



STUDY PROTOCOL

Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya [version 1; peer review: 1 approved with reservations]

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Abstract

Globally, the number of COVID-19 infections is approaching 63 million; more than 1 million individuals have lost their lives. In Kenya, the number of infections has surpassed 80,000 and 1469 people have lost their lives. In Kenya, the community health strategy has been used to deliver essential health services since 2007. Furthermore, the population in Kenya is young (the median age is 21 years old) and Kenya is recognized as a technology hub in the East African region. Community-based health care, youth, and technology, are assets within the Kenyan context that can be leveraged to respond to the COVID-19 pandemic with concurrent strengthening of the critical care capacity at the health system level.

This is a quasi-experimental study with quantitative and qualitative methods of data collection to complete a baseline assessment of community health unit and health facility service readiness in the study site of Siaya County in western Kenya. Following the baseline assessment, service ready community health units and health facilities with oxygen capacity will form intervention groups. At the community level, the intervention will consist of training youth, community health assistants and community health workers in screening, case detection, prevention, management and referral of COVID-19 cases

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report

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

with maintenance of essential health services. The community intervention will be enhanced by youth and use of digital tools. At the health facility level, the intervention will consist of training health care workers in basic critical care and caring for severe COVID-19 patients with maintenance of essential health services.

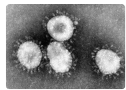
The primary outcome measure will be mortality related to COVID-19 infection both at community and health facility levels.

This study would be the first study to evaluate the effectiveness of an integrated approach in preparing for and implementing a robust pandemic response.

Registration: ClinicalTrials.gov ID [NCT04501458](https://clinicaltrials.gov/ct2/show/study/NCT04501458); registered on 6 August 2020.

Keywords

community health workers, technology, youth, linkage to clinical care, COVID-19 response, critical care capacity building



This article is included in the [Coronavirus \(COVID-19\)](#) collection.

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Introduction

Globally, the number of COVID-19 infections is approaching 34 million; more than 900,000 individuals have lost their lives¹. In Kenya, the number of infections has surpassed 20,000 and 388 people have lost their lives¹. In Kenya, the community health strategy has been used to deliver essential health services since 2007; community health workers are a core component of the strategy^{2,3}.

Community health strategy

The community approach would be built on the community health strategy (CHS), a flagship government policy that is based on the concept of social capital that is uniquely strong in sub-Saharan Africa (SSA)^{4,5}. Social capital is founded on the fabric of trust, shared values and understanding that allows people to work together towards collective outcomes and common goals⁶. According to the conceptualization of social capital includes elements of trust, mutuality and reciprocity, enabling people to be each other's keeper which is critical always but particularly so during emergencies, such as we are in now⁷. In solidarity, people ensure that everyone has access to social structures and vital resources critical for self-protection and survival, and which is the backbone of the proposed integrated community-based case detection, containment, and care⁸.

The CHS policy also involves shifting some tasks to the community level workforce. Task shifting is allocation of tasks in health systems delivery to the least costly worker capable of doing it reliably without compromising quality⁹⁻¹¹. Another critical element in the proposed strategy is the strengthening of the community-based health information system with mobile health technology. Health Information Systems (HISs) offer opportunities to inform health decision making at all levels of the health system which has proved of critical importance during the current pandemic¹². It is critical to design information systems that inform timely decision making in a situation in which the COVID-19 response must be continuously adjusted to the local context and manifestations of COVID-19 in the Kenyan context. This adjustment by decision makers must be informed by accurate, current and timely data to ensure timely action and accountability based on evidence-based decision making¹³. We are proposing that this process starts at the community health unit (CHU), but linked to the health centre and sub-county levels. Issues emerging from the data gathered and analyzed at every level are fed into decision making applying the principles of evaluative thinking¹³⁻¹⁵, leading to evidence based actions announced on a daily basis, and providing feedback on what must be done by the public to contribute effectively to flattening the curve by reducing the occurrence of new cases.

In this strategy we hypothesize that community-based action can be strengthened by mobile technology. In their systematic review assessed strategies, findings and quality of evidence regarding use of mobile technology to improve health¹⁶. Ippoliti and L'Engle found that mHealth is a promising approach in global health interventions; their systematic review confirmed

that digital media and web based platforms had altered the communication landscape especially for disease prevention and risk reduction¹⁷.

Since its adoption in Kenya, the CHS in Kenya, has built the capacity of communities to examine, plan, and implement health-related issues that affect their wellbeing^{2,3}. The CHS is well embedded in the Kenyan health system^{2,3}. It is supported and financed by the Ministry of Health. Therefore, CHS can be leveraged and included in the COVID-19 response. Furthermore, it can be enhanced by youth and technology to accelerate the COVID-19 response in Western Kenya.

CHS in pandemics

Boyce and Katz, in their review of the role of community health workers (CHWs) in pandemics, concluded that CHWs' roles could be expanded¹⁸. Specifically, CHWs could act as community-level educators, organizers, and mobilizers during infectious disease outbreaks; contribute to syndromic disease surveillance systems while completing routine activities; and complete medical tasks unrelated to the infectious disease outbreak to fill health service gaps during or following the outbreak.

Youth

The population in Kenya is young (the median age is 21 years old) and Kenya is recognized as a technology hub in the East African region^{19,20}. To our knowledge youth have not been engaged in health interventions during pandemics.

Rationale

Community-based health care, youth, and technology, are assets within the Kenyan context that can be leveraged to respond to the COVID-19 pandemic with concurrent strengthening of the critical care capacity at the health system level.

Protocol

Central research question

What is the effectiveness of an integrated approach, with technology and youth supported community based action and critical care capacity building, in enhancing increased case detection, more precise isolation/quarantine and improved community and hospital based case management of COVID-19 cases in Western Kenya?

Objective

To evaluate the effectiveness of an integrated approach, with technology and youth supported community based action and critical care capacity building, in enhancing case detection, more precise isolation/quarantine and improved community and hospital based case management of COVID-19 cases in Western Kenya.

Study design

This will be a study with a quasi-experimental design with quantitative and qualitative components (Figure 1).

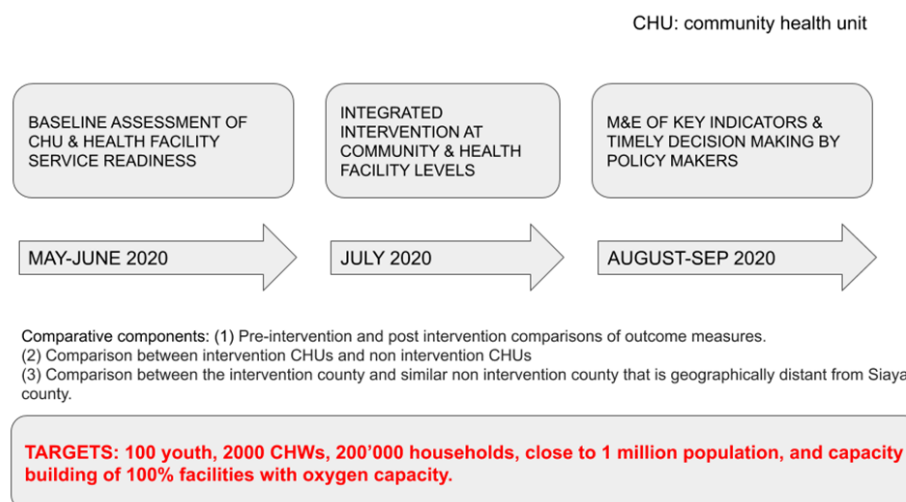


Figure 1. Study design.

There will be 3 comparative components in our design which will allow us to attribute outcomes observed to the intervention:

- (1) Pre-intervention and post intervention comparisons of outcome measures.
- (2) Comparison between intervention CHUs and non-intervention CHUs.
- (3) Comparison between the intervention county and similar non-intervention county that is geographically distant from Siaya County.

This study will be a collaborative research intervention involving policy makers, managers, service providers and researchers.

Setting

The intervention will take place in Siaya, a rural county in Western Kenya with a population of 993,183.

Study population (inclusion criteria)

Youth aged 18 to 30 years old who are interested in contributing to the COVID-19 response.

CHW: community health volunteers and community health assistants (CHAs) linked to the Siaya Ministry of Health.

Clinicians: Nurses, clinical officers, and medical officers working in health facilities in Siaya.

Households: Households in Siaya County.

Exclusion criteria

Populations and households outside of Siaya, individuals older than 30 or younger than 18 years old, non-community health workers, non-clinicians.

Baseline readiness assessment

We will use mixed methods with quantitative and qualitative components to complete a baseline assessment of community and health facility service readiness; as described by Creswell (2014); using standard community health unit and health facility assessment tools (see *Extended data*²¹).

The sampling frames of the study will be the list of all public and private health facilities, and the list of CHUs in each sub-county which will be obtained from the sub-County Health Management Teams.

Baseline knowledge assessment of study participants

At the community level, we will assess knowledge of COVID-19 as a disease. We will assess knowledge of symptoms, signs (including warning signs), basic management, and indications for transfer to a higher level of care for severe cases. At the health system level, we will assess knowledge of the pathophysiology of COVID-19, diagnosis, and treatment of moderate and severe COVID-19. The assessment will be in multiple choice questions format. Questions will cover material that is well established.

Intervention

Following the baseline assessment, functional community health units and facilities with oxygen capacity will form intervention groups. Non-functional community health units and health facilities that choose not to participate in the training will form control groups. Given the ongoing pandemic, community health units that later achieve readiness will be eligible to participate in the intervention as soon as they achieve readiness.

Community intervention. At the community level, using digitized tools, the intervention will consist of training youth, CHAs and CHWs in screening, case detection/contact tracing, prevention, management and referral of COVID-19 cases with maintenance of essential health services (curriculum in *Extended*

data²²). Furthermore, CHAs and lead CHW will be equipped with infrared thermometers and pulse oximeters. Training will take place in person and remotely and will use World Health Organization and Ministry of Health tools developed for the COVID-19 response^{23,24}.

Specifically, we will train CHAs to train CHWs to improve their knowledge and skills regarding COVID-19. Trained CHWs will carry out household screening for fever using non-contact thermometers. In this process they will ensure community infection prevention and control measures (IPC) with handwashing, physical distancing, and mask wearing. They will isolate households with fever and respiratory symptoms. They will be trained to rule out malaria using rapid diagnostic tests (RDT). Cases with fever and respiratory symptoms will then be tested by the Siaya Rapid Response Team consisting of health personnel from Siaya Referral Hospital²⁵. Those testing positive will be isolated in their own houses for 14 days under the care of CHWs. Those with severe disease will be referred to higher levels of care with oxygen capacity. Screening activities will be supported by youth using digital tools (Commcare).

Health facility intervention. At the health facility level, the intervention will consist of training health care workers in basic critical care and caring for severe COVID-19 patients with maintenance of essential health services using the World Health Organization and Kenya Ministry of Health tools²⁶. Furthermore, resources such oxygen tanks and anesthesia machines in unused operating room theaters will be repurposed to build critical care capacity. Health care workers will be equipped with pulse oximeters to improve their diagnostic and monitoring capacity based on the [World Health Organization short course on the critical care management of Severe Acute Respiratory Infection \(SARI\)](#). Any patient with evidence of organ failure (in this case respiratory failure) will be defined as critical. We will train staff (particularly nurses) in providing supportive critical care adapted to the resources available. Maneuvers such as proning and providing supplemental oxygen are now increasingly being recommended. Thus, critical care provided will

focus on providing adequate oxygen, hydration, nutrition, and frequent monitoring of vital signs.

Digital tools for data collection

The screening household behavior and fever survey, the baseline assessment tools and monitoring and evaluation of key indicators will be administered using the digitized version on Commcare. The survey assesses household handwashing behaviors, presence of fever, health seeking behavior, and household economic activity. Commcare is a well-established digital tool that has received security clearance from entities including the Centers for Disease Control. Data will be stored in the cloud and downloaded as needed for cleaning and analysis.

Africa COVID-19 screen

Africa COVID-19 Screen has been developed by a young team of software developers using flutter for the framework, dart for programming language, firebase for the backend, and Git/GitHub for version control, and vscode for code editing. It is based on the algorithm included as part of the household survey²⁷ and can be tested using the following link: <https://covid19-fb626.firebaseio.com/#/>. The algorithm assigns points based on yes or no answers. The total score is calculated and a risk group is assigned. Based on the risk group, a recommendation is given, and will be communicated to the head of the household immediately.

Each CHW will be paired with a youth who will assist in completing the digital tools. We therefore leverage the CHW's knowledge of the community and the youth's tech savviness. All cases with fever will be isolated, and based on the severity of the disease home management will be pursued. Isolated cases will be registered and followed for 2 weeks for signs of progression and need for transfer. Signs for transfer include respiratory distress and desaturation.

Study outcomes

Definition of outcome measures (Table 1):

Table 1. Outcome measures: (captured at baseline, midline, and endline phases of the project).

	Community	Health facility
Primary outcome measures	Number of cases screened, Number of cases isolated, Number of tests performed at community level Number of referrals to higher level of care Number of cases treated at the community level Number of deaths at community level	Number of COVID-19 cases admitted and managed Morbidity and mortality of COVID-19 cases Number of COVID-19 tests performed (laboratory and imaging) Admissions for respiratory symptoms at each level of the system in 2019 Morbidity and mortality related to respiratory illnesses Number of critical care beds with oxygen delivery capacity/vents
Secondary outcome measures	Community Health worker knowledge of COVID-19 Hand washing station per household Number of youth, CHAs, and CHWs trained Service readiness (basic equipment, human resources, and infrastructure)	Demographic characteristics and comorbidities of COVID-19 cases Health worker knowledge of COVID-19 Number of trained health workers at the health system level Service readiness (basic equipment, human resources, and infrastructure)

At the community level:

Number of households screened: number of households screened by the community health worker and youth on a given day.

Number of cases isolated: number of household members placed in isolation due to COVID-19 symptoms (febrile and respiratory illness).

Number of tests performed: number of COVID-19 polymerase chain reaction (PCR) tests performed.

Number of referrals: number of cases referred to the district or referral hospital.

Handwashing and physical distancing: number of households following stay at home rules, and number of households with a washing point with soap and water.

Deaths: Number of deaths at home following symptoms of COVID-19.

At the hospital level:

Number of cases tested: number of patients tested for COVID-19 on a given day.

Number of cases treated: number of COVID-19 cases treated on a given day.

Number of critical care beds: number of beds with a nurse and with oxygen capacity.

Deaths: number of deaths following the diagnosis of COVID-19.

The composite outcome measure is COVID-19 related mortality at community and health facility levels. Poor screening, testing, isolation, referral, and case management will lead to more deaths. If the intervention is effective, it will improve screening, testing, isolation, referral, and case management leading to lives saved (Figure 2).

Data collection

Appropriate ethical approval will be obtained before data collection. Data will be collected using digitized tools including the household survey, Africa Covid Screen, CHU service readiness tool, CHA, CHW and health worker knowledge exams, and digitized spreadsheets for key project indicators at CHUs and hospital levels (Table 2).

Data collection will be carried out throughout from baseline, midline to endline phases of project implementation. Data collection will be performed by a dedicated trained research team. Personal protective wear will be provided during data collection.

Youth will support CHWs to complete the digital tools.

Quantitative data

1. Health facility service availability and readiness assessment²⁸. This will be carried out at baseline and end-line by trained health records officers and clerks using a standard World Health Organization (WHO) tool to assess the health services that are available in each selected sub-county to respond to the COVID-19 pandemic. The tool will be digitized.

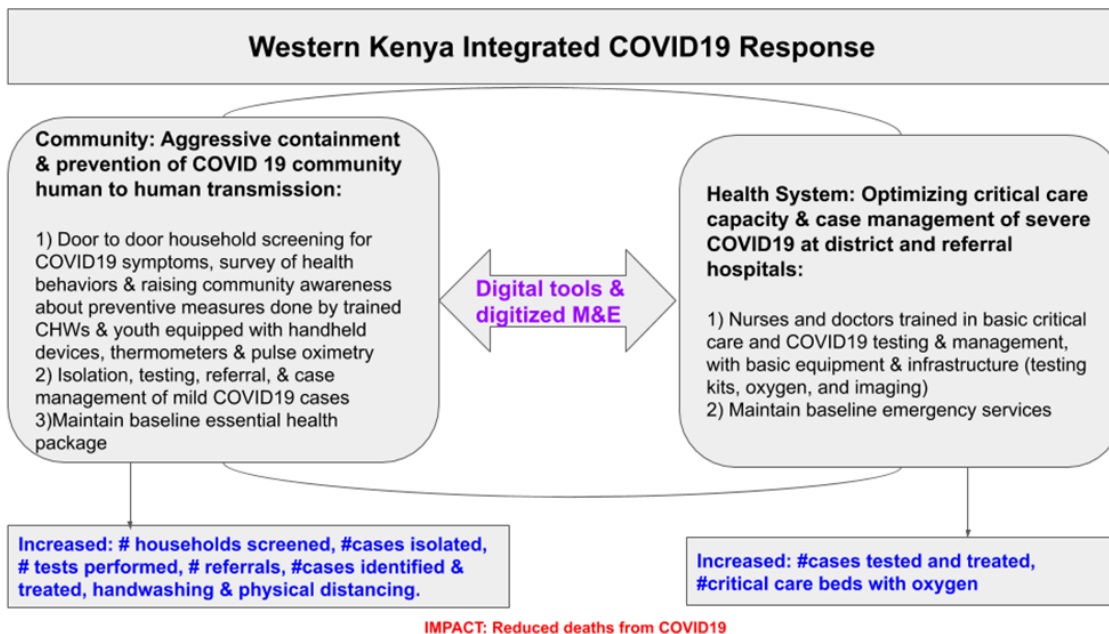


Figure 2. Process analysis of the study in the context of an ongoing COVID-19 pandemic.

Table 2. Study timeline.

Activities	Timeline 2020					
	May	June	July	Aug	Sep	Oct
A. Community activities						
1. Ethics approval	✗					
2. Mapping of Community Health Units (CHUs)		✗				
3. Mapping of active community health workers & create registry		✗				
4. Identify youth & create registry of youth to be paired with CHWs	✗					
5. Develop app triaging individuals & households	✗					
6. Develop COVID-19 CHW curriculum (raising awareness, health leadership case detection & referral, isolation, hand washing & homecare, wellbeing)		✗				
7. Obtain personal protective equipment for community activities (masks, gloves, hand sanitizer & contactless temperature probes)		✗				
8. CHW training: remote and in-person			✗			
9. Youth training: remote and in-person			✗			
10. Follow up household visits, and data collection of key community indicators			✗	✗	✗	
B. Health facility activities						
11. SARA Mapping of health facilities with oxygen capacity/operating rooms ²⁹		✗				
12. Develop COVID-19 curriculum and training for nurses, MDs, and clinical officers based on WHO guidelines		✗				
13. Training of nurses, MDs, and clinical officers on COVID-19 basic & critical care provision			✗			
14. Ongoing remote support of CHWs, youth, and health workers			✗	✗	✗	✗
15. Data collection of key indicators health facilities with critical care capacity, number of nurses, MDs and clinical officers trained, number of referrals received at referral hospitals, number of critical beds created, number tests performed (PCR, ELISA), number of CXR & CTs performed, number of COVID cases discharged home, number of deaths			✗	✗	✗	✗
C. Monitoring and Evaluation						
16. Following intervention, health worker knowledge of COVID-19, number of COVID-19 cases at each level of the system (suspected and confirmed), number of tests, and number of deaths			✗	✗	✗	✗
17. Data analysis			✗	✗	✗	✗
18. Report writing & dissemination					✗	

2. Rapid assessment of CHU. This will be carried out at baseline and end-line by trained CHAs using a standard tool (see *Extended data*²⁹) to determine their readiness for the required COVID-19 community-based response activities. The tool will also be digitized.

3. Household screening for morbidity, and COVID-19 relevant Knowledge and Practices. We will train CHAs, and they will

subsequently train CHWs to carry out baseline and end-line screening of households under their responsibility using the tool that CHWs routinely use to register all households under their care, Ministry of Health (MOH) 513 (Ministry of Health, 2014) but with COVID-19 items. The CHW and youth will interview either the consenting household head, the spouse present, or any adult member of the household, aged 18 years and above. The CHW will explain the screening

household visit, and complete the visit in approximately 15 minutes if consent is provided. The respondent would also consent on behalf of household members under 18 years of age. The CHA will witness each CHW carrying out the screening in at least one household, give feedback, point out gaps, and have errors corrected in obtaining consent, IPC, and data capture, and submission. Model consent and assent forms are available as Extended data³⁰.

4. Household follow-up data collection. Households found to have a member with fever will be reported to the CHA and to the rapid response team for further evaluation and testing if they satisfy case definition. Otherwise the CHWs with the support of CHA will carry out weekly visits with the support of CHAs to record temperature, oxygen tension to monitor disease progression or improvement in accordance with MOH guidance²⁴.

Qualitative data. We will use continuous and data driven theoretical sampling to determine additional data sources to support an emerging theory^{31–33}. We will use purposive sampling to select respondents. We will approach participants by telephone and face to face. The principal investigator and co-investigators will carry out focused group discussions (FGD) using a Discussion Guide (available as *Extended data*³⁴) to capture peoples' past and current experiences with epidemics, their perspectives on community based quarantine, and how to manage visitors in times of epidemics such as COVID-19 applying a narrative study design³⁵.

Credentials of the interviewers: MD, MPH (first author); MD, MPH, PhD (second author); both researchers are trained in public health. The second author has more than 40 years' experience working with communities in Western Kenya (since 1979). The participants know about the second author's previous work in the community; participants have worked with the second author on multiple projects since 1979.

A focus group discussion will be carried out in each subcounty. Because of the COVID-19 pandemic each discussion will not have more than five participants. We will record the number of participants who refuse to participate and the reason for refusal. The data will be collected outside in a sports field for example to reduce COVID-19 transmission risks. In line with social gathering rules, non-participants will not be present. We will describe characteristics of participants including age, gender, and occupation/community role. A discussion guide is provided as *Extended data*³⁴, to capture peoples' past and current experiences with epidemics and their perspectives.

The qualitative data intends to:

- Reveal the experiences of the participants with regard to disease outbreaks within their community in the past, how they were handled, and any roles they played.

- Give insight into the views and beliefs of individual participants in relation to disease control, and containment, sensitive issues such as quarantine, isolation, and handling visitors from outside the community.
- Elicit recommendations to enhance compliance with IPC regulations, reduction of stigma, and coping with stress and inadequate access to basic essentials. The interviews will be both documented and taped. Consent will be asked for both for interviewing and for being taped. Two interviewers will manage each focused group discussion session so that one will conduct the interview freely while the second will tape the conversation as well as take notes.

Each focus discussion group will number five or fewer people including the moderators. Discussions will take place outside in a field (e.g. football field) with ample space and ventilation. Social distance will be maintained. In addition, all participants will undergo temperature checks before the beginning of the exercise. All those with fever or other symptoms will be sent home and will be asked to join a future focused group discussion. All 14 participants will wear a mask at all times during the discussion.

Discussions will aim to achieve data saturation; data saturation will be determined by the non-emergence of new themes. Transcripts will be returned to participants for comments and corrections.

We plan to repeat the interviews during the endline assessment. We plan to use audio recording of discussions. Field notes will be taken during focus group discussions. Discussions will take place for 60 minutes to reduce the risk of exposure to COVID-19. Data saturation will be determined by the non-emergence of new themes. Transcripts will be returned to participants for comments and corrections. Two data coders will code the data. A coding tree will be developed after the initial two focus group discussions. Themes will be derived from the data. Discussions will be recorded and later transcribed in word processing. Following transcription, participants will get the opportunity to review and correct the transcription. Participant quotations will be used to illustrate major themes. We will check for consistency between data presented and the findings. We will present major themes in the findings. We will discuss minor themes in addition to the major themes.

Safety during household visits

To minimize exposure to COVID-19, during household visits, CHWs, research assistants and household members will maintain a distance of 2m, everyone will wear a mask at all times, and the visit will be conducted outside. All will wash their hands or use hand sanitizer at the beginning of the visit and at the end of the visit. When visiting a household with fever, CHWs and research assistants will be provided with proper PPE including masks. All team members will self

isolate and will be tested for COVID-19 if they present any symptoms of COVID-19.

Data analysis

Sample size calculations. To ensure adequacy of sample size that is representative of households in intervention and control CHUs we will use the formula proposed by Israel³⁶.

$$n = \frac{N}{1 + N(e^2)}$$

Where n is the required sample size, N is the total population in each sub-county, averaging 200,000 and e is the level of precision of 5% (0.05). Giving a required sample of 400 households per sub-county, 200 from intervention and 200 from control sub-counties or 10 households from each CHU in the study area, a total sample size of 1,600 households in the four participating sub-counties.

Quantitative data analysis: Using the digital tools at the community and health system levels, we will count the number of households screened, the number of cases isolated, the number of tests performed, and the number of cases referred to higher levels of care. In addition, we will count the number of deaths. These counts will be done on a weekly basis. At the hospital level, we will count the number of cases tested, treated, and the number of deaths related to COVID-19. These counts will be performed on a weekly basis by a dedicated team, and results will be made available to the county ministry of health team for timely input into decision making. Data collected will be compared at baseline, midline, and endline phases of the project. We will calculate differences in means for continuous variables and calculate relative risks for categorical variables.

The main quantitative outcome measure will be COVID-19-related deaths at the community and hospital levels. Poor screening, testing, isolation, referral, and case management will lead to more deaths. If the intervention is effective it will improve screening, testing, isolation, referral, and case management leading to reductions in mortality at community and health system levels.

Qualitative data analysis³³: Qualitative data will be collected through focus group discussions to determine lessons learnt from the proposed intervention; to better prepare for the next pandemic. We will perform the focus group discussion at the beginning of the intervention to highlight any preliminary issues that should be taken into account during the intervention. Furthermore, we will conduct focus group discussion during the monitoring and evaluation phases (to course correct as necessary when issues arise), and at the end of the intervention at 3 months, to verify provisional study results and highlight reasons behind observed quantitative data. During discussions we will seek to understand how health workers and community members understand COVID-19. How do they define their role in the pandemic; how do they want to address the pandemic.

What are the needs, challenges, and priorities? What inherent resources do they have that can be leveraged? What makes them feel vulnerable as they face the pandemic. Following these discussions, we will collate these discussions and identify themes that need to be addressed as we proceed with implementation. As we implement, focus group discussions will seek to quickly identify challenges with implementation that need to be addressed.

We will compare pre-intervention and post intervention outcome measures. We will compare intervention and non-intervention community health units, and lastly, we will compare Siaya to a similar non neighboring county where the intervention was not implemented. We will use SPSS/STATA programs for statistical analyses and calculate differences in means for continuous variables and calculate relative risks for categorical variables. To determine statistical significance between implementation and control sites; and differences between pre- and post-implementation outcome measures, we will use the paired Student's t and Chi square tests; p values <0.05 will be considered statistically significant.

Cost effectiveness analysis. We will use the competing method, given that the implementation and control sites are distinct and separate. We will calculate incremental cost effectiveness ratios. The intervention is the deployment of the community health worker, youth, and digital technology unit at the community level, with concurrent critical care capacity building at the hospital level. We will use the health services perspective. Inputs for cost effective calculations will include: human resources costs, equipment (pulse oximeters, thermometers, and handheld devices, and PPE). We will include programme costs of implementing the project (i.e. training costs, development of tools and education materials, and monitoring and evaluation costs). We will obtain data using hospital records and digitized data from CHWs and youth. Finally, we will add societal costs related to accessing COVID-19 care (e.g cost of transport). Effectiveness will be measured based on disability life years averted to complete the calculation of the incremental cost effectiveness ratio and determine the cost effectiveness of the intervention. The incremental cost effectiveness ratio will be calculated by dividing the difference between intervention cost and the counterfactual (pre- intervention) per site divided by their respective number of disability-adjusted life-years averted.

The initial study duration is 3 months, from May 18th 2020 to August 18th 2020 with possible extension for continued monitoring and evaluation of key indicators.

Data management. Data will be kept under secure storage under lock and key, as well as password protected and will be accessible only to authorised key personnel engaged in the study. Analyzed data will be disseminated for decision-making. No personal identifying information will be recorded on questionnaires that can be used to link recorded information to a specific individual. The respondent will be assured full confidentiality of all responses and the interviewers will take steps to ensure privacy during interviews. The completed

questionnaires on the interviewers' mobile devices will be password protected and deleted once they have been uploaded to the central database which will also be password protected.

Data monitoring committee. An independent data monitoring committee will be formed and will meet on a biweekly basis to review activities of the protocol and data. An interim analysis will be performed at the midway point of the timeline. Results will be made available to the data monitoring committee who will take the final decision on whether to terminate the trial.

Harms. Adverse events can be reported to the ethics committee and the sponsor, and the adverse event will be managed without imposing any financial burden on research participants. A summary of adverse events will be presented to the data monitoring committee on a biweekly basis.

Auditing. An independent review of core processes and documents will be performed during 3 months allocated to the project.

Discussion

This study would be the first study to evaluate the effectiveness of an integrated approach in preparing for and implementing a robust response to an ongoing COVID-19 pandemic. We would be arming communities with knowledge and preventive measures that have been shown to contain COVID-19 infection, and concurrently we will be strengthening the health system with health care worker capacity building in basic critical care provision. We will build evidence for scalable integrated community and health system interventions during pandemics in resource constrained settings.

The approach is innovative because of its engagement of youth and use of technology. In addition, it rapidly builds critical care capacity by training of health care workers in facilities with oxygen capacity.

There are several limitations to the study: the ongoing pandemic may require modifications of components of the intervention, attrition of participants is a possibility, technology tools may be limited by the lack of electricity and poor network connections in rural parts of Kenya. Using non-functional CHUs as controls could introduce confounding bias; however, we will compare known and unknown attributes between the 2 groups before the intervention. Subsequently, we will adjust for any differences between the 2 groups (by performing subgroup analyses for stratum specific relative risks) to obtain a true effect measure following the intervention.

We anticipate challenges in the availability of diagnostics (particularly laboratory testing kits), and the intervention will rely heavily on clinical signs and symptoms.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/PUTCR8>²⁷.

This project contains the household survey tool.

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/JIYRBN>²¹.

This project contains the Shortened County Health facility Service Availability & Readiness Assessment (SARA) tool.

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/WLTX1V>²⁹.

This project contains the community unit rapid assessment checklist.

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/5QJICK>³⁴.

This project contains the focus group discussion guide.

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/1BP8DT>³⁰.

This project contains model consent and assent forms.

Harvard Dataverse: Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya. <https://doi.org/10.7910/DVN/WKO3TY>²².

This project contains the training curriculum.

Reporting guidelines

Harvard Dataverse: SPIRIT checklist for 'Engaging community health workers, technology, and youth in the COVID-19 response with concurrent critical care capacity building: A

protocol for an integrated community and health system intervention to reduce mortality related to COVID-19 infection in Western Kenya'. <https://doi.org/10.7910/DVN/BPLZP3>³⁷.

Extended data and the reporting guidelines checklist are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

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Comments to authors:

Thank you for the opportunity to review your protocol. The protocol is well-developed to be differential for preventive strategies of the COVID-19 pandemic through an integrative strategy. It may also be relevant for potential replication. However, I cannot see the rational of an intervention planned to implement from now-actually predated in 2020. Unless reframing the time cannot be justified and reasonable, proposing a trial protocol at this time seems a retrospective presumption to a research/service that already had been in place or completed. The following issues remained unanswered during my progress through the review. I would suggest a major review to address all these concerns.

1. There is a huge contrast between the introduction text in the abstract and the body of the manuscript. Special attention should be given to the figures reported on both the global and local level of infection and mortality rates.
2. Authors are required to include the time-updated figures on infection and death on the study area.
3. The introduction would need to highlight on the research question to be tested. I would suggest combining the fragmented subtopics under this section and removing headings.
4. The presumed period of the proposed study is not clearly stipulated. Either the proposed protocol is out-dated to assume at this stage, the study should not have been commenced so far, or the interventions might need to be changed-as we cannot assume that all control counties have not been contaminated of the interventions this time ex. the screening and critical care for COVID-19 patients.
5. It is not easy to understand how the composite outcome would be measured from and related with the individual measures on screening, testing, care etc. quantitatively. There was no risk measure, such as risk ratio/ relative risk planned.

6. It is unclear why and how the estimated sample size was going to be used as a household level. The authors stated that intervention will be delivered at community and health facility level. Does it mean that health professionals at control sites will be withheld from training? This seems unethical and fairly not sounding. Which health professionals, and how will they be included? How will sampling of 200 at household level be made?

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Pharmaco-epidemiology, public health, health economics, chronic illness, infectious disease

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
