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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here polynomial multivariable regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

Ethics approval will be obtained from the National Ethics Committee in Cameroon. Administrative approval will be obtained from the Yaounde Central Hospital and the Ministry of Health. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10] Patients who receive them also report high levels of satisfaction.[8 11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of message, timing of message; nature of message (two-way or one way) or source of the message (peers or hospital based) can influence the efficacy of mobile phone text messaging.[13] There is a need for further research for many of these unanswered questions.[14]

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1] poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15] Recent reports suggest that PLHIV would like to receive text messages.[16] The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care (Mbuagbaw L, Thabane L. Opening communication channels with people living with HIV using mobile phone text messaging: Insights from the CAMPS trial, 2013).

Most successful health care programs are characterised by strong community participation.[17] Community participation has played a major role in the control of the HIV epidemic.[18] It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[19] Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[17] For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who

can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?
- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions**:**

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?
- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?
- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[20] The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists

and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[20]

On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval. The protocol we will submit to the National Ethics Committee will contain explicit details about why the data collection tool for the quantitative strand is unavailable.[20]

Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[20] This design has been used for complex research projects like mental health assessment in older adults,[21] healthcare students' educational expectations,[22] health system research,[23] alcohol use among people with liver disease and tobacco use.[24 25] Text messaging interventions are relatively new and to

the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[26] it is progressively gaining ground and acknowledgment in health research.[27] It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [28] In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[29] Figure 1 is a detailed flow diagram of the study procedures.

Study setting:

Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[30] In the HIV clinics, there are 6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[31] This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[32]

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers living with HIV
- They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and narrative data obtained from the cases.[31] PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion and if they meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[31] Consenting participants will be shown to a quiet nearby room prepared for the focus groups. No financial incentives shall be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[33] Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured on a seven-point scale); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% documented in another text messaging study among PLHIV in this clinic.[34] This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic.

Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order. For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in

a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?
How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?
Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
On feasibility

How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?
Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic socio-demographic data, adherence data, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple "yes or no" responses. Complex items like readiness will be presented on a seven-point Likert scale.[35]

Data analyses:

Qualitative data analysis:

Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[36] These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[37] For example pre-set categories like

lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[36]

Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the dichotomous dependent variable in a multinomial logistic regression analysis. Potential independent variables include: socio-demographics, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[38] Inferences will be drawn from both strands and across strands. These “meta-inferences” will be used to draw conclusions.[38] The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that

occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[39]

Table 2: Mixed methods data matrix

Strand					
Qualitative		**Quantitative**			
Themes identified	Number of times mentioned n (%)	Thematic variable	Representativeness N (%)	Influence on community readiness	
				Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[40] Figure 2 demonstrates the steps we will follow for analysis and integration of data.

Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[41] using items identified by as a cross-paradigm framework for trustworthiness and rigor.[42]

Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of quotes; and by comparing codes among several coders.[20 43] In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from those who do. Selection bias can be avoided at the design and analytical stages of a project.[44] Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[44]

External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-

demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[45]. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[46]

Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists, anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct. [47] Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

ETHICS AND DISSEMINATION:

Ethics:

Ethical approval and administrative clearance will be obtained from the Cameroon National Ethics Committee and the directorate of operational research in the Ministry of Health, respectively. These are the only compulsory regulatory bodies in Cameroon. Prior to these, permission to conduct the study will be obtained from the administration of the Yaoundé Central Hospital. We will use the focus group guiding document to prepare a draft questionnaire for the quantitative strand. The Ethics Committee will be informed that this document will be modified as the project unfolds.

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed Methods Research Designs for Health Services and Policy Research course (HRM/NUR 770) at McMaster University.

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COMPETING INTERESTS STATEMENT:

The authors declare none.

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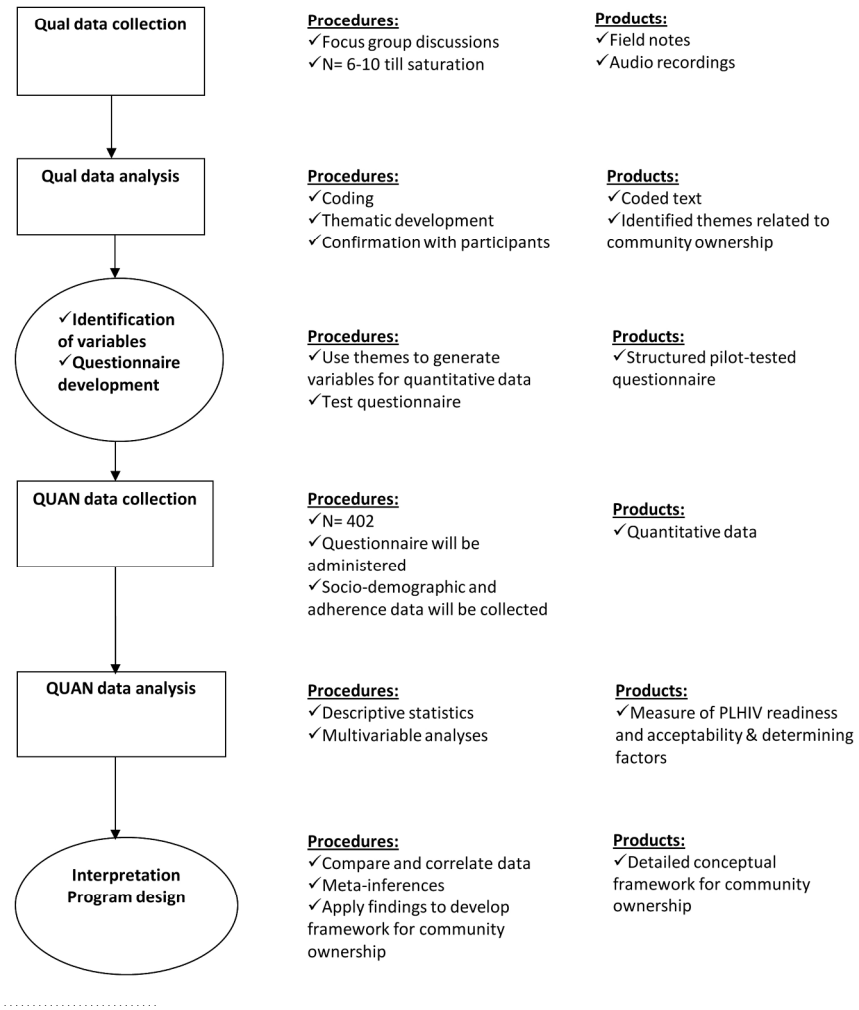

Figure 1: Overview of procedures and products of different strands
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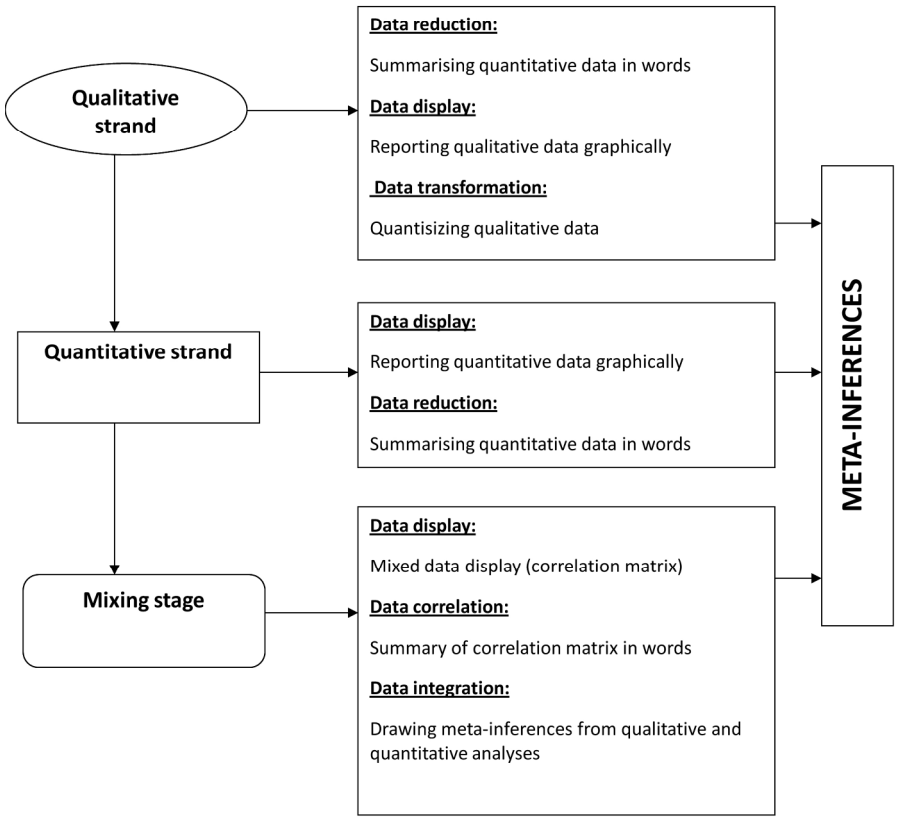

Figure 2: Steps in data analysis and integration
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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

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Antiretroviral therapy, mobile phone, text messages, community ownership

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here ordinal multivariable regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

Ethics approval will be obtained from the National Ethics Committee in Cameroon. Administrative approval will be obtained from the Yaounde Central Hospital and the Ministry of Health. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages (sending brief electronic messages to a mobile phone) can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10] Patients who receive them also report high levels of satisfaction.[8 11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of message, timing of message; nature of message (two-way or one way) or source of the message (peers or hospital based) can

influence the efficacy of mobile phone text messaging.[13] There is a need for further research for many of these unanswered questions.[14]

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1] poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15] Recent reports suggest that PLHIV would like to receive text messages.[16] The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care. [17] Cameroon also has a remarkably high mobile phone penetration, with a 270% increase in mobile subscriptions per annum between 2000 and 2005. [18]Most successful health care programs are characterised by strong community participation.[19] Community participation has played a major role in the control of the HIV epidemic.[20] It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[21] Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[19] For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. We will build upon previous research

using weekly motivational two-way text messaging to improve adherence to ART.[16 17 22] The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change. All references to "community" are made in regards to PLHIV in Yaounde, Cameroon.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?
- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions**:**

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?

- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?

- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[23] The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[23]

On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval. The protocol we will submit to the National Ethics Committee will contain explicit details about why the data collection tool for the quantitative strand is unavailable.[23]

Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[23] This design has been used for complex research projects like mental health assessment in older adults,[24]

healthcare students' educational expectations,[25] health system research,[26] alcohol use among people with liver disease and tobacco use.[27 28] Text messaging interventions are relatively new and to the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[29] it is progressively gaining ground and acknowledgment in health research.[30] It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [31] In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[32] Figure 1 is a detailed flow diagram of the study procedures.

Study setting:

Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[33] In the HIV clinics, there are

6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[34] This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[35]

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and qualitative data obtained from the cases.[34] PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion and if they meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[34] Consenting participants will be shown to a quiet nearby room prepared for the focus groups. Notes will be taken in writing and using an audio recorder by a note taker. No financial incentives shall

be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[36] Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured on a seven-point scale); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% documented in another text messaging study among PLHIV in this clinic.[22] This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic.

Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order.

For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all. The data collected from this strand will be used to formulate questions that best characterize acceptability and readiness.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?
How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?

Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
What roles can the community play in such a project?
On feasibility
How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?
Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand and existing frameworks,[37] to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic socio-demographic data, adherence data, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple “yes or no” responses. Complex items like readiness will be presented on a seven-point Likert scale.[38]

Data analyses:

Qualitative data analysis:

We will conduct a thematic analysis. Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[39] These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[40] For example pre-set categories like lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[39]

Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the ordinal dependent variable in a ordinal logistic regression analysis. Potential independent variables include: socio-demographics, mobile phone ownership, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[41] Inferences will be drawn from

both strands and across strands. These "meta-inferences" will be used to draw conclusions.[41] The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[42]

In the event that the qualitative and quantitative strands do not converge the data will be handled in one of four ways: firstly, the data may be re-analyzed through the lens of a different theoretical framework (reconciliation); secondly, the divergence may introduce new perspectives that generate new research questions (initiation); thirdly, irreconcilable differences may be viewed as best-case and worst-case scenarios (bracketing); and finally a complete re-appraisal of the body of evidence in terms of completeness and validity (exclusion).[43]

Table 2: Mixed methods data matrix

Strand				
Qualitative		**Quantitative**		
Themes identified	Number of times	Thematic variable	Representativeness N (%)	Influence on community readiness

	mentioned n (%)			Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[44] Figure 2 demonstrates the steps we will follow for analysis and integration of data.

Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[45] using items identified by as a cross-paradigm framework for trustworthiness and rigor.[46]

Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of quotes; and by comparing codes among several coders.[23 47] In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community

activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from those who do. Selection bias can be avoided at the design and analytical stages of a project.[48] Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[48]

External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[49]. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[50]

Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists, anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct. [51] Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

ETHICS AND DISSEMINATION:

Ethics:

Ethical approval and administrative clearance will be obtained from the Cameroon National Ethics Committee and the directorate of operational research in the Ministry of Health, respectively. These are the only compulsory regulatory bodies in Cameroon. Prior to these, permission to conduct the study will be obtained from the administration of the Yaoundé Central Hospital. We will use the focus group guiding document to prepare a draft questionnaire for the quantitative strand. The Ethics Committee will be informed that this document will be modified as the project unfolds.

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed Methods Research Designs for Health Services and Policy Research course (HRM/NUR 770) at McMaster University.

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COMPETING INTERESTS STATEMENT:

The authors declare none.

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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here ~~polynomial~~ ordinal multivariable regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

Ethics approval will be obtained from the National Ethics Committee in Cameroon. Administrative approval will be obtained from the Yaounde Central Hospital and the Ministry of Health. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages (sending brief electronic messages to a mobile phone) can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10] Patients who receive them also report high levels of satisfaction.[8 11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of message, timing of message; nature of message (two-way or one way) or source of the message (peers or hospital based) can

influence the efficacy of mobile phone text messaging.[13] There is a need for further research for many of these unanswered questions.[14]

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1] poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15] Recent reports suggest that PLHIV would like to receive text messages.[16] The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care. [17] Cameroon also has a remarkably high mobile phone penetration, with a 270% increase in mobile subscriptions per annum between 2000 and 2005. [18]~~(Mbuagbaw L, Thabane L. Opening communication channels with people living with HIV using mobile phone text messaging: Insights from the CAMPS trial, 2013).~~

Most successful health care programs are characterised by strong community participation.[19]~~[17]~~ Community participation has played a major role in the control of the HIV epidemic.[20]~~[18]~~ It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[21]~~[19]~~ Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[19]~~[17]~~ For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases

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in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. We will build upon previous research using weekly motivational two-way text messaging to improve adherence to ART.[16 17 22] The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

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The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change. All references to "community" are made in regards to PLHIV in Yaounde, Cameroon.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?
- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions:

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?
- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?
- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[23]~~[20]~~ The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé

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Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[23][~~20~~]

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On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval. The protocol we will submit to the National Ethics Committee will contain explicit details about why the data collection tool for the quantitative strand is unavailable.[23][~~20~~]

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Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[23][20] This design has been used for complex research projects like mental health assessment in older adults,[24][21] healthcare students' educational expectations,[25][22] health system research,[26][23] alcohol use among people with liver disease and tobacco use.[27 28][24 25] Text messaging interventions are relatively new and to the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[29][26] it is progressively gaining ground and acknowledgment in health research.[30][27] It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [31][28] In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[32][29] Figure 1 is a detailed flow diagram of the study procedures.

Study setting:

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Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[33]~~[30]~~ In the HIV clinics, there are 6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[34]~~[31]~~ This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[35]~~[32]~~

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers ~~living with HIV~~
- They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and ~~narrative~~ qualitative data obtained from the cases.[34]~~[31]~~ PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion

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and if they meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[34][~~31~~] Consenting participants will be shown to a quiet nearby room prepared for the focus groups. Notes will be taken in writing and using an audio recorder by a note taker. No financial incentives shall be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

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Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[36][~~33~~] Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured on a seven-point scale); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% documented in another text messaging study among PLHIV in this clinic.[22][~~34~~] This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic.

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Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order. For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all. The data collected from this strand will be used to formulate questions that best characterize acceptability and readiness.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?

How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?
Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
What roles can the community play in such a project?
On feasibility
How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?
Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand and existing frameworks,[37] to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic

socio-demographic data, adherence data, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple "yes or no" responses. Complex items like readiness will be presented on a seven-point Likert scale.[38][~~35~~]

Data analyses:

Qualitative data analysis:

We will conduct a thematic analysis. Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[39][~~36~~] These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[40][~~37~~] For example pre-set categories like lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[39][~~36~~]

Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the ~~dichotomous~~ ordinal dependent variable in a ~~multinomial~~ ordinal logistic regression analysis. Potential independent variables include: socio-demographics, mobile phone ownership, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

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Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[41]~~[38]~~ Inferences will be drawn from both strands and across strands. These "meta-inferences" will be used to draw conclusions.[41]~~[38]~~ The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[42]~~[39]~~

In the event that the qualitative and quantitative strands do not converge the data will be handled in one of four ways: firstly, the data may be re-analyzed through the lens of a different theoretical framework (reconciliation); secondly, the divergence may introduce new perspectives that generate new research questions (initiation); thirdly, irreconcilable differences may be viewed as best-case and worst-case scenarios (bracketing); and finally a complete re-appraisal of the body of evidence in terms of completeness and validity (exclusion).[43]

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Table 2: Mixed methods data matrix

Strand					
Qualitative		**Quantitative**			
Themes identified	Number of times mentioned n (%)	Thematic variable	Representativeness N (%)	Influence on community readiness	
				Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[44]~~[40]~~ Figure 2 demonstrates the steps we will follow for analysis and integration of data.

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Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[45]~~[41]~~ using items identified by as a cross-paradigm framework for trustworthiness and rigor.[46]~~[42]~~

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Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of

quotes; and by comparing codes among several coders.[23 47]~~[20 43]~~ In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

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Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from those who do. Selection bias can be avoided at the design and analytical stages of a project.[48]~~[44]~~ Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[48]~~[44]~~

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External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[49]~~[45]~~. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

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Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[50]~~[46]~~

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Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists, anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct.[51]~~[47]~~ Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

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ETHICS AND DISSEMINATION:

Ethics:

Ethical approval and administrative clearance will be obtained from the Cameroon National Ethics Committee and the directorate of operational research in the Ministry of Health, respectively. These are the only compulsory regulatory bodies in Cameroon. Prior to these, permission to conduct the study will be obtained from the administration of the Yaoundé Central Hospital. We will use the focus group guiding document to prepare a draft questionnaire for the quantitative strand. The Ethics Committee will be informed that this document will be modified as the project unfolds.

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed Methods Research Designs for Health Services and Policy Research course (HRM/NUR 770) at McMaster University.

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COMPETING INTERESTS STATEMENT:

The authors declare none.

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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here ordinal multivariable regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

Ethics approval will be obtained from the National Ethics Committee in Cameroon. Administrative approval will be obtained from the Yaounde Central Hospital and the Ministry of Health. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages (sending brief electronic messages to a mobile phone) can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10] Patients who receive them also report high levels of satisfaction.[8 11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of message, timing of message; nature of message (two-way or one way) or source of the message (peers or hospital based) can

influence the efficacy of mobile phone text messaging.[13] There is a need for further research for many of these unanswered questions.[14]

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1] poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15] Recent reports suggest that PLHIV would like to receive text messages.[16] The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care. [17] Cameroon also has a remarkably high mobile phone penetration, with a 270% increase in mobile subscriptions per annum between 2000 and 2005. [18]Most successful health care programs are characterised by strong community participation.[19] Community participation has played a major role in the control of the HIV epidemic.[20] It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[21] Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[19] For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. We will build upon previous research

using weekly motivational two-way text messaging to improve adherence to ART.[16 17 22] The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change. All references to "community" are made in regards to PLHIV in Yaounde, Cameroon.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?
- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions**:**

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?

- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?

- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[23] The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[23]

On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval. The protocol we will submit to the National Ethics Committee will contain explicit details about why the data collection tool for the quantitative strand is unavailable.[23]

Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[23] This design has been used for complex research projects like mental health assessment in older adults,[24]

healthcare students' educational expectations,[25] health system research,[26] alcohol use among people with liver disease and tobacco use.[27 28] Text messaging interventions are relatively new and to the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[29] it is progressively gaining ground and acknowledgment in health research.[30] It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [31] In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[32] Figure 1 is a detailed flow diagram of the study procedures.

Study setting:

Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[33] In the HIV clinics, there are

6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[34] This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[35]

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers
- They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and qualitative data obtained from the cases.[34] PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion and if they meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[34] Consenting participants will be shown to a quiet nearby room prepared for the focus groups. Notes will be taken in writing and using an audio recorder by a note taker. No financial incentives shall

be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[36] Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured on a seven-point scale); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% documented in another text messaging study among PLHIV in this clinic.[22] This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic.

Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order.

For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all. The data collected from this strand will be used to formulate questions that best characterize acceptability and readiness.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?
How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?

Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
What roles can the community play in such a project?
On feasibility
How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?
Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand and existing frameworks,[37] to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic socio-demographic data, adherence data, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple "yes or no" responses. Complex items like readiness will be presented on a seven-point Likert scale.[38]

Data analyses:

Qualitative data analysis:

We will conduct a thematic analysis. Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[39] These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[40] For example pre-set categories like lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[39]

Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the ordinal dependent variable in a ordinal logistic regression analysis. Potential independent variables include: socio-demographics, mobile phone ownership, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[41] Inferences will be drawn from

both strands and across strands. These "meta-inferences" will be used to draw conclusions.[41] The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[42]

In the event that the qualitative and quantitative strands do not converge the data will be handled in one of four ways: firstly, the data may be re-analyzed through the lens of a different theoretical framework (reconciliation); secondly, the divergence may introduce new perspectives that generate new research questions (initiation); thirdly, irreconcilable differences may be viewed as best-case and worst-case scenarios (bracketing); and finally a complete re-appraisal of the body of evidence in terms of completeness and validity (exclusion).[43]

Table 2: Mixed methods data matrix

Strand					
Qualitative		**Quantitative**			
Themes identified	Number of times mentioned n (%)	Thematic variable	Representativeness N (%)	Influence on community readiness	
				Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[44] Figure 2 demonstrates the steps we will follow for analysis and integration of data.

Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[45] using items identified by as a cross-paradigm framework for trustworthiness and rigor.[46]

Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of quotes; and by comparing codes among several coders.[23 47] In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from

those who do. Selection bias can be avoided at the design and analytical stages of a project.[48] Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[48]

External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[49]. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[50]

Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists,

anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct. [51] Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

ETHICS AND DISSEMINATION:

Ethics:

Ethical approval and administrative clearance will be obtained from the Cameroon National Ethics Committee and the directorate of operational research in the Ministry of Health, respectively. These are the only compulsory regulatory bodies in Cameroon. Prior to these, permission to conduct the study will be obtained from the administration of the Yaoundé Central Hospital. We will use the focus group guiding document to prepare a draft questionnaire for the quantitative strand. The Ethics Committee will be informed that this document will be modified as the project unfolds.

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed

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The authors declare none.

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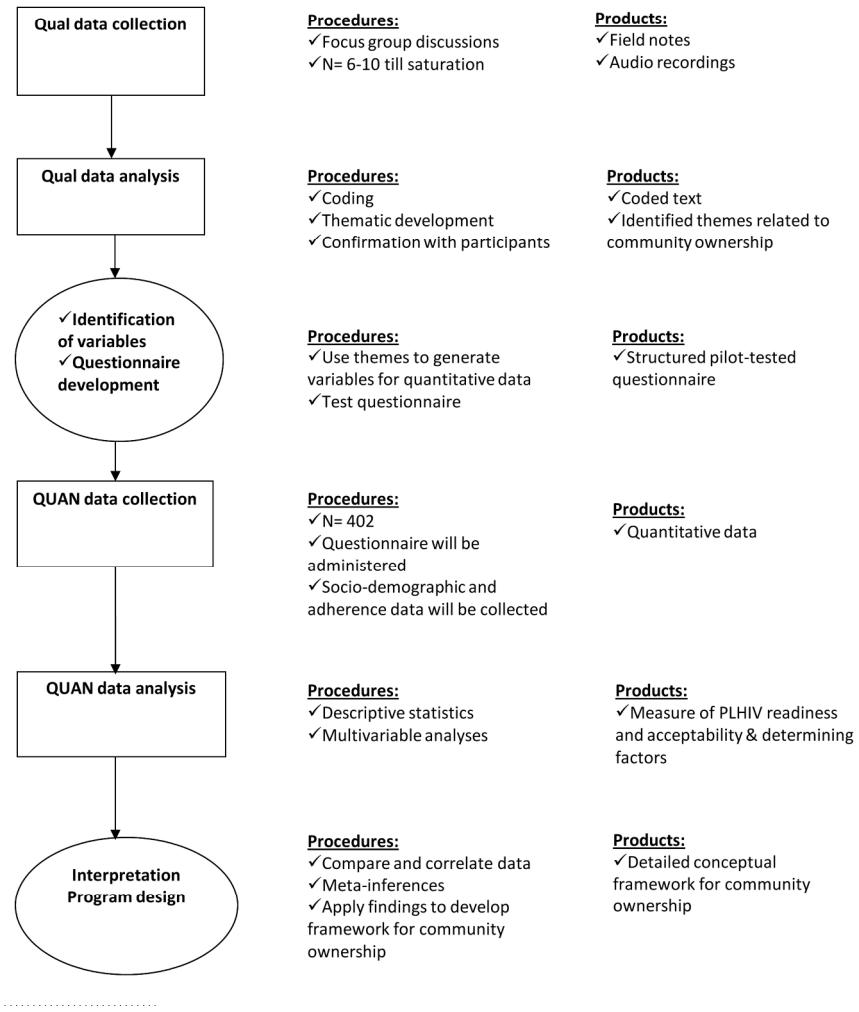

Figure 1: Overview of procedures and products of different strands
254x338mm (300 x 300 DPI)

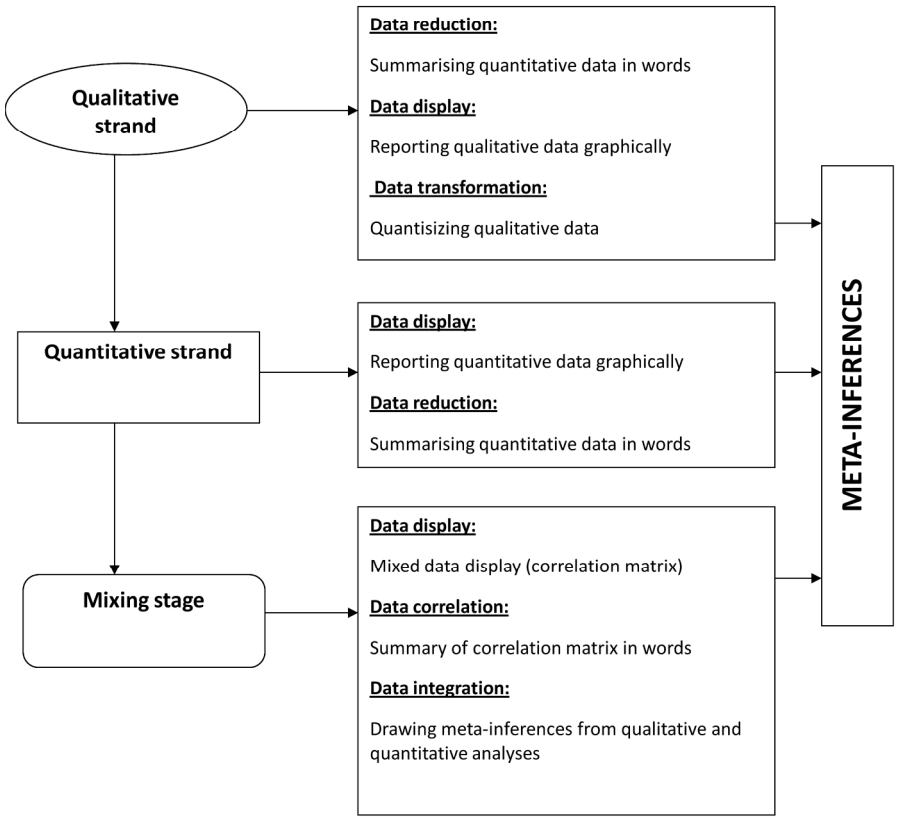

Figure 2: Steps in data analysis and integration
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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

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Antiretroviral therapy, mobile phone, text messages, community ownership

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages within health facilities. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here binary logistic regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

This study has been approved by the Yaounde Central Hospital Institutional Review Board. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages (sending brief electronic messages to a mobile phone) can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10] Patients who receive them also report high levels of satisfaction.[8 11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of the message, timing of the message; nature of the message (two-way or one way) or source of the message (peers or hospital

based) can influence the efficacy of mobile phone text messaging.[13] There is a need for further research which responds to many of these unanswered questions.[14]

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1] poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15] Recent reports suggest that PLHIV would like to receive text messages.[16] The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care, and reduce the overall effects of text messaging. For example, human resource shortages and medication stock-outs can limit the potential of adherence enhancing mHealth interventions. [17] Cameroon also has a high mobile phone penetration rate, with 52 mobile cellular subscriptions per 100 people in 2012. [18] Mobile text messaging and phone calls are mostly affordable, and can be as little as 25FRS CFA ($0.05) per message and 75 FRS CFA ($0.15) per minute, respectively.

Most successful health care programs are characterised by strong community participation.[19] Community participation has played a major role in the control of the HIV epidemic.[20] It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[21] Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[19] For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. We will build upon previous research using weekly motivational two-way text messaging to improve adherence to ART.[16 17 22] The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change. All references to "community" are made in regards to PLHIV in Yaounde, Cameroon.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?

- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions:

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?
- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?
- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[23] The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in

order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[23]

On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval.[23]

Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[23] This design has been used for complex research projects like mental health assessment in older adults,[24] healthcare students' educational expectations,[25] health system research,[26] alcohol use among people with liver disease and tobacco use.[27 28] Text messaging interventions are relatively new and to the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[29] it is progressively gaining ground and acknowledgment in health research.[30] It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [31] In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[32] Figure 1 is a detailed flow diagram of the study procedures.

Study setting:

Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[33] In the HIV clinics, there are 6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[34] This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[35]

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers
- They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and qualitative data obtained from the cases.[34] PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion and if they

meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[34] Consenting participants will be shown to a quiet nearby room prepared for the focus groups. Notes will be taken in writing and using an audio recorder by a note-taker. No financial incentives shall be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[36] Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured as a binary variable); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% - documented in another text messaging study among PLHIV in this clinic.[22] This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic. We acknowledge considerable uncertainty in the variables that will be used in the quantitative phase of the study, but opt for a binary outcome in order to achieve a larger sample size.

Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order. For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all. The data collected from this strand will be used to formulate questions that best characterize acceptability and readiness.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?
How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?
Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
What roles can the community play in such a project?
On feasibility
How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?

Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand and existing frameworks,[37] to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic socio-demographic data, adherence data, phone ownership and autonomy, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple "yes or no" responses. Complex items like readiness may be presented on a seven-point Likert scale.[38]

Data analyses:

Qualitative data analysis:

We will conduct a thematic analysis. Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[39] These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[40] For example pre-set categories like lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if

coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[39]

Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the binary dependent variable in a logistic regression analysis. Potential independent variables include: socio-demographics, mobile phone ownership, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[41] Inferences will be drawn from both strands and across strands. These “meta-inferences” will be used to draw conclusions.[41] The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[42]

In the event that the qualitative and quantitative strands do not converge the data will be handled in one of four ways: firstly, the data may be re-analyzed through the lens of a different theoretical framework (reconciliation); secondly, the divergence may introduce new perspectives that generate new research questions (initiation); thirdly, irreconcilable differences may be viewed as best-case and worst-case scenarios (bracketing); and finally a complete re-appraisal of the body of evidence in terms of completeness and validity (exclusion).[43]

Table 2: Mixed methods data matrix

Strand					
Qualitative		**Quantitative**			
Themes identified	Number of times mentioned n (%)	Thematic variable	Representativeness N (%)	Influence on community readiness	
				Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[44] Figure 2 demonstrates the steps we will follow for analysis and integration of data.

Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[45] using items identified by as a cross-paradigm framework for trustworthiness and rigor.[46]

Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of quotes; and by comparing codes among several coders.[23 47] In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from those who do. Selection bias can be avoided at the design and analytical stages of a project.[48] Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[48]

External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-

demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[49]. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[50]

Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists, anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct. [51] Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

ETHICS AND DISSEMINATION:

Ethics:

Ethics approval has been obtained from the Institutional Review Board (IRB) of the Yaounde Central Hospital (N°288L/MINSANTE/SG/DHCY/Stages on the 16th May 2013).

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis. As part of the ethics approval agreement, a copy of this thesis will be submitted to the Yaounde Central Hospital IRB.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed Methods Research Designs for Health Services and Policy Research course (HRM/NUR 770) at McMaster University.

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COMPETING INTERESTS STATEMENT:

The authors declare none.

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Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol

Authors:

Lawrence Mbuagbaw*[1,2], Pierre Ongolo-Zogo[1], Lehana Thabane[2,3,4,5,6]

Affiliations:

[1] Centre for the Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Avenue Henri Dunant, Messa, PO Box 87, Yaoundé, Cameroon; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, ON, Canada; [3]Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada; [4]Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada; [5]Centre for Evaluation of Medicine, St Joseph's Healthcare—Hamilton, ON, Canada; [6] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada.

E-mail: Lawrence Mbuagbaw* - mbuagblc@mcmaster.ca; Lehana Thabane - thabanl@mcmaster.ca; Pierre Ongolo-Zogo - pc.ongolo@gmail.com

***Corresponding author**

1280 Main Street West,

HSC 2C7, Hamilton,

ON, L8S4K1, Canada

Tel: 9055259140 Ext 22430

Key words:

Antiretroviral therapy, mobile phone, text messages, community ownership

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ABSTRACT:

Introduction:

Mobile phone ownership and use is growing fastest in sub-Saharan Africa, and there is evidence that mobile phone text messages can be used successfully to significantly improve adherence to antiretroviral therapy and reduce treatment interruptions. However, the effects of many mobile health interventions are often reduced by human resource shortages within health facilities. Also, the research projects generating the evidence for health interventions in developing countries are most often conducted using external funding sources, with limited sustainability and adoption by local governments following the completion of the projects. Strong community participation driven by active outreach programs and mobilization of community resources are the key to successful adoption and long-term sustainability of effective interventions. Our aim is to develop a framework for community ownership of a text messaging program to improve adherence to antiretroviral therapy; improve communication between patients and doctors; and as a reminder for appointments.

Methods and analysis:

We will use the exploratory sequential mixed methods approach. The first qualitative phase will entail focus group discussions with people living with HIV at the Yaoundé Central Hospital in Yaounde Cameroon (6-10 participants per group). The second quantitative phase will involve a cross-sectional survey (n=402). Here ~~ordinal~~ binary ~~multivariable regression~~logistic regression techniques will be used to determine the factors associated with community readiness and acceptability of ownership. Data from both phases will be merged.

Ethics and dissemination:

~~Ethics approval will be obtained from the National Ethics Committee in Cameroon. Administrative approval will be obtained from the Yaounde Central Hospital and the Ministry of Health~~This study has been approved by the Yaounde Central Hospital Institutional Review Board. The results of this paper will be disseminated as peer reviewed publications, at conferences and as part of a doctoral thesis.

ARTICLE SUMMARY:

Article focus:

- Text messaging to improve adherence to antiretroviral therapy and communication between patients and providers
- Community ownership of supportive programs

Key messages

- Benefits and strengths of community ownership of programs
- Community readiness to own supportive programs

Strengths and limitations of study

- Robust study design based on mixed methods
- Components of research unfold during the study and may affect initial planning

INTRODUCTION:

At the end of 2010 approximately 34 million people were living with the human immunodeficiency virus (HIV). Close to seventy percent of them live in sub-Saharan Africa even though this region represents only 12 percent of the world's population.[1][1] However, there has been a steady decrease in Acquired Immune Deficiency Syndrome (AIDS) related deaths as free antiretroviral therapy (ART) has become more available in recent years.[1][1] While governments and health systems in sub-Saharan Africa continue to invest in providing free access to ART, their efforts are hampered by health system weaknesses that prevent a continuous supply of ART and sub-optimal levels of adherence.[2][2] Relatively high levels of adherence are necessary to achieve the goals of ART such as viral suppression and immune reconstitution.[3][3] High levels of adherence will therefore lead to reduced morbidity and mortality in people living with HIV, and minimal development of resistant strains.[3-6][3-6]

In recent years the WHO has endorsed the use of cheap and effective technologies to improve health outcomes in low resource settings,[7][7] and there is emerging evidence on the role a mobile phone text message -short message service (SMS) can play in the management of HIV. Text messages (sending brief electronic messages to a mobile phone) can improve adherence to ART, reduce treatment interruptions and reduce viral load.[8 9][8–9] They are useful as appointment reminders and can improve communication between health personnel and patients.[10][10] Patients who receive them also report high levels of satisfaction.[8 11][8-11] These advantages, coupled with the rapid growth of mobile phone ownership and use in Africa,[12][12] make the SMS an important tool to improve care in people living with HIV (PLHIV). The research on mobile phone text messaging is somewhat nuanced by the complexity of the intervention. It is unclear how factors such as community phone ownership, content of the message, timing of the message; nature of the message (two-way or one way) or source of the message

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(peers or hospital based) can influence the efficacy of mobile phone text messaging.[13]~~[13]~~ There is a need for further research ~~for~~ which responds to many of these unanswered questions.[14]~~[14]~~

Cameroon has the highest rate of HIV in West and Central Africa, with a 5.3% prevalence in the adult population;[1]~~[1]~~ poor adherence rates and serious health system weaknesses that pose a threat to the management of HIV.[15]~~[15]~~ Recent reports suggest that PLHIV would like to receive text messages.[16]~~[16]~~ The communication channels opened by text messaging also serve as a platform to identify key individual and health system weaknesses that diminish the quality of care, and reduce the overall effects of text ~~-~~messaging. For example, human resource shortages and medication stock-outs can limit the potential of adherence enhancing mHealth interventions. [17]~~[17]~~ Cameroon also has a high mobile phone penetration rate, with 52 mobile cellular subscriptions per 100 people in 2012. [18] Mobile text messaging and phone calls are mostly affordable, and can be as little as 25FRS CFA ($0.05) per message and 75 FRS CFA ($0.15) per minute, respectively.

Most successful health care programs are characterised by strong community participation.[19]~~[19]~~ Community participation has played a major role in the control of the HIV epidemic.[20]~~[20]~~ It should be encouraged because the programs will have better outreach; community contributions (money, manpower and material) can be mobilised and; more importantly, because communities have a right to take part in the decisions that affect their lives.[21]~~[21]~~ Community participation (in HIV programs) has often been limited to the less technical aspects. Apart from providing an organised front to defend the interests of PLHIV, they also take part in providing care, research, peer education and role modelling.[19]~~[19]~~ For newer interventions such as text messaging which is more structured and technologically oriented, the potential of community ownership needs to be explored.

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We expect to observe an overall acceptability and readiness to own a text messaging program but a lack of skills in how to manage one. Our findings will be used to inform initiatives aimed at up scaling the use of mobile phone technology to improve adherence to antiretroviral therapy and other chronic diseases in resource limited settings and how best community members can be involved in the process. At the end of the project we will develop a framework for transferring technology into the hands of the community and initiating a sustainable community-led project. We will build upon previous research using weekly motivational two-way text messaging to improve adherence to ART.[16 17 22]~~[16 17 22]~~

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The following groups of people will benefit from this project: PLHIV in resource limited areas; people living with other chronic diseases who can benefit from enhanced communication with the health system; and health workers and community health workers who provide care for PLHIV.

The objective of this project is to determine how to set-up a community-owned text messaging program by determining the readiness and acceptability of ownership among PLHIV at the Yaoundé Central Hospital in Cameroon. We will proceed by collecting, analysing and comparing qualitative and quantitative data. The findings from this mixed methods study will be used to establish a framework for community ownership.

For the purposes of this paper, we define community ownership as a process in which the community members design, manage and reap benefits from a project. We also acknowledge that in the course of our research our definition may change. All references to "community" are made in regards to PLHIV in Yaounde, Cameroon.

The following research questions will guide the conduct of this study:

Qualitative research questions:

- Will PLHIV in Yaoundé, Cameroon accept community ownership of a text messaging program?

- How ready is the community of PLHIV in Yaoundé, Cameroon to take ownership of a text messaging program?

Quantitative research questions:

- What factors are associated with acceptability and readiness of community ownership of a text messaging program among PLHIV in Yaoundé, Cameroon?
- What proportions of PLHIV will accept and are ready to run a community owned text messaging program?

Mixed methods research questions:

- Are the themes related to the opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon generalizable to a larger sample of PLHIV in Yaoundé?
- In what ways do the qualitative and quantitative strands converge?

METHODS AND ANALYSIS:

Study design:

We will use an exploratory sequential design.[23]~~[23]~~ The exploratory sequential design is a two-phase design that starts with an initial qualitative phase followed by a quantitative phase. In the qualitative phase, we will identify individuals with experience in community ownership for in-depth interviews. The members of the associations of PLHIV and others with community level experience will be selected from the Yaoundé Central Hospital. This relatively small number of individuals will be interviewed to identify themes, ideas and concepts that will be used to guide the second quantitative phase. Data collected from the qualitative phase will be converted into variables that will be used on a much larger sample in

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order to generalise the findings to all the PLHIV in Yaoundé. This sample will be taken from the Yaoundé Central Hospital. See figure 1 for details on the procedures and products of the different strands of the study.

Figure 1: Overview of procedures and products of different strands

The exploratory sequential design is preferred for this study because of the following reasons. Firstly, the separation of the qualitative and quantitative phases makes it easier for our multidisciplinary team to work together and the separate methods and findings can be described easier. The anthropologists and sociologists will be responsible for data collection and analysis in the qualitative strand. The themes that emerge from their analysis will be converted into variables and built into a questionnaire by both groups. Secondly, the use of both qualitative and quantitative methods makes it more acceptable to researchers from both domains. Even though the overarching goal is to merge and compare qualitative and quantitative data, the findings from each domain still hold merit and can be interpreted separately. Thirdly, it will be used to develop a measurement instrument. The data collection tool for the quantitative phase will be developed from the qualitative strand. Items to measure community readiness and acceptability of ownership will be framed based on the responses in the qualitative strand. Lastly, it is a good design for generalizing qualitative research findings.[23]~~[23]~~

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On the other hand, organizing two separate strategies for data collection will be time-consuming. Separate sampling techniques have to be applied for both strands: the sample of PLHIV for the qualitative strand will be selected purposefully based on their experience with community activities, while the quantitative strand will be probabilistic. Details on the quantitative phase will not be available at the time of Institutional Review Board approval. ~~The protocol we will submit to the National Ethics~~

~~Committee will contain explicit details about why the data collection tool for the quantitative strand is unavailable.~~[23]~~[23]~~

Rationale for design:

Despite these characteristics, the exploratory sequential design is the method of choice when the variables that may come into play are unknown and when there is no guiding framework.[23]~~[23]~~ This design has been used for complex research projects like mental health assessment in older adults,[24]~~[24]~~ healthcare students' educational expectations,[25]~~[25]~~ health system research,[26]~~[26]~~ alcohol use among people with liver disease and tobacco use.[27 28]~~[27 28]~~ Text messaging interventions are relatively new and to the best of our knowledge community ownership has not been investigated for a text messaging program.

In recent years, mixed methods research has emerged as a separate research paradigm-a seamless blend of both qualitative and quantitative research methods. Even though it was not initially used on the basis of its merits,[29]~~[29]~~ it is progressively gaining ground and acknowledgment in health research.[30]~~[30]~~ It offers a "powerful third paradigm choice that often will provide the most informative, complete, balanced and useful research results". [31]~~[31]~~ In order to explore how PLHIV perceive text messages and the eventuality of owning and managing a text message project we are going to use mixed methods to identify common themes which arise and to subsequently generalise these findings to a larger sample. The complex nature of the research question warrants the use of mixed methods to generate a rich and complementary body of evidence to initiate a community-owned program. The methods used to initiate community ownership need to be well spelled-out and should originate from a robust and expanded body of evidence, which cannot be achieved by only qualitative or quantitative designs. We therefore seek complementarity, initiation and expansion.[32]~~[32]~~ Figure 1 is a detailed flow diagram of the study procedures.

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Study setting:

Yaoundé is the capital city of Cameroon, a central African low-income country. The adult prevalence of HIV in Cameroon is 5.3%.[1][1] The Yaoundé Central hospital houses the largest HIV clinic in the country. It has a capacity of 381 beds and is staffed by 95 doctors and 270 nurses.[33][33] In the HIV clinics, there are 6500 regular clients and approximately 40 new cases every week. This hospital is one of the pioneer centres for HIV research in Cameroon, and offers a great potential for recruitment and data collection.

Sampling:

The overall purpose of this sample is to address the research question, in a generalizable way using both purposeful and probabilistic techniques that ensure data collection in breadth and depth.[34][34] This is a useful combination of sampling strategies that helps to generate items and variables for questionnaires; and to generate hypotheses.[35][35]

Qualitative strand:

A purposeful sampling strategy will be used to determine who will participate in the qualitative strand. PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria:

- They should belong to an association of PLHIV (leaders or members)
- They are community health workers
- They are willing to participate in a community owned text messaging program

Focus groups of 6-10 participants will be constituted consecutively until no new ideas emerge. We will focus on depth of information and qualitative data obtained from the cases.[34][34] PLHIV will be recruited from the waiting rooms of the Yaoundé Central Hospital HIV clinic. They will be approached by

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the plain-clothed non-staff moderator to determine their interest in taking part in a group discussion and if they meet the pre-specified criteria. This is typical case sampling, aimed at identifying representative cases.[34]~~[34]~~ Consenting participants will be shown to a quiet nearby room prepared for the focus groups. Notes will be taken in writing and using an audio recorder by a note-taker. No financial incentives shall be offered, but waiting times at the clinic will be reduced (in collaboration with the attending physician) after participation. The protocol will be presented to the hospital staff and the procedures for reducing waiting times will be discussed.

Quantitative strand:

All PLHIV attending the Yaoundé Central Hospital HIV clinic during the study period will be eligible for enrolment, provided they are aged 21 years or more and give consent. Sample size will be determined using the formula proposed by Cochran for surveys.[36]~~[36]~~ Assuming an alpha level of 0.05; a 5% margin of error (for categorical data); a standard deviation of 0.5 (for a primary outcome - community readiness measured ~~on a seven-point scale~~as a binary variable); in a population of 6500 PLHIV at the Yaoundé Central Hospital, we arrived at a sample of 402; taking into account a "refusal to participate rate" of 10% - documented in another text messaging study among PLHIV in this clinic.[22]~~[22]~~ This sample is meant to be representative of the entire population of PLHIV attending the Yaoundé Central Hospital HIV clinic. We acknowledge considerable uncertainty in the variables that will be used in the quantitative phase of the study, but opt for a binary outcome in order to achieve a larger sample size.

Data collection:

Prior to data collection we will organise brief training sessions for the data collectors in the qualitative and quantitative strands. The purpose of this training will be to familiarise them with their working

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instruments and to standardise the procedure for participant invitation, obtaining consent and data collection.

Qualitative strand:

Focus group discussions will be conducted using a pre-established interview guide (See Table 1). It will contain basic socio-demographic information, a description of participant involvement in community activities (eligibility criteria fulfilled), and specific themes related to the phenomenon under study. An experienced moderator and note-taker will invite, request consent and enrol participants, in that order. For each session, the data collectors will be dressed in plain clothes and use a separate room free from distractions for the focus groups. The note taker will be responsible for noting the non-verbal cues emanating from the participants and operating the audio-recorder. The audio recorder will be tested in a mock session for clarity of recordings. Participants will be encouraged to speak in tones that can be recorded. The moderator will be responsible for keeping the discussions in line with the guide while exploring interesting dimensions that arise from the discussions. More importantly, the moderator will be responsible for gaining the trust of the participants and encouraging participation from all. The data collected from this strand will be used to formulate questions that best characterize acceptability and readiness.

Table 1: Focus group discussion guide

Focus Group Discussion Guide
Preparatory steps
Does participant meet criteria?
Have they given written/verbal consent?
Collect socio-demographic data (age, gender); note time; number of participants
On existing community activities
What community initiatives/activities/organisations exist for PLHIV?
What community activity do you participate in?
How do you benefit from these activities?
On a text messaging project
The purpose of this project is to improve adherence to HIV medication and to foster communication with health workers. What other goals do you think can be achieved through text messaging?
Do you think you (as a community) are ready to run a text message project?
Would you accept to run or take part in a text messaging project?
What strengths does the community have that can be used to run such a project?
What weaknesses does the community have that can hinder the project?
What roles can the community play in such a project?
On feasibility
How do you think the project should be financed?
Are you willing to pay to receive a text messages?
Do you think the community is ready to run such a project?

Would you like health workers to be involved in the management of such a project?
Any other issues participants would like to discuss

Quantitative strand:

In the quantitative strand, patients will be approached at the clinic in various locations: the outpatient department, the pharmacy and the laboratory. Four interviewers will concurrently conduct the survey to maximize recruitment. Recruitment and data collection will continue until the required sample is achieved. The trained interviewers will employ the pre-tested questionnaire developed from the qualitative strand and existing frameworks,[37]~~[37]~~ to collect data from all eligible participants. The data collection tool will be developed based on findings from the qualitative strand. It will contain basic socio-demographic data, adherence data, phone ownership and autonomy, information related to participation in community activities and other variables generated from the themes identified in the qualitative strand. The questions will be closed-ended with simple "yes or no" responses. Complex items like readiness ~~will~~ may be presented on a seven-point Likert scale.[38]~~[38]~~

Data analyses:

Qualitative data analysis:

We will conduct a thematic analysis. Qualitative data will be analysed by transcribing into text. Codes will be generated by looking for repetitions in the text.[39]~~[39]~~ These repetitions (codes) will be grouped based on their similarity into categories and the overarching themes will be identified. We will use a number of pre-set categories to guide the process, but emergent categories will also be noted.[40]~~[40]~~ For example pre-set categories like lack of familiarity with text messaging or lack of skills to run a text messaging project shall be identified. This coding will be done by multiple researchers to determine if

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coders agree on the themes assigned to a segment of text. The themes will be displayed visually in a conceptual model, showing how the themes are linked to each other.[39] ~~[39]~~

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Quantitative analyses:

Quantitative data will be analysed using using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc., 2009, Chicago, IL, USA). Statistical significance will be set at alpha= 0.05. Adjusted odds ratios (aOR), 95% confidence intervals (CI) and p-values will be presented. We will explore community readiness for ownership of a text messaging project as the ~~ordinal~~ binary dependent variable in a ~~ordinal~~ logistic regression analysis. Potential independent variables include: socio-demographics, mobile phone ownership, familiarity with text messaging, level of adherence to medication, need for additional support, and level of comfort with community management.

Data integration:

Due to the sequential design of the study, the qualitative and quantitative components will be analysed separately in a sequential qualitative-quantitative analysis. This is the method of choice when the analysis of one strand is necessary to inform the conduct of the next.[41] ~~[41]~~ Inferences will be drawn from both strands and across strands. These "meta-inferences" will be used to draw conclusions.[41] ~~[41]~~ The qualitative and quantitative strands will be merged in a matrix to display how they are related to each other. Table 2 is a sample of how both strands of data will be put together, linking themes to thematic variables and statistical analyses. This correlation matrix will help to identify relationships between themes and thematic variables (statistical triangulation) and strong thematic variables (variables that occur frequently). It will also show how the quantitative data expand on the qualitative findings. These techniques of data integration have been used previously and have been described in detail.[42] ~~[42]~~

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In the event that the qualitative and quantitative strands do not converge the data will be handled in one of four ways: firstly, the data may be re-analyzed through the lens of a different theoretical framework (reconciliation); secondly, the divergence may introduce new perspectives that generate new research questions (initiation); thirdly, irreconcilable differences may be viewed as best-case and worst-case scenarios (bracketing); and finally a complete re-appraisal of the body of evidence in terms of completeness and validity (exclusion).[43]~~[43]~~

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Table 2: Mixed methods data matrix

Strand					
Qualitative		**Quantitative**			
Themes identified	Number of times mentioned n (%)	Thematic variable	Representativeness N (%)	Influence on community readiness	
				Univariate (OR, 95% CI; p)	Multivariable (aOR, 95% CI; p)

aOR: adjusted odds ratio; CI: confidence interval

In the qualitative strand, data will be analysed, reduced, displayed and transformed into quantitative variables. In the quantitative strand, data will be analysed, reduced and displayed. At the final stage (data mixing), data will be displayed, correlated and integrated.[44]~~[44]~~ Figure 2 demonstrates the steps we will follow for analysis and integration of data.

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Figure 2: Steps in data analysis and integration

Validation checks and dealing with sources of bias:

We will draw from published criteria for critical appraisal of mixed-methods studies to validate our research,[45][45] using items identified by as a cross-paradigm framework for trustworthiness and rigor.[46][46]

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Internal validity:

In the qualitative strand, internal validation (credibility) will be performed by using an audio recording device to ensure accuracy; member-checking of collected data for general accuracy and accuracy of quotes; and by comparing codes among several coders.[23 47][23 47] In the quantitative strand we will limit information bias by pilot testing the questionnaire for clarity (participants understand the questions as they were meant to be understood) and using non-staff interviewers. We will also adjust for potential confounding during analysis. For example, participants who already participate in some community activities may be more likely to report readiness to participate in a text message program. We will try to capture this in our analyses.

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Data will be collected from PLHIV at the Yaoundé Central Hospital, the population to whom we want to generalize our findings, so selection bias is unlikely to be significant. However, we will collect socio-demographic data from the participants who refuse to participate to see if they differ significantly from those who do. Selection bias can be avoided at the design and analytical stages of a project.[48][48] Data from the qualitative phase may help to identify variables that are associated with willingness to participate in the survey. These variables can be used to restrict participation or be measured accurately and used for adjusted analyses.[48][48]

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External validity:

The extent to which our findings can be generalized to the rest of the population of PLHIV at the Yaoundé Central hospital will be verified by using a large (pre-determined) sample, comparing the socio-demographics of our sample to the parent population and by investigating any refusals to participate. In this way we will be able to make statistical (external) generalizations[49]~~[49]~~. We also state the purpose of our study, the setting, the data collection procedures and the outcomes we are measuring: community readiness and acceptability of ownership of a text messaging program among PLHIV at the Yaounde Central Hospital.

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Consistency:

We will apply standardised qualitative (focus groups) and quantitative (survey) techniques (described above) to ensure consistent results. A journal of study activities will be kept so that the study procedures can be followed and replicated. Our data collection tools and techniques will be externally audited by the Cameroon National Ethics Committee.[50]~~[50]~~

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Feasibility:

This study will benefit from a number of characteristics that make it feasible. Firstly, the study is situated in a very active HIV centre with a large potential for recruitment in both strands of the study. Secondly, we have a pre-existing multidisciplinary team with collective experience in other qualitative and quantitative research projects. This team is made up of public health physicians, clinicians, sociologists, anthropologists, health economists and public health administrators. Thirdly, surveys in this setting are relatively inexpensive to conduct. [51]~~[51]~~ Finally, our host centre, the Centre for the Development of Best Practices in Health (CDBPH) has the infrastructure and experience for a research project of this scale and can provide administrative, logistic and communication support.

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ETHICS AND DISSEMINATION:

Ethics:

Ethics~~al~~ approval has been obtained from the Institutional Review Board (IRB) of the Yaounde Central Hospital (N°288L/MINSANTE/SG/DHCY/Stages on the 16th May 2013). ~~and administrative clearance will be obtained from the Cameroon National Ethics Committee and the directorate of operational research in the Ministry of Health, respectively. These are the only compulsory regulatory bodies in Cameroon. Prior to these, permission to conduct the study will be obtained from the administration of the Yaoundé Central Hospital. We will use the focus group guiding document to prepare a draft questionnaire for the quantitative strand. The Ethics Committee will be informed that this document will be modified as the project unfolds.~~

Dissemination plan for results:

We plan to disseminate our results at public presentations with stakeholders in Cameroon (Ministry of health staff, journalists, PLHIV, clinicians, community health workers, social workers, mobile communication operators); to publish the manuscript; and publicly present and defend our findings as part of a doctoral thesis. As part of the ethics approval agreement, a copy of this thesis will be submitted to the Yaounde Central Hospital IRB.

AUTHORS' CONTRIBUTIONS:

All three authors contributed to the conception of the study. LM developed the first draft of the manuscript. LT and POZ provided statistical and methodological input. All three authors read and edited several versions of the manuscript. Prof Mark Oremus provided input to this paper as part of the Mixed Methods Research Designs for Health Services and Policy Research course (HRM/NUR 770) at McMaster University.

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COMPETING INTERESTS STATEMENT:

The authors declare none.

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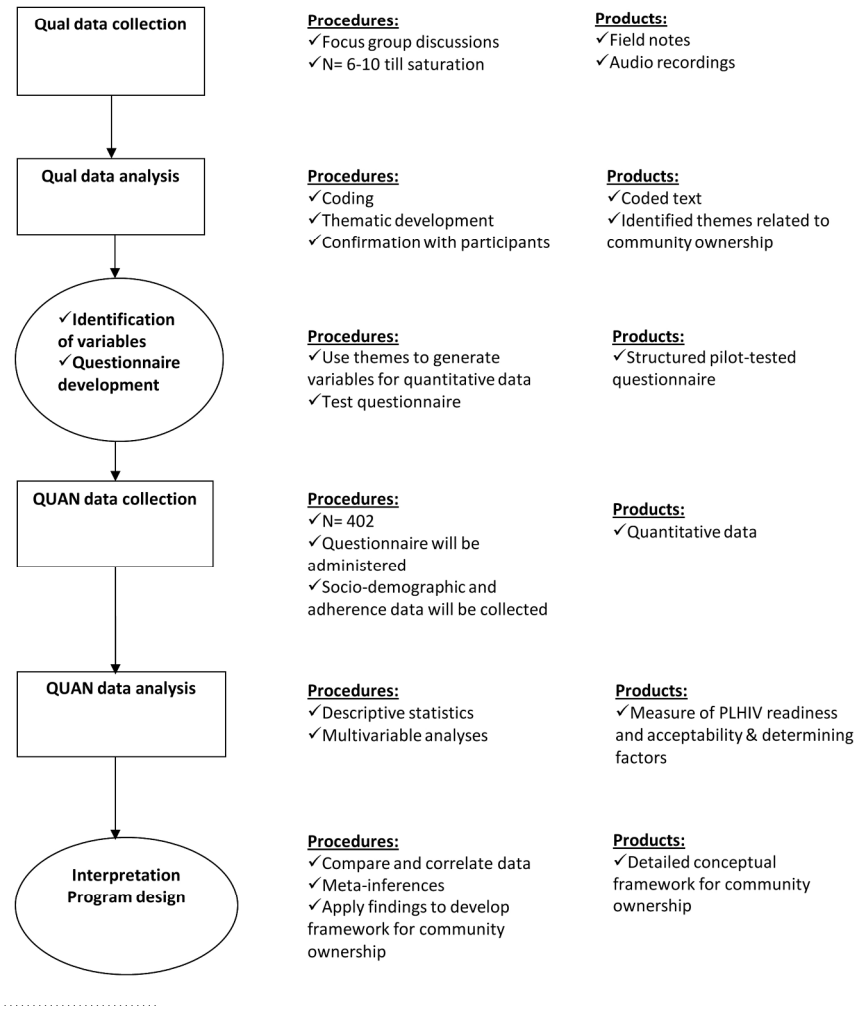

Figure 1: Overview of procedures and products of different strands
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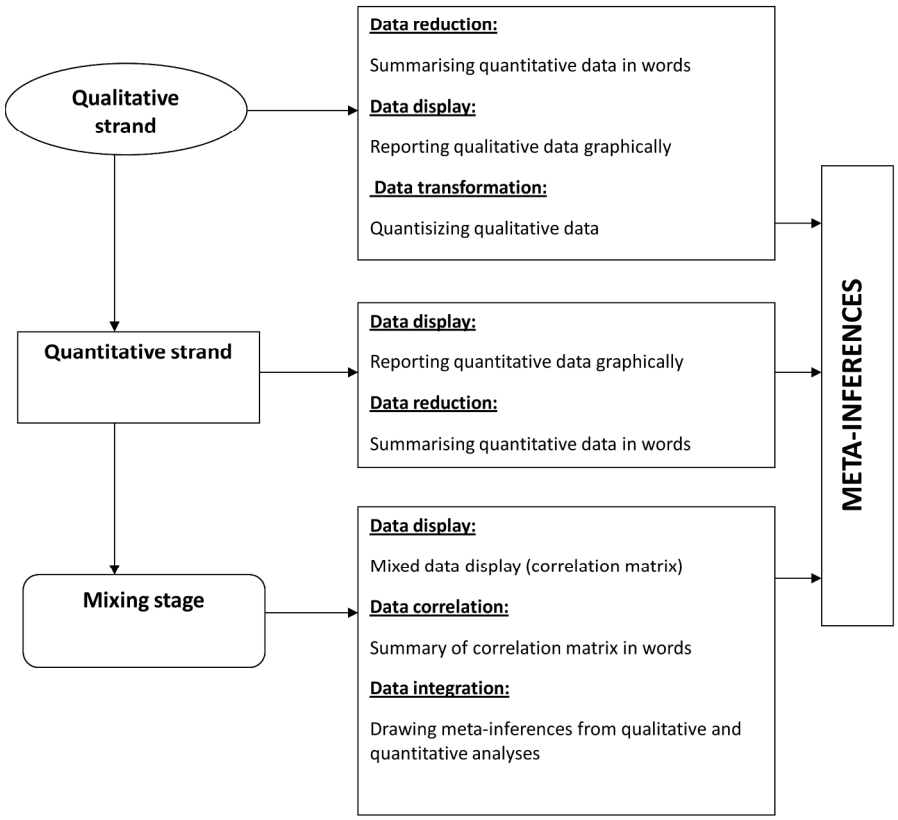

Figure 2: Steps in data analysis and integration
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