**STUDY PROTOCOL**

**A realistic review of community engagement with health research**

[version 1; peer review: 2 approved, 3 approved with reservations]

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**Abstract**

**Introduction:** Community engagement is increasingly recognized as a critical aspect of global health. Recent years have seen an expansion of community engagement activities linked to health research, but debates and inconsistencies remain about the aims of different types of engagement, mechanisms underpinning their implementation and impact, and influential contextual factors. Greater commitment to and consistency around community engagement by health research programs, implementers and funders requires a more coherent evidence base. This realist review is designed to improve our understanding of how and why community engagement contributes to intended and unintended outcomes (including research and ethical outcomes) in different contexts. Given the breadth and diversity of the literature on community engagement in health research, the review will initially focus on malaria research in low- and middle-income countries (LMICs) and draw on wider global health literature where needed.

**Methods and analysis:** Community engagement in practice is often a complex set of interventions. We will conduct a realist review – a theory driven approach to evidence synthesis – to provide explanations for how and why community engagement contributes to intended and unintended outcomes (including research and ethical outcomes) in different contexts. Given the breadth and diversity of the literature on community engagement in health research, the review will initially focus on malaria research in low- and middle-income countries (LMICs) and draw on wider global health literature where needed.

**Ethics and dissemination:** A formal ethics review is not required for this literature review. Findings will be disseminated in a peer reviewed journal.
through national and international conferences, and through a set of short
briefings tailored for audiences with an interest in community engagement.
Outputs and presentations will be informed by and feed into our network of
community engagement experts.

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Keywords
realist review, community engagement, health research, low and middle
income countries, malaria research

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Competing interests: Robin Vincent has worked in a consultancy advisory capacity for the Wellcome trust around support for evaluation of community engagement and development of community engagement strategies.

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Introduction

Background
Community engagement is increasingly recognized as a critical element of global health research, recommended by ethicists, funders and international ethics guidelines, such as the 2016 Council for International Organization of Medical Sciences (CIOMS) guidelines. However, ‘community engagement’ remains a relatively ill-defined term with varied meanings and practices across the domains of health promotion, health related research, health programmes and international development. The diverse conceptual underpinnings of community engagement, the range of goals ascribed to it and wide variety of activities undertaken all complicate the evaluation of community engagement. 

Community engagement has been defined as a process of collaborative work with groups of people affiliated by geographic proximity, interest or health issue, to address social and health challenges affecting those people. In practice in health-related research, community engagement encompasses a wide variety of activities and strategies, such as conducting meetings with community members and representatives, working with community advisory boards and involving members of the community in designing and implementing research activities.

Goals of community engagement
Scholars have identified a series of overarching goals of community engagement in health research. A distinction is often made between the instrumental goals of improving the quality and relevance of research, including achieving recruitment and retention targets, and a range of ethical goals of community engagement, including: respecting individuals, communities and stakeholders; building trust and social relationships; determining appropriate benefits; minimizing risks, burdens and exploitation; supporting the consent process; understanding vulnerabilities and researcher obligations; and gaining permissions, approvals and building legitimacy.

Community engagement initiatives in health research often have more than one goal, however, and the distinction between instrumental and ethical goals in practice can be unclear. Further, studies that have attended to the relational dynamics of engagement, rather than formal ethical procedures, have made visible the ‘human infrastructure’ of research and highlighted how a concern with ethical negotiation of relationships may be integral to achieving more instrumental research goals. The bulk of current literature focuses on the contribution of community engagement to research-related outcomes rather than the range of potential ethical outcomes, including the impact on stakeholder relationships.

Community engagement goals and activities are also potentially affected by the type of research and interventions in which initiatives are embedded and the opportunities and constraints for engagement that they entail. For instance, in mass drug administration studies and vaccine studies, where study success depends upon a high population coverage, community engagement may be emphasized to achieve study related aims rather than other goals. In hospital based clinical trials, community engagement may focus on engaging with patients at the hospital rather than broader communities. There are guidelines for good participatory practice in clinical trials aimed at maximising the meaningful involvement of individuals and communities, but some have nevertheless argued that the nature of clinical trials can circumscribe the scope for community involvement compared to other forms of social and health research.

Community engagement mechanisms
From a realist perspective, diverse community engagement activities may rely on a more limited number of relational mechanisms. Potential mechanisms hinted at in the literature include: respectful interactions facilitate trust, listening and acting to show understanding and express recognition, leads to a sense of people being heard, and responsiveness of research processes increases motivation to participate. A range of different engagement activities may contribute to a mechanism coming into play, and differences in context will affect how these mechanisms work in particular settings, producing a pattern of outcomes. Figure 1 provides a simplified example.

At the same time, several different mechanisms may work in combination, some of which may contribute to intermediate outcomes that, in turn, become an important new context within which other mechanisms may operate. Drawing on some of the potential mechanisms highlighted in the above paragraph, we can see how they may combine and interact with each other (recognising that whether or not they do in practice is an empirical question for the review to consider). For example, building of relationships between researchers and community members may help to establish trust and the credibility of research. At the same time, where community members can provide feedback and voice their concerns about research, members may help to establish trust and the credibility of research. In this way, engagement is likely to involve a number of different mechanisms in combination and their sequencing may prove to be important.

Influence of context
While some of the above mechanisms may be common across a wide range of types of health research, whether or not they come into play may be affected by a particular local social and cultural context. For instance, the impact of community engagement on targeted malaria elimination studies that aims at wide community mobilisation may be enhanced in a cohesive community compared to a politically fragmented community. In recent years, the details of social and
cultural context have been increasingly reported in accounts of community engagement around health research. For example, the geo-political context of Thai-Myanmar border, livelihoods based on subsistence farming, the influence of traditional healing practices and remote and limited health service provision have been highlighted as affecting engagement outcomes. A recent systematic review of the last century’s literature on community engagement and population coverage in mass antimalarial administration identified a range of contextual factors, including: how community engagement and population coverage could be affected by the social cohesion of the communities; the influence of social hierarchies and political factions; cultural beliefs around blood tests (including rumours such as blood stealing); the influence of traditional healing practices; and, more broadly, perceptions around the concept of research, its rationale and the impacts.

To date, however, there is a lack of analysis and explanation of how the factors of local social and cultural context have affected particular outcomes. Similarly, as noted above, a number of potential mechanisms have been hinted at in the literature, but these are often left implicit without any systematic analysis, including how they work in combination and are influenced by context.

Addressing complexity
Realist review and synthesis provides a framework to look at configurations of context, mechanism and outcome and to draw out regularities and patterns that endure across context. Some of the team involved in the current review previously attempted to conduct a conventional systematic literature review, but faced great challenges due to the extraordinary complexity and diversity of the community engagement literature. They recommended that a realist review may better suited to address such complexity. Using a realist approach, the current review will focus initially on malaria research to explore: the intended (and unintended) outcomes of community engagement; mechanisms by which community engagement strategies are believed to generate the outcomes; and important contexts that affect various mechanisms and outcomes. The ultimate aim of this review is to develop transferrable learning about community engagement in health research and programmatic interventions.

Methods
Review aim
This review aims to improve our understanding of the ways in which (i.e. how, why and in what contexts) community engagement interventions contribute to (or do not contribute to) reported outcomes (both explicitly aimed for and unintended) and the roles of context and mechanisms. Given that outcomes are not always clearly articulated in community engagement, the review will also consider revealed outcomes, again attempting to understand the influence of particular mechanisms and context.

Review objective
To conduct a realist review to understand the ways in which community engagement contributes to intended and unintended outcomes, and through which key mechanisms. This will be done with (A) engagement with a diverse range of literature, (B) the development of a programme theory and (C) feedback and advice from stakeholders experienced in the field.

Review research question
Within the existing and available literature pertinent to malaria research, what are the causal explanations for the ways in which community engagement contributes to intended and unintended outcomes?
Sub-questions:

1. What are the intended and unintended outcomes of community engagement strategies?

2. What are the key mechanisms by which community engagement strategies result in their intended and unintended outcomes?

3. What are the important contextual influences on the ways in which different mechanisms produce intended and unintended outcomes?

Study design

Realist review is increasingly recognized as an effective process for consolidating evidence and learning from complex social programming, particularly in public health and community development. The proposed review design is based on the realist review approach, which aims to explore how community engagement produce outcomes in specific contexts through the operation of a number of key mechanisms. This review will initially focus on the community engagement embedded in malaria research in low and middle income countries. The initial search commenced on 21st February and screening from 12th March, 2019. We anticipate the review will be completed by the 30th June, 2020.

Over the years, realist reviews have explored the configurations of context, mechanisms and outcomes for complex issues, such as antimicrobial prescription by doctors, access to primary care for socio-economically disadvantaged elderly populations in rural areas, and the process of appraising the performance of doctors. Because community engagement activities are complex interventions that work through a variety of different mechanisms to produce different outcomes across different contexts, realist review holds the promise of bringing greater clarity and understanding to the variation of engagement in practice.

A realist review eschews the traditional hierarchy of evidence and incorporates a wide variety of data, including those derived from qualitative, quantitative, mixed methods studies, as well as grey literature. The review will include all the pertinent documents published in English language only. In contrast to a more conventional review, in which the data are extracted and aggregated across a selection of studies deemed to be of sufficient quality, in realist review, diverse data are drawn upon depending on their potential value to contribute to refinement of programme theory. Within realist reviews assessments are not made for risk of bias of individual studies or meta-bias across studies. Findings derived from this realist review are expected to be transferable because they will focus on commonly occurring mechanisms through which community engagement produce both intended and unintended outcomes. This will enable us to produce recommendations likely to be useful across domains beyond malaria within global health research. Realist review incorporates iterative cycles of engagement with the literature and with stakeholders with relevant knowledge.

Stakeholder engagement

We aim to involve a wide range of stakeholders with expertise and experience of community engagement. At key stages in the review these stakeholders will provide input and feedback on relevant papers, our literature search strategies, and evolving learning. Figure 2 shows the structure of inputs into the review. We have established a ‘content expert advisor’ group comprised of experts from low- and middle-income countries.
(LMICs) who are community engagement practitioners and scholars. This group has been involved in the generation of the initial candidate programme theories for the review, and will provide input at key moments throughout the process. Our advisory group draws on expertise in bioethics, malaria, realist review and includes health research funders. In addition, we aim to solicit input from community members involved in community engagement processes, including in Kenya and on the Thai/Myanmar border. In both of these contexts, core team members and content experts are able to support this process. An evolving group of wider stakeholders, including academics, policy-makers, funders, research programme managers, implementers and engagement practitioners, will also provide input. The wider stakeholder group will be identified using a snowball approach through the authors’ professional networks, engagement at conferences, and through outreach based on identified literature and relevant programming initiatives.

**Step 1: locating existing theories**

As a first step in realist review, an initial scoping search is conducted to identify theories that begin to explain and develop our understanding of community engagement. This stage is crucial to visualize the underpinning assumptions about why certain components and processes of community engagement are required to achieve one or more desired outcomes.

At the initial stage, these theories are explored in two main ways: 1) drawing on exploratory searches of relevant literature in repeated cycles; and 2) consulting with key content experts who have practical experience of implementing community engagement.

The first stage of our initial scoping of key literature to identify elements of programme theory involved reviewing key literature in the field of community engagement recommended by our content experts. A summary of commonly recognised outcomes of community engagement, potential mechanisms and important elements of context was then discussed among the core team and our context experts to produce an initial programme theory and related visualisation. This was subsequently refined through further discussion among the team. Figure 3 is the consolidated visualisation of elements in an overall programme theory that was then used to help focus our search strategy. It should be noted that at this stage the diagram is a more a summary collection of still (heterogenous) elements, not strictly configured or consistent, and that some of the terms are indicative at this stage rather than strictly defined (since their meaning in practice will depend on how they are evidenced in the literature). Making putative contexts, mechanisms and outcomes as explicit as possible is an important first step to help focus our ongoing systematic literature searches. This stage was not exhaustive but helped to capture key aspects of engagement and to help focus more systematic literature searches in stage 2.

This initial programme theory diagram (Figure 3) will be further simplified to produce a version that can be used in community consultations in Kenya and the Thai Myanmar border. Figure 4
Figure 4. Simplified programme theory for consultations.

shows an early iteration of a simplified version of the diagram, notable for the way it focuses on our initial sense of potential mechanisms and omits aspects of context. Used in addition to some open-ended questions with community representatives, we aim to both solicit community perspectives, but also ‘test’ this initial sense of what may be important in community engagement.

Further development of programme theory will be iterative and incorporate insights from discussions within the project team and advisors, and findings emerging from review of the literature. Regular meetings will be conducted with the aim of challenging, sense-making and synthesizing a range of different elements of context, mechanism and outcome into an initial overall programme theory.

Step 2: searching for evidence

We anticipate that searching for evidence will involve literature searches in up to three broad categories. The first search will identify literature that describes or discusses the common current practice of community engagement in large research programmes, focusing on clinical trials (for example, mass antimalarial administration and malaria vaccine trials). This first search will include a supplementary search based on citation chaining of key international ethical guidance and policy documents on community engagement with clinical trials. If more relevant data are needed then our second search will involve identification of literature that describes community engagement practices in other research paradigms and across disciplines. In addition, the searching will be flexible and if needed will incorporate relevant studies published up to the completion of the review. This search will initially still focus on community engagement in malaria, but we will loosen this requirement if additional relevant data are still needed for programme theory development and testing. Finally, if needed, the third search will involve identification of literature that discusses failure, challenges and problems in community engagement. In addition to searches of electronic bibliographic databases, techniques including forward and backward citation chaining, and methods to identify ‘kinship’ or ‘sibling’ studies of relevant documents will also be employed after the screening to help identify the relevant materials.

The goal of such a search strategy is to identify adequate literature that can further inform the development of a more detailed programme theory. The process of designing, piloting and conducting the formal searches will be conducted with the support of an information specialist (CD). Modifications and adaption of search strategies following the pilot will be documented and implemented across source types.

The following electronic bibliographic databases will be searched: MEDLINE, Embase, Global Health, CINAHL, The Cochrane Library, the Web of Science Citation Indexes (Core Collection), Scopus, the Global Index Medicus, IBSS and ASSIA. Additional databases identified by the information specialist may be added later. Informed by the initial programme theory developed in step 1, each search strategy will be built around two main concepts: malaria and community engagement. Additional terms will be added to identify literature in the three categories described above. A comprehensive set of free text and subject heading terms will be used to identify the relevant documents. Search terms will be chosen based on key documents identified by the project team and wider content expert groups, discussion in these groups, and the initial programme theory. The searches will not be limited by the date and (English) language, although they will be conducted in English. Searching is underway, and the search strategies employed for the first of the planned searches are presented as Extended data.
All screening will be undertaken by BA. RV will screen a random sample of 10% of records to support discussion and refinement of inclusion criteria. Disagreements and consistency between these two reviewers will be discussed amongst themselves first and with the project team members if and when necessary.

Initial screening will be conducted based on the title, abstract and keywords. We will use following inclusion criteria to determine if a document is likely to contain the relevant data:

- Community engagement in malaria research. By community engagement, we are predominantly referring to the range of strategies undertaken alongside research, for example meetings and discussions with the stakeholders, and training and development of responsibilities to community volunteers.
- Document type: all study designs and documents that may contain relevant data.
- Types of (participants) studies: documents that include research focused on community engagement or community engagement embedded in any malaria related research.
- Types of intervention: community engagement conducted alongside research to promote research and ethical outcomes or relevant case studies of community engagement in long established research institutions.
- Outcome measures: both intended and unintended outcomes of community engagement will be explored, for example: (1) research outcomes - recruitment, support for research programme and higher quality research; and (2) ethical outcomes - identification of non-obvious interests, acting on stakeholders’ feedback, and enhanced legitimacy of research.

During the screening process, documents will be excluded based on their content using following criteria:

- Research documents which have only briefly mentioned community engagement but with no further details on how the community engagement was conducted, what it entailed or related outcomes.

Additional searching
As the aim of the realist review is to include a broad range of documents to further inform the development of the programme theory, where needed we will look across disciplines, outside of malaria and in different research paradigms, particularly in relation to the exploration of mechanisms for community engagement to produce both intended and unintended outcomes of interest. For example, we may undertake additional searches as the programme theory develops for a number of reasons: to fill in evidence gaps; develop understanding of potential mechanisms; and borrow analogies or theories from other relevant disciplines.

Step 3: document selection
Documents included from screening of titles and abstracts will be considered for selection into the review. The full text of documents initially screened into the review will be further sorted and selected for inclusion primarily based on two criteria: 1) relevance in terms of how and to what extent they can contribute to the programme theory development and refinement; and 2) rigour, which refers to the credibility and trustworthiness of methods used to generate the data. Documents pertinent to community engagement in clinical trials of malaria or programmes will be initially prioritized for inclusion and analysis. Other health research with relevant information on community engagement will also be subsequently incorporated based on its potential to strengthen our understanding of community engagement processes. These papers will be categorized as having potentially major or minor contributions to answering the research questions.

Major contributions include:

- Documents which contribute to answering the research questions and conducted in the field of clinical trials related to malaria in LMICs
- Documents which contribute to answering the research questions but are not focused on clinical trials; for example, descriptive account of community engagement strategy in a research institution.
- Documents which do not focus on malaria, but health research, for example HIV, tuberculosis or Ebola research, which can significantly inform our review in terms of understanding the processes and mechanisms.

Minor contributions include:

- Documents which report community engagement in high income countries, non-clinical trial contexts, for example development science, but where the mechanism could plausibly operate in the circumstances of LMICs.

This process, together with the developing discussions around the literature, will enable reviewers to focus on data extraction and analysis of papers that provide a conceptually rich contribution, while still including documents that are less conceptually rich.

Step 4: data extraction
Following the methods outlined in a previous realist review, data extraction will take place in two stages. At first, the selected documents including their characteristic details will be extracted into a table. This will provide a descriptive account of the documents included. In the second stage, all the selected documents will be analysed using NVivo. Extraction of data will be undertaken first by BA and will be independently reviewed by RV for consistency and refinement of the codes. Discussions will be held with the core project team members for consistency of codes, interpretation and the (interim) findings. Discussions will be held with the wider project team when there are disagreements within the project team which cannot be resolved. Any discussions and their outcomes among core team members and the wider project team members will be recorded.
Step 5: data synthesis
The main aim of the data synthesis in realist review is to develop and then confirm, refute or refine parts of the programme theory. The initial programme theory will be further developed by drawing on the data found within included documents. Analysis of the data will entail using a combination of various methods of reasoning that includes a deductive approach, in which the codes used to code data are based on the initial programme theory, an inductive approach in which codes will emerge from the documents reviewed and a retroductive approach, where inferences are made based on interpretations of the data contained within included documents of underpinning mechanisms.

Analysis will following the process set out by Papoutsi et al. Primary reviewers BA and RV will develop initial CMOCs and these initial CMOCs together with the emerging CMOCs will be discussed amongst the core team for validation and refinement.

The review will follow the standard Realist and Meta-Review Evidence Synthesis: Evolving Standards (RAMESES) guidelines on quality and reporting.

Step 6: refine programme theory
The final step in realist review is the refinement and validation of the programme theory. To ensure that the final programme theory makes pragmatic sense, experts and practitioners of community engagement will be consulted to inform final refinement of the programme theory. Incorporating the inputs of community members and community engagement practitioners (field staff) will help us to make it practical and realistic. We also aim to hold an international validation workshop approximately 15 months into the review, in order to validate the findings but also to gather input to help develop tailored versions of the findings for a number of different audiences, including funders and policy-makers and global health research managers and engagement practitioners.

Towards the end of this process of refinement, the review team will revisit parts of the review that require re-scrutinizing. This process will be continued until no new information is provided by the evidence or stakeholder involvement, essentially reaching theoretical saturation.

Strengths and limitations
- To our knowledge, this is the first realist review aiming to synthesize evidence and produce conceptualizations on community engagement with health research in LMICs.
- A realist review should enable us to understand the complexity of community engagement and its outcomes in diverse contexts. The programme theories developed through the process should be relevant across contexts.
- Stakeholder engagement during programme theory development will ensure a range of perspectives inform the review and support the relevance and uptake of the findings.
- The breadth and diversity of the community engagement literature remain a challenge. Our review will use community engagement with malaria research as a pathfinder topic and will draw on wider literature on community engagement where necessary.

Ethics and dissemination
Ensuring that the outputs from this review are useful to the community engagement practice in health research is a key priority for us. Aligning with this value, we will produce relevant and appropriate outputs that target a range of audiences, in conjunction with stakeholder consultation:

1. Academic forums: we aim to publish in a high-impact peer-reviewed journal including sharing our work in relevant academic conferences where inter-disciplinary scientists attend.
2. Plain English summaries and briefing documents: apart from the academic outputs, we will produce documents which will be simplified for a range of particular audiences, including for a non-expert audience, with an aim of maximum uptake and dissemination of our evidence.

Study status
The study has piloted the preliminary search strategy and the number of studies resulting from this initial search are undergoing screening and has not been completed yet.

Data availability
Underlying data
All data underlying the results are available as part of the article and no additional source data are required.

Extended data

This project contains the following underlying data:
- Appendix 1.docx (database search strategies for preliminary searches)

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

Grant information
This work was supported by the Wellcome Trust [210505]. GW’s salary is partly supported by The Evidence Synthesis Working Group of the National Institute for Health Research School for Primary Care Research (NIHR SPCR) [Project Number 390].

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
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Tracey Chantler
London School of Hygiene and Tropical Medicine, London, UK

This is a very interesting study protocol and the research that ensues will make a positive contribution to the field.

I have several comments however some of which relate more to the study design, hence may be difficult to change but aspects could be used to improve the paper and possibly refined the methodology.

1. I think that the rationale for using a realist approach needs to be summarized earlier in the paper. Some detail in provided in the methods section however terms relevant to realist evaluation are used earlier in the paper, hence need to be defined at an earlier stage. It would be good to have a text box providing information about this in addition to the Figure 1 example of a mechanism. With reference to this, it can be difficult in practice to distinguish between an intervention/activity and a mechanism. This highlights the importance of providing a full explanation of realist evaluation theory at an early stage of this paper.

2. In your aims and objectives you state that you will develop a programme theory. This needs to be explained. Normally each intervention/CE strategy would have there own programme theory that accounts for the context, the problem, what change is be activated and how this will be measured in terms of outcomes. If I understand correctly you are trying to develop a theory for CE strategies and maybe seeking to identify what are the main mechanism that support 'effective' CE in different contexts. Again mechanisms may vary significantly across contexts, cultures and also be affected by the institutional cultural of the organisations involved.

3. Could you justify more clearly why you are focusing on malaria research. This may have just been a pragmatic decision but please clarify.

4. The stakeholders involved are mainly based at international health research centers - I wonder whether this may result in this work focusing more on CE in these settings rather than more broadly. It is great that you have representation across different institutions, continents and countries, but some areas of the world are missing. This could be due to you focus on malaria research. Thinking about Haiti in the Caribbean and parts of South America.
Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

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

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

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

**Reviewer Expertise:** Immunisation, ethics, community engagement, medical anthropology, evaluation

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 02 July 2019

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**Sanjeev Sridharan**
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I am enthused about the prospects of conducting the realist synthesis on community engagement. I think the field can benefit from such a study. The team has the right mix of competencies to successfully complete a realist synthesis of a complex area such as community engagement. Despite my enthusiasm for such a realist synthesis, I am not fully convinced that the approach as proposed will generate useful knowledge to help plan more meaningful community engagement for global health research. Key concerns that I have include the following points:

1. **Defining 'outcomes' from a community lens:** Perhaps my primary concern is that the paper provides very little focus on defining what “outcomes” actually mean. There is little to no discussion on what outcomes would be measured to understand benefits to the community. This is a significant oversight. The promise of a realist perspective in this study is its potential to generate knowledge of the context and mechanisms that might be associated with community engagement. Because the proposed protocol makes little effort to define outcomes from the perspective of the community, I am a little concerned that this study might not generate useful, actionable information.

2. **Understanding of the community engagement process:** I found very limited discussion on what is community engagement. The process of community engagement is not discussed.
have ideally preferred a little greater clarity on the dynamic nature of community engagement. As it presently reads, the construct of community engagement is under-theorized.

3. **Towards deeper understanding of the multiple shades of community engagement**: Given the formidable complexities that might underlie community engagement, I am sensitive to the challenges of understanding the CMO configurations underlying community engagement. I would recommend a more thoughtful discussion on why community engagement around research in malaria might be a little different than community engagement for other goals (for example, community engagement for gender empowerment). I found the discussion around the concept of community engagement quite mechanical.

4. **A more explicit focus on LMIC contexts**: Given that the research is being done in LMIC settings, I did not find a discussion about the challenges of conducting research in LMIC setting. I found myself wondering which specific contexts in such settings will be explored. In what ways are the mechanisms associated with community engagement different in LMIC contexts?

5. **The need to more explicitly focus on values**: Underlying much community engagement is a set of values. Community engagement can be quite exploitative or can be very respectful recognizing that the community is the seat of the decisions. The present version of the protocol takes a very instrumental approach to community engagement. I was somewhat surprised by an absence of any discussion around values in a realist synthesis protocol on community engagement.

6. **Taking unintended outcomes seriously**: There is a claim that the review will explore unintended outcomes, but there is very little discussion on how the authors plan to explore this. Most evaluations that might form the basis of such a synthesis do not often report on unintended outcomes; in this light it’s not clear how the authors intend to report on a synthesis of unintended outcomes.

7. **The need for prioritization**: Given the complexity of community engagement, wide varieties of CMO configurations might be possible. In the absence of clear prioritization, the complexity of having many CMO configurations with potentially limited evidence (across the multiple configurations of contexts and mechanisms) needs to be more explicitly discussed.

8. **Interrogating the theory of change**: Much of the theorizing is from a researcher’s perspective. The review presently does not have a strong plan to incorporate a community perspective to challenge, interrogate and refine the program theory. For example, I would have liked the authors to more clearly discuss how the community group members within the Wider Stakeholders Group can be utilized to refine the theory of change.

**Comments on Rationale**

While the rationale for the study is well described, it’s unclear in the absence of information on the outcomes how the proposed realist synthesis plans to achieve the objectives of the study. As pointed out earlier, the study also suffers from taking very much of a researcher’s perspective on potential benefits of research without sufficiently incorporating community members in either clarifying what community engagement means or in refining the theory of change.

**Appropriateness of Study**

While there is much to be enthusiastic about the application of realist synthesis in understanding community engagement, many aspects of the proposed approach need to be further refined. The lack of a clear prioritization of CMO configurations, under-theorization of the dynamic nature of community engagement, and an absence of the discussion of the LMIC context that might be appropriate reduce my confidence in the proposed approach’s ability to refine and develop a useful program theory for community engagement. I would recommend focusing on some of these points.

**Details of the methods**

As it presently reads, the details of the realist synthesis follow a general cookie-cutter approach and the
complexity of conducting a realist synthesis for a complex area like community engagement especially in the domain of malaria research is not sufficiently considered. I also would argue that the Figure 3 as presented is not sufficiently clear as the starting point for developing an initial program theory.

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

Is the study design appropriate for the research question?
Partly

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:** Evaluation, Global Health

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 01 July 2019

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Maxine Whittaker
Division of Tropical Health and Medicine, James Cook University, Townsville, Qld, Australia

In Goals of community engagement, the goal of using this method for co-design of health research has been left out. Increasingly there are researchers who are undertaking co-design with communities, the whole approach of participatory research.

Outcomes could also include: community ownership, community empowerment, community leadership, sustainability. These are not considered. It may be that an intended or even unintended consequence of community engagement was a resultant community level outcome not just a malaria research or ethical obligation outcome.

The dissemination activities should also be informed and co-designed with community groups. One example could be the recently formed Civil Society for Malaria Elimination. Dissemination, at least of briefs, in languages other than English would be advantageous for reach.
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?
Yes

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

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

**Reviewer Expertise:** Health systems, medical anthropology, community engagement, malaria control and elimination

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.

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**Reviewer Report 25 June 2019**

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**Suzanne Day**

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This study protocol describes the undertaking of a realist review of community engagement for malaria research in LMICs. The protocol begins by identifying the need for greater understanding of community engagement and how different contexts shape engagement outcomes and, subsequently, have implications for health research outcomes. It then describes the objectives of the review, and details the search strategies that will be used.

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

- Partly. The rationale for the review is well articulated. Under “Review objective” on page 4, one of the stated goals is “To conduct a realist review to understand the ways in which community engagement contributes to intended and unintended outcomes” – but it is not clear whether the authors mean by "outcomes". Does this refer to outcomes for the health research for which community engagement is being conducted, or outcomes of engagement in general? It is not until page 8 that it is specified that both research outcomes and ‘ethical’ outcomes will be examined. Additionally, it is not clear what is meant by ‘ethical outcomes’ – does this refer to outcomes that enhance the ethical conduct of the research? More clarification would be helpful here regarding exactly how ‘outcomes’ are being defined in the context of this review.
Is the study design appropriate for the research question?

- Partly. The authors are conducting a realist review, which is a method to develop/refine programme theory. However, it is unclear what 'programme theory' means in this context: is this a theory of how community engagement impacts health research? In other words, it is not clear what the programme theory will explain, so it is difficult to assess whether a realist review is the most useful study design. A scoping review would have similar elements (e.g. searching through both academic and grey literature; secondary searching of reference lists; consultation with stakeholders for additional inclusions, etc.) but without the goal of building theory, which may be more appropriate here if it is difficult to articulate exactly what the resultant theory is intended to explain.

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

- Partly. There are some inconsistencies and missing information. For example, on page 5, the authors note that “The review will include all the pertinent documents published in English language only.” However, on page 7, they note that “The searches will not be limited by the date and (English) language, although they will be conducted in English.” Please clarify the search strategy and its language limitations. Additionally, location of community engagement should be part of the inclusion criteria for initial screening of literature in order to identify studies based in LMICs, which is a stated goal of the review. Please also specify the definition you are using to determine whether the literature is sourced from an LMIC context (e.g. World Bank definitions of LMICs?)

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

- Not applicable. This protocol describes a literature review which is not yet completed, thus all data have yet to be collected. However, the final dataset (i.e. all literature included in the review) will be fully accessible as a part of the review article once it is completed.

Additional Comments

- The conceptual distinction between “Outcomes” and “Contexts” is unclear in Figure 1. In the example given, it would seem that suspicion/openness to research is more an outcome than a context. Perhaps ‘Prior research experiences (e.g. historical mistrust due to past abuses/lack of engagement, vs. trust in research due to positive experiences)” would more accurately capture the concept of context here. In the smaller (definitional) wheel, you might specify that context refers to underlying social, political, historical, and economic factors within which engagement interventions are embedded.

- It is not always clear what the authors mean by “outcomes” – will the review focus on outcomes of engagement itself, or the outcomes (impact on) the health research for which engagement is conducted? For example, on page 4, 2nd paragraph: The authors note “To date, however, there is a lack of analysis and explanation of how the factors of local social and cultural context have affected particular outcomes.” Which particular outcomes? Does this refer to research outcomes, or something else?

- Figure 3 is very difficult to understand due to a lack of definitions and clear labeling. For example, what do the blue bars signify? What is the difference between “conditions” and “contexts”? How are “interaction qualities” different from “contexts”?

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

Partly

Is the study design appropriate for the research question?

Partly

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:** sociology of health; community engagement; research ethics

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.

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Rosemary Musesengwa

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This is a pertinent review in the field of Community Engagement (CE). Employing a realist perspective is a novel and appropriate method for CE. Their review of the literature is well structured and the need for a realist perspective is well justified. The proposed review shows considerable engagement with the current literature drawing robust conclusions. I agree that current literature on CE does not present a coherent evidence base that will enhance understanding of how different CE mechanisms contribute to research outcomes.

It is a very welcome review at a time when it seems now CE has become rather a technical imperative rather than an ethical imperative as it rightly be. I believe the lack of coherent literature has led to researchers relying on random literature which might not lead to desired or intended outcomes.

The methodology proposed is logical and appropriate. The authors have a clear picture of what the review will entail. I do have reservations on the selection of the broader stakeholders from snowballing. Snowballing for stakeholders will ultimately lead to people who have the same mindset and view of an issue and can be extremely biased at most. A more structured/stratified approach is recommended drawing from all schools of thought from within which snowballing may be employed.

Limitations of the review are well articulated by the authors. The difficulty of searching for CE literature as most of the literature is rarely written with the intention of illustrating CE activities/mechanisms but are usually implied in other types of manuscripts, should be underscored.

The review promises to bring clarity and understanding to CE literature.

**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?**
Yes

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

*Competing Interests:* No competing interests were disclosed.

*Reviewer Expertise:* Community Engagement, Research Ethics

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.