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Scaling bundled health services in rural Sierra Leone

Submission date	Recruitment status	[_] Prospectively registered
10/11/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
16/11/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/11/2024	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

In many poor countries, access to healthcare will be severely constrained. In Sub-Saharan Africa, 150 million people will be over one hour away from the nearest health centre. In more remote areas, poor infrastructure, limited transport, and endemic poverty will make access even more challenging. In Sierra Leone, it will take the equivalent of one week of income for the average person in remote rural communities to reach a health facility. Fiscal constraints will worsen since the COVID-19 pandemic, limiting funding to expand healthcare infrastructure. Innovative and cost-effective solutions will be important to expand the reach of existing health infrastructure. This project will assess 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) will deliver child immunizations, the HPV vaccine, and other health products. Uptake and health outcomes will be compared to 200 control communities. Building on previous work, it will be shown that expanding access can increase healthcare uptake at a low cost. 'Last-mile' delivery of health services through mobile vaccination teams will result in a fivefold increase in vaccination rates for COVID-19. Delivering a bundle of health services and products simultaneously will be more cost-effective. A health bundle co-developed with MoH will focus on routine immunizations and HPV, addressing poor water quality and associated diseases. The primary aim will be to develop and evaluate cost-effective solutions to increase healthcare access among the rural poor in Sierra Leone. Longer-term objectives will include evaluating the impact on well-being, child health, cognitive development, human capital, maternal health, household wealth, and labour productivity. Spill-overs to siblings, other cohorts, and adults, and general equilibrium effects in education and labour markets will also be evaluated. A scalable approach to improving health and well-being through increased healthcare access will be developed. The current registration will focus on short-run effects, with an additional registration expected for longer-run effects

Who can participate?

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 MoH 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, 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 Wageningen University, Oxford University and Yale University, and implemented in coordination with the MoH 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.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized controlled trial of bundled health services in rural Sierra Leone

Study objectives
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 focuses on the short-run effects. We expect to upload an additional registration for the longer-run effects. For longer-run impacts our (combined) hypotheses 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/07/2024, Office of the Sierra Leone Ethics and Scientific Review Committee (5th Floor, Youyi Building, Brookfields, Freetown, -, Sierra Leone; -; efoday@health.gov.sl), ref: 023/07/2024

2. Approved 02/10/2024, Yale Human Research Protection Program Institutional Review Boards (25 Science Park – 3rd Fl., 150 Munson St., New Haven, CT 06520-8327, United States of America; +1 203-785-4688; hrpp@yale.edu), ref: 2000031541

3. Approved 17/10/2024, WUR Research Ethics Committee for Review of Non-Medical Studies with Human Subjects (WUR-REC) (C/O P.O. Box 9101, Wageningen, 6700 HB, Netherlands; +31 (0) 317-488849; REC@wur.nl), ref: 2024-198

Study design
Blocked-cluster interventional unblinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, Home

Study type(s)
Prevention, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prevention of infectious diseases

Interventions
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 out 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 health products and services. Nurses are specialized in the administration of vaccines and the 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. 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 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 vitamin A drops, and distribute appropriate dosages of ORS/Zinc co-packs and chlorination tablets.
• For project households with girls 10-17 years old: HOTs will check the vaccination cards to determine if the 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.

Intervention Type

Behavioural

Primary outcome measure
1. 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
2. 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

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline, and the 3- and 6-month follow-up:
1. 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)
2. For SH2: Knowledge of vaccines and health products score amongst adult caregivers in project households, measured using a survey based knowledge index
3. For SH3: Attitudes toward vaccines and health products score amongst adult caregivers in project households, measured using survey based attitude index
4. For SH4: Reported incidence of malaria amongst children 0 to 5 years in eligible population, measured using survey question (yes/no)
5. For SH5: Reported incidence of diarrhea amongst children 0 to 5 years in project households, measured using survey question (yes/no)
6. For SH6: Reported incidence of diarrhea amongst children above 5 and adults in project households, measured using survey question (yes/no)
7. 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)
8. For SH8: Reported incidence of malaria amongst children above 5 and adults in project households, measured using survey question (yes/no)
9. For SH9: Reported incidence of diarrhea in non-project households, measured using survey question (yes/no)
10. For SH10: Reported household expenditures on curative health expenditures in project households, measured using survey question (yes/no)

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

Overall study start date
01/05/2024

Completion date
01/11/2025

Eligibility

Key inclusion criteria
We primarily focus on households in rural communities that have either (i) at 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 slept 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 to be 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:
1. All members of communities assigned to treatment conditions in our study are eligible to receive relevant information through participation in a sensitization/information campaign implemented at the community level
2. Project households:
2.1. Where children under 5 are eligible to receive Routine child immunization and deworming, Vitamin A, IPTi ORS/Zinc:
2.2. Girls age 10 – 17 are eligible for the HPV vaccine
3. Both types of households are eligible to receive Chlorine tablets.

Inclusion criteria for research activities (led by the research team):
1. All individuals aged 18 or older residing in study communities are eligible to be interviewed in the census. Respondents must consent to the survey.
2. All individuals aged 18 or above from project households are eligible to be interviewed for subsequent surveys. In addition, we include a sample of up to 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.

Participant type(s)
Resident, Population

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
450 clusters (villages), expected cluster size is about 200 adults

Key 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
1. Children in the eligible age range whose caregivers do not consent.

2. Children outside the age range.
3. Children under 5 are not eligible to receive vaccines
4. Girls aged 10-17 are not eligible to receive the HPV vaccine.
5. Children in the eligible age range who may experience severe 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.

Date of first enrolment
11/11/2024

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Ministry of Health of the Government of Sierra Leone Mobile Outreach Teams
Youyi Building, Brookfields
Freetown
Sierra Leone
NA

Study participating centre
Concern Worldwide
20 Old Railway Line, Signal Hill, Wilberforce
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ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
Not defined

Funder Name
Social Science Research Council

Alternative Name(s)
U.S. Social Science Research Council, Social Science Research Council (U.S.), The Social Science Research Council, SSRC

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Givewell

Funder Name
International Growth Centre

Alternative Name(s)
The IGC, IGC

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal as well as policy briefs. We expect to write a paper about the short run effects on vaccine uptake and health product use. We also expect to write a followup paper about the long run welfare effects for which we expect to collect additional data in the future.

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. De-identified data will be made public.

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		10/11/2024	15/11/2024	No	No
Statistical Analysis Plan		10/11/2024	15/11/2024	No	No