STUDY PROTOCOL

Understanding the factors enabling and blocking sustained implementation of cholera interventions in a fragile region of Nigeria: a multi-phase group model building study protocol

[version 1; peer review: 2 approved with reservations]

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Abstract

Introduction: Adamawa and Bauchi are cholera endemic states in the north-east region of Nigeria, each with local government areas classified as cholera hotspots. Ineffective implementation of multi-sectoral cholera interventions in both states could make obtaining the global target for cholera control in Nigeria out of reach. A major contributing factor to this challenge is fragility of the region due to persistent Boko Haram insurgency activities, often characterised by the destruction of health infrastructure and displacement of communities to areas with suboptimal living conditions. Given the complexity of disease control in such a fragile setting, this study aims to systematically examine the barriers and/or facilitators influencing the implementation of existing cholera interventions in these states.

Methods: The study will use a systems dynamic approach. First, we will conduct a health facility survey to determine the current health system capacity to support multi-sectoral cholera interventions, and conduct key informant interviews with purposely selected state and national cholera stakeholders to identify the context-specific facilitators and barriers to the implementation of cholera interventions in these states. We will then conduct nine group model building workshops (four in both the Adamawa and Bauchi states and one in Abuja) among cholera stakeholders similar to those recruited for the interviews.
Conclusion: By engaging diverse and relevant cholera stakeholders, including community members, this study has the potential to provide a rich understanding of context-specific factors influencing the implementation of multi-sectoral cholera interventions in a fragile region of Nigeria, with a view to achieve sustainable progress towards cholera control in the country. Moreover, this study could have an impact on the control of other water-borne diarrheagenic diseases in the country.

Keywords
Cholera; Fragility; Multi-sectoral; System dynamic; Group model building; Adamawa; Bauchi; Nigeria

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Introduction

Despite the possible underestimation due to limited surveillance and reluctance to report cases for economic reasons, approximately 2.9 million cholera cases and 95,000 cholera-related deaths are recorded annually worldwide\(^1\). These occur predominantly in 47 endemic countries\(^2\). Notably, since 2017, the inequitable burden of cholera has continued to increase, with the poorest and most vulnerable populations in fragile settings with inadequate portable water, sanitation and hygiene most at risk\(^3\). Cholera elimination as a target, sits across the United Nation’s (UN) Sustainable Development Goals (SDG) agenda\(^4\), given its roots in inequity, poverty, environmental threats and conflict. This is because public health measures targeting cholera have an explicit implication for water-related diseases within SDG3 (ensuring healthy lives and promoting wellbeing for all) and an implicit implication for tracking progress towards achieving SDG6—universal and equitable access to safe and affordable drinking water, and access to adequate and equitable sanitation and hygiene for all. Additionally, cholera transmission is an important motivation for the development of the 1952 World Health Organization’s (WHO) International Sanitary Regulations\(^5\), given its capacity to impact global health security and economic growth\(^6\).

While substantial progress has been made towards cholera control in the SDG era, a combination of climate change, natural and man-made disasters, and rapid unplanned urbanisation continue to support transmission. The WHO’s Global Task Force on Cholera Control (GTFCC), revitalised in 2014, is a network of more than 50 partners with this global mandate\(^4\). In 2017, it launched and adopted the ‘Ending Cholera: A Global Roadmap to 2030’ strategy. Unlike the previous approach to cholera outbreaks, which was more reactive and short-term, this strategy sets out a long-term plan for cholera elimination for 20 of the 47 endemic countries, with the target of 90% reduction in cholera-related deaths by 2030\(^7\).

The attainment of these goals hinges upon six interventions: water, sanitation and hygiene (WASH); surveillance and reporting; use of oral cholera vaccine (OCV); healthcare system strengthening; leadership and coordination; and community engagement and empowerment. According to the joint WHO and UN Children’s Fund (UNICEF) updated estimates for WASH in households in 2017, 8 out of 10 people in rural areas in sub-Saharan Africa still lacked basic drinking water; 7 out of 10 lacked basic sanitation services; and 3 billion people lacked basic handwashing facilities at home\(^8\). These conditions are drivers of recurrent cholera transmission, especially given that WASH interventions are often reactive during cholera outbreaks in many cholera endemic settings\(^9\). An analysis of the global use of OCV stockpile from inception in July 2013 to the end of 2018 noted challenges relating to timeliness of response to cholera outbreaks and contextualisation of strategies for OCV delivery\(^10\); a significant improvement in vaccine acceptance and safety was however noted. Additionally, existing government’s surveillance systems can become weakened due to limited access to conflict areas, contributing to delayed notification and under-estimation of cholera cases and poor implementation of appropriate public health measures\(^11\).

Cholera endemic countries are required to contextualise and implement the GTFCC strategic roadmap; however a significant constraint—and a possible source of reversal to current gains—is fragility. This can be the result of violence and prolonged conflict, political and economic instability, marginalisation and inequality, weak and distorted national governance structures and processes, and significant environmental threats and natural disasters\(^12\). Fragility can impact public health by limiting a population’s capacity to respond and adapt to stressors and shocks, such as a disease outbreak in a humanitarian setting. A 2020 WHO report indicates a decrease in progress towards cholera control, with nearly double the number of cholera cases during 2019 (923,037) than 2018 (499,447); the number of cholera-related deaths however decreased by 36% (from 2,990 in 2018 to 1,911 in 2019)\(^13\). Notably, 93% of cases in 2019 were from Yemen, a country that has become extremely fragile by recurrent armed conflicts with frequent, widespread cuts in water supplies\(^13\). A similar trend was also noted in Mozambique, where—amidst successive cyclones with heavy rains and population displacement in 2019—over 7,000 cholera cases was recorded in comparison to 910 cases in the previous year\(^13\).

In Nigeria, the burden of diarrhoeagenic diseases is extremely high, having the second highest total of under-5 child deaths from pneumonia and diarrhoea in the world\(^14\). Nigeria has witnessed two major cholera outbreaks in recent years, with over 40,000 cases and 1,716 deaths in 2010\(^15\) and approximately 50,000 cases and 850 deaths in 2018\(^16\). The country is currently classified as a cholera high-burden country\(^17\), with 83 local government areas (LGAs) in 14 states determined as cholera ‘hotspots’. Notably, over half of these cholera hotspot LGAs are located in the north-east region of the country including Borno, Adamawa and Yobe States, where Boko Haram insurgency activities are predominant\(^18\). Boko Haram insurgency activities are often characterised by the disruption of WASH services, displacement of populations to overcrowded camps, and emigration of health workers to safer areas\(^19\). It is therefore no surprise that the highest cholera prevalence and case fatality ratio during the outbreak of cholera in Nigeria in 2018 were recorded by north-eastern states\(^16\).

While reiterating the difficulty of addressing disease outbreaks in the context of fragility, the concentration of cholera burden in the north-east region of Nigeria suggests suboptimal control strategies, particularly with the implementation of existing multi-sectoral cholera interventions. Previous responses to cholera outbreaks in north-east Nigeria have been hampered by inadequate training of healthcare workers, limited supply of emergency response kits and personal protective equipment\(^20\), and poor diagnostic capacity and community misconceptions towards WASH and OCV interventions (with consequent reluctance to accept these interventions)\(^21\). Furthermore, recurrent transmission of cholera in the region is further compounded by the influx of reactive humanitarian responses which often set up reactive and parallel interventions, without long-term goals in mind\(^22\). Thus, given the fragility and cholera endemicity in this region, attaining the global roadmap strategic goals by 2030 in Nigeria will be challenging.
To improve the likelihood of success, it is important to engage all stakeholders to develop a context-specific understanding, and adopt a whole system perspective of the dynamic interactions between health system capacity to support cholera programmes. Furthermore, it is crucial to identify local facilitators and barriers to the implementation of multi-sectoral cholera interventions, and to explore leverage points for interventions and collaboration across stakeholder groups. The systems modelling methodology of group model building (GMB), is an established methodology for engaging stakeholders to gain mutual understanding of complex problems. GMB works with stakeholders to deeply and actively involve them in the process of model construction through exchange, assimilation, and integration of mental models into a holistic system description\textsuperscript{23}. This methodological approach seeks to understand the non-linear behaviour of complex systems over time, recognising the value of engaging all the relevant stakeholders directly, with a view to generate findings that are locally relevant and implementable\textsuperscript{24,25}. To the best of our knowledge, there is a dearth of evidence on the use of GMB approaches to address cholera both in Nigeria and elsewhere. Therefore, the overarching aim of this study is to collaboratively work with cholera stakeholders to examine the factors enabling and blocking sustained implementation of multi-sectoral cholera interventions in the Adamawa and Bauchi states, with a view to addressing recurrent cholera transmission and inform the development of a locally adapted roadmap for Nigeria.

The study’s specific objectives are:

1. To describe current health system capacity to support WASH, OCV, case management and surveillance, and current policy, governance and community engagement structures for cholera action.

2. To describe barriers and facilitators for the implementation of multi-sectoral cholera interventions.

3. To identify potential opportunities in the existing multi-sectoral cholera interventions for strengthening multi-sectorial collaboration.

**Methods**

**Study design and theoretical framework**

This study will utilise a mixed-methods design, conducted in two phases. The first phase will use a cross-sectional descriptive design to address objective 1, and a qualitative study design using key informant interviews, underpinned by the social constructionism philosophical worldview, to address objective 2. The second phase (for objectives 2 and 3) will utilise a GMB approach, underpinned by community-based participatory theoretical framework\textsuperscript{26}. This will identify the dynamic interactions between health system capacity to support cholera programmes and local and national barriers and facilitators for implementing multi-sectoral cholera interventions; and identify leverage points (potential opportunities) for interventions and collaboration across stakeholder groups. GMB introduces social dynamics, which can affect the quality of model, buy-in from stakeholders, and ultimately the likelihood that recommendations from the model will be accepted and implemented by stakeholders. It also provides the opportunity for stakeholders to share their mental models on cholera and adjust their mental models as they learn from other stakeholders through moderated participatory engagement.

**Study settings**

Nigeria is made up of 36 states and the Federal Capital Territory (Abuja), with each state further disaggregated into several LGAs (there are 774 LGAs in Nigeria). The study will be conducted in Adamawa and Bauchi states, in north-eastern Nigeria (Figure 1). These states were selected because they were among the most affected states during the cholera outbreak in Nigeria in 2018\textsuperscript{16}. Adamawa has some LGAs that have been directly affected by Boko Haram insurgency while Bauchi...
has some of its LGAs serving as host communities to persons displaced from Boko Haram affected states of Adamawa, Borno and Yobe. Adamawa state has its capital city in Yola and has an estimated population of 4.7 million people across 24 LGAs<sup>17</sup>. Bauchi state has its capital in Bauchi and has an estimated population of 7.5 million people across 20 LGAs<sup>18</sup>. The estimated number of primary, secondary and tertiary health facilities per 100,000 persons in Adamawa is 24.70, 0.69 and 0.03 respectively; 16.40, 0.36 and 0.03 in Bauchi<sup>19</sup>. In addition to Adamawa and Bauchi, we will also conduct both key informant interviews and GMB in Abuja in order to capture the perspectives of national cholera stakeholders.

**Data collection, management and analyses**

**Phase 1: Quantitative cross-sectional study**

**Preparations for data collection**

A minimum of three research assistants per state will be recruited and trained for data collection, as well as taking informed consent and adhering to ethical practices. Data collection tools will be updated following piloting with healthcare workers in a purposely selected health facility in Abuja to determine completeness, clarity and accuracy. Data collection will be done using Open Data Kit (ODK) Collect installed on password-protected mobile devices.

**Sampling**

Based on pragmatic considerations (e.g. cost and time), we will adopt a purposive stratified sampling approach to recruit 20 rural and 30 urban health facilities in each state (n=100), with a history of confirmed cholera cases during the 2018 outbreak. Only health facilities (government- and private-owned primary, secondary or tertiary) considered functional by the state health authority will be eligible for selection into the study. The selection of contrasting LGAs (urban vs rural) is due to the dependence of cholera attack and case fatality rates on setting type in Nigeria, with higher values in urban than in rural areas<sup>16</sup>. Convenience sampling of healthcare workers of various professional cadres present on the day of the survey will be done.

**Data collection**

In determining the health system’s capacity to support multi-sectoral cholera interventions in both the Adamawa and Bauchi states, we will adapt the WASH health care facility core indicators<sup>20</sup> and the WHO Service Availability and Readiness Assessment tool<sup>21</sup>. The trained research assistants will spend 1–2 days at each selected health facility. They will administer a structured questionnaire with the manager or administrative head regarding the current health system’s capacity to support various cholera interventions (e.g. WASH, OCV, surveillance etc.). Additionally, the research assistants will administer a questionnaire on cholera case management and knowledge with a convenience sample of five healthcare workers who meet predefined eligibility criteria—i.e. willingness to participate in the study and to sign an informed consent form—on the day of health facility survey. Prior to the survey, information about the proposed study will be communicated to healthcare workers via a formal letter to the facility manager or administrator.

When possible, the research assistants will also perform discrete observations to objectively ascertain the presence of cholera interventions. In terms of duration, data collection will be completed within six weeks of the study start date. The study materials and consent form can be found as extended data<sup>22</sup>.

**Data analyses**

The current health system capacity to support various cholera interventions will be determined using descriptive analyses. Continuous variables will be described using mean and standard deviation for normally distributed variables, median (IQR) for non-normal continuous variables, and frequency and percentages (%) for categorical or binary variables. The status of a cholera intervention will be described by calculating its available indicators divided by the total number of indicators. Analyses will be stratified by state, study setting (urban vs rural) and health facility type. The responses on knowledge will be scored as ‘1’ while other responses, such as ‘incorrect’ or ‘don’t know’, will be scored as ‘0’ (zero). The scores will be added to obtain a total score for each study participant and a median score will then be calculated. High knowledge score will be defined as a total score ≥median score and low knowledge score as a score <median score. Factors (e.g. cadre, state, training, recent case management experience etc.) potentially associated with knowledge will be explored using multivariable logistic regression. The findings will be presented as adjusted odds ratios with 95% confidence intervals. A p-value of <0.05 will be considered statistically significant. All analyses will be performed using Stata version 13 (StataCorp, College Texas).

**Phase 1: Qualitative study**

**Study participants**

Three groups of participants (see Table 1 for their distribution by location) will be purposely recruited for the key informant interviews (KII). Participants will include:

At the state level:
- Community members, including previous cholera patients and caregivers, local food retailers, school teachers, local health promoters, community and religious leaders.
- Healthcare professionals, including state epidemiologists, disease notification and surveillance officers, health educators/promoters, community health extension workers, nurses, clinicians, traditional healers, academia, the staff of state ministries (health, water resources, environment, primary health care development agency), technical partners and funders (WHO, MSF, UNICEF).

At the federal or national level:
- Government and non-government cholera stakeholders e.g. staff of NCDC, federal ministries of water resources, health, environment and primary health care development agency, as well as technical partners and funders including WHO, World Bank, UNICEF, United States Centers for Disease Control and Prevention (US CDC), Africa Field Epidemiology Network etc.)

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**Table 1**

| Study phase | Description |
|-------------|-------------|
| Phase 1: Quantitative cross-sectional study | Preparations for data collection |
| Phase 1: Qualitative study | Study participants |

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**Stat**
All study participants must be willing to participate in the study and to sign an informed consent form, and considered a cholera stakeholder (community or healthcare professional). All KIs will be conducted by the lead researcher (KE) either in a health facility or an office at a time convenient for each study participant. Being a qualitative study without a fixed sample size, we will aim for at least 20 participants in each study location, but recruitment will stop once saturation (i.e. when study participants have provided a range of information or perceptions about the study until no additional information is being provided) is reached35. The semi-structured interview guides will be developed separately for each study participant type (i.e. community members, healthcare providers, national public health stakeholders) and piloted before data collection. Where possible, the data collection process will be aided using an audio-recorder. The collected will be transcribed verbatim and analysed using a thematic approach, aided by Nvivo software. Thematic analysis will follow the six-phased approaches recommended by Braun and Clarke34, bearing in mind that these phases are not a linear process, but more of a recursive process where one moves back and forth as needed. The six phases include familiarisation with data, generating initial codes, searching for themes, review of initial themes, defining and naming themes, and producing the report.

Findings from this study component, alongside those from the cross-sectional study, will be triangulated to finalise the script development for GMB in phase 2.

Phase 2: Group model building

GMB workshop process

We will conduct a total of nine all-day GMB workshops, two with community participants and two with health professionals in both states (total of 8), and one with stakeholders in Abuja (i.e. federal government and partners). Table 2 provides an overview.

We will use locations with minimal distractions to the participants, such as an event centre within a hotel or government ministries. The rationale for participant-specific GMB workshops is to minimise the effect of power dynamics and recognise variation in understanding of cholera by various stakeholders. Between 7–10 participants (12–15 in Abuja given it’s a one-day event) with similar characteristics as those in the qualitative study component will be purposely selected for each GMB session. Invitation of potential participants will be facilitated by a combination of letter/email and phone call. We will ensure that public health preventive measures with regards to coronavirus disease 2019 (COVID-19) (e.g. physical distancing and use of face-masks) are in place during each workshop. The protocol and scripts for each workshop will be modified from those available from Scriptapedia35 and based on preliminary findings from study phase 1. The research team members will be assigned roles as outlined in Table 3. After each GMB workshop, the research team will have a debrief session to reflect on processes and to make necessary adjustments as needed.

GMB tools

The GMB process will utilise three interactive system mapping tools (see provisional scripts for these tools in Extended Data): graph over time; cognitive mapping; and causal loop diagrams.

Graphs over time allow the participants to share their understanding of cholera as well as perceived drivers of its recurrent transmission in their community over a specific time period. Using an empty graph with time on the x-axis (with a vertical line for the present time) and a variable on the y-axis, the participants will be guided by the researchers to fill in the graph. They will be prompted with questions such as: “What is the trend of cholera in your community since the 2015 presidential election in Nigeria?” “What are the factors influencing the transmission of cholera in your community?” “What are the interventions available for cholera control in your community?” As well as drawing on the empty graphs the historical trends of cholera, the participants will be asked to identify two future pathways they predict would occur if current cholera trends continued or if intervention occurred.

Cognitive mapping is a visual tool that will introduce participants to systems thinking by exploring their understanding of the facilitators/barriers to the implementation of cholera interventions (e.g. surveillance and oral cholera vaccination) and consequences of implementing these interventions successfully or not35. For this activity, a template will be developed and provided for the participants to complete.

Causal loop diagrams capture the dynamic nature of an issue and the presence of feedback in systems35. This activity focuses on providing the participants with an understanding of why feedback is important in a system, using pictorial examples from

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**Table 1. Distribution of the qualitative study participants by location (n=60).**

| Participants                  | Adamawa (~20) | Bauchi (~20) | Abuja (~20) |
|------------------------------|---------------|--------------|-------------|
|                              | Rural | Urban | Rural | Urban | NA |
| Community members            | 5    | 5    | 5    | 5    | NA |
| Healthcare providers         | 5    | 5    | 5    | 5    | NA |
| National public health stakeholders | NA | NA | NA | NA | 20 |

NA = not applicable

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[i][Note 1]
[ii][Note 2]
[iii][Note 3]
[iv][Note 4]
[v][Note 5]
Table 2. Characteristics of the proposed GMB sessions.

| Location | Adamawa State | Bauchi State | Abuja |
|----------|---------------|--------------|-------|
| **Session locations** | Community members | Health providers | Community members | Health providers | National stakeholders |
| Number of sessions | 2 (1 urban, 1 rural) | 2 (1 urban, 1 rural) | 2 (1 urban, 1 rural) | 2 (1 urban, 1 rural) | 1 (Government & donors/partners) |
| Session duration | 1 day | | | | |
| Session focus | 1x session with a primary focus on home-based management and health-seeking for suspected cholera by community members; 1x community leaders with a primary focus on their roles in cholera outbreak response activities, as well as pathways for mobilisations. | 2x sessions with a focus on cholera case management and participation in cholera routine surveillance and outbreak response at various healthcare levels. | 1x session with a primary focus on home-based management and health-seeking for suspected cholera by community members; 1x community leaders with a primary focus on their roles in cholera outbreak response activities, as well as pathways for mobilisations. | 2x sessions with a focus on cholera case management, and participation in cholera routine surveillance and outbreak response at various healthcare levels. | 1x session with government & with non-government stakeholders, primarily focusing on leadership and coordination of preparedness, response and control of cholera |
| Examples of participants | Ex-cholera patients and caregivers, apparently healthy or at risk of cholera infection, as identified by local health workers. The leaders include traditional leaders, traditional healers, Imams, Pastors, gatekeepers to healthcare services, as identified by local health workers. | Clinicians, community health extension workers, state epidemiologist, DSNOs, laboratorians, risk communication officers etc. | Ex-cholera patients and caregivers, apparently healthy or at risk of cholera infection, as identified by local health workers. The leaders include traditional leaders, traditional healers, Imams, Pastors, gatekeepers to healthcare services, as identified by local health workers. | Clinicians, community health extension workers, state epidemiologist, DSNOs, laboratorians, risk communication officers etc. | Government: NCDC staff, Federal Ministries of Water Resources, Health etc. Non-government: Public Health England, WHO, UNICEF, MSF, US CDC, AFENET, etc. |
| Estimated number of participants | 7-10 per session | 7-10 per session | 7-10 per session | 7-10 per session | 7-10 per session |

relevant studies. Here, simple feedback loops which are a basic operating unit of systems, will be designed from participants’ previous activities (e.g. barriers to the implementation of cholera interventions and consequences of action and inaction). To further consolidate findings from the causal loop diagrams, a sub-set of participants will be asked to critique the collective models by adding, deleting and modifying structures in the map. We will also seek to explore potential interventions to identified barriers to implementing cholera interventions in the both Adamawa and Bauchi states. The primary focus here would be to use the following questions to probe for possible actions which could be taken to address the identified barriers: “What variables could you increase or decrease?” “How could you impact connections: strengthen, or weaken a connection, speed it up or slow it down, add or delete connections?” This activity will require the participants to write potential actions on post-it notes and place them on the causal loop diagrams where they consider appropriate. Finally, all the participants will be required to select the top three actions for each intervention that their group would like to see progressed.

Post-GMB workshop

GMB data, alongside field notes and reflections from the research team, will be analysed thematically. Additionally, findings from
Table 3. Description of roles for GMB workshop.

| Role               | Description                                                                                                                                 |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Convener           | To open the workshop— preferably someone who has status among the participants- and help set the tone for the workshop                        |
| Group facilitators | To facilitate the activities and to organise the products into thematic clusters; to transfer products from participants to modellers.         |
| Modeler/reflector  | To develop and analyse the model and then reflect back model-based insights to the participant                                           |
| Recorders/ translators | To take notes, document products from each GMB session including drawings of models and dynamics; to provide simultaneous translation       |
| Closer/Debriefer   | To give concluding remarks summarising the findings of the workshop; to lead and facilitate the debrief of the facilitation team after the workshop |
| Observers          | To observe but not participate in the process.                                                                                           |
| Choreographer      | To conceptualise and oversee the overall design of the GMB workshop including the development of the detailed agenda, scripts and the pre-workshop training. |

the GMB workshops will be supported with quotes from thematic analysis of transcripts from the KIIs. Lastly, GMB findings will be digitised using VenSim software, version: 8.2 (an open-source software).

Ethics and dissemination strategy

The protocol for this study has been reviewed and approved by the Nigeria National Health Ethics Research Committee (NHREC Approval Number NHREC/01/01/2007-24/08/2020). Additionally, participants for the qualitative and GMB workshops will be required to provide informed consent after reading or listening to the study information sheet, and will be assured freedom to withdraw from the study at any stage. Autonomy and confidentiality will also be maintained throughout the conduct of this study; For example, we will delete all personal identifiers from the dataset prior to management and analyses, and only the research team members will have access to the dataset on a password-protected laptops. Lastly, while participants will be informed that there are no direct benefits from participating in the study, those in the GMB workshops will however be given stipends to compensate the cost of transportation and potential loss of income for the day—this is appropriate in the context of GMB workshops. Expected findings will be disseminated through peer-reviewed publications and local and international scientific meetings.

Discussion

This study will take a systems modelling approach to examine complex factors influencing the implementation of multi-sectoral cholera interventions in a cholera endemic and fragile region of Nigeria. The participatory nature of the study has the potential to improve the quality of findings, acceptance of findings from cholera stakeholders, and ultimately increase the likelihood for implementation of recommendations.

Previous attempts aimed at strengthening the healthcare systems in the north-east region of Nigeria have so far failed to address the complex and persistent burden of cholera in the region. For instance, a health facility survey conducted in Adamawa found the state’s capacity to deliver healthcare services to be extremely poor due, in part, to the destruction of health infrastructure by Boko Haram terrorism group. This survey was however generic without a specific focus on the state’s capacity to respond to or manage communicable disease outbreaks including cholera. Therefore, determining the health capacity of both the Adamawa and Bauchi states to support multi-sectoral cholera interventions could serve two important purposes: to identify needs or gaps for investments and to potentially serve as a benchmark for monitoring progress towards closing the identified gaps.

A study in the state of Yobe, one of the most affected states by Boko haram insurgency, using systems dynamics modelling found a significant decrease in access to health care and human resources for health, largely due to the outward migration of health workers and suspension of public health programmes. A dearth of evidence on the dynamics of health care access and provision in the context of cholera was evident, limiting robust planning. Thus, findings from our proposed study would be timely in ensuring the holistic identification and implementation of appropriate public health measures for efficient cholera control in this Nigerian region.

This evidence will be useful to policymakers and funders given the expected impact of the COVID-19 pandemic on SDG progress, with vulnerable populations in fragile settings projected to be the most affected. In addition to the novelty of using a systems approach to study cholera dynamics in a setting made fragile by armed conflicts, findings from our study could
generate new framework for how cholera interventions are constructed or implemented in fragile contexts, while also offering a new perspective to explore potential leverage points with regards to cholera policy and response.

The qualitative nature of the GMB approach is often considered a limitation, hence there has been a call by researchers to go beyond the qualitative model to create a quantitative simulation model that allows for quantifying the postulated causal relationships established in the qualitative models11. As such, we will seek to conduct a post-GMB quantitative simulation model using historical cholera surveillance data from Nigeria CDC, published literature and other publicly available data (e.g. population census and health metrics) to strengthen the evidence to inform policy decision making. For instance, the quantitative simulation model could provide insights on the relative impact of different cholera interventions (e.g. WASH) on cholera outcomes. Another potential limitation of the GMB approach is limited generalisability of findings, although the aim of a systems modelling approach is to have a highly contextualised understanding of an issue through the prioritisation of stakeholders’ engagement. Nonetheless, we will make deliberate efforts to recruit participants from diverse occupational, socio-economic and gender groups in order to enrich the diversity of the study participants and consequently the expected findings.

Conclusion
The engagement of a diverse range of cholera stakeholders, including community members, in a participatory process could contribute to a renewed desire to bring about positive change to cholera control in an endemic and fragile region of Nigeria. Moreover, this study could have an implicit impact on the control of other water-borne diarrheagenic diseases in the country.

Data availability
Underlying data
No data are associated with this article.

Extended data
Figshare: Understanding the factors enabling and blocking sustained implementation of cholera interventions in a fragile region of Nigeria: a multi-phase group model building study protocol. https://doi.org/10.6084/m9.figshare.13686073.v11

The project contains the following extended data:
- Questionnaire and scripts (all data collection materials)
- Consent form

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

Contributors
KE, CK and TA conceptualised the study. KE, CK, KD, JA, BF, CI and TA are implementing the study. KE had primary responsibility for final content. All authors participated in writing, read and approved the final manuscript.

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We are grateful to the Adamawa State Ministry of Health, Bauchi State Ministry of Health, and the Nigeria Centre for Disease Control for supporting the development of this study protocol. Lastly, we are grateful to the WHO Global Task Force on Cholera Control for its technical support towards the implementation of this study.

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Reviewers report for published study protocol, “Understanding the factors enabling and blocking sustained implementation of cholera interventions in a fragile region of Nigeria: a multi-phase group model building study protocol [version 1]”

General comment
This is a well written study protocol by Kelly Elimian et al., on an important public health issue that is a major cause of morbidity and mortality in study area, Nigeria and globally. The study protocol aims to document factors responsible for sustained cholera outbreaks in Adamawa and Bauchi States of Nigeria. The authors state clearly the study objectives and propose to use robust methodology to achieve these objectives. Furthermore, the proposed study by Kelly Elimian et al., if implemented, has the potential to contributed positively towards the achievement of the UNSDGs targets, specifically UNSDG No. 3 by 2030. However, there are major flaws with this study protocol which have to be addressed if the overall goal of preventing cholera so as to attain UNSDG targets by 2030 is to be achieved.

Major comments
Abstract and introduction
I like the way the authors summarized the abstract and how they wrote the introduction citing relevant literature in order to build their case.

Kelly Elimian et al., rightly state that the Boko Haran conflict is a major factor that is responsible for sustaining cholera outbreaks in the study areas. This is in line with known facts which links the conflicts and cholera outbreaks.

The authors state this from the very beginning (abstract) that Boko Haram destructive activities are important in cholera persistence, "A major contributing factor to this challenge is fragility of the region due to persistent Boko Haram insurgency activities, often characterized by the destruction of
health infrastructure and displacement of communities to areas with suboptimal living conditions" and later (introduction), "Notably, over half of these cholera hotspot LGAs are located in the north-east region of the country including Borno, Adamawa and Yobe States, where Boko Haram insurgency activities are predominant. Boko Haram insurgency activities are often characterized by the disruption of WASH services, displacement of populations to overcrowded camps, and emigration of health workers to safer areas. It is therefore no surprise that the highest cholera prevalence and case fatality ratio during the outbreak of cholera in Nigeria in 2018 were recorded by north-eastern states".

However, subsequently there is little in the study protocol to show how they (authors) plan to collect data that can result in conflict resolution, a root cause of sustained cholera outbreaks in affected areas. Therefore, for this protocol to be more comprehensive, the authors should revise the introduction and method sections to include an objective that can contribute to conflict resolution and articulated in the method section how they plan to achieve that objective.

The title
The title of the protocol, "Understanding the factors enabling and blocking sustained implementation of cholera interventions in a fragile region of Nigeria: a multi-phase group model building study protocol", is open to misinterpretation and may not facilitate replication of the study findings by other interested researchers since a fragile region of Nigeria (a vast country, with 36 states) may be difficult to pinpoint. For example Borno and Yobe states are also Boko Haram affected states that are cholera hotspots but are not study area. Therefore, the authors could revise the title of the study protocol so that it is more specific. Kelly Elimian et al., could consider revision such as “Understanding the factors enabling and blocking sustained implementation of cholera interventions in Adamawa and Bauchi states of Nigeria”

Whole study protocol (Abstract, introduction..)
The authors in several statements keep on referring to cholera stakeholders which is an assumption that the readers are conversant with cholera and they know who the stakeholders are globally, in Nigeria and in the study area. Given that this study protocol addresses an important public health issue and may have global readership with some audience based in communities where cholera was eliminated several decades ago, it would be more understandable if what is meant by stakeholders is well defined. For instance, a reader or a researcher who is knowledgeable on conflict resolution may think of the Government of Federal Republic of Nigeria, Boko Haram leadership, local communities, UN agencies and other as the key stakeholders. While others may omit Boko Haram leadership yet they are one of the actors who may destroy investment put in place to prevent cholera. Furthermore, this clear operational definition may facilitate replication of the study findings by other researchers.

Introduction
Kelly Elimian et al., clearly state the overall objective, “Therefore, the overarching aim of this study is to collaboratively work with cholera stakeholders to examine the factors enabling and blocking sustained implementation of multi-sectoral cholera interventions in the Adamawa and Bauchi states, with a view to addressing recurrent cholera transmission and inform the development of a locally adapted roadmap for Nigeria”.

This is a good statement. However, my concern is related to proposing to use finding from two states of Adamawa and Bauchi to develop plan for entire Federal Republic of Nigeria which is a vast country with 36 federal states. Therefore, the authors will need to revise this statement to fit
the proposed study.

**Minor comments**
These are minor issues but are essential to achieving the objectives of the study.

**Methods**
The authors include Abuja as a study area yet Abuja is not cholera hotspot area and is not conflict affected state which are major criteria for selection of the study area. It is true, the central team in Abuja will be interviewed, however they will be selected because of the role they play in supporting cholera prevention or their role in conflict resolution in the two states. Therefore, the authors should review study area to remove Abuja state.

*Data collection, management and analysis*
The authors focus on health sector and give little attention to other sectors. According to WHO, GTFCC Cholera prevention and elimination require all actors starting from the political head and this is articulated in the GTFCC framework of 2019 that is a guide for development of the national cholera plans. According to these framework several government sectors (prime minister, finance, water, health and others) are required. However, in this study protocol the participants of the study are mainly health workers and organization supporting health care. These is stated by the authors in the protocol, “*Data collection tools will be updated following piloting with healthcare workers in a purposely selected health facility in Abuja to determine completeness, clarity and accuracy. Data collection will be done using Open Data Kit (ODK) Collect installed on password-protected mobile devices*”.

The same (focus on health sector) is also seen in the analysis of data where the data to be analyzed is from the health system and none from other ministries. This is reflected in this statement, “*The current health system capacity to support various cholera interventions will be determined using descriptive analyses...*”.

Therefore, Kelly Elimian *et al.*, will need to revise this sections to ensure that the relevant data on cholera prevention is collected from all key ministries and analysed to comprehensively inform the policy on cholera prevention.

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**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?**
No

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Public Health, Infectious diseases, Cholera

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.

Reviewer Report 23 February 2021

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This is a well-thought study protocol elaborated by Kelly Emilian et al. with the objectives of describing the current health system capacity to support multi-sectoral cholera interventions in two fragile states in Nigeria, describing barriers and facilitators for the implementation of such interventions and identifying potential strengthening opportunities for multi-sectoral collaboration. The authors propose a 2-phase study project with quantitative cross-sectional and qualitative methods in the first part and a group model building (GMB) in the second.

The aim of the study is clear; the title relevant and informative. Relevant and up-to-date references are used (although a suggestion is made below). The study setting is clearly described and the selection process of individuals is clear. Furthermore, the study is highly relevant for the Nigerian context of fragility and cholera endemicity. It is as relevant for other fragile states around the world battling cholera. As such, the research method is suitable to reach the objectives and enough details are provided in order to replicate it.

However, the research question is not clearly outlined in the introduction. In this section, I wonder if the authors question the factors influencing sustained implementations of cholera interventions or the use of a specific method, namely the GMB or the likelihood of eliminating cholera in the context of fragility (lines 1-8 of the 7th paragraph of the introduction). Therefore, in regards to
what is already known about the topic as stated by the authors, and the lack of clarity of the
research question, the gap in knowledge they are trying to fill is also not clearly established. The
authors stated that “there is a dearth of evidence on the use of GMB approaches to address
cholera both in Nigeria and elsewhere.” As stated, they shift the focus from the factors influencing
sustained cholera interventions to the GMB methodology.

Therefore, I would suggest beginning the 7th paragraph with “In order to fully comprehend the
factors enabling and blocking sustained implementation...” and switch the knowledge gap
statement to “to the best of our knowledge, there is a dearth of evidence on factors enabling or
blocking sustained... especially using the GMB method to grasp such factors”.

To shorten the introduction (5 paragraphs instead of 7), I would suggest omitting detailed
information regarding the SDG and the GTFCC as they are not crucial to establish the background
of this study, given the objectives. Furthermore, the last paragraph of the introduction stating the
objectives of the study can be shortened with the objectives presented in the text, not numbered.
The details describing the group model building should be moved from the introduction to be
incorporated in the methods section while avoiding repeats.

In the methods section, please include details in the text regarding the variables and indicators
that will be used in the descriptive analysis to determine the capacity of the health system to
support the cholera interventions (lines 3 and 8 of data analyses sub-heading) and references
indicating how they were chosen. Also, provide complete details/definitions about the factors that
will be incorporated in the multivariate regression model to assess knowledge (line 16-18 of data
analyses sub-heading).

Furthermore, regarding the discussion, the authors define fragility as “...the result of violence and
prolonged conflict, political and economic instability, marginalisation and inequality, weak and
distorted national governance structures and processes, and significant environmental threats
and natural disasters (paragraph 4 in the introduction, lines 4-8)”. This concept seems intertwined
with the notion of complex emergencies (CEs) defined in a study by Bompangue et al. as “a
humanitarian crisis in a country, region or society where there is a total or considerable
breakdown of authority resulting from internal or external conflict, and which requires an
international response that goes beyond the mandate or capacity of any single and/or ongoing
United Nations (UN) country programme”.

Bompangue et al. concluded that CEs may facilitate the spreading of already existing cholera
outbreaks. In light of this parallel, I would like to read some discussions regarding how the study
proposed by the authors may integrate and deepen the knowledge from Bompangue's study in
the Democratic Republic of the Congo.

Overall, the study protocol is well structured and has the potential to bring relevant and critical
knowledge to fighting cholera in a fragile state in order to implement context-specific
interventions.

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PubMed Abstract | Publisher Full Text
Is the rationale for, and objectives of, the study clearly described?
Yes

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?
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Research on operationalization and ecology of infectious disease.

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

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