

RESEARCH NOTE

Recruitment strategies used to enrol healthy volunteers in the first pneumococcal human infection study in Africa: Lessons from Blantyre, Malawi [version 1; peer review: awaiting peer review]

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Abstract

Background

Human infection studies (HIS) also known as Controlled Human Infection Models (CHIM) are a relatively new concept in African countries to clinicians, scientists, and communities alike. We have introduced HIS/CHIM studies to Malawi during the last four years by developing an experimental human pneumococcal carriage model. This CHIM was used to test the efficacy of a licensed 13-valent Pneumococcal Conjugate Vaccine (PCV13) against experimental nasal pneumococcal carriage. Traditional and digital recruitment strategies into this novel trial were explored.

Objectives

To describe various methods of recruitment in this first CHIM study in

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Any reports and responses or comments on the article can be found at the end of the article.

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Methods

The clinical trial within the context of which these data were recorded was registered with the Pan African Clinical Trials Registry (REF: PACTR202008503507113) on 03 August 2020. The project was conducted at the Malawi Liverpool Wellcome Programme (MLW) in Blantyre, Malawi between April 2021, and September 2022. Source populations were college students and community members within Blantyre. Recruitment strategies included sharing study information in written or visual form, community sensitization meetings, snowball contacts (word of mouth from previous volunteers), branded clothing and participating in radio and television programs.

Results

299 volunteers attended screening clinic, of whom 278 were recruited. Sixty-six recruited volunteers (23.7%) were college students and 212 (76.3%) were from the community. Snowball word-of-mouth contacting was the most successful recruitment strategy, with 201 (72.3%) participants recruited using this method. 195 (70.1%) were men of whom 149 (76.4%) joined the study through snowballing.

Conclusion or recommendation

Using a variety of recruitment strategies led to successful recruitment in this novel controlled human infection study. Most participants were recruited through snowballing.

Keywords

Controlled Human Infection Model, Streptococcus pneumoniae, Carriage, Conjugate Vaccine, Clinical trial



This article is included in the Malawi-Liverpool Wellcome Trust Clinical Research Programme gateway.

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Introduction

Rationale

Human Infection Studies (HIS), also known as Controlled Human Infection Models (CHIM) involve introducing a pathogen to a healthy individual under carefully monitored conditions. These studies have made important contributions to prevention and treatment of many infectious diseases. High Income Countries (HIC) have utilized these studies to understand biology and develop vaccines for pathogens of clinical and population health importance such as human influenza viruses, respiratory syncytial virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Staphylococcus and Neisseria species. High literacy levels, equitable access to health care, advanced technology, superior physical and digital health services infrastructure, and high socio-economic status have facilitated the success of these novel studies in HICs.

Malawi, Kenya, Uganda, and Tanzania are four countries that have established HIS in Africa (Malawi: *Streptococcus pneumoniae* challenge¹, Kenya² and Tanzania³: *Plasmodium falciparum* challenge, Uganda: Schistosoma spp challenge⁴).

Other countries such as Zambia⁵, are following with other study pathogens, and priming their populations for introduction of these novel studies⁵. Typically, HIS are conducted first in a HIC and after the technology, standard operating procedures and safety have been established, transferred to a collaborating Low-Income Country (LIC). For example, pneumococcal human challenge trials were conducted in Liverpool for a decade following which technology and standard operating procedures were transferred to Malawi for feasibility testing⁶. Similarly, a study of blood-stage controlled human Plasmodium *falciparum* malaria infection that is ongoing in Tanzania, originated from Oxford University⁷.

The first workshop to be convened on human challenge work in Malawi by a technical working group, which included the authors, met in 20178. Clinicians, scientists, ethicists, and community leaders discussed the potential benefits of human infection studies (accelerated vaccine development, capacity building) and risks (safety, acceptability, ethical concerns)8. The workshop report highlighted: excellent international clinical standards, local capacity building and ownership, a rigorous informed consent process, mitigation of challenges with transport and access to health facilities, appropriate economic compensation, and managing community and media perceptions as key issues to address to ensure success of human infection studies in a setting like Malawi8.

Next, the researchers conducted a study exploring acceptability of human infection studies using focus groups and key informant interviews with Blantyre-based research staff, medical students, and community representatives, clinicians, ethics committee members, and district health government officials⁹. Overall, HIS studies were favourably perceived and potentially beneficial provided the following conditions were met;

voluntary and informed consent, rigorous inclusion/exclusion criteria, provision of medical check-ups and monitoring, appropriate compensation, and robust community engagement⁹.

Acceptability work paved way for feasibility testing of the human challenge model among 24 healthy volunteers, whose experiences with the trial from recruitment methods, compensation, inoculation with live bacteria, study procedures (nasosorption, nasal scrape with rhino probe, nasal wash, throat swab, saliva collection quarantine and residential stay post-challenge, were sought after trial completion¹⁰. Motivation for joining the study despite initial reservations included altruism, patriotism, and monetary gains¹⁰. Although the participants did not experience adverse events in the short duration of the study (21 days) they were concerned about future unanticipated risks¹⁰. The volunteers admitted that the concept of human challenge trials was completely novel and recommended extending information and education about the model to the wider Malawian population¹⁰.

In the present paper, we discuss experiences and lessons we have learnt about recruitment through the process of scaling up from a feasibility study in tens of participants to a randomized controlled vaccine trial requiring screening of more than 250 participants.

Objectives

We describe methods used in recruiting participants in a pneumococcal CHIM study in Blantyre Malawi and highlight lessons learned in the process.

Methods

Trial design

This was a qualitative description of recruitment methods used to recruit participants in a double-blinded, parallel-arm, randomized controlled trial investigating the efficacy of PCV13 or placebo (allocation ratio PCV13: placebo 1:1) against experimental pneumococcal carriage of *Streptococcus pneumoniae* serotype 6B (SPN6B). The study protocol has been published in Wellcome Research Open¹¹.

Methods

Sensitization meetings: Sensitization meetings were conducted at eight surrounding colleges in Blantyre namely Malawi College of Health Sciences², Malawi University of Business and Applied Sciences, formerly The Polytechnic², Kamuzu University of Health Sciences¹, Malawi Institute of Journalism and Malawi Institute of Tourism¹. Each sensitization meeting was attended by approximately 50 students. Additional sensitization meetings were conducted at the Malawi-Liverpool-Wellcome Programme main site and invited research and clinical staff. Individuals interested in the study provided their telephone numbers to the study staff and verbally consented to be phoned to schedule an information session at the clinic. Sensitization meetings were interrupted from July to August 2021 by school closures due to the fourth COVID wave but resumed in September 2021.

Snowball recruitment: Snowball recruitment or sampling, also called chain-referral sampling, is an informal spread of study-related information to potential participants by word of mouth¹¹. Snowball recruitment in this study occurred naturally without study staff influence. Potential participants and existing participants shared study information with their peers, who came to volunteer for the study as a result.

Radio and Television: While initially the study team was careful to perform only targeted sensitization during the feasibility study, the proven safety of the model demonstrated for over three years provided later confidence to expand awareness of human infection studies to the wider community. In May 2022, four weekly radio broadcasts about human infection studies and the PCV13 study were conducted by study clinic and laboratory team members. The broadcasts were one hour long, with a text and phone dial in segments for listener engagement. These broadcasts were all live and recorded in both English and Chichewa. There was very high engagement from the listeners during the radio programmes. Similarly, a television programme was recorded with a live studio audience and aired twice in June 2022. The live audience engaged well with the study team and asked relevant questions.

Digital media: The study team recorded a video for MLW's YouTube channel describing the importance of human infection studies in Africa and detailing the PCV13 trial. In addition, a digital study flyer was circulated on WhatsApp.

Increased visibility: The study team utilized branded clothing for participants and staff members to increase visibility and generate interest about the study.

Clinic recruitment: Recruitment to the pneumococcal CHIM study itself was as follows. Potential participants who showed interest were invited via telephone to an in-person information visit (visit A) to the research clinic. The information visits were conducted in groups and lasted approximately an hour. During this visit, A study nurse or clinician provided detailed information about the study including screening, vaccination, inoculation, quarantine, and safety procedures and follow up. Risks were discussed in detail. Materials used to collect samples were also demonstrated. At this stage, participants did not require to disclose whether they will join the study or not but were encouraged to think about it and to decide later. At the end of the visit, the potential participant's information, including their name, contact number, age, sex, residence, and their information sources regarding the study were recorded. Information sources included college sensitization campaigns, snowballing, adverts, social media and digital programs on radio and television. In addition, information to define the participants' community category was collected. They were defined as a college student or not a college student (referred to as 'the community').

During a second visit intended to obtain individual consent (visit B), data were collected to show how many participants from each category showed interest in joining the study and

how many of each category were both eligible and were successfully recruited, consented and vaccinated.

Following screening and recruitment, participants underwent randomization, vaccination, inoculation and follow up including residential stay and exited the study. Study procedures are summarized in Figure 1.

Ethical approvals

The CHIM study including recruitment strategies was approved in Malawi by the National Health Sciences Research Committee on 1 May 2020 (REF: 16/07/2519) and Pharmacy Medicines and Regulatory Authority (REF: PMRA/CTRC/III/10062020121) and in the United Kingdom by the Liverpool School of Tropical Medicine on 23 April 2021 (REF: 20-021). The trial was registered with the Pan African Clinical Trials Registry (REF: PACTR202008503507113) and can be found on https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=12124.

Results

A total of 299 participants were screened for the study, of which 278 were recruited. 209 (69.9% and 195 (70.1%) of the screened and recruited volunteers, respectively, were males.

Screening and recruitment by recruitment strategy Snowballing: 215 of 299 (71.9%) screened indicated that

they were motivated to join through snowball recruitment. Of these, 201 were eventually enrolled in the study. 21 volunteers were excluded for not meeting one or more of the inclusion criteria (Table 1).

Sensitization: 82 of 299 (21.4%) screened were motivated after a sensitization event (Table 2a and Table 2b).

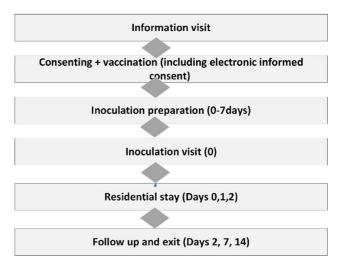


Figure 1. Summary of recruitment and follow up procedures in the main trial; PCV13 trial. This figure is an original figure produced by the author(s) for this review article.

Table 1. Inclusion and Exclusion Criteria.

Inclusion criteria	Exclusion criteria
 Adults aged 18–40 years Fluent spoken and written Chichewa or English Own a cell phone 	 Previous pneumococcal vaccination HIV-infection seropositive Close physical contact at-risk individuals Allergy to penicillin/amoxicillin Acute illness Chronic illness that may impair immune response or impair ability to comply with study procedures and safety Pregnancy History of drug or alcohol abuse History of Smoking Unable to give informed consent Participant is positive for Streptococcus pneumoniae serotype 6B

Table 2a. Screening methods by sex.

	Total screened (N=299)	Snowball n (%)	Sensitization n (%)	Radio and television n (%)	Poster n (%)
Male	209	160 (76.6)	48 (23.0)	1 (0.4)	0 (0.0)
Female	90	55 (61.1)	34 (37.8)	0 (0.0)	1 (1.1)

Table 2b. Recruitment methods by sex.

	Total recruited (N=278)	Snowball n (%)	Sensitization n (%)	Radio and television n (%)	Poster n (%)
Male	195	149 (76.4)	45 (23.1)	1 (0.5)	0 (0.0)
Female	83	52 (62.7)	30 (36.1)	0 (0.0)	1 (1.2)

Radio and television: This strategy motivated only one individual to screen and enrol in the study (Table 2a and Table 2b).

Poster: Only one individual was screened and enrolled after seeing a study poster (Table 2a and Table 2b).

Participant feedback on exiting the PCV13 study

213 participants accepted to be interviewed regarding their experience in a CHIM at study exit. Responses were recorded using a Likert scale survey. The majority either strongly agreed or agreed that study processes from informed consent,

through recruitment, safety monitoring, compensation and quarantine-were a positive experience. 95.3% stated that they would recommend study participation to a friend (Table 3).

Discussion

In this article, we describe recruitment methods utilized in a pneumococcal human infection study. An overwhelming number of participants were recruited via snowballing or word of mouth networking.

This is the first study of its kind of which we are aware. The strengths of this study are that several institutions and potential

Table 3. Participant feedback at study exit.

Column1	Strongly agree n(%)	Agree n(%)	Neutral n(%)	Disagree n(%)	Strongly diasgree n(%)
The approach used for study recruitment was appropriate	146(68.5)	62(29.1)	5(2.3)	0	0
The information provided before consenting was appropriate	155(72.8)	58(27.2)	0	0	0
The medical questions and tests used before consenting were appropriate	142(66.7)	66(31.0)	5(2.3)	0	0
There was sufficient time to consider the study before consenting	147(69.0)	60(28.2)	5(2.3)	1(0.5)	0
The finger print scanner was acceptable way to confirm my identification	164(77.0)	46(21.6)	3(1.4)	0	0
The clinical team treated you with respect and kindness.	173(81.2)	39(18.3)	1(0.5)	0	0
The safety monitoring procedures for the study were appropriate	151(70.9)	59(27.7)	3(1.4)	0	0
The study follow up procedures did not cause inconvenience	122(57.3)	73(34.3)	14(6.6)	4(1.9)	0
The accommodation provided after inoculation was satisfactory	146(68.5)	54(25.4)	11(5.2)	2(0.9)	0
The meals provided at the accommodation were satisfactory	155(72.8)	49(23.0)	8(3.8)	1(0.5)	0
The location of the accommodation was convenient	137(64.3)	65(30.5)	8(3.8)	3(1.4)	0
The compensation provided by the study was appropriate	99(46.5)	72(33.8)	34(16.0)	5(2.3)	3(1.4)
I would recommend participant in this study to a friend	142(66.7)	63(29.6)	7(3.3)	1(0.5)	0

volunteer groups were observed, and many methods of recruitment were attempted. The limitation is that not all of the recruitment processes and decision making can be observed.

We suggest that hearing about the study from a former or current volunteer may reinforce trust in the safety of the study in potential volunteers and encourage them to join. There has been evidence suggesting this in participant studies in Malawi and in Kenya⁹.

On reflection, we consider that the tools used by the study team to inform and educate the community about the study may not have been well understood or accepted by the targeted audience and may need to be reviewed. While radio and television, done in both English and Chichewa, attracted an audience and active participation, this did not directly translate to an increased number of volunteers. The suitability of the messaging tools needs further exploration. Engaging former and current volunteers to participate in study sensitization activities may need to be considered.

Our study recruited more male than female volunteers. Possible reasons for this could be greater autonomy and decision-making power regarding consent to research participation among men than women in Malawi, although this was not formally explored in this study¹². Another reason could be that the information visits reached more men than women and via snowballing they predominantly enlisted their friends, mostly men too. Thirdly, if the study was viewed as risky, males may have had a greater risk tolerance. Targeting women through

women church groups and community village banks might increase participation of women in CHIM studies in Malawi.

Conclusions

In conclusion, engaging current and former volunteers in novel trials like human infection studies is a possible strategy that can encourage community acceptance and participation in settings like Malawi. More work needs to be done to explore how increased participation from women can be ensured.

Data availability

Underlying data

Figshare: Underlying data for 'Recruitment methods and participant experiences in the first controlled human infection study in Blantyre, Malawi.' https://doi.org/10.6084/m9.figshare. 22567513.v1

This project contains the following underlying data:

• Data file 1. (The attached file contains the following information: VisitA_month: Date of information visit, VisitB_date: Screening visit, Age, Sex, Recruitment and, Vaccination status, Study completion status, Column I to U represents Likert scale of participant experiences with summary of findings in Table 3 in this article.)

Extended data

Figshare: Extended data for 'Recruitment methods and participant experiences in the first controlled human infection study in Blantyre, Malawi.' https://doi.org/10.6084/m9.figshare. 22567513.v1

This project contains the following extended data:

Data file 1 (Description of data.)

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 Public domain dedication).

Software availability

Data was collected electronically using Open Data Kit (ODK) on an Android device. To complement ODK functionality, an additional in-house application was used called ODK lookup updater application, which helped to enforce data validation at the point of data collection.

Data was validated at the point of entry using field restrictions embedded within the form to avoid collection of invalid and out of range data for numeric fields. Skip logics were also built into the form to eliminate collection of irrelevant or redundant data. Form level calculations were used to evaluate and validate data like eligibility criteria to avoid human error in decision making for such critical study decisions. And finally, an inhouse application was used for cross form verification of previously collected critical participant information.

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Authorship: The two first authors (Edna Nsomba and Anthony E Chirwa) contributed equally to this paper. The two senior authors (Stephen B Gordon and Dingase Dula) also contributed equally.

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