Community Engagement and Tuberculosis Drug Research:
A 2011 Mapping Exercise of the Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regiments Initiative
This is a public version of a report commissioned by the Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens initiative. Some appendices have been removed to preserve the confidentiality of respondents.

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Our sincere thanks go to the participants who took the time to answer our questions; their commitment to ensuring that communities benefit from tuberculosis research is an inspiration.
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Executive Summary

The Critical Path to TB Drug Regimens (CPTR) initiative was created to accelerate the development of new TB drug regimens. In recent years, and particularly in light of the experience of HIV/AIDS researchers, effective community engagement (CE) has become increasingly recognized as an important component of the successful conduct of biomedical research. Community engagement can be defined as any form of consultation, collaboration and partnership put in place to enable a dialogue between community representatives and researchers to ensure that research projects are understood, acceptable and meaningful to participants. To date, very few resources to guide CE activities in the context of TB research have been developed. In response to this gap, the CPTR initiative has created a Stakeholder and Community Engagement workgroup mandated to provide appropriate guidance on CE to CPTR partners. This report summarizes one of the foundational activities undertaken by the Workgroup.

During the 2011 summer, a mapping exercise was conducted to identify the resources and activities related to CE that might already be in use by the TB research community. Specific goals of the mapping exercise also included the identification of useful examples of CE programs in TB research and an exploration of the role that the Workgroup could play in meeting the needs of TB researchers interested in conducting effective CE. Stakeholders from various organizations and research groups (including pharmaceutical companies, academic research centers, trial sites, funders, product development partnerships, and advocacy organizations) were contacted to discuss their experience with CE.

The report describes some of the findings of this mapping exercise. These observations include the fact that there is no apparent common understanding of what constitutes ‘community engagement’, that CE programs are often run by single staff members, that strategies to evaluate CE programs in TB research are urgently needed, and that concerns over the sustainability of CE programs are shared by many stakeholders. As part of the mapping exercise, informants were also asked to describe the kind of resources they thought would help facilitate and strengthen CE in TB research. The informants’ ‘wish-list’, which ranged from means of transportation to mentorship opportunities and additional human resources, is presented in the section entitled ‘Resources Requested by Informants’. This wish-list forms the basis of the following section, which proposes a number of projects the Stakeholder and Community Engagement workgroup should consider tackling to help meet the needs identified by respondents. Among these projects, the creation of a network to favor more concerted action and the development of minimum standards for CE stand out as high priorities.

Overall, greater advocacy for CE in TB research will need to ensure that all relevant parties, including pediatric patients, benefit from greater emphasis on developing lasting partnerships between researchers and endemic communities. This mapping exercise demonstrates that the Stakeholder and Community Engagement workgroup of the CPTR initiative could play a key role in ensuring that effective community engagement becomes a core component of TB research.
**Introduction**

The call for action from the 2008 Bamako Global Ministerial Forum on Research for Health included an explicit recommendation that all relevant constituencies in research be properly involved.\(^1\) Since then, the importance of engaging communities in biomedical research has continued to be increasingly well recognized, particularly in the field of HIV/AIDS. For a number of years, HIV/AIDS research teams have benefited from a number of guidance documents detailing how to engage communities. A well-known example of these is the *Good participatory practice guidelines for biomedical HIV prevention trials* that were developed following the early termination of the pre-exposure prophylaxis (PrEP) trials in Cambodia and Cameroon.\(^2\)

With the current revitalization of TB research,\(^3\) of which the creation of the Critical Path to TB Drug Regimens (CPTR) initiative ([www.cptrinitiative.org](http://www.cptrinitiative.org)) is an important example, the need for guidance on how to conduct effective community engagement (CE)\(^4\) in TB research is rapidly increasing. TB investigators however do not currently have access to the kind of resources available to their counterparts in HIV/AIDS research.\(^5\)

Against this background, the CPTR initiative has demonstrated its commitment to CE through the creation of a Stakeholder and Community Engagement workgroup mandated to provide guidance on effective CE practices in TB drug regimen trials. As an important first step, the Workgroup conducted a mapping exercise to identify resources and activities that are already in use by the TB research community. More specifically, the mapping exercise, which was conducted between May and August 2011, was guided by the following goals:

- To compile a list of existing activities, resources, and contacts that may be relevant for CE as part of the CPTR initiative
- To identify existing guidance for CE associated with TB trials
- To identify potential case studies of CE in TB research
- To identify areas where the Stakeholder and Community Engagement workgroup could make contributions to strengthen CE in TB trials

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2. The *Guidelines*, which have been recently revised, are available at: [http://www.avac.org/ht/d/sp/i/309/pid/309](http://www.avac.org/ht/d/sp/i/309/pid/309)
3. The increase in funding over the years allocated to TB research has been document by the Treatment Action Group. See their annual “Report on Tuberculosis Research Funding trends” (The report for the 2010 financial year is available at: [http://www.treatmentactiongroup.org/publication.aspx?id=4450](http://www.treatmentactiongroup.org/publication.aspx?id=4450))
4. Defined by the Stakeholder and Community Engagement workgroup of the Critical Path to TB Drug Regimens as “any form of consultation, collaboration and partnership put in place to enable a dialogue between community representatives and researchers to ensure that research projects are understood, acceptable and meaningful to participants.”
In order to meet these objectives, a brief questionnaire was developed and administered to relevant stakeholder organizations. The exercise was conducted with key informants identified as representatives of one or more groups with expertise in the field of TB research. An initial round of personalized emails was sent on May 23, 2011 to a preliminary list of stakeholders identified by members of the Workgroup prior to the formal launch of the mapping exercise. While our sample emphasized CPTR members, we also recognized that other organizations that conduct TB research might have relevant experience with CE that could be valuable for CPTR. These included organizations involved in TB vaccine trials, operations research and diagnostics research. Time and resource constraints did not permit us to study relevant examples of CE in other areas of research, such as malaria and HIV/AIDS.

Following initial contact, follow-up emails were sent to each potential informant, either until a response was received or until the Workgroup deemed them to be a non-respondent on a case-by-case basis. Throughout the duration of the mapping exercise, additional informants were identified. In total, 50 organizations and research groups were contacted via email. These included pharmaceutical companies, academic research centers, trial sites (particularly of the REMoxTB trial), funders, product development partnerships, and advocacy organizations. Thirty-three (66%) groups provided information: 18 through phone interviews, 7 by completing the questionnaire directly and 9 (generally those without experience with CE) through email communication. Sixteen (32%) organizations did not respond to our inquiries. Half of these were pharmaceutical companies, while the other half was comprised of NGOs, research sites and international organizations.

The interviews were semi-structured, with questions based on a questionnaire originally developed by the Workgroup, but tailored to each informant’s background and activities using publicly available information (e.g., organizations’ websites, presentations available online). Interviews lasted 30 minutes, on average. They were not transcribed, although a number of relevant quotes are reported verbatim below. These are identified by double quotation marks, while single quotation marks are used to indicate paraphrasing. Data analysis involved the review of interview and written content to identify salient concepts and common themes. Informal exchanges with informants who reported no experience with CE and who did not complete the interview or a questionnaire were also included in data analysis when appropriate. The interviews and data analysis were conducted by a single researcher (RB). The results presented below are not intended to be representative of the field of TB research as a whole, but rather to reflect the perspectives of CPTR partners and an informal selection of other organizations known to the Workgroup to have relevant experience. A conscious

6 The total number of people contacted is larger than this because: 1) we were sometimes asked to contact other people within an organization, 2) we sometimes tried to approach other individuals from within an organization when initial contact was unsuccessful. On the other hand, some individuals were able to speak on behalf of more than one organization.
decision was made not to exclude relevant perspectives, ideas or suggestions that arose during the interviews, even if they were mentioned by only one informant.

**Results**

**Observations on Community Engagement in Tuberculosis Research**

This section highlights some of the key insights about the status of CE in TB research reported by respondents. Many of these observations refer to barriers to effective community engagement during TB research. As one informant summarized, there are currently many barriers to engaging TB-endemic communities: “Community engagement is expensive, time and energy consuming, other players in the research field do not see it as an important part in research; the problem is that there is no direct way of measuring or evaluating the impact of all these efforts.”

1. There is no common understanding of what constitutes 'community engagement'

Respondents were informed during initial contact that the Stakeholder and Community Engagement workgroup’s working definition of ‘community engagement’ is “any form of consultation, collaboration and partnership put in place to enable a dialogue between community representatives and researchers to ensure that research projects are understood, acceptable and meaningful to participants.” The findings from the interviews however made it clear that respondents interpreted this definition broadly. Respondents from all types of organizations used a wide range of terms interchangeably with community engagement to describe their activities, including: ‘community involvement’, ‘health literacy’, ‘research literacy’, ‘communication’, and ‘advocacy’.

This broad understanding of community engagement was also apparent in the kinds of activity that respondents reported under the concept of ‘community engagement’. These included:

i. Distributing research-related material to clinics and health professionals;
ii. Making public announcements on the radio;
iii. Presenting skits and shows in communities;
iv. Getting input on drafts of informed consent forms;
v. Actively supporting the creation of Community Advisory Boards (CAB); and
vi. Organizing community-wide question and answer (Q&A) sessions to address concerns of community members.

Overall, the notion of ‘dialogue’ emphasized in the Workgroup’s definition of CE was not clearly reflected in many of the activities described. For a small number of respondents, CE instead appears to be reduced to a unidirectional provision of information to communities. For many others, increasing TB and research literacy is seen as a main priority of CE programs. Some informants implicitly justified this by
suggesting that ‘dialogue’ with participating communities could not be attainable until the health and research literacy of community members was drastically improved: “The main reason we had to form these groups was mainly because clinical trials were still not known (...) [T]he concept of a placebo was difficult for most to comprehend and so we wanted to have groups that could help us educate the community and the participants on this as well as educating them on what IPT [isoniazid preventive therapy] really was. Thereafter, the use of these groups was broadened to include advice on any study issue that was perceived to be a challenge.” The belief that ‘speaking the language of researchers’ is essential for dialogue about medical research appeared to be common among respondents.

Informants conceived of CE in differing, sometimes conflicting ways. Distinctions along two criteria were evident in the responses gathered:

A) The value of community engagement: Intrinsic or instrumental?

Some of the respondents appear to view CE primarily as instrumental to another goal, conceiving it for example, as a clinical trial manager did, “in terms of actively recruiting participants and advertising the study.” For others, it is clear that CE has a more intrinsic value: CE “is not about saying hello to a bunch of people and getting them to sign forms” but instead, about empowering them to make demands about issues that concern their health and wellbeing. This distinction between the intrinsic and instrumental value of CE has important implications for program planning, with informants committed to the intrinsic value more likely to mention post-study plans for their CE programs (speaking, for example, of reaching “higher levels” of engagement over time and ‘transforming the CAB into an advocacy body’).

B) Conceptualizing community engagement: An approach or a set of activities?

Broadly speaking, our respondents were a mix of those working directly at research sites and those working at a more global level, such as advocates and principal investigators who oversee a study from afar. Those working at local research sites had titles such as community engagement coordinators or community engagement officers and were in charge of overseeing the day-to-day aspects of a research project’s CE program. At the more global level, respondents talked about their role in promoting CE across institutions and study sites.

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7 To ease reading, the term ‘community engagement coordinators’ is used throughout the report to designate those individuals directly in charge of a community engagement program at a trial site. Other official titles given to these individuals include ‘community liaison officer’, ‘community engagement officer’, ‘community engagement scientist’, ‘recruitment, retention and CAB coordinator’, etc.
These two groups tended to conceptualize community engagement differently. The CE coordinators tended to refer to CE as a specific set of activities and responsibilities. On the other hand, promoters of CE at the global level tended to conceptualize it more abstractedly as an approach to doing research.

The apparent lack of a shared understanding of what constitutes CE was reflected in discussions about Community Advisory Boards. While there was a general tendency to associate CE with the use of CABs (all study sites interviewed reported using them), CE coordinators reported a remarkable range of CAB structures (including membership criteria), roles and responsibilities. There was little indication that these variations were a result of active reflection about what ‘type’ of CAB would be best suited to a specific community or trial circumstances prior to implementation.

Some of the activities and roles of CABs described by CE coordinators included:

i. Helping the research team set up educational meetings in target communities;
ii. Actively participating in sharing information about the study to community members;
iii. Providing feedback on the design of the study and helping develop accompanying material (e.g., informed consent forms and information sheets) that is culturally and contextually relevant;
iv. Being informed about the progress of the study by the research team;
v. Receiving training in TB research advocacy so they can take an active role in mobilizing the community; or
vi. A combination of some of the above.

Membership structures similarly varied considerably:

i. At one study site, the CAB was composed of well-educated or influential individuals, such as a representative from the government, people from a local university, and a businessperson. Meanwhile, the site had a distinct group called a Patient Advisory Group (PAG) only composed of patients. The two groups had not been meeting together until recently.
ii. At another site, each CAB member was chosen by the CE coordinator to represent a specific subpopulation: youth, women, people with HIV, TB patients, religious affiliations, local leaders, etc.
iii. Another site brought together people from each of twelve different geographical communities participating in a trial on the same Community Advisory Board.

While no concerns over the diversity of types of CAB were raised, a TB research advocate did raise a concern about CABs’ overall financial dependence on research teams. The advocate worried about potential conflicts of interest and proposed that more permanent structures could be put in place to level the power relations between research teams and community representatives.
While not an explicitly probed topic, it became evident that it was generally unclear who should be engaged by researchers as part of CE activities. In other words, the definition of the 'community' seemed to differ between respondents. While some have limited themselves to trying to identify relevant groups that should sit on a CAB so that it is 'representative' of the study population, others have questioned if having a 'representative' sample is the best way to represent the interests of a community. For them, recruiting local health authorities and other officials might seem more conducive to a dialogue. A representative of the non-profit product development partnership Aeras thought that the organization "need[s] to do more in terms of involving communities that are not directly taking part in trials." The relevant ‘community’ to be engaged as described in this case would include the geographical regions where the disease is endemic but where research is not ongoing. While Aeras’ focus on vaccines sets it apart from the other informants interviewed as part of this mapping exercise, it nonetheless hints at the lack of agreement on how to define the community to be engaged by researchers.

Finally, interviews revealed that misunderstanding of what CE entails might confuse research teams about the resources they might need to launch a CE program. For example, an investigator explained: “I do not involve community groups in my clinical trials. Indeed, it would be difficult to do so in clinical trials as all those involved have to be GCP [Good Clinical Practice] certified.”

2. Community engagement programs are often run by a single staff member

Many informants reported that CE is still seen by and large as an addendum to TB research, rather than as a necessary, integral component of the endeavor. As such, CE programs often rest on the shoulders of one committed individual, who is charged with overseeing all related activities. This person is expected to act as the “bridge” between the research team and the participating communities. Such individuals generally became responsible for CE either because they were able to convince the rest of their research team that involving communities would be important or, more frequently, because they were hired for this job specifically. Typically, these CE coordinators have a wide range of responsibilities. For example, one CE coordinator reported being responsible for recruitment strategies, preparing material for study marketing, coordinating the CABs, and educating participants.

Interviewees often reported that it was an uphill battle to get the support of the rest of the research team and that they continually needed to convince their peers of the importance of CE activities. There is a worry, best described in an academic paper written by an informant, that any additional requirement on the part of researchers might lead TB trials to be “so expensive that applications for funding (…) are (...) rejected as
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‘not competitive’. In spite of this, there was a general sense among respondents that scientists increasingly understand the importance of engaging communities. As an informant commented, “at first, investigators only saw this as a way to recruit participants, but now this mentality is changing.” In spite of this gradual change, CE activities continue to be delegated to a sole member of the research team.

3. Research funders rarely expect or require CE

Community engagement, as reflected in the Workgroup’s definition, is rarely expected by sponsors of TB research. The British Medical Research Council, for example, explains that “(i)n general terms, we encourage the development of community engagement in all of our trials, although we do not require formal Community Advisory Boards in all of them.” Similarly, there is currently no explicit requirement that research teams that would want to join the Pan-African Consortium for Evaluation of Anti-tuberculosis Antibiotics (PanACEA) would have to implement a CE component at their site. The European and Developing Countries Clinical Trials Partnership (EDCTP) appears to be an exception among TB research funders: “all the TB [studies] we fund are supposed to have community engagement strategies under their communication plans and this is one of the obligatory sections of each and every work plan of the funded projects.” The EDCTP has no specific standards that investigators must meet however. In general, funders of TB research who participated in this mapping exercise did not report being asked about CE guidelines or frameworks by funded teams or applicants.

The creation, in 2007, of a Small Grants Program by the Global Alliance for TB Drugs (TB Alliance) to support CE at REMoxTB trial study sites is an important step towards establishing CE as a standard feature of TB trials. This program has allowed several research teams to launch CE programs and some activities have been reported online. Other funders of TB research interviewed as part of this mapping exercise however did not mention plans to launch programs similar to the one led by the TB Alliance. An informant confirmed that the way TB studies are funded might in part explain this situation: because studies are often co-funded, there are few incentives for a funding agency to introduce new categories of eligible expenses, or to allocate

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9 Of the ten top sponsors of TB research identified by the Treatment Action Group in their “2010 Report on Tuberculosis Research Funding Trends” (Available at: http://www.treatmentactiongroup.org/uploadedFiles/About/Publications/TAG_Publications/HIV-TB_Publications/TBRDV2HI.pdf), only three were contacted as part of this mapping exercise. A number of more minor funders were also contacted.
10 The TB Alliance was established in 2000 as a not-for-profit product development partnership (PDP) to lead the search for new TB drugs and cures.
11 See, for example: http://www.tballiance.org/newscenter/view-brief.php?id=978
resources to CE if one of the co-sponsors already has a dedicated funding program for CE.

The lack of funders’ demand for CE means that related activities are often not included in the core budgets of research projects. Funding for CE activities is, instead, mustered in some cases by reallocating resources from other research-related activities, such as communications and discretionary funding. Alternatively, some groups have been able to secure additional funding from other sources, such as sponsorship from local businesses or from international agencies. These funds tend to be either activity-specific (e.g., to create a comic strip) or time-limited (e.g., a one-year grant).

4. Community engagement programs are ad hoc and impromptu

This mapping exercise confirmed that there is no widely accessible guidance on how to conduct CE in TB research. As a result, respondents working at trial sites emphasized that they had access to very few resources at the time of developing their CE strategies and planning their related activities. A recurrent theme in the interviews was the lack of a mechanism to facilitate dialogue between research teams interested in CE and those who already have some experience and could act in a mentorship capacity.

Given the reported lack of funding, replicable models, experienced personnel, expectations from funders, or adequate time to plan, most CE programs are developed in a manner that is ad hoc (for the specific circumstances of the trial) and impromptu (without extensive prior preparation). This extemporaneous character of CE efforts is reflected in several research sites’ lack of long-term vision for CE programs. The ad hoc nature of CE programs was apparent when comparing the activities conducted across the various sites of a trial. In the case of the REMoxTB trial for example, significant differences were apparent in the way communities were engaged at each site and CE coordinators seemed to have had few opportunities to exchange views and experiences about their work. Even within a single study site, CE activities are not necessarily consistent across the geographical communities involved. For example, as part of the REMoxTB trial, TASK Applied Science works with approximately twenty-five different communities. However, the CE program mainly focuses on one large, somewhat isolated and ethnically diverse community. In that community, a CAB was formed and has been active since November 2010. In 10 or 12 of the other communities, modest CE activities are ongoing, while no formal activities were reported for the other half of the enrolled communities.

5. Demand for guidance vs. doubts about replicability

While some respondents decried the lack of guidance on how to conduct CE, doubts were also expressed by many about the value of sharing case studies and lessons learned due to the perceived ‘uniqueness’ of each research project. Because the types of research (e.g., vaccine, pediatric, MDR-TB) and the locations of studies differ, there
is a widespread belief that CE activities and programs are explicitly trial- and context-specific. In other words, informants were not convinced that lessons learned from previous projects could be applied to new projects.

6. Rigorous evaluations of TB community engagement programs are lacking

The lack of agreement on what constitutes high quality CE programs, and strategies to evaluate and monitor them, was raised frequently by stakeholders. While all stakeholders interviewed believed that CE in TB research was important, a number of them felt that empirical data demonstrating its value were greatly needed. A CE coordinator for example insisted that having tools to evaluate CE programs would make it easier to convince fellow research team members of the value of these programs. The fact that few appraisals of CE in the context of TB research have been published was widely believed to limit the credibility of statements about the importance of involving communities.

7. Networking across research sites is infrequent

Community engagement in the context of TB research has only recently started to attract attention; it is difficult to find any group aside from Robert Horsburgh’s (from the Boston University School of Public Health) that was actively pursuing it more than six years ago.12 As a result, and as observed by several of our interviewees, the community of people actively conducting or managing CE activities in TB research remains extraordinarily small. In fact, some informants suggested that ‘everyone knows each other’ in the field. But this statement is somewhat misleading: there is a wide disparity in the networking opportunities available for people working primarily at trial sites compared to those working at a more global level. While it may be true that TB research advocates frequently work in collaboration (or are at least aware of each other’s work), people working at trial sites tend to be much more isolated from one another. Established forums for networking and exchanging views about various challenges arising in TB trials, such as international and regional conferences, training programs, and listserves, are less known or attended by site level CE coordinators than global stakeholders. In their response to our survey, many CE coordinators requested improved access to information about this type of networking opportunity.

Most CE coordinators mentioned not knowing any other project that might serve as a useful example of good practice for CE. Only one informant mentioned having been in

touch with another person managing a CE program – and that person was working on HIV/AIDS rather than on TB. As a group, the CE coordinators we interviewed appeared more likely to know of the work of global stakeholders than of other CE coordinators (several of them were familiar, for example, with the work of the Treatment Action Group). Overall, respondents working at trial sites were less likely to have access to resources about CE than the more mobile group of individuals who take part in the conversation about CE in TB at a more global level – such as some activists and principal investigators.

8. Mobilization among communities affected by tuberculosis is rare

According to respondents, and in contrast to what can be observed in the case of HIV/AIDS, there are few communities that have self-mobilized around TB. For example, practically no community-based organizations or groups of people advocating for better treatments or for research were known to our informants. When there is some mobilization around TB at the local level, it often seems to originate from the HIV/AIDS sector. One of the few instances of such mobilization at the local level can be found in Zambia, where CITAM+, a community-based organization with a network of TB/HIV support groups, is very active. Unfortunately, representatives from the organization reported that Zambia has not been a prime destination for TB research, and, as a result, there have been no opportunities for CITAM+ to collaborate with TB researchers locally to date. When asked why mobilization might be less frequent in TB than in HIV/AIDS, respondents generally felt that it might be because TB is (usually) curable, while HIV/AIDS is not.

9. Sustainability is a shared concern

Concerns over the sustainability of CE programs were shared by respondents. For example, a representative of the International Union Against Tuberculosis and Lung Disease felt that “donor support for community engagement activities will be necessary for The Union to continue its work”. At the PanACEA consortium, where plans currently

13 Community mobilization can be defined as the “capacity building process through which local individuals, groups or organizations identify needs, plan, carry out and evaluate activities on a participatory and sustained basis, […] to improve health and other needs, either on their own initiative or stimulated by others.” See: http://www.aidsconsortium.org.uk/OVCWorkingGroup/OVC%20PDFs%20&%20other%20docs/OVCTechConsult 06/Josh%20Levene.ppt An example of a community mobilizing around TB would be if a community-based organization was advocating for new treatments or better care for members of the community.

14 One respondent suggested that advocacy for TB research, which was reported to be rare at the local level, might be even rarer in communities highly affected by multidrug-resistant TB (MDR-TB) because they often are particularly marginalized.

15 One respondent challenged this interpretation, raising the issue of XDR-TB. Additional data will be needed to confirm how the issue of mandatory isolation and length of illness can affect the mobilization of XDR-TB patients and their communities.
exist to scale up the discussions around CE, there is concern that the consortium could be dismantled in 2014 if the EDCTP does not re-fund it. Such uncertainty seemed to threaten efforts to build momentum for CE.

Some informants also wondered if they would be able to continue to engage communities after a trial ended. For example, one respondent explained that once the REMoTB study ends, “it will be also the end of TB Alliance funding for CE activities, and so far we do not have another sponsor to support the activities conducted now (...), especially radio sessions and community educational meeting on TB basics and research.”

RESOURCES BEING USED BY INFORMANTS
Appendix 1 describes the resources that informants reported as being relevant and helpful for their CE work.

RESOURCES REQUESTED BY INFORMANTS
Informants were asked to describe the kind of resources they thought would help facilitate and strengthen CE in TB research, either within their own work or at a more global level. The desired resources vary significantly, ranging from means of transportation to mentorship opportunities and additional human resources. The informants’ ‘wish-list’ is presented below without consideration either to feasibility or to the relevance of the request to the mandate of the Stakeholder and Community Engagement workgroup:

i. Introductory-level resources for researchers
   • TB researchers are perceived to be, in the words of an informant, “so far behind in terms of community engagement” that introductory-level resources should be developed specifically for them. Primers should cover topics such as ‘What is community engagement’, ‘What are Community Advisory Boards’, etc.

ii. Repository of resources developed and/or used by other TB research teams
   • Being able to examine CE resources developed at other sites might help use available human resources more efficiently by limiting the resources that must be spent to redevelop already-existing strategies and materials.
   • Informants did not think that a standalone database would likely be useful; a better alternative might be to add these resources to existing repositories (e.g.: www.findtbresources.org) and publicize these better.

iii. Evaluation and monitoring strategies for community engagement programs
   • Strategies for monitoring and evaluating CE programs were one of the most frequently mentioned needs. Champions advocating for CE felt that it was often difficult to convince the rest of their research team of the importance of investing time and resources due to the lack of rigorous
strategies to monitor and evaluate programs and activities. The TB Alliance has been reported to be working on the development of such tools.

iv. **Health literacy materials for tuberculosis**

- The variety of health literacy materials that exists for TB was reported by respondents as paling in comparison to what is available for HIV/AIDS. As an advocate from CITAM+ noted, efforts have been made to render the pathology of HIV/AIDS easy to describe and teach in many languages, but the core concepts of TB natural history have not been similarly simplified. For example, while role play and theatre have been widely used to promote understanding of HIV/AIDS, TB is still largely too ‘complicated’ or technical for it to be ‘accessible’ to laypersons.

- The problem with health literacy materials is not only about their range and quality but also their accessibility. High-quality, visually attractive material can be expensive to produce and CE programs can quickly run out of copies. Hence, some informants also requested help with the printing of T-shirts, brochures, leaflets, banners, posters, etc. Interestingly, no informant specifically mentioned the CDC order form for TB resources ([http://wwwn.cdc.gov/pubs/tb.aspx](http://wwwn.cdc.gov/pubs/tb.aspx))

v. **Tuberculosis research literacy materials**

- Aside from health literacy, informants also thought that more materials to promote TB research literacy would be needed. Such materials, however, are not only needed to educate communities or CAB members. They are also needed by local activists and advocates who might be less familiar with the principles of research generally, or TB research specifically. An informant suggested that the core materials developed to promote TB research literacy could be very similar for all types of research, but that specific modules should be developed for specific types (e.g., vaccine research).

vi. **Resources for members of Community Advisory Boards**

- The lack of resources made available to CAB members was a concern for a few respondents. It was suggested that more resources are needed to help CAB members get training to represent their community more effectively. Stipends, it was suggested, would also help ensure that membership is not limited to the few community members who can afford to volunteer.

vii. **Mapping of potential partners (networking brokerage)**

- The idea here would be to complement currently ongoing efforts to map and evaluate potential future sites for TB research by adding a CE

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16 The Clinical Trials Infrastructure workgroup of the CPTR initiative is currently working on a similar project.
component to the evaluation. The ultimate goal would be the creation of a comprehensive database of individuals and groups interested in CE at these various sites. Such database would help researchers have a better idea of which organizations, individuals, etc. they might approach locally when considering a new site.

viii. **Network/Mentorship program**
- Several informants showed interest in the creation of a network of people with experience with, or interest in CE in the context of TB research. This network could provide an opportunity for newcomers to tap into the expertise of people with more experience. The goal of the network would be to share experiences, best practices, and mentorship opportunities between members.

ix. **‘Who’s Who in TB research’ database**
- This idea was mentioned by one interviewee who was interested in getting a better grasp of ‘who’s who’ in TB research. To maximize usefulness, the database could be divided by sector (e.g., advocacy, industry, academic), area of research or area of interest (e.g., MDR-TB, pediatric TB) and type of research (e.g., vaccines).

tax. **Training and conferences for coordinators of community engagement programs**
- Building a CE program for a TB trial from scratch requires a diverse set of skills and experiences. Several informants expressed a desire for training opportunities to help them with these challenges. Indeed, several interviewees mentioned training as an overall priority area, even though they were generally not explicit about what training should focus on specifically (aside from lessons learned from other sites and methods to appraise CE programs).

xii. **Global advocacy for community engagement**
- It was suggested by a senior researcher that global advocacy towards making CE a requirement of every research project right at the outset is critically needed. The researcher thought that ‘add-on’ CE programs (i.e., those that are not integrated with the core research project from the get go) cannot be as effective as those that are integrated with the core research project, in part because delays will be inevitable and because
principal investigators (PIs) “won’t get it”. Another informant suggested that the creation of permanent, regional organizations modeled on the European Community Advisory Boards (ECAB) would help increase global advocacy for CE in TB research.

xiii. **Information about upcoming CE events and learning opportunities**
- Several informants mentioned they would like to be informed of new opportunities to learn about how to conduct CE, such as conferences and training.

xiv. **Funding**
- Additional funding for CE was the informants’ most frequent request.

xv. **Ways to tap into the knowledge and experience of people who have been involved in the HIV/AIDS sector**
- Many interviewees recognized that tremendous work has been done on CE by dedicated HIV/AIDS advocates, activists and researchers and asked for better ways to tap into the insights of these experienced individuals to improve CE in TB research. According to one of the informants, individuals who combine knowledge of TB with direct experience of the ‘HIV/AIDS revolution’ are the greatest asset currently.17

xvi. **Case studies documenting experiences with community engagement**
- Detailed descriptions of CE programs and their impact could help stakeholders learn from the experience of others and provide ideas on how to conduct CE most effectively. Informants were adamant that case studies should not solely focus on positive experiences and outcomes, but on mistakes too.

xvii. **Innovative channels to disseminate information**
- Stakeholders who do not work at trial sites, such as those in communication departments of international organizations or pharmaceutical companies, reported being uncertain about how to reach some communities from their headquarters. An informant described how their usual practices, such as issuing press releases, are not useful for disseminating information to certain communities. At the moment, it appears that there are few information channels to disseminate news about TB to endemic communities. Innovative ways to disseminate relevant information on a large scale to potential participants or patients are therefore needed. One method that was reported to have increased

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17 This view was not necessarily shared by all informants. One interviewee emphasized that it is important to keep in mind that “you can’t transpose the 1980s activist model everywhere”: there is a lot that can be learned from the experience of HIV/AIDS advocates, but tuberculosis is a distinct disease with distinct issues.
participant enrollment in TB trials is the use of radio programs during which community members are invited to call in to ask questions.

xviii. Additional human resources
• Almost every informant mentioned that limited human resources were preventing the expansion of their existing CE program or the launch of new initiatives.

xix. Ways to support communities to tell their stories
• Informants argued that people affected by a disease are its most convincing advocates, and suggested that endemic communities should be empowered to tell their stories and become advocates for TB research. Many communities, it was emphasized, understand the burden of TB and are interested in making sure that solutions are found.

xx. Transportation
• An informant mentioned how reaching people, especially in rural communities, can be difficult. Hence, one type of support they saw as necessary for nurturing CE was the provision of adequate means of transportation. Having a car, for example, could help facilitate active case finding, while making it much easier to organize meetings closer to where patients live.

xxi. Social science investigations
• Several informants mentioned the need for more social science research to be conducted alongside biomedical research on TB. Areas to be explored by social science investigations are numerous and diverse. For example, a representative from a pharmaceutical company explained that they would like social scientists to speak with local healthcare professionals in countries such as India and Peru, where MDR-TB rates are high, to learn more about what is happening on the ground. MDR-TB was an area of interest to more than one informant and it was suggested that better understanding of the specific requirements for CE in MDR-TB research settings, compared with drug-sensitive research settings, could be achieved by using social science research.
• Another informant thought that fieldwork about socio-cultural issues, beliefs and perceptions of the current BCG vaccine is needed to help facilitate communication and mobilization efforts. Similarly, a senior researcher suggested that the CPTR initiative should deploy efforts to find out from communities what they really need with respect to TB, what they
think are the limitations of current regimens, etc. The same respondent explained that there is a tendency for researchers to think that they already know what patients want and/or need. It was suggested that working in collaboration with social scientists, such as anthropologists, could prove useful to address this gap. Overall, respondents felt that social scientists could help researchers better understand the communities with which they work, thereby potentially facilitating CE.

The Way forward

This section proposes a number of projects that the Stakeholder and Community Engagement workgroup might consider pursuing to meet some of the needs that were identified by respondents. These options vary in their ability to meet the needs of both local and global stakeholders interested in CE in TB research and will require different amounts of resources to put in place and sustain. The projects are presented in an order that tries to balance the expressed interest of informants and the complexity of putting these projects in action.

1. Create an online network

Description

The Workgroup could create an online platform for individuals interested in CE to meet and to distribute resources. An online network would offer mentorship opportunities, while not being too taxing for participants. Participants should be able to ask questions to the group and be able to interact with other members. At the same time the platform should not be bandwidth-intensive, so as to ensure that individuals with limited access to the internet might participate fully. A good platform might be one such as LinkedIn.com, as a high number of the people interviewed are already members of the online professional network (see http://learn.linkedin.com/groups/ for a description of ‘Groups’ on LinkedIn). The GlobalHealthTrials.org platform might also be an interesting one to explore (there is already a CE thread). An alternative approach would be the creation of a mailing list. However, mailing lists offer limited opportunities for direct networking compared to social media. A good way to identify potential members would be by keeping track of new research grants being awarded for TB research (using tools such as the upcoming TB Clinical Trials Inventory website).

Priority for mapping exercise informants:

High

18 A similar exercise was undertaken by the TB Alliance in 2006, though few patients and laypersons were included in the survey. See the report “New TB Regimens: What Countries Want” (Available at: www.tballiance.org/downloads/publications/TBA_VPSreport_final_flat.pdf)
Initial resources needed:
Low
→ Setting up an online community and inviting potential members could be done in less than 5 hours.

Ongoing resources needed:
Low
→ Aside from occasional moderation, the network should be self-sustaining.

2. Write a white paper to guide CPTR regimen trials

Description
The Workgroup could write a white paper to provide CPTR members with guidance about CE and its practice. The white paper should introduce and advocate for CE, while focusing on helping CPTR members make decisions about how they can best engage communities in their respective trials. The white paper could be modeled on the well-known Good participatory practice guidelines for biomedical HIV prevention trials. While the primary target of the white paper could be CPTR members, the white paper should be made publicly accessible and widely disseminated to support non-members struggling with the issue of CE in the context of TB research. Based on some of the observations that were made during the mapping exercise, some additional issues that the white paper should touch upon include: 1) the relationship between CE and health literacy, 2) how to best tap into the work and networks of TB activists, 3) when CE should be started, 4) how to document researchers’ interactions with the community, and 5) how to monitor and evaluate the effectiveness of CE programs.

Priority for mapping exercise informants:
High

Initial resources needed:
High

Ongoing resources needed:
Low
→ The white paper might need to be updated over time as CPTR partners and non-members start implementing the recommendations.

Available at http://www.avac.org/ht/d/sp/i/309/pid/309
3. ** Maintain an annotated database of relevant CE resources **

**Description**
Several informants mentioned their interest to hear about existing and new resources on CE in TB research. The Workgroup could keep a running bibliography of relevant resources. Ideally, this bibliography would be shared with already-existing repositories of TB resources, such as FindTBResources.org, where subfolders for CE in research could be created. The CPTR website might also be able to host some material. The resources mentioned by stakeholders during the mapping exercise have already been pre-reviewed, providing a basis for this work. Additionally, material developed and used by CE coordinators, such as pictures, brochures, presentation slides and templates, should be collected when possible.

**Priority for mapping exercise informants:**
High

**Initial resources needed:**
Moderate
→ Estimated to be around 50 hours (systematically search for already-existing material, review and annotate).

**Ongoing resources needed:**
Moderate
→ Estimated to be around 3 hours/week (set up news alert for new material, review and annotate material, update bibliography, communicate updates to relevant stakeholders).

4. ** Organize a symposium on community engagement **

**Description**
The Workgroup should consider organizing a symposium to bring together relevant stakeholders involved or interested in CE in TB research. Presentations should include explanations of what constitutes CE, discussions of various approaches, and reflections about good practices. Ideally, the symposium would bring together CE coordinators to facilitate the emergence of a strong network. Support to organize such a symposium could be requested from the Brocher Foundation (http://www.brocher.ch/pages/appel_projets.asp). It has also been suggested that a panel or workshop could be organized at the 43rd Union World Conference.

**Priority for mapping exercise informants:**
High
Initial resources needed:
High
→ The need for resources will be more limited if support is secured through the Brocher Foundation or if the symposium is not a standalone event (e.g.: part of a Union World Conference). In such cases, the bulk of the work will be to put together a proposal and identify and select key participants.

Ongoing resources needed:
Variable (None to Moderate)
→ It could be valuable to aim for the publication of symposium proceedings, in which case additional resources will be needed.

5. Conduct case studies on community engagement

Description
There are many potential opportunities to conduct case studies on good CE practices in TB research. These case studies should not only emphasize success stories, but also examples in which CE did not go well. The Workgroup would be in an ideal position to conduct such a series of case studies. The Workgroup could: 1) act as a catalyst, by putting together a proposal for an edited volume and circulating a call for chapters; 2) conduct some or all of the research itself; or 3) secure funding to delegate the research. In both options 2 and 3, an appropriate dissemination platform (e.g.: website, casebook, academic papers) should be determined.

Case studies would also help the Workgroup gain a better understanding of how CE programs can be evaluated and monitored.

Priority for mapping exercise informants:
High

Initial resources needed:
Variable – from moderate to high
→ Depending on whether the Workgroup works in collaboration with non-members to put together the series of case studies, this initiative could either be very resource-intensive or only moderately so.

Ongoing resources needed:
Low
→ Once the case studies are be completed, resources will only be needed to ensure appropriate dissemination.
6. **Present at conferences and meetings**

**Description**

There is already consensus within the Workgroup that its work should be presented to relevant stakeholders globally at relevant conferences and meetings. Doing so might help contribute to the emergence of a consensus on what constitutes good CE. Efforts need to be deployed by the Workgroup however to identify opportunities, determine key messages, write up abstracts, put together slides, and present. Where the Workgroup’s goal is to share key insights on how communities can be involved in the research process, efforts should be made to travel to meetings that CE coordinators are more likely to attend.

Confirmed opportunities to present at conferences:
- a) 42\textsuperscript{nd} Union World Conference – October 26-30, 2011 – Lille, France
- b) CPTR Annual Meeting – November 9-10, 2011 – Arlington, Virginia, USA

Invitations to present at conferences:
- a) ECAB Tuberculosis Meeting – December, 2011 – Brussels, Belgium

Other opportunities to be explore:
- a) Regional IUATLD conferences
- b) 2013 EDCTP Forum

**Priority for mapping exercise informants:**

Perceived to be low

\[ \Rightarrow \] Interest is likely limited both by the lack of opportunities faced by many informants to attend conferences and by the fact that they might prefer more tangible resources.

**Initial resources needed:**

Moderate

\[ \Rightarrow \] Abstract for the 42\textsuperscript{nd} Union World Conference is already drafted; slides need to be put together. Presentation for the CPTR Annual Meeting needs to be developed.

**Ongoing resources needed:**

Variable

\[ \Rightarrow \] Depends on the number and variety of conferences attended, but could involve high costs for travel and accommodation. On the other hand, slides, with minor adjustments, can be reused at different events.
7. **Maintain a list of funding opportunities**

**Description**
While the Workgroup should clearly advocate for CE activities to be part of core research funding to ensure that CE programs are sustained throughout research projects, it might not be realistic to expect funders to put appropriate mechanisms in place immediately. Even if CE can be budgeted for by research teams, additional funds might be needed either occasionally (to run special activities or projects, for example) or to help sustain useful aspects of community mobilization beyond the conclusion of a research project. Hence, TB researchers or their local partners likely will have to rely on external sources of funding at some point or another. For this reason, the Workgroup should consider putting together a list of funding opportunities from which TB research teams and local partners could get support.

**Priority for mapping exercise informants:**
High

**Initial resources needed:**
Moderate

**Ongoing resources needed:**
Low

8. **Continue to develop and maintain a database of stakeholders working in community engagement**

**Description**
The Workgroup could continue to catalog CE activities, resources, and stakeholders, as initiated through this mapping exercise. Since TB research is accelerating, it will be important to keep track of CE initiatives arising in new TB trials. To do so, new TB grants awarded should be followed and CE coordinators identified. At the same time, stakeholders already contacted as part of the initial mapping exercise could be re-contacted on a regular basis to keep track of the evolution of their CE programs. Using questionnaires rather than interviews will help reduce the resources needed to keep the database up-to-date.

**Priority for mapping exercise informants:**
Low

**Initial resources needed:**
Moderate

**Ongoing resources needed:**
Moderate
9. Use the Workgroup as a ‘consulting’ group

**Status:** N/A

**Description**
As a group of people with a diverse set of skills and expertise in the field of CE and TB, the Workgroup could provide valuable advice and technical assistance on the design of CE programs for new CPTR trials. However, to perform this role, the Workgroup would have to develop a model for how this type of consultation should be managed, including the scope of services, what evidence would be used as the basis for advice, and how would the service be managed.

**Priority for mapping exercise informants:**
- **Moderate**
  - While informants generally mentioned the need for more guidance on how to design and conduct CE, including direct mentorship, the fact that CE programs have highly limited resources could constrain the demand for such services if there were costs associated to it.

**Initial resources needed:**
- **Very high**

**Ongoing resources needed:**
- **Very high**
Conclusions

Though limited both in scope and representativeness, the mapping exercise undertaken by the Stakeholder and Community Engagement Workgroup of the CPTR initiative has yielded important data and revealed interesting patterns about the state of community engagement in tuberculosis research. It has shed light on a number of ongoing initiatives and has helped identify both relevant stakeholders and existing resources. The mapping exercise has also made clear that several areas need further work before CE becomes fully integrated into the TB research culture.

First, greater clarity about the meaning of the term ‘community engagement’ is needed. ‘Community involvement’, ‘health literacy’, ‘research literacy’, ‘communication’, and ‘advocacy’ were expressions frequently used by informants interchangeably with ‘community engagement’. However, the differences between CE and these other types of activities or approaches may be considerable. Greater clarity about those could contribute to a clearer common understanding of the goals and purpose of CE.

Second, the role of Community Advisory Boards in TB research should be further investigated. In particular, more attention should be paid to the goals and indicators of effectiveness of CABs, and to their limitations. While variability in structures, membership criteria and goals of CABs might be necessary to demonstrate responsiveness to the specific socio-political environments of trial sites, the current diversity of CAB structures seems more reflective of the general ad hoc and impromptu nature of CE in TB research. More attention should also be paid to complementary or alternative mechanisms of engagement, especially those that might promote more effective and inclusive dialogue with communities.

Third, the lack of evaluation and monitoring strategies for CE programs has been undermining the credibility of claims about the value and importance of engaging communities. The lack of evaluation also poses a threat to the accountability and transparency of CE programs and, as such, is a particularly problematic issue if TB research funders are expected to support CE more consistently. Developing evaluation methodologies for CE will require greater agreement on the ethical and practical aims of CE, which to date remain poorly developed. Particular attention needs to be given to developing tools that are easy to understand and implement so as not to discourage their use on a frequent basis. It might be possible to capture the ‘dialogue’ and ‘partnership’ components of the Workgroup’s definition of CE in evaluation tools by using a combination of qualitative and quantitative methods. The role of ‘ancillary CE activities’, such as TB literacy training, should also be clarified and reflected in evaluation tools.

Fourth, few experiences of CE programs in TB research have been published to date, which means that there are few models that can be replicated or adapted to local needs. Programs are currently designed in an ad hoc and impromptu manner, which may make the development of more uniform approaches across sites and studies more challenging. The current diversity of CE programs, however, offers an excellent opportunity for cross-comparison, discussion and reflection about what constitutes good CE practice and minimum standards. If absolute uniformity of CE activities across trial sites might not be desirable, establishing the concept of guiding frameworks for CE, developed through in-depth case studies, might encourage more structured and deliberate reflection both about the specific needs of each participating community and the most ethically and practically appropriate CE program.

Fifth, current efforts to promote CE remain somewhat disjointed and, especially at the trial site level, CE is the responsibility of a few, relatively isolated, individuals. More concerted action is needed to facilitate networking among CE coordinators and greater uniformity and minimum standards for CE. Research consortia such as PanACEA should, in addition, be encouraged to develop standardized policies on CE across studies. Additionally, because coordination at the local level and promotion at the global level can both contribute to the uptake of CE, increased opportunities for CE coordinators and global advocates to work together more effectively are necessary. Support for CE coordinators to attend conferences and symposia where TB research advocates and activists meet could be a useful way of encouraging greater attention to CE and its impact.

The mapping exercise further revealed that interactions between various groups of stakeholders (e.g., healthcare professionals, activists, research team) in the context of a TB trial might be difficult to coordinate and might result in barriers to CE efforts. Suggestions on how to develop productive partnerships between these groups need to be an integral component of future guidance on how to conduct effective CE in TB research. Incentive structures for investigators should be examined and research funders should be encouraged to recognize CE activities beyond CABs as a necessary component of TB trials. Meanwhile, clearer minimum standards for CE in TB research would help not only funders to justify additional program costs associated with CE, but

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21 Notable exceptions include, first, the publication of the experience of the Consortium to Respond Effectively to the AIDS / TB Epidemic (CREATE) with community engagement during the Thibela TB study and, second, the publication of the South African Medical Research Council’s experience with the establishment of a Community Advisory Board in KwaZulu-Natal. For details on community engagement in the Thibela TB study, see: Grant AD, Coetzee L, Fielding KL, Lewis JJ, Ntshеле S, Luttig MM, Mngadi KT, Muller D, Popane F, Mdluli J, Mngadi N, Sefuthi C, Clark DA, Churchyard G. ‘Team up against TB’: promoting involvement in Thibela TB, a trial of community-wide tuberculosis preventive therapy. AIDS. 2010; 24 Suppl 5: S37-44. See also: Lavery JV, Popane F, Ntshеле S, Sefuthi C. What the Thibela TB prevention trial has taught us about effective community engagement. (Forthcoming).

For details on the KwaZulu-Natal CAB, see: Ntshanga SP, Ngcobo PS, Mabaso ML. Establishment of a Community Advisory Board (CAB) for tuberculosis control and research in the Inanda, Ntuzuma and KwaMashu (INK) area of KwaZulu-Natal, South Africa. Health Policy. 2010; 95(2-3): 211-5.
also investigators to better anticipate the resources needed to integrate CE to their research projects.

Sixth, More attention will also need to be paid to the role that health literacy and community mobilization around TB prior to the arrival of research teams can have on the CE process. For instance, communities where individuals wait for a long time before seeking help to treat TB due to stigma might not be predisposed to CE to the same extent as others. Similarly, in communities where BCG vaccination is widely administered, individuals might not understand the need for a new vaccine if they think that it is effective and that the protective effect of the BCG vaccine does not wane over time. Prior community mobilization might further facilitate CE by making both community entry and the mapping of relevant local resources much easier for researchers. At the same time, efforts might need to be deployed to ensure that researchers unaccustomed to working with community-based organizations and advocates understand how to best tap into the opportunities offered by a vibrant civil society.

Overall, greater advocacy for CE in TB research should focus on ensuring that all relevant parties benefit from greater emphasis on developing lasting partnerships between researchers and endemic communities. This mapping exercise has helped highlight some of the ways the Stakeholder and Community Engagement workgroup might encourage and support CE in TB research fruitfully. These contributions include: 1) facilitating the emergence of a consensus on what constitutes CE, 2) developing guidance on how to engage communities effectively, 3) providing a platform to increase exchanges between the various stakeholders – from local CE coordinators to global advocates, and 4) identifying and disseminating relevant resources for CE in TB research.
# Appendices

## APPENDIX 1 – ANNOTATED LIST OF RESOURCES MENTIONED BY INFORMANTS

<table>
<thead>
<tr>
<th>Title</th>
<th>Details</th>
<th>Link</th>
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<tbody>
<tr>
<td><strong>Articles</strong></td>
<td></td>
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<tr>
<td>Integration of participatory research in rural health survey</td>
<td>Article describing one of the early instances (mid-90s) of 'community engagement' in the context of TB research.</td>
<td>PubMed</td>
</tr>
<tr>
<td>Challenges to the development of new drugs and regimens for tuberculosis</td>
<td>Suggests that there is &quot;an urgent need to harmonise all the existing guidelines and to ensure that these guidelines do not make it impossible for trialists to carry out clinical trials but, rather, strike a balance between the possible and the practical.&quot;</td>
<td>PubMed</td>
</tr>
<tr>
<td>Experience with Phase III Clinical Trials of Antituberculosis Drugs and Regimens: Conclusions and Lessons for the Future</td>
<td>Holds that increasing ethical regulations pose a significant challenge to academic institutions wishing to undertake phase III trials, ultimately leading to the commercialization of such trials. Authors suggest that current and increasing ethical regulations might be a serious threat to attaining the TB Millennium Development Goal.</td>
<td>Karger</td>
</tr>
<tr>
<td><strong>Book chapters</strong></td>
<td></td>
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</tr>
<tr>
<td>Community involvement in tuberculosis research</td>
<td>Chapter written by members of the KNCV Tuberculosis Foundation. Nice review of community engagement that points researchers to several other useful resources. Also offers specific, step-by-step recommendations on how to engage communities.</td>
<td>Priorities in Operational Research to Improve Tuberculosis Care and Control</td>
</tr>
<tr>
<td><strong>Briefing papers</strong></td>
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<tr>
<td>Community engagement in clinical trials – A briefing paper</td>
<td>2006 lit review and interviews conducted by the TB Alliance that 1) presents some key insights on the use of community advisory boards; 2) calls for the documenting of experiences and lessons learned.</td>
<td>Available upon request from Global Alliance for TB Drug Development</td>
</tr>
<tr>
<td><strong>Database</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Find TB Resources</td>
<td>A database of various TB resources; while it does not focus on community engagement resources, some material might be relevant and useful (e.g.: health literacy material, images, etc.).</td>
<td>Find TB Resources</td>
</tr>
<tr>
<td><strong>Documented experiences</strong></td>
<td></td>
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<tr>
<td><strong>World TB Day 2009 - REMoxTB sites</strong></td>
<td>Describes the activities organised by the TB Alliance-funded REMoxTB sites as part of the celebration of the 2009 World TB Day.</td>
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<tr>
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</tr>
<tr>
<td><strong>World TB Day 2011 - REMoxTB sites</strong></td>
<td>Describes the activities organised by the TB Alliance-funded REMoxTB sites as part of the celebration of the 2011 World TB Day.</td>
<td><strong>World TB Day 2011</strong></td>
</tr>
<tr>
<td><strong>Empowering communities for TB Advocacy - The TAG-ICW Model</strong></td>
<td>The publication documents &quot;lessons learned from two years of capacity building for HIV treatment activists to integrate tuberculosis (TB) and TB/HIV collaborative activities into their advocacy work.&quot;</td>
<td>Available upon request from Treatment Action Group</td>
</tr>
</tbody>
</table>

**Guidelines**

| **Good Participatory Practice (GPP) Guidelines for biomedical HIV prevention trials** | Several informants mentioned the guidelines for community engagement that have already been developed by the HIV/AIDS research community. While few informants reported using these resources actively, there was a consensus that these resources might easily be 'translated' for the TB context, providing an interesting starting point for organizations interested in developing guidelines for TB research. | **AVAC** |
| **Communication handbook for clinical trials** | Developed by Family Health International in partnership with USAID and others, this 280-page document describes strategies, tips and tools to manage controversy and disseminate information and study results. | **FHI 360** |
| **Executive Summary: Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research** | (see below for full report) | **HIV Vaccine Trials Network** |
| **Full Report: Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research** | Document was mentioned as an example of the sort of document needed for TB research. As the preface explains, "This document is the product of extensive community experience and expertise from around the world. With it, the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) and Community Partners hope to provide a tool for researchers and community representatives to further expand and deepen existing partnerships and forge new ones in clinical trials research". Many parts of the document are not actually AIDS-research specific, i.e. could easily be rephrased to include TB. | **National Institute of Allergy and Infectious Disease** |

**Human resources**
<p>| <strong>Treatment Action Group</strong> | Several informants greatly treasure TAG’s work. Being at the forefront of TB research advocacy, TAG is seen by participants as the go-to group for everything related to advocacy and community engagement. As someone put it, “TAG has been brilliant. You can't emphasize this enough.” | - |
| <strong>TB Alliance</strong> | A few informants who have benefitted from the funding of the TB Alliance appreciated that representatives came to their site to help train CAB members, thereby helping build much needed health research capacity. | - |
| <strong>Global Community Advisory Board</strong> | While not yet launched, informants privy to TAG’s plans to create a Global Community Advisory Board expected that this new group would prove a very important resource for the field of TB research as a whole. Expectations for the group seemed quite high. | - |
| <strong>Stop TB Partnership</strong> | The Stop TB Partnership, and in particular its Work Groups, was mentioned by several informants as a group that will be worth keeping an eye on: being increasingly active in the field of TB research, many expect that resources will be developed for TB researchers interested in community engagement. At the moment however, little guidance is provided for TB researchers in Stop TB Partnership documents (e.g.: the revised Plan to Stop TB only briefly mentions the importance for TB researchers to work with Community Advisory Boards). | - |
| <strong>Networks</strong> |  |
| <strong>3I's Advocacy Network</strong> | Mentioned by CITAM+, this network was created with support from CREATE and ZAMBART. The network brings together community organizations, NGOs, faith-based organizations, and a few health care providers. It is the kind of resource that researchers might find can facilitate community entry and community engagement more generally. | - |
| <strong>TBVACSIN</strong> | Though not active at the moment, this network of TB vaccine trial sites is seen as a potential platform to exchange best practices about community engagement. | Aeras |
| <strong>Newsletters</strong> |  |
| <strong>CREATE’s Policy and Advocacy Bulletins</strong> | Provides updates on community engagement activities conducted by CREATE. | CREATE |
| <strong>PowerPoint presentations</strong> |  |
| <strong>Best Practices for CE in TB Drug Research</strong> | PowerPoint presentation developed by Jane Ong’ang’o from KEMRI describing her experience putting together a CAB as part of the REMoxTB study. The presentation is not available online. | Available upon request from Jane Ong’ang’o |
| <strong>Engaging HIV Civil Society in TB</strong> | Documents the experience of CITAM+ in getting involved in tuberculosis. | Stop TB Partnership |
| <strong>The Brazilian Experience in Conducting Clinical Trials</strong> | Presentation given as part of MSF’s 2007 Symposium on ‘Overcoming gaps in TB R&amp;D’. | Médecins Sans Frontières |</p>
<table>
<thead>
<tr>
<th><strong>Combating TB together:</strong> role of Partnerships and Networks in capacity building</th>
<th>Presentation given as part of MSF’ 2007 Symposium on 'Overcoming gaps in TB R&amp;D'.</th>
<th>Médecins Sans Frontières</th>
</tr>
</thead>
<tbody>
<tr>
<td>Building clinical trial capacity - Working Group’s summary</td>
<td>Presentation given as part of MSF’s 2007 Symposium on 'Overcoming gaps in TB R&amp;D'.</td>
<td>Médecins Sans Frontières</td>
</tr>
<tr>
<td><strong>Proceedings</strong></td>
<td><strong>Engaging Community in TB Research</strong></td>
<td>Proceedings from a CREATE-sponsored meeting held in Paris in 2008 about community engagement in tuberculosis research. The meeting reportedly brought together researchers, clinicians, ethicists, leading treatment activists and treatment literacy experts to think about how to productively engage communities in TB research.</td>
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<td><strong>Summaries of project</strong></td>
<td><strong>Enhancing CE in TB research and communication</strong></td>
<td>Description of a Wellcome Trust-funded project led by 'Panos Eastern Africa': &quot;The project is also geared towards increasing information on TB in the public domain and therefore boosting the public’s contribution towards addressing the burden of TB through participating and influencing research process and outcomes.&quot;</td>
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<td><strong>Training resources</strong></td>
<td><strong>FHI Research ethics curriculum for community representative</strong></td>
<td>A resource developed by Family Health International that seeks to help community representatives understand their roles and responsibilities better &quot;so that they have a stronger voice before, during, and after the research process&quot;.</td>
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<td><strong>Aids Vaccine Literacy Toolkit</strong></td>
<td>Developed by the International AIDS Vaccine Initiative (IAVI), this would be an interesting resource to replicate for TB research: &quot;The Core Content contains basic information about AIDS vaccines, explained in simple language, in a user-friendly format. The text is divided into eleven chapters covering a range of topics, from basic science and clinical trials to social and ethical issues related to vaccine development and testing, as well as future access and use.&quot;</td>
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<td><strong>Research fundamentals for activists</strong></td>
<td>Hosted on the Working Group on New TB Drugs’ website, this book is a health research primer written with activists in mind. The goal of the publication is to help them engage in advocacy that is evidence-based.</td>
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<td><strong>TB Drug Research Literacy Toolkit</strong></td>
<td>This toolkit was developed by the TB Alliance to support the work of individuals interested in conducting training workshops about basic drug development and clinical trials. The toolkit provides background information, as well as suggestions for activities on CE (strong) emphasis on CABs.</td>
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