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# Engaging communities in tuberculosis research

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According to a growing consensus among biomedical researchers, community engagement can improve the ethics and outcomes of clinical trials. Although successful efforts to develop community engagement practices in HIV/AIDS research have been reported, little attention has been given to engagement with the community in tuberculosis research. This article aims to draw attention to some existing community engagement initiatives in tuberculosis research and to resources that might help tuberculosis researchers to establish and implement community engagement programmes for their trials. One of these resources—the good participatory practice guidelines for tuberculosis drug trials—offers a conceptual framework and practical guidance for community engagement in tuberculosis research. To build momentum and to improve community engagement, lessons need to be shared, and formal assessment strategies for community engagement initiatives need to be developed. To build successfully on the promising activities described in this personal view, research funders and sponsors should show leadership in allocation of resources for the implementation and assessment of community engagement programmes in tuberculosis trials.

### Introduction

When WHO declared tuberculosis a global emergency in 1993,<sup>1</sup> the resulting attention helped to mobilise new private and public resources for tuberculosis research. These investments have led to the most promising pool of new tuberculosis drug and vaccine candidates in more than 40 years, with several new drugs, and drug regimens, poised to enter late-stage clinical trials throughout the next few years.<sup>2</sup> As these trials progress, opportunities to apply lessons learned about effective design and management of clinical trials from other areas of global health, including HIV/AIDS, will arise.

One aspect that has garnered attention recently is the engagement of stakeholders and communities that host and help with the conduct of trials.

The US Centers for Disease Control and Prevention define community engagement as “the process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest, or similar situations to address issues affecting the wellbeing of those people”.<sup>3</sup> In the context of a clinical trial, community engagement might involve a wide range of interactions with various stakeholders, from negotiation of agreements with local public health authorities, to the seeking of guidance from local community leaders about appropriate communication strategies, to consultations with a range of stakeholders on how best to address issues such as ancillary care or post-trial obligations. We use the term community engagement here, but many labels are in circulation, such as stakeholder engagement or community mobilisation. A great deal of conceptual work needs to be done to forge better agreement about the precise meaning of community engagement in research.<sup>4,5</sup> Even in HIV/AIDS research, for which community engagement has been a requirement of funding in some research programmes, the term has a range of meanings. The most common form of community engagement in HIV/AIDS research is the community advisory board (CAB), which is typically a small group of individuals recruited by the investigators to represent the perspective of the local community at a clinical trial site on a range of issues related to the trial, such as trial design, the culturally appropriate design of informed consent forms, and community benefits.<sup>6</sup> More elaborate programmes of community engagement have also arisen out of the unique circumstances of specific trials. For example, the RV144 Thai HIV vaccine trial<sup>7</sup> began with a conventional

### Key messages

- There is an increasing consensus that community engagement can improve the ethics and outcomes of trials
- Little attention has been given to community engagement in the context of tuberculosis research specifically, and although a range of community engagement-related activities and programmes is emerging, information about them is scarce
- More reliable and systematic descriptions of community engagement activities are essential to improve and establish the value of the evidence base
- The good participatory practice guidelines for tuberculosis drug trials provide a shared conceptual and practical framework for community engagement in tuberculosis research
- Trial funders and sponsors must show leadership in the appropriate allocation of resources to community engagement to ensure the proper implementation, assessment, and continuous improvement of community engagement in tuberculosis research

plan for a CAB to be created and serve as the main mechanism of engagement with the host communities, but as complex challenges related to recruitment and retention arose, it became clear that consultation with a CAB alone would be insufficient. The plan evolved into an extensive and complex initiative of community mobilisation and coordination, and included the creation of participant volunteer clubs and a wide range of events to raise the profile of the trial and help with successful completion.<sup>8</sup>

Community engagement is a well recognised component of tuberculosis prevention and care programmes,<sup>9–13</sup> although, even in this context, concerns have been expressed that community efforts are regarded and resourced as supplementary, instead of central, to the tuberculosis response.<sup>14</sup> Community engagement has not achieved the same status in tuberculosis research as it has in HIV/AIDS research.<sup>15</sup> Additionally, few examples of community engagement in tuberculosis trials have been reported in the scientific literature.<sup>16,17</sup> As the pipeline of new tuberculosis drugs, drug regimens, and vaccines begins to move towards late-phase trials,<sup>18</sup> the role and potential value of community engagement in tuberculosis research needs to be examined, and practices that are most likely to make positive contributions to the ethical quality and scientific success of trials need to be adopted. In this personal view article, we aim to stimulate this process by: discussing some examples of community engagement activities already undertaken in tuberculosis research, introducing the new good participatory practice (GPP) guidelines for tuberculosis drug trials (a basis for tuberculosis-specific community engagement and framework to guide further research and quality improvement), and suggesting some next steps and key challenges for the development of community engagement in tuberculosis trials.

### The rise of community engagement in biomedical research

In 1989, the US National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) formalised its commitment to community engagement in its initial Programs for Clinical Research on AIDS grants by requiring CABs as a condition for funding, effectively establishing CABs as the main feature of community engagement in HIV/AIDS trials.<sup>19,20</sup> The NIAID-funded HIV Prevention Trials Network (HPTN), established in 2000, further raised the status of community engagement in HIV/AIDS trials by implementing programmes that aimed to improve community involvement<sup>21</sup> and by publishing in-depth case studies of community engagement activities at several HPTN trial sites.<sup>22</sup>

Since early on in the HIV/AIDS epidemic, community engagement has been assisted by a proactive and cohesive political activist movement in high-income countries<sup>23</sup>

that is rooted in a sound understanding of the relevant science.<sup>14</sup> And because HIV disproportionately affected marginalised communities, this political activism was heavily imbued with justice and human rights overtones, which raised the political stakes, especially for public institutions such as the NIH.<sup>24</sup> As a result, HIV/AIDS activism helped to shape the priorities and public profile of HIV/AIDS research, and was instrumental in the mobilisation of additional funding for HIV/AIDS research and commitments to community engagement.<sup>24,25</sup>

Activism by communities and civil society organisations has effectively halted HIV/AIDS research perceived to be insufficiently attentive to local interests. For example, public protests led to the highly publicised closure of pre-exposure prophylaxis tenofovir trials in Cambodia and Cameroon.<sup>26–28</sup> The monetary and reputational costs of this activism for public and private sponsors, and the global media coverage of associated protests at international AIDS conferences, helped to consolidate community engagement as a core practice in HIV research. In the aftermath of these trials, an increasingly sophisticated HIV/AIDS advocacy apparatus, including civil society organisations now supported by research funders and multilateral organisations, responded to the difficulties revealed by these cases by generating guidance on the roles and responsibilities of those involved in HIV/AIDS trials. A popular example is AVAC (Global Advocacy for HIV Prevention) and UNAIDS GPP guidelines for biomedical HIV prevention trials.<sup>29</sup> The original GPP HIV document was developed as a companion to the UNAIDS and WHO guidelines document on ethical considerations in biomedical HIV prevention trials.<sup>30</sup> The document sets out the social complexities of HIV prevention trials, presents guiding principles, such as respect, mutual understanding, and scientific and ethical integrity, and outlines standards of practice in 16 areas, including formative research activities, stakeholder advisory mechanisms, site selection, and future access to new HIV prevention technologies.

Despite specific successes in implementation of community engagement practices in HIV/AIDS research, many challenges remain, including necessary capacity building to better integrate social and biomedical sciences,<sup>31</sup> and persistent pockets of resistance to the idea that community engagement should be viewed and funded as an integral element of clinical trials, which some see as compounding existing demands on research teams, and potentially diluting fixed pools of funding for trials. Overall, improved community engagement in research remains a high priority for HIV advocacy.<sup>26,32</sup>

### Emerging examples of community engagement in tuberculosis research

The recent rediscovery of tuberculosis by public and private research funders, and by private sector drug developers, has been a boon for tuberculosis advocacy.<sup>25</sup>

**Panel: Examples of community engagement initiatives in tuberculosis research****Trial-specific initiatives***Mexican Consortium against TB*

This high profile trial of DOTS in populations with high levels of drug-resistant tuberculosis in Orizaba, Mexico,<sup>33</sup> had a community engagement programme that focused on complementing the local public health system with community health workers to establish a presence in marginalised communities, thereby increasing the reach of the DOTS programme

*Thibela TB trial*

This cluster randomised trial studied the preventive effect of a tuberculosis treatment intervention in South African gold mines; community engagement was a high management priority and specific activities included the development of a strong project brand and discussions with opinion leaders (eg, trade unions) on how best to communicate information about the study<sup>16</sup>

**Research programme initiatives***Community Research Advisors Group to the TB Trials Consortium*

Autonomous advisory body founded in 2007 to ensure the meaningful representation and engagement of affected communities in the Tuberculosis Trials Consortium; advisory group members are based in enrolment areas and foster communication and understanding between local communities and trial staff<sup>14</sup>

*Community Engagement Program of the TB Alliance*

Began in early 2007 with the REMox TB phase 3 trial;<sup>35</sup> activities have now been extended to include all late-stage phase 2 and 3 tuberculosis trials of the TB Alliance; the programme provides technical assistance, guidance and training to community engagement coordinators and community advisory boards at participating sites, and small grants that site teams can use for community engagement activities

*Community Advisory Board of the South African TB Vaccine Initiative*

Holds awareness events, including World TB Day activities, public meetings, and cultural and artistic activities to promote tuberculosis education, and collaborates with the South African

TB Vaccine Initiative to communicate with the community through meetings, posters, pamphlets, newsletters, local weekly print media, community radio, and popular comics on tuberculosis and vaccines<sup>36</sup>

*Kenya Medical Research Institute*

Community advisory boards (or where these are not established, representatives from community-based organisations) provide advice through various forums; the programme offers workshops and training programmes designed to empower community representatives<sup>37</sup>

*Global Community Advisory Board of the AIDS Clinical Trials Group*

Instituted in 1990, its mission is to provide broad community input into the scientific research of the NIAID AIDS Clinical Trials Group by ensuring that its scientific priorities represent the needs of all people living with HIV/AIDS, including those affected by tuberculosis;<sup>38</sup> members are assigned to tuberculosis protocol teams early in development and assist with design, contribute research questions, and provide community perspective on trial feasibility

**Global initiatives***Community Task Force of the Stop TB Partnership*

Created to involve community perspectives in the Stop TB Partnership's working groups and coordinating board; the aim of the Community Task Force is to ensure that the priorities and interests of the community are considered and integrated into the priorities and initiatives of the Stop TB Partnership<sup>39</sup>

*Global TB Community Advisory Board*

Group of research activists from Africa, the Americas, Asia, Australia, and Europe who are involved in HIV and tuberculosis research networks; the board interacts with developers in late-stage clinical trials to ensure responsiveness to community interests (eg, it contributes to local research capacity) and needs of neglected populations<sup>40</sup>

DOTS=directly observed treatment, short-course. TB=tuberculosis. NIAID=National Institute of Allergy and Infectious Diseases.

One result has been a greater emphasis on the representation of the interests of patients with tuberculosis and affected communities in tuberculosis research, which has served to reinvigorate the commitment to community engagement.<sup>25</sup> The panel provides an overview of some community engagement activities in tuberculosis research. These examples have been chosen from the Stakeholder and Community Engagement (SCE) working group of the Critical Path to TB Drug Regimens (CPTR) survey of the tuberculosis research community, described below, or because they have achieved some public attention. The extent to which these examples are representative of tuberculosis research in a broader sense is unclear, but they draw attention to three important features of community engagement practices in tuberculosis research.

First, community engagement is taking place at different levels across a range of research. Although trial-specific activities might be more in line with traditional views of community engagement, the existence of robust approaches to engage stakeholders at broad programmatic levels, and even globally, shows the wide range of interests at stake in tuberculosis trials, and an emerging infrastructure to acknowledge and respond to these interests.

Second, this nascent infrastructure for engagement with a wide range of stakeholders seems particularly well integrated with advocacy efforts for tuberculosis research. High-level advocacy efforts make use of effective cooperation and communication channels across the range of community engagement practices to mobilise resources and foster the necessary political will and

collaborative attitudes to encourage stakeholders to take tuberculosis research and product development more seriously at the global level. This integration should help to ensure that advocacy and community engagement activities are complementary and mutually reinforcing.

Third, the trial-specific examples of community engagement presented in the panel show that much attention is given to the relation between the interventions being tested and the relevant public health systems. The adoption of community health outreach practices and fostering of close cooperative relations with key players within the public health system help to extend conventional thinking about community engagement beyond hand-picked advisory boards of local community representatives, to more complex interactions with a wide range of stakeholders. The quality of these relations and the improved mutual understanding that can arise from them will probably prove to be invaluable in the eventual transition from efficacy trials to implementation of new treatment and prevention modalities within public health systems. These factors were an important contributor to the SCE working group's decision in 2012 to pursue tuberculosis-specific community engagement guidelines.

### GPP guidelines for tuberculosis drug trials

The SCE working group of the CPTR initiative surveyed CPTR partners and a wide range of other organisations involved in tuberculosis research to gain an understanding of their community engagement activities in tuberculosis research worldwide. The findings of this survey made clear that researchers support community engagement in tuberculosis trials, but need additional guidance and resources to make community engagement a normal part of their research operations.<sup>41</sup>

In response to these findings, the SCE working group collaborated with AVAC to adapt the GPP guidelines for biomedical HIV prevention trials<sup>42</sup> so that they applied to tuberculosis drug trials. The result was the publication of the GPP guidelines for tuberculosis drug trials,<sup>43</sup> which emphasise unique features and circumstances of tuberculosis trials. Although the core features of community engagement are broadly relevant to global health research into any disease,<sup>33</sup> speaking directly to a disease-specific research community also has strategic value. The GPP guidelines for tuberculosis drug trials aim to establish common principles, practices, and language for trial implementers, their sponsors, and relevant stakeholders, in part to make these practices commonplace in tuberculosis trials.<sup>43</sup> They retain the core architecture of the GPP HIV guidelines and offer a detailed summary of the extensive experience of community engagement in HIV prevention trials that is currently missing in tuberculosis trials. The guidelines also respond to specific features of tuberculosis trials. For example, the tuberculosis epidemic is fuelled by economic instability, poverty, migration, discrimination, stigma, social marginalisation, inadequate access to health and

social services, and lack of political voice. Understanding how these factors operate at individual trial sites is essential to ensure that they are not inadvertently exacerbated by the trial, and that they do not threaten the successful completion of the trial. Additionally, the lack of effective biomarkers for tuberculosis means that trial participants have to endure frequent and unpleasant trial procedures, such as sputum induction and blood draws. Effective community engagement practices can help researchers understand the significance of these events for participants and develop appropriate management strategies. The SCE working group is focused on supporting the effective dissemination and implementation of the GPP tuberculosis guidelines, including the planning and delivery of webinars and workshops to familiarise interested parties with the ideas and practices in the guidelines and to provide guidance for implementation in specific trials.

### Next steps and challenges ahead

Although the community engagement initiatives discussed show an evolving appreciation of the role of community engagement in tuberculosis research, a clear account and shared understanding of how these community engagement mechanisms work is still missing—ie, what outcomes they bring about, and how. The result is that we have no established or widely accepted ways to assess what makes community engagement effective in any given research setting. The adoption of the GPP guidelines for tuberculosis drug trials as a common template for community engagement might help to address this issue immediately, and improvements in the publication of examples of community engagement should also help with assessment of the effectiveness of community engagement.<sup>4</sup> The TB Alliance is developing a monitoring and assessment toolkit for community engagement in several disease contexts in collaboration with the Wellcome Trust, AVAC, and the NIAID. More robust indicators of the quality and effectiveness of community engagement would provide a crucial feedback loop for the new GPP guidelines for tuberculosis drug trials, and thus contribute to the improvement of the evidence base for community engagement.

The key challenge is to overcome scepticism about the value of community engagement in research and about whether community engagement should rightfully receive a proportion of tuberculosis trial budgets. Important efforts have been made to expand the relationship between researchers and advocates to promote the development of new tuberculosis vaccines,<sup>43</sup> but the case for an increase in community engagement in tuberculosis research in a broader sense has not been made convincingly enough. Identification of shared approaches and improvements in the assessment of community engagement should help. However, funders and sponsors need to better recognise that the ultimate public health effects of new drugs and

vaccines will be determined by social as well as biological factors. The importance of these social factors should be more clearly acknowledged by funding the necessary research about community engagement and by improving the incorporation of community engagement into trial planning and design.<sup>14,32</sup>

Greater attention should be given to the development of a credible evidence base to ensure that community engagement has a fair opportunity to show its potential value, and that resources are allocated accordingly. As the first meaningful pipeline of new tuberculosis drugs, drug regimens, and vaccines begins to deliver products ready to be tested in late-phase clinical trials, a unique opportunity to establish community engagement as an integral aspect of good practice in tuberculosis trials will arise.

#### Contributors

RFB and JVL reviewed the scientific literature and conceived and drafted the manuscript. All authors contributed to the writing and editing of the manuscript, including specific input as follows: SS, EL, and LRM collected and compiled information about existing tuberculosis research efforts; LP-M provided context on tuberculosis pertaining to community engagement; SDW added clarifying information on AIDS Clinical Trial Group's community engagement efforts; CS provided information about the Stop TB Partnership; AYC assisted in reviewing the scientific literature and references. RFB, AYC, and JVL coordinated the revision of the final article, with input and approval from all authors.

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#### Conflicts of interest

RFB works as an independent consultant for the Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens. LP-M is employed by the Bill & Melinda Gates Foundation, which has provided funds for some of the tuberculosis research and community engagement activities described in the manuscript. All other authors declare that they have no conflicts of interest.

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