Good Participatory Practice

Guidelines for TB Drug Trials

2012

Critical Path to
TB Drug Regimens

Acknowledgments

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Abbreviations and acronyms

AIDS	Acquired Immunodeficiency Syndrome
CAB	Community Advisory Board
CAG	Community Advisory Group
CBO	Community-Based Organisation
CPTR	Critical Path to TB Drug Regimens
GPP-HIV	Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials
GPP-TB	Good Participatory Practice Guidelines for Tuberculosis Drug Trials
HIV	Human Immunodeficiency Virus
MDR-TB	Multi-Drug Resistant Tuberculosis
NGO	Non-Governmental Organisation
SCE-WG	Stakeholder and Community Engagement Workgroup
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS

Preface

Stakeholder engagement is becoming more widely recognised and endorsed as a critical component of research (1–5). At the core of stakeholder engagement is the commitment to create a beneficial, respectful, sustained, and transparent partnership that addresses the interests of *all* stakeholders in the research project, while supporting its ethical and scientifically rigorous conduct. In general, stakeholder engagement is justified either pragmatically or through appeal to intrinsic value. This document focuses on the pragmatic considerations of stakeholder engagement, which suggest that adhering to good participatory practice throughout the entire research life cycle can help facilitate local ownership of research, enable more equitable relationships, and increase the likelihood of successful research conduct, trial completion, and application of research results.

The participatory approach is already well established in some fields of biomedical research, most notably in HIV/AIDS, where resources such as the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* (GPP-HIV), developed by AVAC and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2007, are rapidly gaining recognition. In stark contrast, there are few resources available to guide the implementation of stakeholder engagement programmes, and particularly *community* stakeholder engagement programmes, in the context of tuberculosis (TB) drug trials (6).

As a first step towards addressing this gap, the Critical Path to TB Drug Regimens (CPTR) initiative formed a Stakeholder and Community Engagement Workgroup (SCE-WG) mandated to provide guidance on how to implement stakeholder engagement in the context of CPTR drug regimen trials. A mapping exercise conducted by the Workgroup in 2011 confirmed that the creation of guidelines describing how to conduct stakeholder engagement was a pressing need of the TB research community (7).

In 2012, the CPTR SCE-WG undertook to develop guidelines that could be useful for TB drug trials. A strategic partnership with AVAC led to the choice of the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* as the template for TB-specific guidelines. Through an iterative writing process that recognised both the parallels between HIV prevention trials and the issues specific to TB and drug trials, the *Good Participatory Practice Guidelines for Tuberculosis Drug Trials* (GPP-TB) were created. The document is the result of a reflection on the best available evidence regarding stakeholder engagement in TB research at the time of writing. As more TB researchers report their experience with stakeholder engagement, this document will evolve to take into consideration new data and recommendations.

The GPP-TB document is divided in five sections. Section 1 presents the objectives, scope, and intended audience of the GPP-TB, as well as a summary of the development process and suggestions for implementation. Section 2 defines some of the key terms used in the document. Section 3 describes how the context in which TB drug trials are conducted explains why a participatory approach is necessary. Section 4 lists the overall considerations that are the basis of the participatory process outlined in this document. These considerations are a mixture of principles and benchmarks that should guide implementers of GPP-TB. Finally, Section 5 describes some good participatory practices that can be used to ensure the success of stakeholder

engagement. Each topic area in this last section focuses on the different stages of the research life cycle.

Comments on this version of the GPP-TB can be submitted to: info@gpptb.org

- The members of the Stakeholder and Community Engagement Workgroup of the CPTR initiative

Section 1: Introduction

1.1. Objectives of the GPP-TB

The *Good Participatory Practice Guidelines for Tuberculosis Drug Trials* (GPP-TB) provide trial funders, sponsors, and research team members (including but not limited to community engagement coordinators[1]) involved in TB drug trials with a principle-based framework on how to effectively engage stakeholders in TB drug trials.

The broader objective of these guidelines is to encourage greater attention to the interests of all stakeholders affected by TB to help establish shared standards, expectations, and accountability for effective and outcome-driven engagement throughout *all* phases of TB drug trials. Although the specific interests of each stakeholder for this document will vary depending on their activities and perspectives, the guidelines offer an opportunity to develop a shared understanding of stakeholder engagement in TB drug trials.

1.2. Scope of the GPP-TB

The GPP-TB were drafted with the understanding that they should both be used in conjunction with the already-existing guidance documents that address the scientific and ethical conduct of drug trials (8–12) and be interpreted in the context of the published research ethics literature. The GPP-TB are however unique to the extent that they address a gap in the resources available to trial funders, sponsors, and research teams by providing a principle-based framework for the development of a strong relationship between all stakeholders involved in TB drug trials. In doing so, the GPP-TB explicitly take into consideration the impact that the complexity of TB drug trials and the context in which they are conducted has.

The GPP-TB do not provide a list of steps that should be followed precisely in all TB drug trials to engage stakeholders and/or special trial populations, such as children or pregnant women. Instead, the principle-based guidance offers general considerations on how TB drug trial stakeholder engagement programmes can be structured. As such, the document supports the development of effective stakeholder engagement programmes that span the design and conduct of TB drug trials.

Similarly, the document does not describe how consultations about the agenda for TB research should be conducted outside of a specific trial. While such consultations are certainly crucial, the focus of the document is on the conduct of stakeholder engagement in the context of a specific trial. However, some ideas on how to conduct global consultations can be gleaned from this document. The ethical framework described in Section 4, for example, might serve as a useful platform for guiding global consultations on the future of TB research.

[1] 'Community engagement coordinators' is used to designate those individuals directly in charge of a community stakeholder engagement programme at a trial site. Other official titles frequently given to these individuals include community liaison officer; community engagement officer; community engagement scientist; and recruitment, retention and Community Advisory Board coordinator.

Although the GPP-TB recognise that specific stakeholder engagement processes must be tailored at the site level, they can serve as a foundation for the development of training, implementation, monitoring and evaluation tools.

1.3. Intended audience

The intended primary audience of the GPP-TB is the partners of the CPTR initiative. For this reason, the complete GPP-TB guidelines are most relevant for large trials, those that have substantial impacts on individuals and the geographic areas where they are conducted. However, the guidelines can also serve as a general guide for other types of TB trials and studies, such as smaller safety studies, follow-on studies, or behavioural studies. For this reason, we think that all members of the TB research community can benefit from reading, understanding, and implementing these guidelines.

Trial funders, sponsors, and research teams can utilise these guidelines to effectively engage with the communities where trial sites are located, as well as with other stakeholders. On the other hand, stakeholders not directly involved in funding, sponsoring, or implementing trials can use these guidelines both to better understand how they can have an impact on TB drug trials and to advocate for stakeholder engagement more actively.

1.4. Development of the GPP-TB

Given the already widespread endorsement of the GPP-HIV guidelines, their adaptation to the context of TB drug trials was done using an accelerated process. Members of the Stakeholder and Community Engagement Workgroup (SCE-WG) of the Critical Path to TB Drug Regimens (CPTR) initiative, which spans a broad spectrum of experience and background, proposed TB-specific modifications to the original *Good Participatory Practice* framework.

Once an initial draft of the GPP-TB had been developed, comments were sought from individuals experienced with conducting stakeholder engagement in TB drug trials. In particular, participants at the 3rd Community Engagement Forum organised by the Global Alliance for TB Drug Development (TB Alliance) in June 2012. This group, including representatives working on TB trial sites in Kenya, Tanzania, and South Africa, provided in-depth feedback which was used to revise the document. Following these first revisions, additional comments were sought from members from a wide range of organisations with expertise or interest in the matter.

The limited experience in the field is reflected in the fact that the recommendations put forth are largely consensual rather than empirically tested. As data on the conduct of stakeholder engagement in TB drug trials increases over time, the GPP-TB will continue to evolve.

1.5. Implementing the GPP-TB

The implementation of the GPP-TB must be viewed as a shared responsibility among all stakeholders, with the recommendation that trial funders and sponsors adopt them as a requirement, monitor their implementation, and evaluate their effectiveness. Other stakeholders, such as national authorities, ethics committees, and community stakeholders

have the responsibility to encourage trial funders, sponsors, and research teams to use the GPP-TB when TB drug trials are conducted in their country, area, or institution.

To ensure success, the roles and responsibilities of each group of stakeholders should be tailored to the specifics of a given research plan. In general however, all of the good participatory practices described in Section 5 of this document require that trial sponsors ensure sufficient funding (13) and that research teams allocate resources, including staff time,[2] to their conduct. In addition, it is expected that research teams maintain clear written records of discussions and agreements that include stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.

Throughout implementation, the various parties must also remain focused on addressing potential barriers – such as power imbalances, differences in languages or cultural practices, and diverging priorities – to ensure the development of strong and resilient partnerships.

A variety of resources and tools may help stakeholders understand, implement, and monitor the GPP-TB. Readers are invited to consult the *Good Participatory Practice* portion of AVAC's website (www.avac.org/gpp) for materials that might be adapted to specific TB trials. In addition, Appendix 1 lists some additional material that might be of use to readers. Finally, the SCE-WG welcomes requests for specific tools and/or submissions of materials already in use (info@gpptb.org).

[2] One of the observations commonly reported by those conducting TB research is that staff members involved in the stakeholder engagement process tend to have limited training and limited support from the research team as a whole. Their position within the research team's structure and organisation also tends to be unfavorable to making stakeholder engagement a priority. This observation should be taken into consideration when planning resources and staff time for stakeholder engagement.

Section 2: Definitions and Concepts

This section defines key terms and concepts in the *Good Participatory Practice Guidelines for Tuberculosis Drug Trials*.

2.1. Who are stakeholders?

In these guidelines, we define stakeholders as all individuals, groups, organisations, government bodies, and communities who have an interest in the conduct and outcomes of a specific TB drug trial. The circumstances of the trial will dictate which stakeholders must be engaged, and to what extent. They may include:

- current and prospective trial participants;
- families of trial participants;
- individuals residing within, or surrounding, the area where TB drug research is conducted;
- people affected by TB;
- community engagement coordinators;
- health service providers, such as community health workers;
- community-based organisations (CBOs);
- community or interest groups;
- non-governmental organisations (NGOs);
- advocates and activists;
- religious groups;
- educators;
- local politicians and chiefs;
- key opinion leaders;
- media;
- national and local healthcare authorities;
- governments;
- research teams;
- academic institutions;
- companies; and
- public-private/product development partnerships.

As depicted in Figure 1, a subset of stakeholders can be described as "community stakeholders". Community stakeholders refer to individuals and groups that are either directly affected by the conduct of a drug trial or that represent the interests of parties that are. Examples of community stakeholders include participants and their relatives; communities where the trial is conducted; and local advocates and activists. The other stakeholders depicted in Figure 1 also have significant interests and potential impact on the conduct of TB drug trials.

Figure 1. The various levels of stakeholders who can be engaged in a TB drug trial.

Different types of stakeholders may influence or be affected by TB drug trials. Stakeholders include trial participants and other community stakeholders, but also a broader range of national and international stakeholders.

Active identification of stakeholders is essential to the success of engagement activities. The dynamic process of identification is generally incumbent on research teams, but in cases where stakeholders come forward, research teams should be receptive to such initiatives.

2.2. What is (community) stakeholder engagement?

Stakeholder engagement in TB drug trials refers to any form of consultation, collaboration, and partnership put in place to enable a dialogue between all parties having a stake in a specific trial with the goal of reaching a point where that project is understood, acceptable, and meaningful to all (7). As such, stakeholder engagement is intrinsically multi-directional.

Community stakeholder engagement, often referred to as community engagement, refers to trial funders, sponsors, and research teams developing meaningful relationships with a specific subset of stakeholders. Historically, community stakeholders have not had the opportunity to be as involved in the process of biomedical research as other types of stakeholders, such as researchers, research ethics committees, or trial funders and sponsors. As part of the participatory process discussed in this document, the emphasis moves away from focusing on specific types and 'levels' of stakeholders to emphasise the importance of engaging all of them. As a result, the trial dynamics historically observed will also evolve.

2.3. What are stakeholder advisory mechanisms?

The term "stakeholder advisory mechanisms" refers to approaches, strategies, or structures used to seek advice from relevant stakeholders. Stakeholder advisory mechanisms both provide trial funders, sponsors, and research teams with information about relevant stakeholders' perspectives on the design, planning, and implementation of a specific clinical trial and facilitate open communication about research goals, processes, and results. Stakeholder advisory mechanisms may be informal[3] or formal,[4] and they can either be built and sustained by the trial site or they may already be in existence before the beginning of a trial. For example, in TB research, local community-based structures addressing TB could either be integrated in new stakeholder advisory mechanisms or seen as a mechanism on their own.

Stakeholder advisory mechanisms are an integral part of the participatory process in TB drug trials: they provide stakeholders with the opportunity to engage with research teams during the entire life cycle of a trial. The need to identify and establish new stakeholder advisory mechanisms at the beginning of a trial may vary from site to site, but also within a single site over time. Their establishment and maintenance throughout the research process is key to establishing meaningful partnerships with community stakeholders and to ensuring ongoing dialogue. For example, to address the challenges identified in relation to consent processes and to ensure harmonisation and careful review of consenting processes, a "Consent and Communication Committee" might be useful early on in the trial (14).

Another common example of a stakeholder advisory mechanism is the community advisory board (CAB), also referred to as community advisory group (CAG). CABs are ordinarily composed of stakeholder representatives and, as such, facilitate broader involvement in the research process. They are expected to meet regularly with research team representatives; inform community stakeholders about proposed and ongoing research; and provide feedback to research teams about local norms, beliefs, and concerns that arise during specific trials. The composition of CABs varies from site to site but should be intended to reflect the diversity of community stakeholder interests, needs, and culture. CABs may include members or representatives of the surrounding area; individuals in the population from which participants will be recruited; people living with or affected by TB; current or former trial participants; religious or opinion leaders; and representatives of other sections of society, as indicated by the trial location. An example of a more global CAB initiative is the Global Tuberculosis Community Advisory Board (www.tbonline.info/about/), composed of research activists involved in TB and HIV research networks.

Overall, careful consideration needs to be given to the range of stakeholder advisory mechanisms that are required to best support effective engagement. Specifically, though

[3] Informal stakeholder advisory mechanisms may be events or less formal means by which research teams seek relevant stakeholders' views on proposed or ongoing research. Examples include stakeholder meetings, local events, focus group discussions, interviews, consultations, and suggestion boxes.

[4] Formal stakeholder advisory mechanisms typically involve established groups that develop an ongoing relationship with the research team at a particular trial site. Examples of established groups can be trial participant groups (former or current participants), professional groups (local scientists, service providers, media, or experts on local socio-cultural issues), non-governmental organisation advisory groups (with representatives from different non-governmental organisations or community-based organisations), and community advisory boards.

now seen as a standard element of HIV research worldwide (15), the establishment of a CAB may not translate as best practice in all locations. Indeed, in many settings, they may be helpful but not sufficient for gaining adequate and appropriate community stakeholder input. On the other hand, since community health workers (CHWs) often occupy a central role in TB control and treatment programmes, their involvement in stakeholder advisory mechanisms for TB drug trials should be encouraged.

Section 3: The Importance of Good Participatory Practice in TB Drug Trials

Following the development of antibiotics effective against the disease around the mid-twentieth century, funds allocated to clinical TB research decreased rapidly. For several years, even though TB continued to wreak havoc on most of the world's populations, no new therapeutic compounds were introduced to the market. As a result, there is limited recent experience with conducting TB drug trials. Of late however, the TB product pipeline has been expanding (16,17), mostly as a result of a growing consensus that "yesterday's TB treatment is inadequate to handle today's complex epidemic" (18).

The rise of drug resistant strains, the length and toxicity of current standard regimens, as well as the creation of product development partnerships have all contributed to this renewed interest in TB treatment innovation (18). This has resulted in some progress in the understanding of the biology of TB (19) and in the number of therapeutic compounds under evaluation (20). The resulting surge in planned clinical trials has already given rise to concerns about whether there is adequate capacity to conduct the trials in endemic countries (21,22). Among the many aspects of capacity that must be considered is the ability of trial funders, sponsors, and research teams to engage successfully with host communities and other stakeholders who have an interest in a particular trial.

The well-known controversy of the Tenofovir HIV pre-exposure prophylaxis trials[5] (23–26), which were stopped early and were a driving factor for the publication of the GPP-HIV, provided clear evidence of the need for improvement in the way we conceptualise and develop relationships with stakeholders and helped raise interest for stakeholder engagement in other fields.

There are many reasons to believe that having stakeholders involved throughout the life cycle of a research project could have significant positive impacts. First, community stakeholders can be strong advocates for research, especially in areas such as multi-drug resistant TB (MDR-TB). Community stakeholders also have expertise that trial funders, sponsors, and research teams may lack: they possess critical knowledge and understandings of the local cultures; languages; dynamics of the local epidemic; concerns of vulnerable or marginalised populations; and local priorities. Hence, effective community stakeholder engagement could help ensure that research questions and procedures are relevant, culturally sensitive, and appropriate. This, in turn, could improve recruitment, retention, adherence, and overall trial quality. Having stakeholders advocate for and hold health authorities accountable for rolling out treatments proven effective could lead to better uptake of new

[5] A report reflects on the event this way: "To the considerable surprise of researchers, advocates, and donors, the trials became embroiled in escalating controversies, sparked by protests by some AIDS activists. The activists not only raised questions about how the research was being conducted, but also challenged some of the fundamental ethics and underlying motives of the research. (…) [W]hat is perhaps most remarkable in retrospect was not the critique itself but the inability of stakeholders – all committed to ethical HIV prevention research – to deal with each other during the window of opportunity when dialogue may have been able to resolve some of the differences and allow the research to move forward. Eventually, a French television programme on France 2 picked up and magnified the controversy through sensationalised reporting. […] The governments that had approved the trials were called to account by the media and the community. Not surprisingly, in less than a year, approvals for the trials in both Cameroon and Cambodia were suspended." (24)

regimens. Finally, stakeholder engagement, particularly at the community level, could lay the foundation for a supportive environment for research that extends beyond the life cycle of a specific trial, ultimately helping to build capacity for TB research.

Several key features of TB trials make stakeholder engagement a particularly important consideration for the field. First, the underlying determinants of the TB epidemic are entrenched in the cultural, economic, institutional, legal, and political fabric of endemic societies. These determinants include economic instability, poverty, migration, discriminatory practices, stigma, social marginalisation, and inadequate access to healthcare services, housing and education. Understanding how these factors operate at individual trial sites is important to ensure that they are not inadvertently replicated or reinforced.

Second, the determinants of the TB epidemic are also associated with vulnerability more broadly construed. Many populations where TB is endemic might for instance feel that their bargaining power is limited. Promoting stakeholder engagement in TB drug trials can help ensure that power dynamics do not disadvantage some stakeholders more than others. Otherwise, the threat of exploitation – perceived or real – must be taken seriously. A common manifestation of the concern about exploitation is suspicion about the motivation of the (guest) research teams.

Third, the lack of valid biomarkers that could serve as short-term proxy efficacy endpoints for TB drug trials means that they are typically lengthy and burdensome for participants, who must endure frequent study procedures that are unpleasant (e.g., sputum induction, blood draws). Stakeholder engagement can help ensure that the burden associated with TB drug trials is fully apprehended by trial funders, sponsors, and research teams, making it easier to make adjustments to the protocol.

Fourth, the prospect of stigma or involuntary isolation may be very real in the environments where many TB drug trials are conducted. A full stakeholder engagement process will help trial funders, sponsors, and research teams understand the significance of these events and help make their management a priority.

Finally, since the conduct of TB drug trials is a relatively new endeavor in this era, a great deal of uncertainty remains both around what issues might arise during a research project and around what the concerns of relevant stakeholders might be. Thorough engagement programmes are thus particularly indicated in TB drug trials at this point.

In summary, the unique social, ethical, and medical context of TB drug trials in endemic countries call for more robust engagement with host communities and stakeholders more broadly. And since important factors might limit the transferability of lessons learned about stakeholder engagement in other fields,[6] guidelines specific to TB drug trials are important.

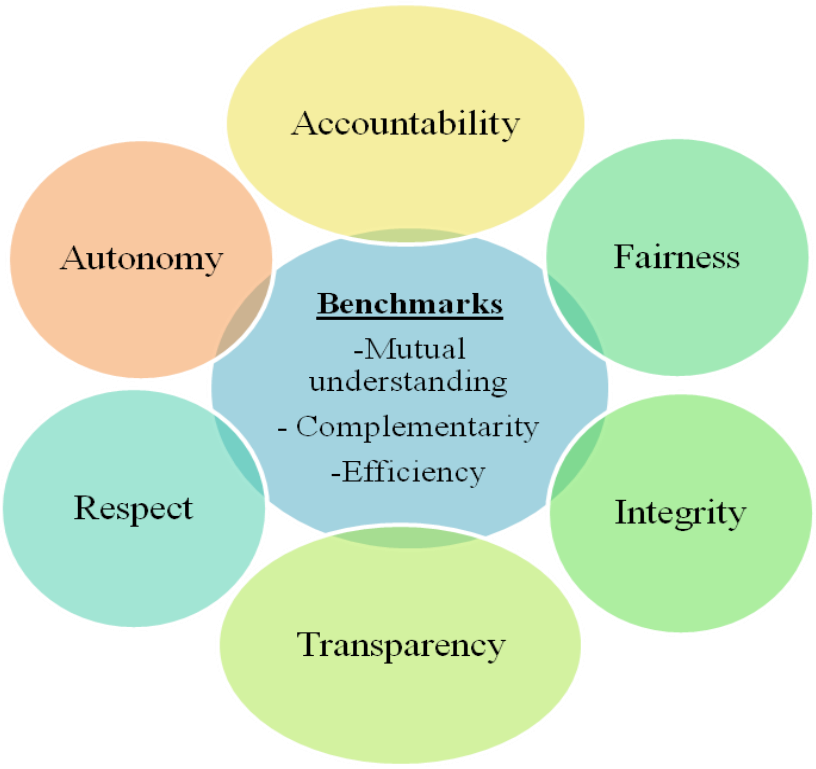
[6] Among these limiting factors are the type of treatments and life prospects of those falling ill; the amount of resources available to conduct trials; and the limited TB health literacy worldwide (38). On the other hand, TB has not been surrounded in conspiracy theories to the extent that other diseases have. This near-absence of distrustful convictions about the motives of the TB research enterprise is expected to facilitate dialogue between all stakeholders during drug trials.

Section 4: The Guiding Considerations of GPP-TB

The principles and benchmarks described in this section serve as the ethical framework underlying the GPP-TB. This ethical framework should help research teams and stakeholders plan and implement their stakeholder engagement program by pointing to the considerations to keep in mind throughout the life cycle of a TB drug trial. The importance of these considerations becomes particularly acute when conducting trials with populations that might be vulnerable, such as children or MDR-TB patients.

As understood here, *principles* are values that can be adhered to, while *benchmarks* are outcomes indicating whether or not the principles are being realised. Benchmarks can play a useful role in the development of monitoring and evaluation indicators, though specific ways to measure them should be developed at the site level until validated tools become available. The benchmarks listed here are only a subset of those that could be used to evaluate stakeholder engagement programmes. As experience with GPP-TB implementation increases, the list of relevant benchmarks is likely to increase too. The current list of benchmarks and principles is summarised in Figure 2.

Figure 2. The principles and the benchmarks underlying the GPP-TB.



The fact that several considerations are part of the ethical framework of the GPP-TB means that some of them might need to be balanced against each other under some circumstances. There are however no simple, 'off-the-shelf' mechanisms to adjudicate between or among these

considerations. A solution is to adopt **deliberation** as the basis of well-functioning participatory processes. Deliberation refers to formal discussions and negotiation between the various stakeholders who have a legitimate interest in the consequences that a trade-off between considerations might have.

Adopting deliberation as a way to decide how to best act can help stakeholders recognise that certain considerations may have to yield to one another on the basis of reason, depending on the circumstances. Emphasising deliberation as a mechanism to determine how the considerations outlined in Figure 2 can be upheld highlights the importance of envisioning the engagement process as an exercise where all stakeholders are heard; interests balanced; and options for mutual gains that are tailored to local circumstances pursued. An example where deliberation might be necessary is in the discussion around payments for participation in the stakeholder engagement process. While some notions of respect would suggest that participants should be compensated for their time when taking part in an advisory mechanism, the principle of autonomy might suggest differently.

4.1. Principles

4.1.1. Respect

The notion of respect implies a special relationship based on acknowledgment, attention, and value. Parties demonstrate respect when they communicate and act in ways that value each other's perspectives and are responsive to each others' interests. Respect in TB drug trials can be demonstrated, for example, by taking steps to ensure that the expressed beliefs and expectations of community stakeholders are taken into consideration in the decision-making process – even when this implies unforeseen compromises. Respectful relationships help foster effective communications, trust, and partnerships that achieve the goals collectively set.

4.1.1. Fairness

In the context of stakeholder engagement, fairness refers to the way stakeholders treat and negotiate with each other. The notion of 'fair dealings' emphasises the honest acknowledgment of one's interests and motivations to ensure that there is no active or passive deception when negotiating with other parties. During the engagement process, no group of stakeholders should privilege their interests arbitrarily over any other's as a result of greater power, influence, access to resources, or knowledge.

The principle of fairness takes on particular importance when trial funders, sponsors, and research teams seek to establish a dialogue with trial populations that might be more vulnerable and require special attention, such as youth, homeless individuals, and participants with a high burden of co-morbidities.

4.1.2. Integrity

In its most general sense, integrity refers to choosing actions that are consistent with one's value system and living up to commitments and promises – on the terms that they

were made and with reliability. For representatives of stakeholder groups, this might mean representing the interests of their constituency even in cases where this might lead to intricate negotiation with other stakeholders.

From a scientific perspective, integrity takes a particular connotation that emphasises adherence to accepted scientific standards. Maintaining the highest standards of *both* scientific and ethical integrity in TB drug trials must be a driving force of the engagement process.

4.1.3. Transparency

Transparency in a TB drug trial is ultimately about bringing to the open one's interests and motivations in that trial. Transparency requires operating in such a way that it is easy for parties to understand each others' interests; to see what actions are being planned or performed; and to understand the relevant lines of authority and accountability. Clear, honest, open, and timely communication is a hallmark of transparency and fosters collaborative, trusting and constructive relationships.

In general, transparency can be about the research process itself or about the roles of the stakeholders involved in the trial. Transparency about the *research process* includes ensuring that truthful and understandable information about the objectives and processes of a trial, as well as its sources of funding, is made available – either publicly or, under specific circumstances, privately to the relevant stakeholders. In essence, transparency about research boils down to answering the following questions:

- What is being planned?
- Why is it planned?
- How will it be implemented? (i.e., what are the interests in play?)
- What are the communication and accessibility strategies that will be employed to make sure that all the information is clear and accessible to all of the interested parties?

Transparency about the *roles of the stakeholders* refers to clear communication about their respective expectations; the agreed-upon responsibilities; the constituents they each represent; and the extent to which their input may influence trial-related decisions.

Adherence to the principle of transparency also means that research teams communicate about circumstances or developments that may affect previously determined levels of consultation, involvement, collaboration, and decision-making.

4.1.4. Accountability

In the context of biomedical research, accountability is often construed as the duty of research teams towards funders to ensure the responsible stewardship of resources and the successful conduct of the project. In the context of stakeholder engagement, the principle of accountability should be understood more broadly as a bidirectional commitment to thinking through the justification for one's actions. This commitment is based on the recognition that one's actions have direct repercussions on the various stakeholders involved in the partnership. Hence, accountability should not be reduced to a mechanism

of control and power-wielding, but as a way of achieving a common goal by ensuring that all stakeholders' interests receive fair consideration and diligence. An example of accountability in a TB drug trial might be when researchers divulge new scientific information to community stakeholders when it becomes available.

4.1.5. Autonomy

Autonomy in the context stakeholder engagement describes the stakeholders' privilege both to have input into a proposed research project and to initiate activities that may not be directly supported by trial funders, sponsors, or research teams. In particular, the principle of stakeholder autonomy recognises the entitlement of stakeholders to support, amend, or refuse proposals to conduct research in the particular geographic location in which they are active.

At the centre of the principle of autonomy in TB drug trials is the recognition that the independence of the advisory mechanisms and structures put in place to elicit feedback from community representatives must be ensured and preserved. For instance, Community Advisory Boards (CABs) created as part of a specific trial should remain accountable to the constituencies they are expected to represent, even though they may receive funding from the entities organising a trial. In this case, the onus also falls on those creating the CABs in the first place – to ensure, for example, that the terms of reference of the advisory mechanism are clear.

Because autonomy is dependent on knowledge, efforts must be deployed as part of good participatory practice to maximise the possibility for stakeholders both to understand the local, national, and global issues specific to a trial *and* to make informed decisions regarding the appropriateness of the project.

4.2. Benchmarks

4.2.1. Mutual understanding

To ensure the effectiveness of collaborations, the involved parties must come to a mutual understanding of each other's interests in the trial. Two key areas in which interests are commonly under-examined are socio-cultural issues and the meaning and significance of various research processes. These often require stakeholders to improve their knowledge and skills – to acquire competencies – in order to collaborate and deliberate. Mutual understanding can be developed through adherence to the principles described above.

Socio-cultural competency includes understanding the norms, practices, and beliefs of relevant cultures; social circumstances; diverse stakeholder perspectives on research and research priorities; and appreciation of the implications of power differences among stakeholders. Building socio-cultural competency enables collaboration among stakeholders with diverse priorities and backgrounds and it informs the development of appropriate trial designs and procedures.

Research competency includes understanding the scientific process of defining research questions; developing appropriate trial designs; and collecting, analysing, and disseminating data to ensure valid results. Developing research competency might enable and empower communities and other stakeholders to provide meaningful input into the research process and enhance their understanding of the concepts, purposes, practices, limitations, and results of TB drug trials.

Whereas the initial competency level of different stakeholders will depend on their prior exposure to specific socio-cultural environments and to biomedical research, all groups must strive to develop these competencies by taking advantage of opportunities to learn about one another and about each other's interests and needs.

4.2.2. Complementarity

The concept of complementarity suggests that the interaction of stakeholders can produce an effect that is greater than the sum of the individual contributions. In other words, when stakeholders strive to see themselves as *partners* in the search for the most advantageous project for all, better outcomes can be achieved.

In the context of TB drug research, complementarity might refer to the trial funders, sponsors, research teams, and local public health systems all striving to maximise the impact that research and health care have on local populations. To achieve such synergy, TB drug research must be careful not to participate directly or indirectly in the diversion of resources away from public health system infrastructures and instead enable existing efforts. This can be done, for example, by ensuring that research does not compete with the public health system for human resources; that infrastructure built for the trial use standards relevant for the local health system; and that communication networks are established for the effective reporting and monitoring of the TB cases identified. From a research perspective, complementarity with community stakeholders can be manifested in various ways, such as better understanding of the disease; higher recruitment; more efficient use of limited resources; and sustainability of the trial.

4.2.3. Efficiency

Emphasising efficiency as a benchmark of ethical research highlights the importance of maximising the use of resources – in other words, ensuring that wastes of time and efforts are eliminated as much as possible. In the context of stakeholder engagement in TB drug trials, the paucity of available data about the cost-benefits implications of specific engagement activities makes an efficiency-based selection difficult. Given the positive effect the principles outlined above have on the ongoing relationship between stakeholders, abiding by them may be the most promising way for trial funders, sponsors and research teams to ensure the efficiency of their stakeholder engagement program until data from monitoring and evaluation becomes more readily available.

Section 5: Good participatory practices in TB drug trials

This section describes a framework that trial funders, sponsors, and research teams can use in collaboration with delegated staff and community stakeholders to develop meaningful and sustained partnerships in the planning and conduct of TB drug trials. The practices described below are not meant to be interpreted as comprehensive or definitive; as experience conducting TB drug trials increases, the recommendations made in this document are likely to evolve.

The section organises the community stakeholder engagement process in the general sequence in which it may occur over the course of a TB drug trial. Many of the steps outlined in Figure 3 are in fact not time-limited; they can take place as parallel or overlapping activities. Committing to a participatory process may also lead to a slight rearrangement of the traditional life cycle of a research project. For instance, site selection is traditionally done after the protocol is completed or far into the drafting process. However, by identifying a target community earlier, trial funders, sponsors, and research teams can make it easier to tailor a TB drug trial to the locales where they are to be conducted and afford the host community greater opportunity to participate meaningfully in the planning and execution of the trial. The application of each set of practices described here will be dictated, to some extent, by specific features of the location and host community; by the type and stage of trial being conducted; and by the community's experience hosting trials, if any.

Figure 3. The fourteen steps found in a stakeholder engagement program in TB drug trials.

Note that all resources created for stakeholders as part of the steps outlined below should be developed in languages and formats appropriate for their target audience – including, for example, the use of Braille, large print, and non-electronic supports where relevant.

When working on the following steps, readers might want to consult the resources and tools that have been developed by AVAC to facilitate the implementation of the GPP-HIV guidelines, including a 'GPP Trial Site Binder' and a 'GPP Community Stakeholder Checklist'. Some of these resources (available at www.avac.org/gpp) will be useful to implementers of the GPP-TB.

5.1. Site selection

A. Definition

Site selection is the process by which trial funders, sponsors, or research networks evaluate potential sites for a clinical trial and choose the most adequate one(s).

B. Relevance to good participatory practice[7]

Assessment during site selection of the sites' stakeholder engagement programmes – or plans for their development – is critical to anticipating a site's ability to conduct a trial according to good participatory practice principles.

C. Special considerations

1. New sites may not have previous experience with stakeholder engagement; they should be assessed based on their willingness and expected ability to develop strong stakeholder engagement programmes and advisory mechanisms.
2. Previous successful experience with community stakeholder engagement in a specific disease area does not guarantee appropriate engagement in TB. The site selection process must consider the fact that sites may need to re-evaluate their approach to include activities or mechanisms more relevant to TB drug trials.

D. Good participatory practices for site selection

Trial funders, sponsors, and research teams:

1. Seek input on the interest of local community stakeholders to host a TB drug trial.
2. Assess sites with respect to stakeholder engagement programmes, taking into account the following issues:
    a. Availability of findings from previous community mapping activities – or evidence of plans for completing such activities.
    b. Evidence of – or plans for – the development and maintenance of successful and meaningful partnerships with community stakeholders.

[7] It must be emphasised that the steps highlighted in this section are not only "relevant" because they matter for the participatory process. Informed consent, for example, has value beyond its potential impact on the overall participatory process.

c. Evidence of – or plans for – a stakeholder engagement and training plan to enhance stakeholders' understanding of the clinical research process.
d. Availability of sufficient staff with relevant skills (including linguistic abilities) and experience to interact with community stakeholders in culturally appropriate ways.
e. Previous development of stakeholder advisory mechanisms – or evidence of plans to facilitate their development.
f. Awareness and consideration of issues that may be raised by the trial, particularly in relation to the vulnerable, marginalised, or criminalised groups. This can be demonstrated by the development of relevant policies or activities.

5.2. Community mapping

A. Definition

Community mapping activities typically constitute the initial phase of stakeholder engagement when a site has been selected, or is being considered for selection. Community mapping involves the collection of data about a prospective study site with the purpose of gaining an informed understanding of local populations; disease impact; socio-cultural norms and practices; local power dynamics; institutions; local perceptions; channels of communication and decision-making; local history of research; as well as the needs and priorities of people who are locally affected by, and who can influence, the trial.

B. Relevance to good participatory practice

Community mapping serves as an important foundation for community stakeholder engagement. It highlights factors and processes to which trial funders, sponsors, and research teams need to pay attention to throughout the participatory process. By understanding the interests and dynamics within the community early in the process, researchers are less likely to encounter unanticipated barriers throughout the engagement process. When possible, collaborating with community stakeholders on the mapping exercise also helps build initial trust and lay a strong basis for later engagement.

C. Special considerations

1. Community mapping can be conducted either informally or formally (i.e., as part of approved, funded protocols).
2. Different sites will have specific needs regarding community mapping:
    a. Whereas new TB trial sites may require extensive efforts to become familiar with the local communities, experienced sites may require more focused or specific efforts.
    b. Reasons why experienced trial sites may benefit from community mapping exercises include: studying an experimental option new to the area; recruiting

from a new location or population; gathering stakeholder feedback regarding previous trials; and the changing nature of cultures and stakeholders.

3. It is important that stakeholders' expectations and the risk for misinformation be carefully managed during the mapping process. A modified process of Communication Planning (see section 5.5) can be used.

D. Good participatory practices for community mapping

Trial funders, sponsors, and research teams:

1. Identify key informants and relevant stakeholders that can assist in planning, implementing, and reviewing the process and results of community mapping.
2. Designate staff responsible for managing the activities that are part of the community mapping exercise.
3. Develop a community mapping plan in collaboration with relevant stakeholders to describe:
    a. Key information that needs to be gathered to support the effective planning and implementation of the trial.
    b. The most appropriate methods to collect the required information.
    c. Approval or notification processes[8] that are required for specific activities.
    d. Research team members and/or community stakeholders who are best suited to collect the data.
    e. Timelines and required resources.
4. Identify local stakeholders in order to determine which ones have legitimate interests in the conduct and outcomes of the trial and/or are key to trial implementation.
5. Document and make publicly available a description of the community mapping activities and findings, including:
    a. Techniques used for data collection.
    b. Data collected.
    c. Areas where clarification or attention is needed.
    d. How findings will inform the trial planning and implementation process.

E. Additional guidance

1. Tindana PO, Rozmovits L, Boulanger RF, Bandewar SVS, Aborigo R a, Hodgson AVO, et al. Aligning community engagement with traditional authority structures in global health research: a case study from northern Ghana. American Journal of Public Health. 2011 Oct;101(10):1857–67. (27)
2. Beebe J. Rapid assessment process: an introduction. Walnut Creek: AltaMira Press; 2001. p. 199. (28)

[8] This may include, for example, gaining a local Chief's permission to organise a public gathering.

5.3. Trial planning

A. Definition

Trial planning is the ongoing process of determining and, in some cases, revising the rationale; objectives; methodology; statistical considerations; ethical considerations; and organisation of the trial. Traditionally, trial planning often predates applications for funding and site selection, though it may be less so when trial funders, sponsors, and research teams pursue community stakeholder engagement early in the research life cycle.

B. Relevance to good participatory practice

Involving community stakeholders in the planning of trials demonstrates an important commitment to the participatory process early in the life cycle of the trial and can increase the sense of ownership of the project by community stakeholders. As a result, community stakeholders may be more inclined to provide meaningful input throughout the duration of the trial to ensure that it is locally appropriate; conducted in a fashion acceptable to their constituencies; and optimised for successful implementation.

C. Special considerations

1. Opportunities for input into trial design by local research teams and relevant stakeholders can vary by trial. Particularly in multi-country or multi-site trials, opportunities for local community stakeholders' contributions to the design of protocols may be more constrained.

D. Good participatory practices for trial planning

Trial funders, sponsors, and research teams:

1. Provide relevant stakeholders with study-related material, such as draft versions and summaries of the protocol, in an accessible form (e.g., translated).
2. Provide opportunities for local research teams and community stakeholders to participate in the process of designing TB drug trials, including the determination of the compounds to be tested; trial objectives; recruitment strategies; informed consent materials and procedures; reimbursement policies; counselling approaches; follow-up procedures; and post-trial access.
3. Document community stakeholders' input into trial design and make these recommendations explicit to review bodies – even when not required by such bodies.
4. Maintain clear and transparent communication about the protocol development process with relevant stakeholders, and especially with formal stakeholder advisory mechanisms.
5. Provide regular updates to community stakeholders on protocol reviews and approval processes.
6. Make the final version of their protocol publicly available whenever possible.

5.4. Engagement planning

A. Definition

The engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders. In particular, it outlines the strategies to be put in place to provide relevant information and training to community stakeholders and it details the mechanisms to be established to receive stakeholder input and feedback.

B. Relevance to good participatory practice

A comprehensive engagement plan enables research teams to collaborate with stakeholders more effectively by ensuring the smooth conduct of engagement and training activities throughout the trial. Engagement planning provides an additional opportunity to help all parties understand what interests may be affected by the trial and to take these interests seriously.

C. Special considerations

1. The goals and outcomes of stakeholder engagement and training are different from those of recruitment activities. While stakeholder engagement and training may positively influence trial recruitment activities, the engagement plan should clearly highlight the differences between participant recruitment activities and stakeholder engagement activities.
2. Using the data collected during community mapping activities to understand and appreciate the background, knowledge and power dynamics among community stakeholders is important when developing stakeholder engagement and training plans.

D. Good participatory practices for engagement planning

Trial funders, sponsors, and research teams:

1. Support and provide capacity building to the site staff responsible for planning engagement and training activities.
2. In collaboration with relevant community stakeholders, discuss, negotiate, and develop stakeholder engagement and training plans to cover the life cycle of the trial. The plans should detail the following:
    a. The objectives for engaging and training stakeholders in the TB drug trial that is being conducted, including assumptions and expected outcomes.
    b. The range of stakeholders to be engaged and trained, specifically ensuring that a broad range of *community* stakeholders is included.
    c. The type of engagement that is appropriate for each stakeholder, such as being informed, consulted, or empowered to make specific decisions.

d. The strategies to be used for the identification, establishment, and maintenance of stakeholder advisory mechanisms – including the type of support to be provided to those mechanisms.
e. The process by which new relevant stakeholders will be identified and engaged throughout the duration of the trial.
f. The frequency with which and by whom the stakeholder engagement and training plan will be reviewed.
g. The training that would be helpful to enhance stakeholder knowledge and understanding of planned trials and TB drug research more generally. This includes determining:
    i. The range of different stakeholders that could benefit from specific training.
    ii. The level of knowledge that is optimal and desired by stakeholders to support effective engagement throughout the TB drug trial.
    iii. The adequate methods and frequency of training activities.
    iv. The designated staff and other key community stakeholders who could facilitate training.
h. The training that would be helpful to enhance trial funders, sponsors, and research teams' knowledge and understanding of the interests and perspectives of community stakeholders. This includes determining:
    i. The adequate methods and frequency of training activities.
    ii. The designated staff and key community stakeholders who could facilitate training.

3. In collaboration with local stakeholders, identify the advisory mechanisms needed to ensure inclusive involvement of community stakeholders. For each stakeholder advisory mechanism, parties determine actual or expected:
    a. Purpose.
    b. Terms of reference or by-laws.
    c. Scope of responsibilities, such as the development, review, discussion, and provision of input on relevant trial documents and procedures.
    d. Structure (including the size of the committees, which may result in establishing guidelines to elect a chairperson and define the duration of service for members).
    e. Frequency of meetings or occurrences.
    f. Frequency with which principal investigators and other key trial staff members attend meetings.
    g. Reimbursement policies, if appropriate.
    h. Ways in which members can communicate with research teams between meetings.
    i. Mechanisms by which individuals or groups can raise concerns with trial funders, sponsors, and research teams in the event that a conflict or concern related to the site emerges.
    j. Mechanisms put in place to safeguard the autonomy of the stakeholder advisory mechanisms.

E. Additional guidance

1. Global Alliance for TB Drug Development. TB Drug Research Literacy Toolkit [Internet]. New York; 2011, 103p. Available from: http://www.tballiance.org/downloads/Access/community-resource-docs/TB Drug Research Literacy Toolkit First Edition.pdf (29)
2. Macaulay A, Delormier T, McComber A, Cross E, Potvin L, Paradis G, et al. Participatory research with native community of Kahnawake creates innovative Code of Research Ethics. Canadian journal of public health. 1998;89(2):105–8. (30)

5.5. Communication planning

A. Definition

The communication plan describes policies and strategies that will increase awareness of the trial; facilitate dissemination and understanding of correct information about trial design, conduct, and results; and coordinate communication between the research team and relevant stakeholders, including trial participants.

B. Relevance to good participatory practice

Ongoing, transparent, and accurate communication with relevant stakeholders, including trial participants, is critical throughout a TB drug trial: it builds trust among stakeholders, ensures respectful partnerships, and overall creates a supportive and conducive environment for the participatory process. Additionally, continued communication with volunteers beyond their active participation in the trial will help increase ownership, while potentially pre-empting the emergence of negative feelings if trial results are disappointing or concerning. Adequate planning is necessary to ensure that the objective of opening channels of communication with all stakeholders is met.

C. Special considerations

1. The communications strategy should include planning for both external communications (with community stakeholders) and internal communications (among trial coordinators and staff).
    a. A comprehensive plan that includes strategies for both internal and external communications and a clear communication cascade process for reporting concerns will allow for more effective engagement.
    b. Stakeholder communication is especially important when referring to multi-site or multi-disciplinary trials in which different research teams and different communities collaborate.
2. Certain communities adhere to specific protocols or hierarchies to guide the communication process. When it is acceptable, these should be adhered to when communicating trial-related information.

D. Good participatory practices for communication planning

Trial funders, sponsors, and research teams

1. Identify, with input from relevant stakeholders, the potential audiences within, surrounding, and outside the study site area.
    a. This should include both internal (research teams and staff) and external (potential trial participants, community members, NGOs, etc.) audiences.
2. In collaboration with relevant stakeholders, discuss and negotiate a communications plan to support open channels of communication about the trial throughout its life cycle. The plan describes the following:
    a. The information needs of the different stakeholders at various stages of the life cycle of the trial, from early phases of stakeholder engagement to recruitment, enrolment, trial closure, and results dissemination.
    b. The key messages to be communicated about the trial, such as the purpose, risks, benefits, and ongoing progress.
    c. The various communication methods and tools needed for disseminating messages to, as well as obtaining feedback from, specific stakeholders, taking into account literacy levels and language needs.
    d. Individuals, including community stakeholders, who could facilitate communication activities after receiving specific training.
    e. Procedures and timelines for disseminating information.
    f. The frequency with which the communications plan will be reviewed.
    g. The criteria by which to review the success of the communications plan.
    h. The materials and strategies used to receive and share information, including celebrity endorsements, mailing boards, outreach meetings, phone calls, press conferences, press releases, SMS, or surveys.
3. Develop communication materials in understandable language and translate them as needed.
    a. The communication materials should be developed based on the data obtained from the community mapping exercises conducted at the beginning of the research process.
    b. The materials should be tested locally before they are finalised and used broadly.
4. Publicly post the communication materials developed for a trial so they can be reviewed by stakeholders globally and improved over time.

E. Additional guidance

1. Robinson ET, Baron D, Heise LL, Moffett J, Harlan S. Communications Handbook for Clinical Trials - Strategies, tips, and tools to manage controversy, convey your message, and disseminate results [Internet]. Research Triangle Park; 2010, 280p. Available from: www.fhi360.org/en/RH/Pubs/booksReports/comm_handbook.htm (31)

5.6. Issue management planning

A. Definition

Issues management describes how research teams plan to manage concerns or unexpected developments[9] that may emerge before, during, or after a specific trial and that could limit the support for, or the success of, ongoing or future TB drug trials.

B. Relevance to good participatory practice

Identifying risks associated with the planning and conduct of TB drug trials is essential to the implementation of mitigating strategies. Considering issues ahead of time through planning allows research teams to be better equipped to deal with them as they arise, making it easier to avert a breakdown of the participatory process.

C. Special considerations

1. While some issues will be associated with all TB drug trials, the specific regimen being tested, as well as the trial population, will determine to some extent the issues with highest probability and/or priority.
2. Research teams may find it helpful to participate in forums or networks of TB trials to exchange experience and strategies for the management of risks.
3. Community stakeholders can help trial funders, sponsors, and research teams identify, understand, and foresee issues that may arise.

D. Good participatory practices for issue management planning

Trial funders, sponsors, and research teams:

1. In collaboration with community stakeholders, identify and rank by probability and possible consequences all issues they foresee that could emerge before, during, or after completion of the trial.
2. Along with relevant stakeholders, discuss and develop customised strategies to handle each of the identified issues. Customised strategies should include, if feasible:
    a. The specific actions to be taken to prevent or mitigate the issue.
    b. The person accountable for taking those actions.
    c. The resources required.
    d. The indicators that can be used as a warning sign of an emerging issue.
    e. The chain of communication within the research team and the communication strategy to be used.
    f. The key public messages created ahead of time.
    g. A process for handling information requests from community stakeholders, including local media.

[9] Examples of the types of issues that may emerge are numerous: stigmatisation and social isolation of patients by family or community; adverse events or deaths associated with the study treatments; recruitment and retention challenges; delays in ethics approvals; ethical and protocol violations; or socio-cultural taboos around certain trial procedures.

3. Along with relevant stakeholders, review the list of potential issues and the adequacy of the mitigating strategies put in place.
4. Enrol the support of community stakeholders to monitor the indicators thought to be warning signs that an issue is arising.

E. Additional guidance

1. Robinson ET, Baron D, Heise LL, Moffett J, Harlan S. Communications Handbook for Clinical Trials - Strategies, tips, and tools to manage controversy, convey your message, and disseminate results [Internet]. Research Triangle Park; 2010, 280p. Available from: www.fhi360.org/en/RH/Pubs/booksReports/comm_handbook.htm (31)
2. Centers for Disease Control and Prevention. Issue Management [Internet]. Atlanta; 2006, 4p. Available from: http://www2.cdc.gov/cdcup/library/practices_guides/CDC_UP_Issue_Management_Practices_Guide.pdf. (32)
3. Wellington Project Management. Issue Management Guidance [Internet]. Windsor; N/A, 7p. Available from: http://www.wellingtone.co.uk/Document/Issue Management Guidance - Wellingtone Advantage - v1.pdf (33)

5.7. Site activation

A. Definition

The transition period between the planning phases and the start of a TB drug trial at a site is called the site activation. It is a period during which the stakeholder advisory mechanisms that were identified as being needed are put in place.

B. Relevance to good participatory practice

Site initiation is a fertile phase of community stakeholder engagement: new structures are put in place and partnerships evolve rapidly. The participatory process is still fragile and care must be taken to address quickly any emerging issue to ensure positive resolution.

C. Special considerations

1. The site activation phase may be less delicate for sites that have had successful community stakeholder engagement programmes in the past.
2. At the time of site activation, a clear commitment to appropriate site closure (see section 5.12) must be taken. In other words, a research team should not activate a site if it is not committed to closing it appropriately.

D. Good participatory practices for site activation

Trial funders, sponsors, and research teams:

1. Ensure that the development of stakeholder advisory mechanisms is transparent to community stakeholders.
2. Monitor the site's progress towards resolving issues identified up to this point.
3. Train site staff, when necessary, on how to create respectful relationships with participants and fostering an environment that is nonjudgmental and welcoming.
4. Ensure that designated community stakeholder engagement staff have adequate knowledge and skills needed to oversee, manage, and implement the stakeholder engagement and the training plans.
5. Develop material[10] to improve community stakeholders' understanding of TB drug research and development, knowledge of the specific trial being conducted, and understanding of the role of stakeholders in TB drug trials.
6. In collaboration with community stakeholders, pilot the educational material.
7. Submit the material developed to local research ethics board, if necessary.
8. Designate staff responsible for managing activities involving stakeholder advisory mechanisms, prioritising those who have been involved in the community mapping activities.

E. Additional guidance

1. Global Alliance for TB Drug Development. TB Drug Research Literacy Toolkit [Internet]. New York; 2011 p. 103. Available from: http://www.tballiance.org/downloads/Access/community-resource-docs/TB Drug Research Literacy Toolkit First Edition.pdf (29)
2. Community Recommendations Working Group of Community Partners. Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research. Bethesda; 2009. (15)

5.8. Development of a policy on research-related harms

A. Definition

Policies on research-related harms describe both 1) how research teams will treat and compensate trial participants should they experience physical, social or other harms associated with trial participation, as well as 2) how such harms will be mitigated. A key ethical obligation of research teams is to maximise benefits and minimise harms for trial participants. Research-related harms are a reality in any drug trial; individuals and communities participating in TB drug trials are similarly prone to harms of various types and proportions.

[10] The resources should be developed in languages and formats appropriate for their target audience – including, for example, Braille, large print, and non-electronic supports.

B. Relevance to good participatory practice

Paying attention to the risk for research-related harm demonstrates respect and a commitment to the well-being of community stakeholders, which ultimately facilitates engagement. Equally important, discussing with stakeholders before a trial starts and clearly explaining how research-related harms will be mitigated can significantly influence community stakeholders' perceptions of the trial and of how well their concerns will be addressed.

C. Special considerations

1. Trial sponsors typically give specific and binding guidance to research teams on how to determine and report physical harms as adverse events. It is good practice to define similarly stringent procedures for the determination, documentation, reporting, and management of other harms (including psychological and social) that trial participants may experience. Examples of harms due to trial participation include: stigma; discrimination; anxiety; loss of economic opportunities; and verbal, emotional, or physical abuse.

D. Good participatory practices for the development of policies on research-related harms

Trial funders, sponsors, and research teams:

1. Along with relevant stakeholders, identify and list anticipated physical, psychological, social, and other types of harms that might occur due to trial participation.
2. Along with relevant stakeholders, discuss and develop policies on research-related physical, social and other harms before the start of a trial. The plan should consider the following issues:
    a. Strategies to prevent or reduce the risk of research-related harms.[11]
    b. Procedures to investigate events that have been reported indirectly, such as through a third party, while taking confidentiality issues into account.
    c. Procedures to facilitate the reporting of harms, even if not specifically required by sponsors, ethics committees, or regulatory bodies.
    d. Procedures for ensuring optimal referrals to appropriate services.
    e. Compensation or insurance policies for specific research-related harms, coverage provided by the policies, how claims are to be made, and how participants are to be informed of their rights in relation to the policies.
3. Discuss plans and procedures for research-related harms with trial participants thoroughly to ensure they understand the possible harms they might incur as a result of participating in the TB drug trial.
4. Along with relevant stakeholders, review follow-up strategies to reduce research-related physical, social and other harms over the course of the trial.

[11] For example, in communities where TB is associated with stigma and discrimination, the TB drug trial may include some masking strategies that make it difficult for community members to identify those who have active disease. Alternatively, the research team may consider preceding the trial with an educational campaign aimed at reducing stigma and discrimination.

5. Recognise that community stakeholders can provide valuable input about possible harms brought about by trial participation.

E. Additional guidance

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. [Internet]. Helsinki; 2008. Available from: http://www.wma.net/en/30publications/10policies/b3/index.html (9)
2. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects [Internet]. Geneva; 2002. Available from: www.cioms.ch/publications/layout_guide2002.pdf (11)

5.9. Trial conduct

A. Definition

The conduct of a TB drug trial as defined in this document spans from the accrual to the exit of trial participants, which includes the recruitment, screening, enrolment, treatment, retention, follow-up, and exit of participants. Though the informed consent process is part of trial conduct, it is addressed separately below.

B. Relevance to good participatory practice

Even though many stakeholders will not be directly involved in the TB drug trial, the process is likely to have important ramifications on their lives. For this reason, the way the trial is conducted has an undeniable impact on the sustainability of the participatory process overall. Given the impact a trial can have on community stakeholders after it is launched, it may be easiest to interest them in the participatory process. At the same time, due to the length of TB drug trials, attention must be paid to ensure that stakeholders do not come to a point where they suffer from ‘engagement fatigue’.

C. Special considerations

1. Regardless of recommendations made by other stakeholders, retention and follow-up strategies must respect the agreement made with each specific participant.
2. Exiting a trial after participation may lead to changes in what individuals have become accustomed to in terms of clinical care. For example, individuals may now have to pay for medical procedures that were covered by the trial during their participation. Anticipating and discussing this issue openly with community stakeholders will help in the development of appropriate exit strategies.

D. Good participatory practices for trial conduct

Trial funders, sponsors, and research teams:

1. Designate staff to manage community stakeholder engagement throughout the conduct of a trial, giving preference to individuals who have been involved since the community mapping stage.
2. Consult with relevant stakeholders about accrual, adherence, retention, and exit processes taking into account the following:
    a. Strategies and messages should be socially and culturally appropriate, meet the needs of specific stakeholders in terms of language and literacy, and draw on a range of communication modes (written, oral, and visual).
    b. Procedures must be developed to anticipate, monitor, and mitigate trial-related stigma resulting either from ineligibility to enrol or from enrolment itself.
    c. Strategies to ensure the confidentiality of participants during trial visits, follow-up outside the clinic, and after trial exit must be planned.
    d. Procedures for transfer of care after follow-up or trial exit must be discussed with the local public health authorities and community stakeholders.
3. Enlist the support of community stakeholders to mitigate trial-related stigma, misconceptions, or miscommunication while paying attention to the ethical implications of perceived coercion.
4. Provide relevant stakeholders with ongoing updates on trial accrual, informed consent, adherence, retention, and trial exit.
5. Ensure that follow-up of participants after missed visits respect agreements between the participant and research team about how to contact them.
6. Understand and support the stakeholder engagement efforts, even when delegated to specific staff members.
7. Strive to integrate the TB drug trial into the public health system by engaging relevant parties.
8. Strive for interactions with all stakeholders to be meaningful and responsive.
9. In collaboration with community stakeholders, review on an ongoing basis the composition of existing advisory mechanisms and the need for new ones to ensure that community stakeholders and their perspectives continue to be represented adequately over the course of the trial.
10. Take precautions to ensure the independence and integrity of the stakeholder advisory mechanisms, especially when they are involved in their creation or sustaining.
11. Ensure that members of advisory mechanisms who are not research staff do not participate in trial procedures, such as recruitment of prospective participants.

5.10. Informed consent process

A. Definition

Informed consent is a process by which a competent individual is provided, on an ongoing basis, with enough information about a trial to make an independent decision about participating in a trial. In this process, prospective participants learn about the trial, including the potential risks and benefits, trial procedures, and what is expected of them.

B. Relevance to good participatory practice

The informed consent process is relevant to good participatory practice in part because it is an important mechanism of information dissemination. When prospective participants are approached by a research team and then share their experience with their relatives and other community stakeholders, this constitutes a form of indirect outreach. For this reason, the experience of individuals going through the informed consent process can have a crucial impact on the ability of research teams to sustain community stakeholders' interest for the participatory process throughout the TB drug trial. In addition, planning for the informed consent process offers an excellent opportunity to develop materials and resources that can be used during other community stakeholder engagement activities.

C. Special considerations

1. The planning and preparation for informed consent discussions can themselves be the focus of community stakeholder engagement: a wide range of stakeholders, including community representatives, can help research teams develop locally acceptable and effective informed consent procedures and resources.
2. The actual implementation of the informed consent process between an individual and the research staff must be confidential and conducted in accordance with *Good Clinical Practice*.

D. Good participatory practices for informed consent

Trial funders, sponsors, and research teams:

1. Discuss the following topics with community stakeholders during the development of the informed consent materials:
    a. The general literacy level of the population to be recruited.
    b. How to assess the literacy level of prospective participants.
    c. In what languages the informed consent should be obtained.
    d. The length of the informed consent forms.
    e. The estimated time required to complete the informed consent process.
    f. Strategies to be used to facilitate comprehension of informed consent materials and critical trial-related terms and concepts, including the use of visual or audio formats, flipcharts, props, analogies, and other supportive methods.

   g. How to best explain the potential research-related harms and how they will be addressed.
2. Discuss the following topics with community stakeholders during the development of the informed consent procedures:
   a. Who needs to be consulted locally for research teams to be allowed to invite individuals to join the trial.
   b. How best to approach potential participants in a respectful way.
   c. What local cultural practices may affect individual decision-making ability, and how working within these structures can be done while ensuring the protection of individual autonomy.
   d. Considerations and requirements for illiterate participants, including discussions of who may serve appropriately as a witness to the informed consent process.
   e. Culturally and legally acceptable forms of identity verification and use of names.
   f. The legal and local definitions of a "minor" and the legal and local determinations of who can serve as a minor's guardian.
   g. Appropriate reimbursement and compensation.
   h. Appropriate strategies to ensure participants' rights are protected, including voluntariness and freedom from undue inducement.
   i. Techniques to assess comprehension of trial participation and the frequency with which they are to be used.
3. Pilot the informed consent materials and procedures with community stakeholders and improve them based on the feedback received.
4. Investigate what will be the preferred ways for participants to contact them to ask questions or express concerns about trial participation.
5. Facilitate community stakeholders' outreach to independent stakeholders when requested to do so.

E. Additional guidance

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. [Internet]. Helsinki; 2008. Available from: http://www.wma.net/en/30publications/10policies/b3/index.html (9)
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5.11. Development of a policy on access to treatment and ancillary care[12]

A. Definition

The provision of treatment and ancillary care refers to the care and treatment services made available to individuals identified as having TB and/or other diseases over the course of a research study.

B. Relevance to good participatory practice

The relevance of access to treatment and ancillary care to the participatory process in TB drug trials is two-fold. First, communities and trial participants who know that a trial sponsor is interested in their well-being are justifiably more likely to be supportive of the research. Second, improved access to treatment and ancillary care increases the health of community stakeholders, which helps ensure that they can fully partake in the engagement process. This is particularly the case in high incidence settings, which are often settings of relative deprivation and disempowerment with limited access to health care.

C. Special considerations

1. Since TB treatment guidelines vary by country, trial implementers should either provide treatment as stipulated in the trial protocol or refer to the best standard of care that is locally accessible.
2. In trials that do not follow participants for the full duration of TB treatment (such as some Phase II trials), participants should be provided access to quality TB care based on national protocols for the remainder of their treatment.
3. Treatments for multi-drug resistant tuberculosis (MDR-TB) are complicated and require access to quality-assured drug-sensitivity testing; a reliable supply of second-line drugs; and clinical expertise to define treatment and monitor progress. MDR-TB

[12] Treatment in this instance refers to any TB or trial-associated care provided to a participant. Conversely, ancillary care refers to health care that is needed but that is required neither to answer the scientific question under scrutiny nor to avoid or mitigate harm resulting from participation in the research (39).

trials should include an optimised background regimen for all participants even though quality care for MDR-TB is not available in many settings.
4. If an individual is diagnosed with a strain of TB that has few treatment options, researchers should investigate the expanded access programmes[13] available.

D. Good participatory practices for the development of policies on treatment and ancillary care

Trial funders, sponsors, and research teams:

1. Negotiate with community stakeholders what treatment and ancillary care should be made available, in particular for the following populations:
    a. Individuals who are identified with active or latent TB during the screening process but do not meet enrolment criteria.
    b. Individuals with MDR-TB.
    c. Individuals who are not responding to treatment and may need access to salvage therapy.
    d. Individuals with pre-existing co-morbidities, including HIV.
    e. Individual with health conditions identified in the course of the study.
    f. Individuals who relapse during the trial.
2. Identify local health care and support services; determine their capacities; and seek their views and perspectives.
3. Consider the impact that any service offered by the trial, or to which participants will be referred, will have on local services. Where existing services are already overburdened, research teams remain open to requests by community stakeholders that these services be provided directly.
4. Design optimal referral mechanisms in collaboration with relevant stakeholders, making sure that all individuals screened and enrolled are aware of how to access care.
5. Explore the possibility of negotiating provisions for priority access to national treatment programmes for drug-resistant TB.

E. Additional guidance

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. [Internet]. Helsinki; 2008. Available from: http://www.wma.net/en/30publications/10policies/b3/index.html (9)
2. Participants in the 2006 Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries. The ancillary-care obligations of medical researchers working in developing countries. PLoS Medicine. 2008 May 20;5(5):e90. (36)

[13] Expanded access refers to the use of an investigational product outside of a given trial by patients with serious or life-threatening conditions who do not meet the enrollment criteria for the clinical trial in progress. Access can be granted directly ('compassionate use') or as part of expanded access studies. The term 'Name Patient Program' is also frequently used.

5.12. Site closure

A. Definition

Trial site closure occurs when all participants at a site have exited from a specific trial and all trial-related procedures have been completed. It is different from trial or study closure, which implies that all sites participating in the trial have been closed individually. When multiple trials are ongoing at a site, 'site closure' is trial-specific.

B. Relevance to good participatory practice

Effectively engaging relevant stakeholders about the process of site closure in a transparent process is essential for sustaining trust and laying a positive foundation for future research. In the event that a site is stopped early or unexpectedly, proactive initiation of a dialogue with relevant stakeholders will minimise the risk of misinformation.

C. Special considerations

1. Sites may run trials to completion or they may stop them early. Reasons for stopping trials early may be trial-related (e.g. evidence of a clear protective effect, harm, or futility). Trials may also be stopped at the site level due to unforeseen circumstances, such as administrative or financial reasons, local objection, or sudden social unrest. Different reasons for closure at the site level will require different approaches to stakeholder engagement.
2. In multi-country or multi-site trials, sites may complete participant follow-up at different times. Thus, while some sites might be closed for participant follow-up, research teams at other locations may continue to see participants.
3. Plans for results dissemination at the local level must be put in place by the time a site is closed.

D. Good participatory practices for site closure

Trial funders, sponsors, and research teams:

1. Develop a site closure plan with relevant stakeholders early in the research life cycle. The plan addresses a range of possible closure scenarios, including:
    a. Trial closure as scheduled per protocol.
    b. Early closure due to evidence of harm, futility, or clear protective benefit in interim analyses of trial data.
    c. Early closure because of evidence of harm or of clear protective benefit from a different trial evaluating the same product.
    d. Early closure due to unforeseen circumstances.
2. Ensure that the closure plan and scenarios are discussed in detail with trial participants, including during the informed consent process.
3. Organise in collaboration with community stakeholders an exit and/or award reception for participants and community members.

4. Inform community stakeholders of timelines regarding trial closure and results dissemination.
5. Write a final report detailing and evaluating the stakeholder engagement process used at the site level.

5.13. Trial closure and results dissemination

A. Definition

Trial closure refers to the completion of all trial-related activities, including follow-up, across all participating sites. At the time of trial closure, all sites have been closed. Following trial closure, once the data have been analysed, study results are disseminated to participants, stakeholders, and the public at large.

B. Relevance to good participatory practice

Engaging relevant stakeholders about trial closure and results dissemination in a transparent process is essential for sustaining trust and laying a positive foundation for future research. In the event that a trial as a whole is stopped early or unexpectedly, proactive initiation of a dialogue with relevant stakeholders about available results will minimise the risk of misinformation.

C. Special considerations

1. Trials may run to completion as per protocol or may be stopped early. Reasons for stopping trials early may be evidence of a clear protective effect, harm, or futility. Trials may also stop early due to other unforeseen circumstances, such as administrative reasons or stakeholder objection. Stakeholder engagement should be tailored to the reasons underlying trial closure.
2. Where trial product manufacturers are publicly traded companies, there may be legal requirements that affect the timing and methods for public announcement of a trial closure.
3. At the close of a trial, participants should be the first to be informed of the results when possible. Although this may represent a challenging issue in trials that have lengthy time courses such as TB drug trials, efforts should be made to ensure that participants are informed of the results by the research team before they are communicated externally with the public and the media. This will ensure that the information is communicated from a trusted source and in a reliable manner.
4. Ownership of data, issues of publication, and release of trial results vary by trial and may be delineated by sponsors or product manufacturers.

D. Good participatory practices for trial closure and results dissemination

Trial funders, sponsors, and research teams:

1. Ensure that trial closure scenarios are discussed in detail with trial participants, including during the informed consent process.

2. Consult with relevant stakeholders, and particularly the stakeholder advisory mechanisms that were in place during the trial, to develop a results dissemination plan that details the following issues:
    a. Strategies to manage expectations about trial results, including by preparing participants and relevant stakeholders for *all* possible outcomes.
    b. Planned timelines for site and overall trial closure, data analysis, and availability of results.
    c. Procedures and timelines for those who will be informed of trial results in confidence prior to public release.
    d. Process for the development, piloting and finalisation of key messages once the trial results are known by the research teams.
    e. Range of communication methods to be used to disseminate the results.
    f. Roles and responsibilities of the various parties (e.g. possible involvement of stakeholder advisory mechanisms).
    g. How the communication plan will explain the implications of the results for the geographical area where the trial was conducted; the limitations of the trial; and the generalisability of the trial's findings.
    h. How to best disseminate trial results that may be of a sensitive nature or that may put certain individuals or groups at risk of harm or stigmatisation.
    i. Procedures for contacting and informing trial participants of research results before they are announced publicly.
    j. Whether and how to disseminate additional findings that are not related to the primary trial question but that may be of interest to some stakeholders.
    k. How and when participants will be informed of their trial group assignment (randomisation).
    l. Issues around ownership of the data, data access, and publication – including how the research team will facilitate community stakeholders' access to the published results of the trial.
    m. How the community stakeholder's responses to the results will be systematically collected and documented.[14]
3. Ensure, whenever possible, that trial participants are provided with opportunities to learn about the trial results before they are announced publicly.

5.14. Access to investigational products

A. Definition

Access to investigational products refers both to making the compound tested in the trial available to trial participants and local community stakeholders 1) after it is approved by relevant authorities and 2) before it is approved but after it is scientifically validated – i.e. after an efficacy or effectiveness trial has a compelling positive finding, with no or minimal safety concerns.

[14] Although community stakeholder agreement may not be a prerequisite for publishing or sharing research results in a scientific forum, it is important that the community stakeholders' interpretations of the results be noted – particularly if they differ from predominant scientific analyses.

Access to investigational products outside of trials is normally granted after approval and registration of the drug by national drug regulatory authorities. After approval, post-study access can be facilitated by demand-driven pricing, drug donations, follow-on studies, etc. Before approval of a new drug, it may also be possible for communities and individuals to gain access as part of an expanded access program or as part of follow-on studies (open label, etc.).

B. Relevance to good participatory practice

How trial funders, sponsors, and research teams communicate and interact with community stakeholders about issues of access to the investigational product under study is likely to have a significant influence on community stakeholder perceptions of a trial. Research ethics calls for maximising benefits to stakeholders who participate in research and so it is commonly received that testing a new product in a population that will not have access to the product once proven efficacious is exploitative. In recognition of their contribution, communities participating in research are thus to be among the first to gain access to investigational products found to be safe and effective.

C. Special considerations

1. The availability of newly identified products to trial participants and other community stakeholders will depend on the product being tested.
2. After a trial is completed, other trials may be needed to corroborate safety and/or effectiveness findings.
3. National regulatory authorities make the ultimate decision as to whether an investigational product is approved for use within a particular country. After results from trials are available, it may take time for the appropriate agency to approve the investigational product. Approval processes and timelines will also differ by product.
4. National regulatory authorities make the ultimate decision about whether or not an expanded access program can be put in place.
5. Availability and pricing of new products may be affected by product-manufacturer parameters as well as by agreements with trial sponsors.

D. Good participatory practices for post-trial access to investigational products

Trial funders, sponsors, and research teams:

1. Discuss with relevant stakeholders early in the trial process about issues affecting future product availability, including the need for corroborated biomedical evidence; pursuit of licensure; expanded access programmes; production rights; and additional marketing and distribution research.
2. When conducting efficacy or effectiveness trials, discuss with relevant stakeholders, early in the trial life cycle, expectations about possible pre-licensure access and plans for follow-on, open label, or other such studies.
3. Collaborate with multiple stakeholders, such as development partners, local governments, and NGOs to design and support the overall access strategy.

4. Discuss openly how pre-licensure access will be funded, if scientifically warranted.
5. Along with relevant stakeholders, develop a clear strategy and funding mechanisms to make the product available to participants rapidly, affordably, and sustainably.
6. Discuss, negotiate, and agree on responsibilities and funding requirements with national governments concerning licensure requirements and access issues.
7. Inform community stakeholders of their rights, the access plan, and the factors that could postpone or prevent their gaining access to the new – such as the need to secure regulatory approvals.
8. Provide community stakeholders with updates as they become available.

E. Additional guidance

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. [Internet]. Helsinki; 2008. Available from: http://www.wma.net/en/30publications/10policies/b3/index.html (9)
2. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects [Internet]. Geneva; 2002. Available from: www.cioms.ch/publications/layout_guide2002.pdf (11)
3. National Bioethics Advisory Commission. Ethical and policy issues in international research: Clinical trials in developing countries [Internet]. Bethesda; 2001 p. 154. Available from: http://bioethics.georgetown.edu/nbac/pubs.html (37)

Conclusion

With growing rates of drug resistance and the lengthy time course of treatment regimens, biomedical research will be essential to the continued fight against TB. As discussed in Section 3, there are good reasons to believe that stakeholder engagement should become an essential component of TB drug trials. The GPP-TB, adapted from the original *Good Participatory Practice* guidelines developed by UNAIDS and AVAC, fill an important gap in the TB research literature by proposing the only set of global guidelines directly addressing how to engage stakeholders in the design, conduct, and outcome of TB drug trials.

In line with the original *Good Participatory Practice* guidelines, the GPP-TB propose that adherence to good participatory practices is an investment that benefits the research process by levelling the significant power imbalances that can otherwise exist between all stakeholders having legitimate interest in a given TB drug trial. As such, a core aim of the guidelines is ultimately to enhance the opportunities of individuals and groups who are most vulnerable to TB and its impacts to make valuable contributions throughout the life cycle of a drug trial. In particular, the GPP-TB guidelines help build community stakeholder capacity for more robust engagement in the TB research process and increase decision-making opportunities.

In putting forth the GPP-TB, the SCE-WG of the CPTR initiative recognises that investing in establishing mutually respectful relationships and building the capacity of stakeholders is a long-term process that should extend throughout and beyond the life cycle of any single drug trial. This latter aspect may prove challenging, but being able to support key staff at trial sites and sustain relationships with local partners beyond the course of a trial will likely prove invaluable to the TB research globally in the long-term. For this reason, it is important to reiterate that effective stakeholder engagement can only exist when appropriate resources are made available and when proponents of engagement are not isolated within a research team.

In closing, we would like to invite readers to submit recommendations for modifications and refinements of the current guidelines. With the number of TB drug trials set to increase in the coming years, it is important that experiences with stakeholder engagement be recorded and used to enhance the value and relevance of the GPP-TB. Recommendations can be sent to info@gpptb.org.

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Appendix 1: Additional Online Resources

1. Community Involvement in TB research
   Book chapter, *Priorities in Operational Research to Improve TB Care and Control*
   http://whqlibdoc.who.int/publications/2011/9789241548250_eng.pdf

2. Community Engagement in Clinical Trials
   Briefing paper
   http://www.tballiance.org/downloads/Access/Community-Engagement-in-Clinical-Trials.pdf

3. CREATE's Policy and Advocacy Resources
   Database of resources
   http://www.tbhiv-create.org/resources/policy_advocacy

4. Find TB Resources
   Database of resources
   http://www.findtbresources.org/

5. Community Advisory Boards, REMox TB trial, and World TB Day
   News and events
   http://www.tballiance.org/newscenter/view-brief.php?id=978

6. Engaging Community in Tuberculosis Research
   Report
   http://www.tbhiv-create.org/sites/default/files/EngagingCommunityinResearch_Oct16Report%5Bofficialversion%5D.pdf

7. Partnership Assessment Toolkit
   Toolkit
   http://www.ccghr.ca/Resources/Documents/Resources/PAT_Interactive_e.pdf

8. TB Drug Research Literacy Toolkit
   Toolkit
   http://www.tballiance.org/downloads/Access/community-resource-docs/TB Drug Research Literacy Toolkit First Edition.pdf

A Work of the CPTR initiative
Stakeholder & Community Engagement Workgroup
www.cptrinitiative.org

In Collaboration with AVAC
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