

GPP at TB Alliance

Engagement across discovery, development and delivery

Stephanie Seidel / Robyn Waite GPP Webinar June 12, 2024



TB Alliance is a not-for-profit organization dedicated to the discovery, development and delivery of better, faster-acting and affordable tuberculosis drugs that are available to those in need.



Delivering on the Promise



Discover

- Immunotherapies
- Artificial intelligence
- Long-acting injectables
- Active disease and latent infection
- Adjacent diseases (NTM)

Novel Targets and Classes New Technology



Develop

- Clinical efficacy
- Formulation sciences
- Multilateral consortia
- Active disease and latent infection
- Adjacent diseases (NTM)

Novel, Universal Treatment



Deliver

- Global, national subnational
- Earlier market and feasibility work
- Increased diagnosis for increased treatment

Widely Adopted, Affordable Available Treatment



GROUNDED IN COMMUNITY, EQUITY AND CONTINUOUS FEEDBACK LOOP

Engagement in TB Drug R&D: TB Alliance CE Program

- Good Participatory Practice (GPP) a cornerstone of our CE strategy
- CE program began in 2007 Phase 3 clinical trial (ReMox) to develop new models for engagement in TB R&D
- Developed a large network of site-level CE strategies for TB drug trials using a variety of sitelevel engagement mechanisms
- Support CE from site selection to results publication and dissemination
- Funding site-level CE strategies in Phase 2 and Phase 3 clinical trials
- Helping to build sustainable models of CE at the research site-level, while committing to engagement at all levels and across the entire discovery, development and delivery pipeline



GPP-TB Guidelines

Adapted by the Stakeholder and Community Engagement Workgroup of CPTR in 2012

Represents a commitment of all stakeholders to:

- Create a beneficial, respectful, sustained and transparent partnership between researchers and communities throughout the trial process
- Address the interests of all stakeholders in specific clinical trials

Supports the ethical and scientifically rigorous conduct of TB drug clinical trials

Promotes a shared responsibility for implementation of TB drug trials

View guidelines **HERE**





Supporting CE Strategies at the Site Level

Empowering stakeholders to participate in the TB R&D process by supporting an **enabling environment**

Increasing knowledge and understanding about TB and TB drug research through education and skills building

> Research Literacy

Cross-Site Engagement

Providing opportunities for sites to learn from one another, discuss best practices and challenges, and develop new skills

Supporting local CE leadership, peer-to-peer mentoring, guidance and evaluation

CE Leadership

Funding Mechanisms

Supporting sustainable CE strategies across clinical trial programs by providing funding, guidance and technical assistance

Shared commitment to global standards for stakeholder engagement in TB drug trials

Good Participatory
Practice



Principles of Community Engagement

Responsibility Enabling and participating in engagement **Sustainability** Supporting CE from planning to results dissemination Consultation Proactively seeking input from stakeholders Respect Understanding the needs of local stakeholders **Partnership** Strengthening relationships Preparing stakeholders for research outcomes **Transparency** Joining communities in the fight to end TB Advocacy



Patience Molefe, CAB Member, PHRU



Supporting CE Strategies at the Site Level

Best Practices

- Early CAB consultation: study design, feasibility and acceptability, possible barriers to participation
- CE start-up at least 6 months prior to trial initiation
- Strong relationships with clinic nurses, frequent visits, education, reinforcement of knowledge
- Broad community sensitization to clinical trial
- Co-development of local and cross-trial CE strategies based on shared principles of engagement
- Incorporation of CE staff into clinical operations teams at sponsor and local research site levels

Lessons Learned

- Trust and understanding of trials can lead to partnership and advocacy
- Engagement with community at local and global levels is critical for success of TB drug R&D
- Dedicated CE staff on site-level research teams play a key role in clinical trials and need to be supported with funding
- CABs need to be supported for their time and participation and given autonomy
- Recruitment and retention can be improved where strong engagement mechanisms are in place
- Inclusion of groups underserved by TB trials in CABs can improve the R&D process



Cross-Site Coordinated Strategies for Successful Trial Outcomes

Case Example: BPaMZ/Semen Study



Phinda Galela, 8th South African TB Conference, June 2024. *Engagement of Males with Pulmonary Drug-Resistant Tuberculosis for Participation in Pretomanid Regimen (BPaMZ) Testicular Safety Study*







Securing Access to New Treatments for All

We work with community partners in high-burden countries on custom approaches in countries.



Awareness raising and education



Advocacy and political engagement



Community education and capacity building

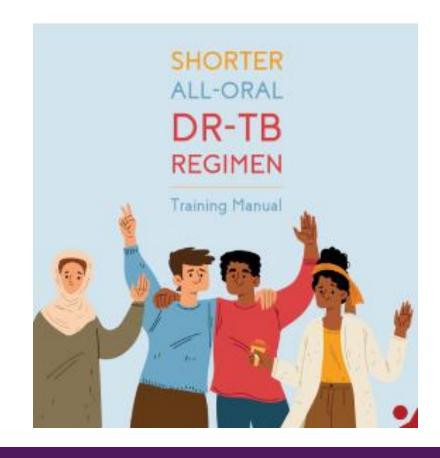


TB Community Education and Capacity Building

GCTA creates and distributes community brochures and training manuals on new DR-TB treatments.

Empowering communities and civil society to engage effectively in the TB response can play a major role addressing challenges:

- finding missing people with TB
- ensuring early diagnosis and initiation of treatment
- treatment adherence and loss to follow up
- treatment success rates
- stigma
- reaching and working with key vulnerable populations
- · demand for new tools
- low engagement between the NTP with civil society and TB affected communities
- and more (recall Declaration of Alma Alta, September 1978).





Public Awareness Raising and Education

Fast Track the Cure and #6MonthsMax social media and influencer campaigns

- Check out @FastTrackTheCure on Instagram, YouTube, Twitter and Facebook.
- Partners are finding, developing, and delivering BPaL/M user stories.
- With greater public awareness of new treatments, people are equipped and empowered to demand access and understand treatment options.
- With greater understanding of the facts of new treatments, people are less hesitant, more likely to complete treatment and better supported by their peers.



Screenshot of the @FastTracktheCure Instagram page



Advocacy and Political Engagement

TB People Philippines engages local mayors across cities with an ask to Fast Track the Cure.



Mayor Lucy Torres Gomez representing Ormoc City records a video message making a commitment to fast-track access to new treatments for DR-TB in her community.

- Despite new treatments becoming available and being recommended by WHO, national TB programs could take a long time to shift from old to new regimens.
 Targeted advocacy can help speed adoption.
- With political champions and buy-in, new regimens can be rolled out programmatically nationwide fast.
- Without champions, roll-out can be unduly protracted.
- Political support means resources for the cause.
- Strong civil society is worth investing in to Fast Track the Cure and create healthy societies.



Supporting NTPs with Community Engagement

Together with partners, we launched PeerLINC as a model for peer-to-peer learning and knowledge exchange — with community engagement at the core of training and planning.



This is a slide from the PeerLINC community engagement training module, which is presented to all NTP staff participants on country trainings.

Where and how to engage communities

Communities should for example, engage in:

- · development of strategic plans for TB,
- · programme reviews,
- technical working groups,
- advocacy (including for resource mobilization and/or demand creation)
- monitoring and evaluation activities,
- · community-led monitoring,
- research and provision of TB services.

To engage meaningfully and effectively, communities need enabling environments with:

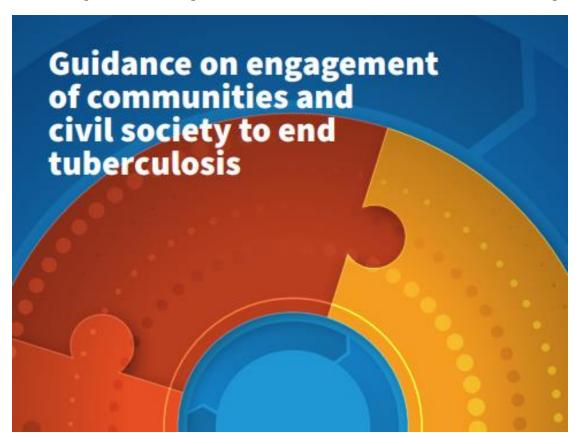
- sustainable financing,
- · supportive legal and policy frameworks,
- coordination platforms to discuss with ministries of health and their NTPs,
- continuous learning and capacity building,
- access to information,
- support for an "equal partnership" in the entire process (planning to service delivery monitoring)

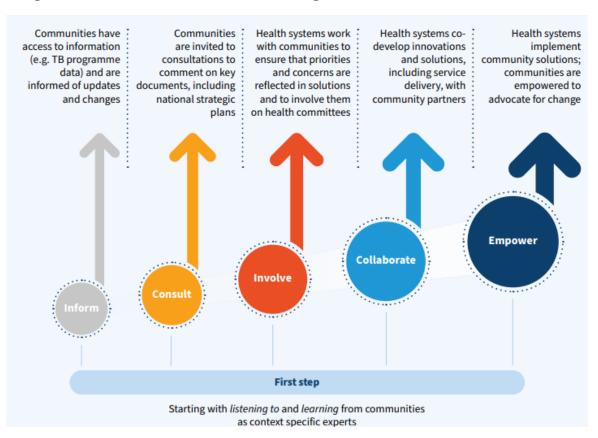
15 | COMMUNITY ENGAGEMENT



Foundation for Delivery GPP Work and PeerLINC

Best practice published in 2023 and developed by the WHO Civil Society Task Force







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