns about the bundle that the household residents may have. The community sensitization will take place at the *court barry*[2] or another central location within the community.

After the sensitization meeting, the HOT will visit each project household in the community to deliver more information and the relevant health products/services contained in the bundle to project households.

- For project households with children under 5 years old: the team will check the vaccination cards to determine the vaccines that children already have and what doses are due. If the caregiver of the child consents, the HOT will vaccinate the children under 5 with missing and due routine immunizations, administer deworming pills, supply Vitamins A drops, and distribute appropriate dosages of ORS/Zinc co-packs and chlorination tablets.[3]
- For project households with girls 10-17 years old: HOTs will check the vaccination cards to determine if HPV vaccine is due, give the HPV vaccine if the caregiver consents and provide chlorination tablets. Project households will receive a supply of chlorination tablets and (if relevant) ORS/Zinc co-packs and enough for 3-4 months. The vaccinators will also talk to the caregivers of children about when the next vaccine dose is due and where and when they should take their children to receive the required doses of immunization (i.e. the clinic closest to their community).
- The HOT will also inform the households they will return after 3 months.

4.1 Main research question

Our primary research question are:

For short run impacts:

[1] Social mobilizers will follow verbatim a pre-specified script during the sensitization meeting. This script will also include a section with frequently asked questions (FAQ) that the social mobilizers will use to answer questions from the meeting participants. If a question is not included in the script or in the FAQ, social mobilizers direct participants to the medical staff of the HOT for individual consultation.

[2] Open space or building used by communities to meet regularly in a central location in the village.

[3] We will distribute enough chlorination tablets such that, if used correctly, they are enough for three-four month's supply of treated water (for drinking and cooking) for a family of five.

- What is the impact of extending access to healthcare through community outreach with a bundle that includes routine child immunizations, deworming, Vit A supplement, HPV vaccine, chlorination tablets, and ORS/Zinc co-packs on the uptake of these products?

- What is the cost-effectiveness of extending access to healthcare?

The current registration focusses on the short run effects. We expect to upload an additional registration for the longer run effects. For long run impacts our research questions are:

- What is the impact of extending access to healthcare through community outreach on child health and cognitive development, accumulation of human capital, maternal health, households' wealth, and labour productivity.
- What is the impact of extending access to healthcare through community outreach over the longer run**?**

4.2 Study hypothesis

For short run impacts:

Primary Hypothesis:
H1: Access to bundled health services through community outreach increases coverage of health routine child immunization, HPV, and health products for young children

H2: Access to bundled health services through community outreach increases the availability and use of chlorine for water treatment

Secondary Hypotheses:

SH1: Access to bundled health services through community outreach increases use of ORS/Zinc to treat diarrhea amongst children by project households
SH2: Access to bundled health services through community outreach increases knowledge of vaccines and health products
SH3: Access to bundled health services through community outreach improves attitudes toward vaccines and health products
SH4: Access to bundled health services through community outreach decreases the incidence of malaria for children under 5 in eligible population
SH5: Access to bundled health services through community outreach decreases the incidence of diarrhea for children under 5 in project households
SH6: Access to bundled health services through community outreach decreases the incidence of diarrhea amongst children above 5 and adults in project households
SH7: Access to bundled health services through community outreach increases use of ORS/Zinc to treat diarrhea amongst children above 5 and adults in project households

SH8: Access to bundled health services through community outreach decreases the incidence of malaria amongst children above 5 and adults in project households
SH9: Access to bundled health services through community outreach decreases the incidence of diarrhea in non-project households
SH10: Access to bundled health services through community outreach decreases household curative health expenditures
SH11: Treatment effects (across all primary and secondary outcomes) are larger for villages further away from health facilities.

The current registration focusses on the short run effects. We expect to upload an additional registration for the longer run effects. For longer run impacts our (combined) hypothesis are: Access to bundled health services through community outreach to increase vaccine demand, child health, cognitive development, the accumulation of human capital, maternal health, labour productivity and household wealth.

4.3 Data

Survey data

This study primarily leverages data collected from surveys to conduct the analysis. In the first wave of data collection, we utilize several instruments to collect the required data, each with different sampling strategies. All these surveys are under the responsibility of the research team.

In all villages:

1. Chief survey: This is completed on arrival of the survey team in the community and its purpose is to get basic information about the community. This survey includes questions like how many people live in the village, whether the village has a school, the location of te nearest health facility, and the general sentiment about vaccines in the community. The enumerators also record the boundaries of the community in this survey.
2. Census survey: the main purpose of this survey is to get a listing of every household residing in the community and to identify project households.[4] It is carried out both in communities assigned to treatment and in communities assigned to control. In this survey we collect demographic information (i.e. population, age, occupation, marital status) of each community member. Among project households, this survey is used to capture basic outcomes such as vaccination of children, water quality, healthcare received by children, and prevalence of diarrhea in children.

[4] A household is defined as a group of people who have usually sleep in the same dwelling and taken their meals together for at least 9 of the 12 months preceding the interview (except for infants). If there is any ambiguity (e.g. children of the household head who have been studying another district in the last year), we consider the household members are part of a single financial unit to determine whether they are part of the household.

3. Baseline survey: this survey is asked to 20 project households[5] that are randomly selected by the research team from all project households as identified in the census listing. This is a more in-depth survey including questions about household assets, food security, child investment[6], vaccine knowledge, intention to use products in the health bundle, and chlorine use.[7] We also target 10 non-project households.
4. Distance survey: This questionnaire seeks to understand where the nearest health facilities are, how long it takes the get there, and how much it costs. This survey is asked to motorbike drivers and mothers identified during the household listing[8], as they are most likely to visit health facilities for healthcare of children.
5. Endline survey: In this survey, enumerators return to households from the baseline survey. This instrument captures many of the same questions about vaccine knowledge, attitude, hesitancy and intention to assess the impact of the intervention. We also target 10 non-project households.

In treatment villages only:

1. Attendance survey: as households arrive at the sensitization session, the enumerator team will take a register of all those which are present. During the census survey, each household is given a unique voucher which enables the enumerators to verify which families have indeed attended the sensitization in this survey.
2. Exit survey: this survey is conducted immediately after the intervention is delivered to each project household. It records which vaccinations each child received and the other items from the bundle the household received.
3. HOT survey: a brief survey of each HOT member to capture characteristics and reflection of the visit to each village. The team asks this survey after the door-to-door visits are completed. With this questionnaire we record demographic information and vaccine perception from the HOT members. We also ask information about the quality of the delivery, the topics discussed during the HOT visit, and the doses delivered from each vaccine

In Control villages only

1. Mini Census: To record of any each child in project households received any vaccines during the prior 3-4 days. To records if any project households acquired any health products during the prior 3-4 days. This survey just repeats the relevant sections of the census instruments.

Administrative data

[5] If there are less than 20 project households in a community, all project households are included in the baseline survey. For example, if there are only 17 project households, 17 households will be included in the baseline survey.

[6] This includes how much money is spent on each child's education and healthcare (when a child falls ill), how much time is parents spend helping children with their education, how much time children spend doing chores and whether this impacts school attendance and how hard children work at school.

[7] Enumerators use test strips to verify the presence of chlorine in the household's drinking water.

[8] Motorbikes or *okadas* are the most common mode of transport in rural Sierra Leone.

To verify the accuracy of the vaccination status data recorded in the census and mini-census, we ask for permission of care givers to access vaccination records in the Expanded Program on Immunization (EPI) of the Ministry of Health. To verify the accuracy of the exit survey, we ask for permission of care givers to access the administrative records of the HOT. MoH will then provide vaccination status data of the consented study participants. The study team will only receive data of consented respondents (ie of teens or children for which the caregivers consented).

Data protection

MoH will link consented study participants to information about vaccination status in their records. The study team will only receive data of consented respondents (ie of teens or children for which the caregivers consented). There are minimal risk of violation to privacy. We are conducting a Data Protection Impact Assessment (DPIA). As part of the process, we are gathering expert feedback (with local and international experts) on the assessment of risk sources and nature of potential impact on individuals (in general and specific to this case).

4.4 Tracking households and children across surveys

We distribute invitation vouchers and wristbands to keep track of the households and children across the different surveys (see an example in appendix A.3.). During the census survey, project households located in communities assigned to treatment will receive an invitation to the sensitization meeting. This invitation has a unique randomly generated ID for each household. Before the sensitization meeting, as enumerators conduct the attendance survey, they will ask the attendant for their invitation voucher. If they have one, they will enter the ID into the survey and use it to pre-load the household information and confirm the identity of the respondent.

Similarly, during the census survey enumerators will distribute wristbands to every child that can benefit from the vaccination (i.e. children under 5 and girls aged 10-17). If the child is not present during the survey, the wristband is handed to the caregiver of the child. Each wristband has a unique ID at the community level. During the exit survey, enumerators will ask if the child has a wristband and, if so, they will use its ID to preload the child's information and confirm their identity.

The purpose of the invitations and wristbands is solely to keep track of the identity of study participants. None of this are required for the participants to be able to attend the sensitization meeting or to benefit from the bundle delivery.

4.5 Timeline of activities

Table 1 provides an overview of the intervention and data collection activities carried out by the research team and the HOT. Enumerator Teams (ETs) travel to the communities on Day 1.

As soon as they arrive, they communicate with the community leader and ask for their approval for the data collection. If the community leader approves, the enumerators implement the chief survey.

The data collection continues on Day 3 and Day 4 with the census of the community. Every community resident is recorded in this instrument. Once the census is completed, the research team randomly selects respondents for the baseline and distance survey. Specifically, the 20 project and upto 10 non-project households for the baseline survey, and 3 motorbike riders and 3 mothers for the distance survey. The teams complete the baseline and distance survey between Day 4 and Day 5.

Up until this point, these activities are the same across communities assigned to control and treatment.

On Day 5, in treatment communities, the research team will use the census data to inform the HOT about the number target population. The HOT will stock up with health products and vaccines, and travel to the community. The intervention is delivered between Day 5 and Day 7. After all baseline surveys have been completed, the HOT conducts a sensitization meeting on Wednesday afternoon. During this meeting, the enumerator team completes the attendance survey to record the identity of the households who went to the meeting.

The door-to-door delivery of the bundle will begin after sensitization, approximately between Day 6 and Day 7. The visit of the HOT starts with a short version of the sensitization script and continues with the delivery of the health bundle. Concurrently, the ET will record the exit survey among beneficiaries. The endline survey is completed after the exit survey among every household that completed the baseline survey.

After the HOT finishes the delivery, they complete the HOT survey that gathers information on their background, challenges in implementation, and overall impression on the delivery activity.

In control communities, enumerators conduct the mini census and endline survey between Day 6 and Day 7. The mini census is carried out in all project households. After the mini census is completed, the enumerators proceed with the endline survey among households that completed the baseline.

Table 1 Timeline of intervention and survey activities

<table>
<tr><th colspan="2">Team & Community</th><th>Day 1</th><th>Day 2</th><th>Day 3</th><th>Day 4</th><th>Day 5</th><th>Day 6 and 7</th></tr>
<tr><td>Health Outreach team (HOT)</td><td>Treatment</td><td colspan="3"></td><td>Travel</td><td>Sensiti-zation meeting</td><td>Door-to-door bundle delivery</td></tr>
<tr><td>Enumerator team (ET)</td><td>Treatment</td><td>Travel and chief survey</td><td>Rest day</td><td colspan="2">Census survey</td><td>Baseline survey</td><td>Atten-dance survey</td><td>Exit + HOT Survey survey</td></tr>
</table>

					Distance survey	Endline survey
	Control				Baseline survey	Mini census
					Distance survey	Endline survey

4.6 Roadmap

The bundle will be delivered three times, first during November 2024 - January 2025, and then again three and six months later. The items in the bundle and delivery mechanisms will remain the same in these visits. The survey data will differ in the second visit: the census, baseline, and endline survey will become one follow-up survey asked to every project household identified during the first visit. This survey will include the same questions as the baseline surveys, and additional questions on the use of health products, visits to health facilities, and health outcomes of the prior three months.

5. Experimental design

6.2. Arms and interventions

Participant group / arm	Intervention / treatment
Experimental: delivery of the bundle	Door-to-door delivery of under-five routine immunization, HPV vaccine, and distribution of health products (chlorination, deworming, ORS/Zinc co-packs, IPTi and vitamin A supplements)
No intervention: usual care	

6. Sampling frame and randomization procedure

7.1 Sampling frame

The research team worked closely with the MOH and CWW to determine the sampling frame. The study is implemented in seven of the sixteen districts of Sierra Leone (Koinadugu, Bombali, Karene, Falaba, Port Loko, Tonkolili and Kambia District) some of which have the highest number of zero-dose children. In these seven districts CWW has been supporting MOH clinics. Within these districts:

1. As starting point we (i) use the list of all communities in the 2015 Sierra Leone census that fall in the 7 study districts (Bombali, Falaba, Kambia, Karene, Koinadugu, Port Loko, and Tonkolili), and (ii) we surveyed all listed health facilities (which come in three types CHC, MCHP, CHP), in these districts and presented them with a list of communities the census listed as being within 10km of the clinic. From this list, the facility cross checked which communities were part of their catchment area, OR SERVICED?. Clinic staff then also provided the names of any further communities within its catchment OR SERVICED? that had not been provided in the preloaded census list.
2. We then did a record linkage between the communities in the health facility survey, and communities in the Sierra Leone census. For communities selected from the preloaded list, this was straightforward. However, the ”additional” communities required fuzzy merging. We aimed to prevent the chance of false positives (ie to avoid sending MoH teams to places that do not exist (anymore). Almost 90% of these names could not be matched to a census community. This represented about 30% of all communities within clinic catchments.
3. We then filtered the list of census communities according to whether they had been mentioned by at least one health facility. Any duplicate communities, communities that were not directly mentioned by an interviewed facility.
4. We also dropped small communities, for which the census or health facility survey mentioned they contained fewer than 100 people, or temporary mining camps.
5. For each of the remaining communities, we computed the minimum euclidean distance to a health facility.
6. We filtered out any communities that were either within 2 miles of a health facility, or further than 10 miles.
7. We separated the remaining communities into categories based on distance to their nearest health facility. We found that the majority of communities lay between $2 - 5$ miles, with a median of 2.73 miles for communities in this category. We therefore split communities into categories of $x < 2$, $2 \leq x < 2.73$; $2.73 \leq x < 5$; $5 \leq x < 10$; and $x \geq 10$, where x denotes the distance in miles to the nearest health facility.
8. We then performed density-based clustering (DBSCAN) across all remaining communities, with a maximum distance of 1.8km and a minimum cluster size of a single community. For clusters containing more than one community, we filtered out all but the largest community by census-recorded population.
9. We computed strata by finding the intersection of a community's district, distance category, and the type of health facility (CHC, MCHP, CHP) the community was closest to. Communities ≥ 5 miles from their 4 nearest clinic were relatively sparse, so communities in this category were not further stratified according to nearest clinic type. There are 3 clinic types in Sierra Leone, and we used 3 different categories of distance to clinic, meaning that there were $(3 * 2) + 1$ strata per district, with 7 study districts, and therefore 49 strata overall.

7.2 Randomization procedure

After determining the sampling frame, the research team used a block random assignment procedure to assign eligible communities to treatment and control.

1. Communities that were randomised into either replacement control or replacement treatment groups were assigned a random priority order. Information regarding replacement communities is only accessible to research professionals working on the project. If and when a community initially sampled for the study is rejected as inappropriate, the research professional should consult this list to find, for communities within the same implementation cluster and of the same treatment assignment, the next highest priority community. By sampling a large number of replacement communities, we hope to avoid scenarios where an urgent second randomisation is necessary.
2. Amongst communities assigned to either treatment or control groups, we k-medians clustered communities at the district level into 9 clusters in order to compute implementation clusters for 9 HOT and enumeration teams. These also serve as replacement for our replacement algorithm.
3. When enumerators arrive in a village they do a quick stan of the number of structures. Of Community X has less than 20 structures, it is deemed too small, and is replaced with the first next village from the replacement list.

In total we assigned 203 communities to control and 252 to treatment.

7. Outcomes

8.1 Primary Outcome Measure

For H1: Verified vaccination status for routine childhood immunization, HPV and health products or young children (Vit A ,Deworming, IPTi) amongst the eligible population, measured using vaccine cards, at baseline, 3 and 6 month follow-up)

For H2: The availability or verified use of chlorine amongst the project households, measured using household surveys and chlorine strips at baseline, 3 and 6 month follow-up.

8.2 Secondary outcomes

For SH1: Reported use of ORS/Zinc to treat diarrhea amongst children 0 to 5 years in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH2: Knowledge of vaccines and health products score amongst adult caregivers in project households, measured using a survey based knowledge index at baseline, 3 and 6 month follow-up.

For SH3: Attitudes toward vaccines and health products score amongst adult caregivers in project households, measured using survey based attitude index at baseline, 3 and 6 month follow-up.
For SH4: Reported incidence of malaria amongst children 0 to 5 years in eligible population, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH5: Reported incidence of diarrhea amongst children 0 to 5 years in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH6: Reported incidence of diarrhea amongst children above 5 and adults in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH7: Reported use of ORS/Zinc to treat diarrhea amongst children above 5 and adults in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH8: Reported incidence of malaria amongst children above 5 and adults in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH9: Reported incidence of diarrhea in non-project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.
For SH10: Reported household expenditures on curative health expenditures in project households, measured using survey question (yes/no) at baseline, 3 and 6 month follow-up.

Outcomes for longer run analysis will be specified as part of a separate registration at a later stage.

To assess cost-utility we will calculate DALY and QALY under different scenario simulations (see SAP).

Outcomes for longer run analysis will be specified as part of a separate registration at a later stage.

8.3 Measurement strategy

For vaccine status and health product uptake:

Outcome Measure	Measure Description	Time frame
BCG: indicator variable representing whether a child has received the BCG vaccine.	During census, we will use the child's documented vaccination status (eg. vaccination card) to check the vaccines and health products available in the	We record routine immunization for all children under 5. We record this information three ways: (i) during the
OPV: indicator variable representing whether a child has received recommended dose of the Oral Polio Vaccine.		
DPT: indicator variable representing whether a child has received recommended dose of the pentavalent (DPT) vaccine.		

Pneumococcal: indicator variable representing whether a child has received recommended dose of the pneumococcal vaccine.	household. (We also record unverified self-reported vaccines but will use this specification of the outcome as a robustness check.) In treatment villages: During the exit survey, we record the vaccines and health products that children received on the spot. In control villages: in a mini-census record any changes in vaccination status, By due doses we are referring to the doses due at the time of measurement according to the immunization schedule of the MOH. We will use the birth date of a child to determine whether they are due or not for a vaccine or health product.	first data collection visit to the community using the census , exit surveys and mini-census; (ii) three months later during the follow-up visit with later surveys; (iii) using administrative records linking the child to vaccines provided elsewhere. We record health product use and availability for all households
Rotavirus: indicator variable representing whether a child has received recommended dose of the rotavirus vaccine.		
IPV: indicator variable representing whether a child has received recommended dose of the Inactivated Polio Vaccine (IPV)		
RTS-S: indicator variable representing whether a child has received recommended dose of the RTS-S vaccine against malaria		
Yellow fever: indicator variable representing whether a child has received recommended dose of the yellow fever vaccine.		
MR: indicator variable representing whether a child has received recommended dose of measles vaccine. In counting the doses received, we also consider MCV vaccine as the MOH recently changed the vaccination schedule and the MCV was offered to protect the children against measles.		
IPTi: indicator variable representing whether a child has received recommended tablet of the Intermittent Preventive Treatment for infants (IPTi) against malaria.		
Deworming pills: indicator variable representing whether a child has recently taken de-worming pills (in the past 6 months)		
Vitamin A: indicator variable representing whether a child has received their due doses of Vitamin A supplements.		
ORS/Zinc: indicator variable representing whether a child has ORS/Zinc pills available to them		
Chlorine: indicator variable representing whether a child has chlorine pills available to them.		
HPV vaccine: indicator variable representing whether a girl aged 10-17 has received recommended dose the HPV vaccine.	During census, we will measure this by checking the HPV vaccination cards of girls aged 10-17. We also record unverified self-reported vaccines but	We record HPV vaccination for all girls aged 10-17. We record this information three ways: (i) during the first data collection

	will use this specification of the outcome as a robustness check. In treatment communities: the exit survey records the injection of HPV In control communities: the mini-census we record any HPV vaccination status from prior 3-4 days.	visit to the community using the census and exit surveys; (ii) three months later during the follow-up visit with later surveys; (iii) using administrative records linking the girl to vaccines provided in other health facilities.

Health product use

Outcome Measure	Measure Description	Time frame
Chlorine use: indicator variable of chlorine presence in the drinking water of the household. This variable is at the household level in the past three months	We will use chlorine strips to measure whether a household has used chlorine in their drinking water. Enumerators will ask respondents to show them the water that they would normally drink that day and will test for chlorine presence in it.	This will be measured at each visit: (i) in the first data collection visit among all of the project and non-project households surveyed in baseline and endline; (ii) each additional data collection visit.
ORS/Zinc use in project households: indicator variable of whether a child of any age or adult has used ORS/Zinc to treat diarrhea episodes and how often in the past three months ORS/Zinc use in non-project households: indicator variable of whether a child of any age or adult has used ORS/Zinc to treat diarrhea episodes and how often in the past three months	This variable is reported by the caregiver of children under 5 and indicates whether and when they have used ORS/Zinc to treat diarrhea episodes.	This will be measured at each visit: (i) in the first data collection visit among all of the project and non-project households surveyed in baseline and endline; (ii) each additional data collection visit.

Vaccination progression

Outcome Measure	Measure Description	Time frame
Per vaccine uptake	As above	As above
Zero-dose indicator	Indicator variable representing whether a child has received zero-doses out of all of the doses due. This is measured separately for each antigen in the immunization schedule. We only consider verified reports of vaccination using the vaccination cards of children.	We record routine immunization for all children under 5.[9] We record this information three times: (i) during the first data collection visit to the community using the census and exit surveys; (ii) three months later during the follow-up visit with later surveys; (iii) using administrative records linking the child to vaccines provided elsewhere.
Share of doses missed	Number of doses missed as a share of the total doses due for a vaccine. This is measured separately for every vaccine in the immunization schedule. If a vaccine only has one dose (as yellow fever and BCG), this is equivalent to the primary outcome.	
Timeliness of vaccination	Average delay (in days) across all of the doses and vaccines that a child has received.	
Partly immunized	Children that are partly immunized relative to the childhood immunization schedule. This is measured separately for every vaccine in the immunization schedule.	

Knowledge and Attitudes

Outcome Measure	Measure Description	Time frame
Vaccine trust indicator	This is measured as the average across six questions related to trust in vaccines and that go from 0 to 10.	This is recorded during the baseline and endline interviews in the first visit. We also record this each subsequent visit.
Vaccine hesitancy WELCOME?	An indicator variable of whether a caregiver would be willing to get their child vaccinated.	
Vaccine knowledge	Score of questions that ask facts about vaccines.	
Knowledge of health product use	Appropriate use of chlorine and ORS/Zinc	

[9] Even though only children under 5 may benefit from the bundle, we record for all children under 10 as this may allow us to compare vaccination rates of future cohorts in later studies.

Health outcomes

Outcome Measure	Measure Description	Time frame
Diarrhea episodes: number of episodes in the last three months among project and non-project households	Number of diarrhea episodes for each child during the last three month as reported by the caregiver.	We recorded for all children under 10. We ask about this in census during our first visit for data collection and three months later during the follow-up surveys.
Malaria episodes: number of episodes in the last three months among project and non-project households	Number of malaria episodes for each child during the last three month as reported by the caregiver.	We recorded for all children under 10. We ask about this in census during our first visit for data collection and three months later during the follow-up surveys.

Health expenditure

Outcome Measure	Measure Description	Time frame
Curative health expenditure	Household level measure of curative health expenditures over the past 3 months	Recorded in baseline and endline surveys, and any subsequent survey.

Appendix

A.1 Teams and responsibilities

This is a collaborative project with a clear division of labor and responsibilities:

Ministry of Health from Sierra Leone (MoH): the MoH in charge of the national health system in Sierra Leone. The MoH is launching three rounds of a health campaign (vaccinations and the provision of health products) that we evaluate. We will work alongside MoH-trained vaccinators and social mobilizers to oversee the implementation and evaluate the effectiveness of the campaign.

Concern Worldwide (CWW): CWW is an international humanitarian organization that has the goal of delivering lifesaving interventions to the world's poorest and most vulnerable people. It is our implementing partner in this project, and they work with the MoH to carry out the procurement and delivery of vaccines and health products in the communities.

The research team: is responsible for the evaluation of the program using multiple rounds of surveys among participants and non-participants.

The table below outlines the activities and responsible team

More details of each activity can be found in the data collection and intervention sections.

Activity	Description	Team
Sample frame and randomization	Restriction of eligible health facilities and communities to eligible pool. Randomization of eligible communities into treatment or control.	MOH, CWW, and research team
Sensitization meeting	Meeting with community members to discuss about the bundle campaign and questions on the items in the bundle.	MOH and CWW
Door-to-door delivery	Vaccine administration and distribution of health products to the target population.	
Chief survey	Survey asked to the village chief including questions such as the location of the closest health facility and basic demographics.	Research team
Census survey	Listing of every household member from every household residing in the community.	
Baseline survey	Survey to 20 randomly selected project households and 10 randomly selected non-project households with children.	

Endline survey	Survey of the households that were interviewed at baseline.	
Exit survey	Record of vaccination and product delivery to beneficiaries	
Attendance survey	Register of all the participants of the sensitization meeting.	
Distance survey	Survey to caregivers and motorbike riders about distance to the closest health facilities	

A.2. Vaccination schedule by MOH

Vaccine / Health product	Child age													
	Birth	6wks	10wks	14wks	5mo	6mo	7mo	8mo	9mo	12mo	15mo	18mo	22mo	24mo
BCG	**1**													
Oral polio vaccine (OPV)	**0**	**1**	**2**	**3**										
DPT-HepB-Hib (penta)		**1**	**2**	**3**										
Pneumococcal		**1**	**2**	**3**										
Rotavirus		**1**	**2**											
Inactivated polio vaccine (IPV)				**1**										
SP-IPTi			**1**	**2**					**3**					
Measles rubella (MR)									**1**		**2**			
Yellow fever									**1**					
Malaria (RTS-S)						**1**	**2**	**3**						
Vitamin A						**1**				**2**		**3**		
De-worming pills										**1**		**2**		**3**

A.3. Invitation voucher and wristbands

Figure A1 Example of invitation voucher to sensitization meeting

YOU ARE INVITED FOR AN INFORMATIONAL MEETING ABOUT VACCINES AND HEALTHCARE PRODUCTS!

A team of health professionals will visit this community in the next two days. This meeting has been approved by both the Village Headman and the Paramount Chief. You are cordially invited to attend. Please bring this invitation with you. We will have your name on the Check-In list and hope you will come. This invitation is only for you and your household and can not be given to someone else.

Your personal invitation ID is: 747664

Figure A2 Example of wristband distributeds to target children