MDR-TB Clinical Trial Capacity Building Webinar Series

Community Engagement for MDR-TB Clinical Trials

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REDE-TB
Webinar Objectives

• To describe the role and objectives of community engagement (CE) in clinical research
• To describe models for CE
• To address practical aspects of CE implementation including resource requirements
Webinar Outline

1. What is CE and why is it important for MDR-TB trials?
2. Objectives of CE
3. Methods and Means
4. Examples of CE in TB trials
5. Practice aspects of implementing CE activities
6. Q&A
1. What is CE and why is it important for MDR-TB trials?

• What is CE?
  - Communication and cooperation among representatives of affected communities, researchers, developers, governments
  - Lessons learned and practices from HIV/AIDS into TB

• Why CE for MDR-TB Clinical Trials?
  - CE provides information, support, and understanding around the context of the disease and treatment
CE in TB Trials

• Context: difficult to implement policies and guidelines, lack of transparency, no innovation, no new tool for decades

• How CE in TB trials started – 16 years on the road
  - TB social mobilization in Rio de Janeiro State TB Program, 2002
  - First TAG TB capacity building for HIV advocates, Union Conference, 2002

• Ethical requirement for any tuberculosis trials

• Good Participatory Practices in research

• Accountability mechanism
  - To the society, governments and donors, study participants and affected communities
Benefits of CE

• Improves feedback to researchers of real scenario, context, needs to overcome research obstacles (regulatory agencies, info dissemination, recruitment)
• Increases feedback to governments on performance of health system
• Informs stakeholders of new developments and opportunities
• Legitimates clinical studies
• Supports evidence-based advocacy for policy change
2. Objectives – What does CE aim to achieve?

• Same objectives as TB programs and governments
  - Improve care; decrease incidence; increase cure rates; eliminate TB

• Bridging researchers and communities
  - Concept of CABs (Treatment Action Group)
  - Policy transfer from HIV/AIDS to TB trials*
  - Effort by community advocates to work in the academic environment and conduct research since 1990s, Brazil**

• How?
  - Understand the health system, treatment, and research
  - Meet the needs of people affected
  - Adopt better tools and technologies while understanding country context

*Santos Filho, ET. Movimento social e mudanças das políticas públicas de tuberculose no Brasil, UFRJ: 2015.

3. Means and Methods

The STREAM CE example:

1. Sensitize
2. Map
3. Engage
4. Educate
5. Follow up
6. Interact
7. Document
Community Advisory Boards (CABs)

- CE can be conducted through a CAB
- Administration and management
- Workplan
- Budget
Who is part of the CAB?

- Affected people
- Members of community based organizations
- Health advocates
4. Examples of CE in TB Trials
Evidence CE in TB research is worthwhile

Contributions to diverse studies, presentations, publications from:

- TBTC-CDC
- CRAG
- CREATE
- TB Alliance
- TREAT TB
Engagement in research as a strategic choice

REDE-TB

- Seminars of Communities & Research, 2007 & 2009
- PROVE-IT CABs, Brazil
- STREAM, CE component
- Brazilian National TB CAB
CABs at STREAM Stage 2 Sites

- Ethiopia (2)
- Georgia
- India (2)
- Moldova
- Mongolia
- South Africa (4)
- Uganda
STREAM Stage 1 preliminary results dissemination

- Common dissemination plan for all sites
- Provided information to stakeholders, partners
- Interaction of local research team with representatives from affected communities, trial participants and family members
  - Study results made simple and in local languages
  - Consulted local researchers and CAB coordinators prior to dissemination events
  - Increased ownership of the research by trial participants and affected communities
  - Strengthen study’s legitimacy to the country
- Prepared us for STREAM Stage 2 dissemination – using strategic information to generate common understanding of study results and potential application in each country context.
Findings from Dissemination of Preliminary STREAM Stage 1 Results

• Interest and appreciation from stakeholders

• Respect to participants

• Participating in a clinical study matters
  - Even if inconclusive, results are important and inform services
  - Practice towards better schemes: improvement for most impactful choices
  - Learning practice towards significant change

Source: Notes and reports from Dissemination activities, March 2018
PROVE-IT

• Comparing MDR-TB rapid diagnostic tools (Xpert, MGIT960, LPA) in programmatic conditions
• Aimed to offer the most appropriate algorithm for public services
• CE in PROVE-IT
  - 5 CABs formed at each Brazilian site
  - Active participation in recruitment process
  - CAB members reviewed the protocol analysis and tools before ethical and scientific approval
  - CAB members actively, regularly sharing information on TB State Committees
• Results
  - Contribution in ethical revision, recruitment and dissemination of results
  - Empowerment of communities engaging in research
  - First experience with CE for most TB researchers
THRIO (CREATE)

- Implementation of testing for TB and isoniazid prophylaxis among persons living with HIV. The primary goal was to reduce incident TB disease in the HIV clinic population.

- CE in THRIO
  - CAB formed in 2005 prior to approval of protocol
  - Ongoing discussion with the communities – improved uptake of isoniazid prophylaxis during intervention
  - Results dissemination
  - When demobilized, healthcare workers did not proceed to tuberculin testing or prophylaxis with isoniazid
  - Very well structured initiative with dedicated personnel
  - Engagement of communities has to be regular part of services!!!
5. Practical aspects of implementing community engagement activities
What are the mechanisms we need?

• Apply Good Clinical Practices, Helsinki Declaration
• More than recommend – donors should require TB researchers to engage communities
• Regular funding structure
• Generate and maintain capacity for CE
• Develop structures for ongoing engagement of community representatives – before protocol approval to results dissemination
• Continued education
• Community participation in the creation of a national TB research agenda

*It is possible, AIDS community does it! (see ACTG and others)*
Some concrete tips

Engage and participate

• Understand to whom you are speaking: clear and transparent language
• Share results local participants: they are the ones who matter
• Consult and listen – consider different perceptions
• Document experiences
A robust list of partners in CE

- Made possible by donors investing in communities and research
  - U.S. Government – USAID
  - Open Society Foundations
  - Bill and Melinda Gates Foundation
  - ANRS, French Government
  - Other European Agencies
  - U.K. Government
  - Canadian Government
  - Brazilian Government
  - ... others ...BRICS!

- Time for increased investment by other donors
Where we can improve together

• Follow-up, share information
• Communication – internal and external
• Use new tools – e.g. FB and social media
• Training (protocol aspects, health economics)
• Cross learning among sites
• Engage communities early and throughout research process to increase their input
• Engage community representatives before protocols are submitted for approval
• Raise awareness among researchers about the importance and benefits of CE
• Share and discuss results with communities, even if results are not what were expected
6. Questions
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