ORIGINAL RESEARCH

A Comparative Analysis of Physical and Mobile Phone Tracing in Clinical Trials in Lilongwe, Malawi

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Abstract

Background

Patient retention is important for proper adherence to clinical trial protocols. Mobile-phone and physical tracing have been implemented at clinics across Malawi to improve retention but tracing effectiveness and attitudes towards tracing have not been sufficiently studied.

Methods

In a site-specific phone retention pilot study embedded within the HIV Prevention Trials Network (HPTN) 052 study in Lilongwe, Malawi, all tracing records and additional semi-structured questionnaires from 50 participants were used to obtain attitudes towards tracing efforts and methods. During a retrospective evaluation study at UNC Project, over 20,000 tracing records were analyzed across 49 studies from 2011 to 2019. Success in reaching participants, bringing participants to clinic, and overall tracing costs were analyzed.

Results

In the phone retention pilot study, 47 participants (94%) had positive attitudes towards tracing and 41 (82%) preferred mobile-phone tracing. Of all tracing attempts in the phone retention pilot study, mobile-phone tracing (232/309, 75%) was more successful than physical tracing (147/244, 60%) in reaching patients, and the cost of mobile-phone tracing was less ($4.21 versus $36.63 per tracing attempt). During the retrospective study period, mobile-phone tracing (7808/9522, 82%) was more successful than physical tracing (7742/10606, 73%) in returning patients to the clinic. Mobile-phone tracing saved approximately $32.08 and 92 minutes per tracing attempt.

Conclusion

Mobile-phone tracing is acceptable, feasible, and efficient for clinical trials in Lilongwe, Malawi. Mobile-phone tracing can be used to strengthen patient engagement and improve collection of primary-outcome data for clinical trials.

Key Words: Clinical Trial, Retention in Care, Malawi, Patient Participation, Cost Analysis, No-Show Patients, Contact Tracing

Background

The Government of Malawi recognizes the importance of health research for socio-economic development and demands scientifically rigorous research[1,2]. For clinical trials, the success and scientific merit is contingent upon adequate retention and adherence of research participants to the study protocol[3,4]. Unfortunately, poor retention of patients in clinical research is common[5–7]. These low rates of retention not only adversely affect clinical trial implementation but can also confound accurate interpretation of trial results[8]. It is therefore important to identify strategies for engaging participants in clinical trials to maximize retention.

One strategy for improving retention in clinical trials is building strong relationships and developing consistent communication channels between patients and study staff. If well implemented, this strategy can improve retention, accelerate participant recruitment, reduce trial costs, shorten study duration, and increase the likelihood of trial successes[9]. In low- and middle-income countries, the traditional strategies for patient engagement include providing written appointment reminders for patients and collecting locator information to physically trace patients if they miss[10]. Mobile phone technology has emerged as an alternative strategy to physical tracing[11–13]. In South Africa, phone tracing among people living with HIV/AIDS improved adherence to medication, enhanced disease monitoring, increased successful tracings of contacts and partners, and offered effective communication with healthcare workers[14]. However, the acceptability, effectiveness, and cost and time-saving associated with mobile phone tracing in clinical trials have not been evaluated in Malawi.

We conducted two studies (a phone retention pilot study and retrospective analysis) to compare patient acceptability and clinic costs between mobile phone tracing and physical tracing. We also evaluate the subsequent uptake and continued cost of mobile phone tracing compared to physical tracing after the initial phone retention pilot study.

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Methods

Study setting

This study was conducted at the University of North Carolina (UNC) Project, a non-profit HIV/AIDS biomedical research institution based in Lilongwe, Malawi. The project operates at Kamuzu Central Hospital, Bwaila District Hospital, and the George Joaki Research Centre. The catchment area for participants recruited for studies at UNC project is a 50km radius which covers rural, peri-urban, and urban populations. Since its inception in 1999, UNC Project has maintained a field-based patient tracing system when conducting its research activities. In 2011, mobile phones were introduced as an additional tool for patient tracing. Before project-wide implementation, in 2010, the HIV Prevention Trials Network (HPTN) 052 study was ongoing at the UNC Project Malawi at Kamuzu Central Hospital, and we piloted the use of mobile phone as an additional tool to aid tracing and retention.

Study Design and population

The Phone Retention Pilot Study

The pilot study aimed to demonstrate whether mobile phones could be used as a tool for tracing at UNC Project before scaling up to all studies. The pilot study was conducted among participants enrolled in the HPTN 052 clinical trial from February 2010 to January 2011. HPTN 052 was a multi-center phase III randomized clinical trial which recruited 250 participants at UNC Project. The purpose of HPTN 052 was to assess whether immediate versus delayed use of ART by an HIV positive partner would reduce transmission of HIV to the negative partner[15]. All HPTN 052 participants receiving ART who consented to report for all scheduled visits were eligible for our study and included in tracing record review. We randomly sampled 50 participants to take part in in-depth interviews 6 months after phone introduction to explore their attitude towards tracing and the tracing method used. All participants were provided with phones by UNC Project, which could be used for personal use. Participants who required tracing were first contacted through phones then physical tracing.

A trained nurse used a pre-tested semi-structured questionnaire as the in-depth interview guide to collect data on attitudes and perceptions of individual patients towards tracing in general and towards the different tracing methods, as well as the patient's reasons for their attitudes or perceptions. Attitude was defined as a predisposition or a tendency to respond positively or negatively towards tracing and tracing method. Additional closed-ended questions were asked using a five-point Likert scale to ascertain the degree of individual patient's agreement or disagreement towards tracing and tracing methods in clinical trials. A score of 3 (neutral) was defined as neither agreeing nor disagreeing.

The phone retention pilot study aimed to evaluate the effectiveness (tracing outcomes) and cost of tracing methods. Data was collected for the pilot study from all participants through record review from Community, Transport, and Accounts Department databases. The Community Department data includes study name, reason for tracing, outcome of tracing, tracing method, and where the tracing took place (distance in km). The Transport Department maintains a database of all fuel and vehicle costs used in the physical tracings. The Accounts Department maintains a database of costs for airtime, mobile handsets, and all other staff expenses from tracing efforts.

The cost of participant tracing was calculated with consultation from the Community, Accounts, and Transport Departments at UNC Project using average tracing times with corresponding breakdowns of community tracer and driver salaries, lunch stipends, vehicle costs, fuel prices, mobile phone airtime, and average phone prices.

The Retrospective Study

We conducted a retrospective analysis on tracings data of all HIV studies conducted by UNC Project in the Lilongwe District from 2011 to 2019. The tracing data was obtained from the Community Department online database that includes tracing frequency, reason for patient tracing, tracing outcome, and tracing response.

Tracing frequency was defined as the total number of tracing attempts conducted by either mobile phone or traditional physical tracings. For mobile tracing, patients could be called for other reasons than loss to follow-up or a late visit (i.e., appointment reminders), however, for this analysis, the tracing records were only included when the reason for contact was one of these two reasons. The reason for patient tracing was defined as the clinical need to reach a patient. Tracing outcome was defined as 'successful' for mobile phone tracing if a contact tracer spoke directly with a patient over the phone or 'unsuccessful' otherwise. Tracing outcome was defined as successful for physical tracing if a contact tracer was able to speak with a patient in-person during the tracing attempt and unsuccessful otherwise. All physical tracing attempts included information on outcome reasoning for patients who were unsuccessfully contacted to discern if a patient was not at home during the tracing attempt, if a patient had relocated, if a patient's home could not be found, or if the patient had passed away. Tracing response, defined as the patient outcome of a tracing attempt, was operationalized into three categories: if the patient returned to clinic as needed, if the patient did not return to clinic but was needed, or if the patient was not required to return to the clinic.

We calculated time and cost saving estimates of mobile phone tracing compared to physical tracing using the descriptive analysis comparisons and expense data from the Transport Department and Accounts Department databases. Expense data included costs for community tracer and driver salaries, lunch stipends, vehicle costs, fuel prices, mobile phone airtime, and average phone prices. Phones were not provided for any UNC Project study participants after the pilot study. Cost estimates accounted for inflation and revaluation of the Malawian kwacha from 2011 to 2019 using World Bank reported yearly fuel prices and annually reported airtime prices from Airtel Malawi.

Data analysis

In-depth interviews were tape-recorded then translated and transcribed verbatim. The transcripts were analyzed using Thematic Content Analysis 11. The principal investigator listened and read all transcripts at least twice to confirm their accuracy.

Quantitative data was analyzed using Statistical Package for Social Sciences (SPSS) version 14.0. Descriptive statistics (mean, mode, median, and frequencies) were used to summarize the distribution of continuous and categorical variables as appropriate. We used Pearson Chi-Square test to

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assess association between patients' attitudes towards tracing and the tracing methods, as well as comparing success with phone tracing compared to physical tracing. We also used t-test statistics to compare difference between characteristics of participants.

For cost estimation of physical tracing, we calculated the average physical tracing time and then applied this to the rate of pay for the driver and research assistant salary, fuel cost (based on distance and vehicle fuel efficiency), vehicle rental cost, and lunch stipends. For cost estimation of mobile phone tracing, we calculated the average mobile tracing time and then applied this to the rate of pay for research assistant salary, airtime, and phone costs. Rates for this were also based on yearly averages, which accounted for inflation over time. All time estimates accounted for inflation and revaluation of the Malawian kwacha using World Bank reported yearly fuel prices and annually reported airtime prices from Airtel Malawi. We then compared time and cost savings between mobile phone tracing and physical tracing.

Ethical Consideration

Ethics approval was obtained from the National Health Sciences Research Committee of Malawi (NHRSC) and University of North Carolina School of Medicine Institutional Review Board. During routine HPTN 052 clinic visits, we approached and invited potential participants into the pilot study, and they all consented. For the retrospective evaluation, all participants provided informed consent for tracing through their parent study.

Results

The Phone Retention Pilot Study

Participant characteristics

Of the 50 participants enrolled, 34 (75%) were female. The mean age was 32.4 years (standard deviation = 10.3 years). Women enrolled in this study were relatively younger (mean =28.7 years, standard deviation = 7.2 years) compared to men (mean = 40.4 years, standard deviation = 11.6 years), P<0.001.

Attitude towards tracing

Most participants (94%, n=47) had positive attitudes towards tracing by the community staff if they missed their appointments. During interviews, many felt that tracing was beneficial to appointment adherence.

"I strongly feel like someone (clinic) cares for me when they frequently contact me which gives me the courage to go on with the study despite many side effects due to drug reaction" (Study Participant, 2011).

Confidentiality and privacy issues were cited as reasons for negative attitudes towards tracing from 3 (6%) participants.

Preferred tracing method

Forty-one (82%) participants preferred mobile phone tracing to physical tracing, because they felt it was safer and more convenient (i.e., the flexibility to communicate at any time from any location, the ability to contact the clinic and community staff directly, and the ability to code messages which surmount stigmatization and discrimination for their involvement in a clinical trial).

"I remember one day when I had a problem that I wanted to communicate to the clinic, but I failed to do so because it was outside clinical working hours. Thanks to the new system because it is able to address our needs since I can now communicate with the clinic regardless of what time of an hour it is" (Study Participant 2011).

For the 9 (18%) participants that preferred physical tracing, they felt it was personally cheaper than phone tracing because of transportation assistance from the community staff.

"Sometimes we fail to go to the clinic on a scheduled visit due to lack of transport money. When the community tracer nurses come to our homes during tracing, we take advantage of the vehicle they are traveling in and pick us to the clinic, which will not be the case if they completely use mobile phone based patient tracing system" (Study Participant, 2011).

Examination of Attitudes towards tracing versus Preferred tracing method

Of the 47 patients that had positive attitudes towards tracing, 6 preferred physical tracing. All 3 participants that had negative attitudes towards tracing preferred physical tracing. Patient attitude (positive or negative) towards tracing was significantly associated with the preferred tracing method (p <0.001).

Tracing prevalence

We reviewed 553 tracings records from the HPTN 052 study. Of the 553 tracings, 244 were physical tracings and 309 were mobile phone tracings, representing 44% and 56% of tracings respectively.

Outcomes, cost, and time for physical tracing

Of the 244 physical tracings conducted during the HPTN 052 study, 147 (60.3%) were successful (i.e., patients found in their homes). Of those patients who were found, 109 (74.2%) reported to the clinic. The minimum time taken to reach a participant's home (5 km away) from the clinic was 11 minutes. The maximum time taken to reach a participant's home (50 km away) was 105 minutes. On average, it took 114 minutes to reach a participant's home and return to the clinic.

The average cost to physically trace a single patient during the phone retention pilot study was equivalent to $36.63. This includes both the community tracer and driver salaries broken down per tracing, lunch stipends for both, vehicle rental prices, and the average cost of fuel needed to conduct one tracing. Annual car maintenance was not factored into the cost of physical tracings, which may have led to an underestimation in the total cost of physical tracings. The total cost of all physical tracing during the phone retention pilot study was approximated at $8,936.80.

Outcome, cost, and time for mobile phone tracing

A total of 309 voice calls were made, of which 232 (74.9%) successfully reached the participant. Of the 232 reached, 207 (89.2%) reported to the clinic. The minimum and maximum times for a voice call were approximately 1 minute and 5 minutes respectively. The average duration for a voice call was approximately 3 minutes.

For mobile phone tracings, the cost of airtime per minute of calling was equivalent to $0.61. The airtime cost incurred by all voice calls was approximately $565.47. These call rates were standard costs for the networks used and were not part of a negotiated contract. The other cost associated with mobile phone tracing was purchasing mobile phone

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Table 1. Frequency and proportion of community tracings by tracing method at the UNC Project in Lilongwe, Malawi from 2011 to 2019

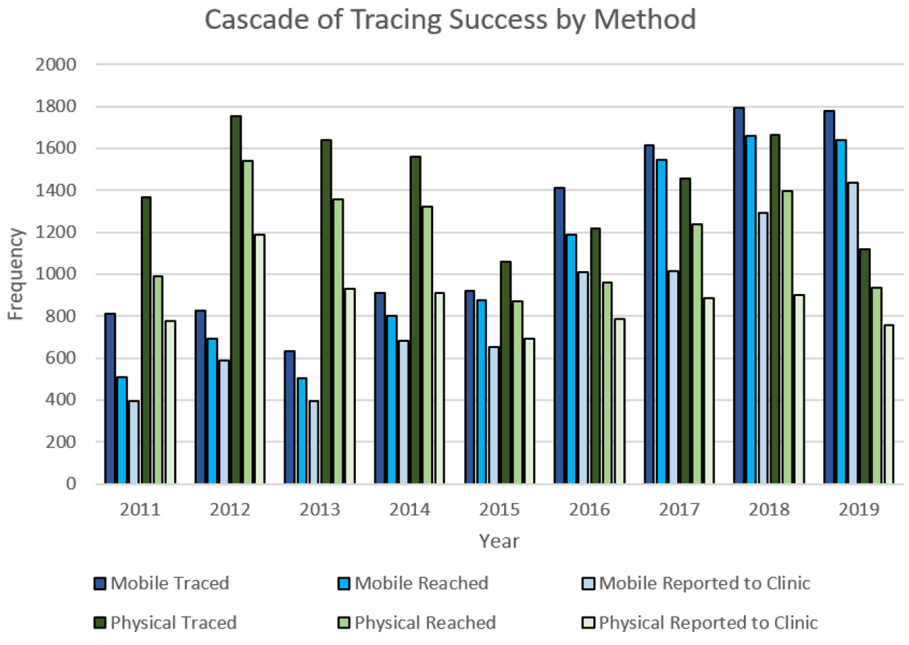
Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Phone Tracing Frequency	809	828	634	912	920	1413	1615	1795	1780	10706
Phone Tracing Proportion	37%	32%	28%	37%	47%	54%	53%	52%	61%	46%
Physical Tracing Frequency	1366	1752	1637	1561	1057	1217	1456	1665	1118	12829
Physical Tracing Proportion	63%	68%	72%	63%	53%	46%	47%	48%	39%	55%
Total	2175	2580	2271	2473	1977	2630	3071	3460	2898	23535

Table 2. The average cost of each item included in the physical tracing cost analysis for tracing at UNC Project in Lilongwe, Malawi

Item	Cost
Community Tracer Compensation	$ 4.15
Driver Compensation	$ 2.60
Lunch Stipend for Tracing Team	$ 1.00
Vehicle Rental	$ 13.75

Table 3. The average cost of each item included in the mobile tracing cost analysis for tracing at UNC Project in Lilongwe, Malawi

Item	Cost
Community Tracer Compensation	$ 0.13
Airtime from Airtel Malawi	$ 0.86
Total	$ 0.99



handsets to distribute to patients. An average cost for one handset was $15.34, and 50 phones were bought amounting to $766.89. Thus, the cost for mobile tracing was $4.31 per tracing attempt for a total cost incurred during the pilot study of approximately $1,332.36.

The Retrospective Study

Findings from Subsequent Tracings at UNC Project

Between 2011 and 2019, 23,535 tracings were conducted in 49 HIV research studies by the UNC Project Community. These included 5627 (23.9%) tracings from HIV observational studies, 9177 (39.0%) tracings from 12 HIV prevention studies, 6119 (26.0%) from HIV treatment studies, and 2612 (11.1%) tracings from 5 other studies. Most of the tracing (54%, n=12829) were through physical tracing. Mobile phone tracing increased from 35% in 2011 to 62% in 2019 while physical tracing decreased from 63% in 2011 to 39% in 2019 (Table 1).

Patient Tracing Outcomes by Method

Of the 10,715 mobile phone tracings, 9,522 (89%) successfully reached the participants and 10,606 (83%) of the 12,829 physical tracings successfully reached the participants. Since 2014, mobile phone tracings were consistently more successful each year in reaching participants than physical tracings ($p < 0.001$; Figure 1). For physical tracings that were not successful in reaching participants (2,223), 867 (39%) tracings found that the participant had relocated, 778 (35%) of the tracings located the participant house but the participant was not found, 548 (25%) tracings did not locate the participant house, and 30 tracing (1%) were notified of the participant's death.

Patient Response to Tracing Attempts

Of the 9,522 successful mobile phone tracings between 2011 and 2019, 7,808 (82%) resulted in participants successfully reporting to the clinic, 762 (8%) resulted in participants failing to come to the clinic

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when needed, and 952 (10%) did not require participants to report to the clinic. For physical tracing, 7,742 (73%) resulted in participants successfully reporting to clinic, 1,273 (12%) resulted in participants failing to come to the clinic when needed, and 1,591 (15%) did not require participants to report to the clinic. Mobile phone tracings have recently resulted in more participants successfully reporting to clinic compared to physical tracings (Figure 1).

Time and Cost Saving Estimates

Between 2011 and 2019, mobile phone tracing saved UNC Project on average $32.08 and 92 minutes of working hours per tracing attempt compared to physical tracing. Mobile phone tracing conducted by the Community Department resulted in a savings over the 9-year period of approximately $365,013.19 and 16,394 working hours. The total costs of physical and mobile phone tracing during from 2011-2019 were $424,311.31 and $10,621.14, respectively.

On average, physical tracing cost a total of $33.07 per tracing. The average physical tracing distance was 80 km to the patient's residence and back to the clinic and took 95 minutes. The average car's fuel efficiency was 10.6 km/L, resulting in $11.57 of fuel per physical tracing. Further cost breakdowns for physical tracing can be found in Table 2.

On average, mobile phone tracing cost a total of $0.99 per tracing. The average mobile phone tracing call lasted 3 minutes with airtime from Airtel Malawi costing $0.29 per minute for an average airtime cost of $0.86 per mobile phone tracing. It is important to note that after the HPTN 052 pilot study, mobile phones were not purchased for participants in subsequent studies, thus reducing the average cost of mobile phone tracing from $16.33 to $0.99. Further cost breakdowns for mobile phone tracing can be found in Table 3.

Discussion

Patient tracing is important for continuous engagement of participants in clinical trials to ensure best health outcomes, keep resource and staffing costs low, and ensure proper adhere to study protocols for accurate interpretation of trial results. Employing novel tracing techniques and understanding their implementation implications is of utmost importance, especially in low-resource settings. In this study, mobile phone tracing was both acceptable to participants and feasibly integrated into the routine tracing efforts of the Community Department, reducing the time burdens and financial cost of participant tracing for UNC Project. To our knowledge, this is the first study that quantified the benefits of mobile phone tracing as an alternative or complimentary tracing method for clinical trials in Malawi.

The results of the pilot study show that most of the participants felt tracing by community staff was acceptable and necessary, while a strong majority preferred mobile phone tracing over physical tracing. Thus, using the mobile phone system can enhance the ability and desire of patients to engage in their care more actively while not on clinic site, potentially offering improved research outcomes.

Our study demonstrated that implementation of mobile phone tracing in clinical trials is feasible in our context, as the community staff conducted consistently higher proportions of mobile phone tracings each year. After the initial pilot study, mobile phone tracings were found to have a greater success rate in reaching patients compared to physical tracings (89% to 83%) and had a lower rate of patients failing to report to clinic when compared to physical tracings (8% to 12%). Although some studies indicate that mobile phone technology has no significant improvement in clinic attendance, our findings are consistent with the results from several other studies in similar settings that demonstrated improved clinic attendance after mobile phone tracing[16–20]. Increased use of mobile phone tracing by the community staff, along with continually higher success rates of contact with patients, indicate an increase in access to mobile phone technology among the population seeking to enroll in clinical trials. This is consistent with the general population trend in Malawi of mobile phone penetration, which has had substantial growth from roughly 3% in 2005 to nearly 45% in 2017[21]. Still, physical tracing is needed as an alternative tracing method for those without access to mobile phone technology. For example, while 96% of women in urban Malawi have reported access to mobile phones either themselves or through family/friends, women in rural Malawi are 3.5 times less likely to be connected[21]. Thus, mobile phone tracing and physical tracing methods should complement each other in order to continue strengthening patient engagement.

While it is exciting to know that mobile phone tracing can work in our setting, it is imperative to understand the cost implication due to the resource restraints of clinical research. Our analysis indicates that implementation of mobile tracing saved an average estimate of 45 minutes and $32.08 per tracing equating to an approximate total average of 1,821 hours and $40,557 savings per year. This is a substantial sum that can be reinvested into UNC project for further improvement in clinical care in Lilongwe, Malawi.

Despite mobile phone tracing being acceptable, effective, and cost-efficient in Lilongwe, there are still some challenges associated with the use of mobile phones in Malawi. Participants cited personal costs for airtime, inability to charge battery phones, limited network coverage, and lack of access to appropriate phone repair as potential hurdles to use. These findings are not unique to Lilongwe, as they are documented in other settings[22,23]. Improvements in the mobile phone technology infrastructure throughout Malawi will help to ensure better uptake and continued use of mobile phone technologies in clinic settings everywhere, both urban and rural. Alternative tracing methods, such as the use of WhatsApp or social media, may offer promising tracing results in the future as these methods are less likely to change. Following the results of our study, this has the potential to reduce clinic costs, save time, and improve access to care.

Limitations

As participants in the pilot study were provided with mobile phones, their responses to phone tracing acceptability may be biased in a positive direction. Cost estimates for physical tracing in the pilot and retrospective study did not incorporate car maintenance, which likely resulted in an underestimation of total physical tracing costs and an underestimation in the cost-savings of mobile phone tracings. While data was abstracted from over 20,000 tracings, we were not able to determine individual-level benefits of disease prevention or long-term health impact of mobile tracing. Tracing efforts were measured for research participants therefore may not directly apply to treatment and clinical programs, but the general trend is expected to be similar. Lastly, the comparison of tracing methods may be biased in favor of mobile tracing, because physical tracing methods are more frequently applied

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in more challenging tracing settings when mobile phone tracing was already attempted and unsuccessful.

Conclusion

Our study findings suggest that mobile phone tracing is highly acceptable among clinical trial participants and has the potential to effectively improve patient adherence to research protocol. Mobile phone tracing was found to be highly time and cost effective compared to physical tracing and was easily integrated into existing community staff tracing protocol. These findings will help contribute new, Malawi-specific evidence to the growing body of literature on the implementation of mobile phone technology in health services. These results may also inspire further research into the effects of mobile phone technology tracing on individual patient health outcomes.

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Competing Interests

None declared.

Patient Consent for Publication

All participants voluntarily agreed to have their views disseminated through publication and also presented during conferences locally and internationally.

Patient and Public Involvement Statement

The public were involved through the Community Advisory Board in the conduct, reporting, and dissemination plans of our research.

Data Availability Statement

Data from the study is available on reasonable request from the principal investigator at wkumwenda@unclilongwe.org. Proposals requesting data access will need to specify how data will be used.

Authors' Contributions

WK, NC, GW, MH developed the study design. WK, NM, NC, and GW were involved in the data collection and extraction. WK, NM, ES, MC, GW, and MH were involved in the statistical analysis, and initial drafts of the manuscript. WK, NM, IM, DK, IH, FM, and MH were involved in the preparation and editing of the final manuscript. All authors have read and approved the final version of the manuscript.

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