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Solving the last-mile delivery challenges of COVID-19 vaccines in rural Sierra Leone

Submission date
16/03/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
10/04/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sierra Leone has received over 1.5 million doses of COVID-19 vaccines. However, vaccination rates are low with about 10% of the target population having received their first dose and less than 3% having received their second dose as of late 2021. A recent study reported that over 80% of respondents in rural Sierra Leone say they would be willing to take a COVID-19 vaccine if available. The fact that uptake remains low in rural Sierra Leone despite this relatively high acceptance of COVID-19 vaccine suggests that there are some limiting constraints in last-mile delivery and access. This project designs and implements interventions that target the critical access constraints, especially in remote rural areas. The goal is to determine whether a scalable set of strategies can increase vaccination rates cost-effectively.
The longer-term goals are to:
1. Create a replicable model that can be rolled out in similar contexts around the world
2. Rigorously demonstrate that it is possible to cost-effectively vaccinate rural populations in low- and middle-income countries (LMICs), and then aggressively publicise that result in the international media. Such advocacy is necessary to change the narrative being pushed by certain powerful actors in high-income countries (HICs) that "sending doses to LMICs is not a high priority, given difficulties with distribution and hesitancy, which results in doses getting wasted."

Who can participate?
All adult residents of selected rural communities eligible for the COVID-19 vaccine in Sierra Leone; 150 communities selected from seven rural districts from the North out of 16 districts in Sierra Leone (Koinadugu, Falaba, Karene, Kambia, Tonkolili, Bombali and Port Loko)

What does the study involve?
150 rural communities are assigned to either a control group (50 communities), or treatment groups to receive either an individualised outreach program (50 communities) or a small group outreach program (50 communities). As part of the intervention both treatment groups will receive increased access to COVID-19 vaccines in the form of 2-3-day vaccination camps set up by mobile vaccine teams in the community. In order to encourage village members to take the vaccine, social mobilizers from the vaccination team will conduct information sessions with community leaders such as town-chiefs, mammy queens, imams and other influential personnel as well as sensitization through a general community meeting organised by the local leaders. In

addition, in communities assigned to the individualised outreach program a subsample of structures will receive visits from the social mobilizer, who will then proceed to give them information about the vaccine and answer any specific questions or concerns they might have. In communities assigned to the small group outreach program, social mobilizers will target certain groups such as women's groups, farmers' groups, youth groups or religious groups to encourage them to take the vaccine.

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 effectiveness and safety. This information is intended to increase awareness about COVID-19, and increase the adoption of behaviour that would reduce the risk of contracting COVID-19 by taking the vaccine. The combination of the information session and increased access to the COVID-19 vaccine, should increase the uptake of COVID-19 vaccine, and reduce the likelihood of infection. This would benefit individual participants, as well as the communities they are part of by reducing the spread of COVID-19. The study's findings could also benefit society at large by providing reliable causal estimates of the benefits of vaccination and on the effectiveness of community measures to promote vaccine take up, which could inform public health officials and practitioners on the role of mobilisation strategies in vaccination campaigns as a measure to tackle the COVID-19 pandemic. 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 respiratory diseases (including COVID-19) and related symptoms in their households. There might also be stigma attached with participants' choice to get vaccinated. There is minimal physical risk to participants from this study, except the rare risks associated with specific COVID-19 vaccination. There is a potential risk of loss of confidentiality and data breaches. However, responses will be confidential and protected. Answers will never be shared with others in our outside the village. Information which identifies individuals will not be shared outside of research, internal quality assurance, or research oversight teams.

Where is the study run from?
This study is running in 150 communities across seven districts in Sierra Leone and is coordinated by Wageningen University (Netherlands), the International Growth Centre (UK) and Yale University (USA), 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?
November 2021 to April 2022

Who is funding the study?
WAM Foundation Inc (USA)

Who is the main contact?
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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of mobile vaccination teams and community mobilisation on vaccination rates in adults in rural Sierra Leone

Study objectives
H1: Access to vaccines via Mobile Vaccination Teams increases vaccine uptake.
H2: Individualised outreach changes the type of person that takes a vaccines compated to small group outreach

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/02/2022, Sierra Leone Ethics and Scientific Review Committee: (5th Floor, Youyi Building Brookfields, Freetown, Sierra Leone; Tel: not provided; efoday@mohs.gov.sl), ref: not applicable
2. Approved 23/02/2022, Wageningen University Social Science Ethics Committee (Wageningen University: Social Science Ethics Committee, 6706 KN, Wageningen, the Netherlands; +31 (0)317 484334; esther.roquas@wur.nl), ref: not applicable
3. Approved 03/03/2022, Yale University Human Research Protection Program Institutional Review Boards (FWA00002571, 25 Science Park – 3rd Fl., 150 Munson St., New Haven CT 06520-8327, USA; +1 (0)203 785 4688; email: not provided); ref: MOD00049110

Study design
Cluster interventional unblinded randomized trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Based on the pilot, the researchers decided to experiment with two different ways to conduct outreach after the basic required elements of the intervention (bringing vaccines into the village, addressing the access difficulties, conducting meetings with the group leader and the entire community) are first implemented.

Common elements in the two treatment arms:
The basic design of the intervention includes the following elements. First, the social mobilizer will engage with the traditional authorities. During this engagement with the traditional authorities, the social mobilizers will inform the authorities about the purpose of the visit and seek their support and permission to engage with the rest of the population. The social mobilisation team will ask the traditional authorities to call a community meeting, and during this meeting they deliver a general information session to all attendees. This engagement with the traditional authorities and the general meeting are common to all the study communities. This is followed up with two different forms of outreach, randomized 50-50 across the 100 intervention communities.

Variations in intensified sensitization:
One variation is called individualised outreach and the other variation is called small group outreach.

The individualised outreach consists of delivering door-to-door private information sessions to residents in selected structures. The researchers randomly select around 17-20 structures to receive this individualised outreach. Social mobilizers visit those structures to deliver a more private information session and urge residents to come to the vaccination clinic. Those residents get an opportunity to privately discuss any concerns they have about the vaccines, side effects, or even their personal fear of needles.

The small group outreach involves identifying small groups of influential people who may gather at a fixed spot (e.g. groups of farmers, young people at ataya bases, people going to the mosque, women collecting water), and understanding their social dynamics. The enumerators will conduct this mapping and share details with the social mobilizers. The social mobilizers will then be requested to engage with these groups to have joint small-group conversations about vaccines.

The researchers are experimenting with these two approaches because there is true equipoise and uncertainty regarding which strategy is more likely to be successful. On the one hand, some people might be reluctant or ashamed to ask certain questions or voice certain concerns in public, but they would feel comfortable in more private settings. Having the opportunity of

having a more private space could allow them to express their concern more freely, and have the social mobilizers address those directly. On the other hand, more people could be reached quickly using the small group outreach strategy. The open deliberation process in small groups may also be valuable, where friends get to discuss common concerns with the social mobilizers, and social norms quickly form.

The researchers are allocating 50 communities to pure control, 50 communities to individualised outreach, and 50 communities to small group outreach. The duration of the intervention is about 4 hours. Baseline and follow-up interviews take about 30 minutes. The endline interview is 1 day after the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Vaccination rate among the adult population, measured using a respondent-level question on whether they took the vaccine (any type) and inspection of their vaccination card (if consented) at baseline and follow-up (1 day)

Key secondary outcome(s))
Measured using a household survey at a baseline and follow-up (1 day):
1. Knowledge of vaccines: Do you know what a vaccine/marklate is? (yes/no), How are vaccines administered? (1 if correct answer), How much do you agree with this statement: Vaccines are safe (agree - scale), How much do you agree with this statement: Vaccines are effective (agree - scale)
2. Social demographics (age, gender, wealth) of the people taking the vaccine measured using a survey question at baseline

Completion date
03/04/2022

Eligibility

Key inclusion criteria
All adult residents of selected rural communities eligible for the COVID-19 vaccine in Sierra Leone; 150 communities selected from seven rural districts from the North out of 16 districts in Sierra Leone (Koinadugu, Falaba, Karene, Kambia, Tonkolili, Bombali and Port Loko)

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
31885

Key exclusion criteria
Current exclusion criteria as of 12/09/2022:
Aged under 12 years

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Previous exclusion criteria:
People below 18 years old

Date of first enrolment
03/03/2022

Date of final enrolment
02/04/2022

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Ministry of Health of Government of Sierra Leone Mobile Vaccination Teams
Sierra Leone
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Sponsor information

Organisation
Wageningen University & Research

ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
Charity

Funder Name
WAM Foundation Inc

Results and Publications

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 publicly available.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/03/2024	10/04/2024	Yes	No