STREAM
Community Engagement Plan

2016 – 2021

treat TB

Technology, Research, Education,
and Technical Assistance for Tuberculosis

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International Union Against
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Overview

When clinical research is undertaken in a community, there is a need to incorporate the community structures. The research that is proposed must fulfill health related needs within the community. In addition, community members need to have some understanding of research itself, ethics, and regulatory requirements. To achieve this in a meaningful way, a shared and trusted structure of communication needs to be established via a community engagement (CE) plan.

Little is known in many communities about multidrug-resistant tuberculosis (MDR-TB), including communities with a high tuberculosis (TB) burden. The existing standard treatment regimen for MDR-TB lasts up to 24 months and requires daily intramuscular injections for which permanent hearing loss is a serious side effect. The current standard of care is based on expert opinion and not on randomized controlled clinical trials. The current regimens pose a significant burden for both patients and health systems tasked with administering treatment.

Stage 1 of STREAM was the first randomized controlled clinical trial for a new 9-month MDR-TB treatment regimen. Results of this stage are expected in late 2017. In the second stage, a new anti-TB medicine bedaquiline will be tested in two new regimens: a 6-month regimen and an all-oral 9-month regimen. Results are expected in 2021.

The STREAM Community Engagement Plan is a guide to creating opportunity for communication and cooperation among local stakeholders (i.e., TB/HIV activists, community representatives, health professionals, researchers, and program managers). Through CE, local communities can access and be involved in trial implementation. Consequently, they can maximize benefits gained for the local community while giving researchers a realistic perspective of local health system functions that aids in successful trial completion. CE improves research literacy in the communities, builds sustainable partnerships, and provides legitimacy to trial goals and objectives. Ultimately, this engagement will generate advocacy around trial results and help to legitimize the implementation of trial results in the health system. This plan acknowledges the importance of upholding principles from Good Participatory Guidelines for TB Drug Trials 2012.

The World Health Organization recommends CE efforts against TB to strengthen stakeholders' commitments to improve access to prevention, diagnostics, treatment, and care. The International Union Against Tuberculosis and Lung Disease (The Union), REDE-TB (The Brazilian Network of TB Researchers) and other partners will support CE efforts for the STREAM clinical trial. STREAM Stage 2 CE activities are built upon pilot CE activities in Stage 1 with consideration for site and cultural conditions.

The STREAM CE Plan builds upon the CE experience of the Policy Relevant Outcomes from Validating Evidence on Impact (PROVE IT). This trial, which assessed costs associated with the roll-out of Line Probe Assays, was implemented in part by REDE-TB with support from The Union. A community advisory board (CAB) of local stakeholders was formed at each site in Brazil to share study development and help overcome challenges. These CABs were successful due to the preexisting culture of CE, close contact with committees and policy forums, local expertise, knowledge of health system functions, and cooperation of stakeholders.

Objectives

SHORT TERM

- Assess community's needs, and capacity for MDR-TB research involvement
- Establish CE mechanism (e.g., CAB)

MEDIUM TERM

- Improve communication and cooperation between community representatives and researchers
- Improve treatment and research literacy of community representatives
- Allow community participants to give input on and resolve challenges for the trial

LONG TERM

- Establish sustainable culture of community participation in research locally
- Generate advocacy around implementation of trial results in health system
- Share local CE experiences globally

Activities

This plan promotes culturally sensitive and comprehensive community engagement and full use of local expertise to guide trial implementation. Not all sites may be able to implement the optimal model of CE, especially where no CE activities have previously been undertaken. Nonetheless, all trial sites can learn from this plan, from documented progress in other sites throughout the trial, and, at minimum, take the initial steps towards a successful CE experience. CE and STREAM teams will assess the local capacity to tailor CE efforts in each country.

Ezio Tavora and REDE-TB will be a lead resource for CE throughout the trial. In addition to developing this plan, the CE team has conducted a pilot program in Mongolia – lessons from which can guide future CE efforts in other STREAM sites (refer to Appendix A). The team will also provide direction to other STREAM sites where activities may be in progress or undertaken by other STREAM partners.

The optimal model for CE is organized around seven concepts: **sensitize, map, engage, educate, follow up, interact, and document.** Activities conducted simultaneously or consecutively complement each other and promote a consistent effort in order to achieve short, medium, and long term goals.

1. Sensitize

- **Sensitize health authorities (e.g., managers of the National TB program (NTP), local authorities, and partners involved)**
- **Introduce trial members (e.g., researchers, health professionals) to program managers**

As STREAM CE will be conducted in different cultural contexts, it is essential to approach local stakeholders to explain CE objectives and strategy in the initial phases of the trial.

This initial contact allows STREAM to:

- invite stakeholders to participate in a CE seminar;
- present experiences from other studies and credentials of the team;
- request support and authorization to develop CE;
- understand local dynamics and culture regarding community representation from the perspective of local authorities;
- assess willingness of researchers, health professionals, and authorities to work with community representatives.

2. Map

Map local community organizations

Mapping local communities permits a better understanding of:

- local culture and practices;
- community's relationship with researchers and health authorities;
- local TB and research literacy;
- conditions and willingness to engage in research follow up to form a CAB or committee.

One entry point will be the Country Coordinating Mechanisms (CCMs) of the Global Fund (in countries where they exist) due to their international multi-sector nature. Organizations participating in the CCM will likely understand and maybe even practice oversight, as it is a basic requirement for CCMs. Community representatives with all levels of TB knowledge or research skill will be encouraged to participate in STREAM CE efforts.

3. Engage

- **First local workshop**
- **First local seminar**

At the first local workshop, community activists and representatives of people affected brainstorm and agree on ways to promote their participation in STREAM. At the seminar, the stakeholders are expected to understand and support community participation in the trial. By the end of the seminar, stakeholders will agree on a model of CE, with CABs as one option.

4. Educate

- **Basic TB and research literacy workshop**
- **Annual training of trainers (ToT)**
- **Education via CAB or regular meetings**

TB and research education is important to boosting interest and understanding in the trial and its objectives. The first workshop and seminar will be shaped in accordance to TB and research literacy of local community representatives.

Regular interaction between sites will provide the opportunity for community (or CAB) coordinators from each STREAM site to broaden skills and share experiences with each other. This exchange of information may occur both online and in person.

As the CE Team continuously provides support to the local coordinators, communities are expected to increase their knowledge of TB, research, and the STREAM trial.

5. Follow up

- **Supporting focal points**
- **CAB coordinators; Cross site learning**
- **Follow-up assessments**

CE Team and Union partners will follow up with STREAM sites via Skype, e-mail, and other online platforms to support the ongoing CE efforts and expansion of community activities (i.e., CABs or regular meetings) for the trial. Local community coordinators will regularly report challenges and achievements, and collectively strategize solutions. Where possible, the CE team or partners will conduct follow-up assessments to further aid sites.

6. Interact

Regular meetings to report and present outcomes.
Community representatives will be encouraged to present progress and outcomes in forums such as the annual Union conference. The conference provides an ideal opportunity to publicize CE efforts and allow representatives to learn about other community, policy, and research experiences around the globe.

7. Document

Publish the CE experience in STREAM
The outcomes of STREAM CE should be well documented and published to highlight CE best practices in MDR-TB trials.

Appendix A

Mongolia CE Pilot: The STREAM Mongolia CAB

Background

Ulaanbaatar, the nation's capital, is home to approximately 46% (1.377 million in 2015[1]) of Mongolia's population (2.993 million estimate in 2015[1]). The STREAM Stage 2 trial site is located in Ulaanbaatar at the National Communicable Disease Department (NCCD) of the Ministry of Health (MOH) with linkage to the TB National Reference Laboratory. In 2014, the World Health Organization (WHO) estimated an incidence of 5,000 new cases, representing 170/100,000 population.[2] The National Drug Resistance Survey of 2007 estimated a prevalence of 1.4% MDR among all TB cases.[2] Although not among the 27 high burden MDR-TB countries,[3] the annual 225 MDR-TB among newly diagnosed and retreated cases (estimated in 2014)[4] represent high risk for a country with a TB incidence of that magnitude and with other severe respiratory issues due to heavy air pollution and poor living standards.[5] The STREAM Stage 2 CE was piloted in Mongolia in late 2015 under an agreement between REDE-TB and the Union.

Objectives

Objectives of this pilot were to generate understanding of the trial by improving research and treatment literacy, and promote engagement and advocacy in adopting new practices and treatment guidelines based on trial results. This was done through engaging community representatives and organizing a locally led CAB.

Activities

CE activities of the pilot can be divided in four parts: 1) map, meet, and engage stakeholders; 2) train trainers send interactive messages to community participants while avoiding highly technical language; 3) deliver events via CE workshop and seminar; 4) decide on CAB meetings. Plans were made to use HIV/AIDS expertise in community mobilization and also to integrate efforts with the local Global Fund CCM.

Though mapping revealed that TB-HIV is considered a small issue due to low HIV/AIDS prevalence, educating stakeholders on TB significantly bolstered CAB participation in December 2015. In Mongolia, community mobilization is structured around community health care workers who deliver DOT and conduct outreach. TB organizations were invited to a TB treatment and research literacy workshop that introduced STREAM, and were encouraged to established their own meeting format. A dedicated team was formed with qualified individuals, some of whom had experience with TB CABs.

The CE team approached the Secretariat of the CCM and the Principal Recipient Offices who were supportive, actively participated in the sessions, and helped mobilize participants. As a partner of the NCCD in the implementation of STREAM and also Vice-Chair of the Mongolian CCM, the Mongolian TB Coalition (MTC) is an association of health professionals led by Dr. Naranbat, a former NTP Manager of over ten years. Though MTC is a small organization, the support of Dr. Gankhuu was key to networking with local organizations and personally helping to settle and coordinate activities.

1 The World Factbook 2013-14. Washington, DC: Central Intelligence Agency, 2013. https://www.cia.gov/library/publications/the-world-factbook/geos/mg.html

2 Global TB Report 2015. Geneva: WHO, 2015. http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf, p.159, p.183

3 The use of high burden country lists for TB by WHO in the pos-2015 era. Geneva: WHO, 2015. http://www.who.int/tb/publications/global_report/high_tb_burdencountrylists2016-2020.pdf

4 Mongolia Tuberculosis Profile. Geneva: WHO, 2014. https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MN&LAN=EN&outtype=pdf

5 SAIJAA N. "Air pollution and health – Ulaanbaatar city of Mongolia". Ulaanbaatar: Environmental Health and Human Ecology Center, Public Health Institute, 2010. http://www.mongolhealthnetwork.org/presentations/2010/1009_Air_pollution_and_Health_Saijaa_Eng_HROs_Meeting_092910_01.ppt

The CE team visited diverse key institutions and organizations, introducing the STREAM CE Pilot in Mongolia, and inviting the following stakeholders to participate in the workshop and seminar:

1. National Communicable Disease Department, NCCD, responsible for STREAM in Mongolia
2. MTC health professionals association led by former NTP Manager
3. NTP
4. MATA, the largest health NGO in the country for service delivery
5. CCM in Mongolia
6. Mongolian Implementing Office for Global Fund grants
7. MSM and TG Community Centre (main LGBT and AIDS organizations in Mongolia)
8. Family Health Practitioners Association
9. World Vision (works with TB in the prison and homeless populations)
10. District health units and hospitals to talk to volunteers and deliver services

During the second week, stakeholders met to deliver the interactive workshop, the content of which was discussed, agreed upon, and translated into Mongolian. Facilitators were taught to use simple interactive techniques and to avoid highly technical language to allow participants to easily understand. Qualitative explanations were sometimes used instead of numbers and statistics. One mistake was hiring the interpreter only for training of trainers due to limited time to interview and select an interpreter. Though fluent in the local language, the interpreter did not fully understand and participate in the discussions during the events.

The workshop was held on November 18 and 19, 2015. The first day was dedicated to introducing: 1) objectives and agenda, 2) tuberculosis: infection, disease, and treatment, 3) MDR-TB: forms and treatment, and 4) the STREAM trial. An assessment of participants' knowledge in the themes was conducted in the beginning and at the end of the first day via pre- and post-tests. Test results showed an average increase of 40% to 80% for questions answered correctly. The second day was used to introduce: 1) formats of community engagement around a trial, 2) willingness to engage in trial follow-up, and 3) the STREAM follow-up model. The STREAM Mongolia team and MTC staff were dedicated in supporting all activities such as managing attendance and distributing transportation allowance.

The two day community workshop was attended by 56 people including the local facilitators and resulted in four working groups. After intensive discussions, stakeholders agreed on a CAB plan. Members decided on monthly core CAB meetings with 10 key participants at the STREAM office to reduce costs and to interact in facilities with the trial site's professionals. A general CAB meeting should be organized three times a year to dedicate time to provide treatment and research education and updates on outcomes. Members also decided that MTC should lead the STREAM CAB and appointed Dr. Gankhuu as coordinator.

The STREAM Community Engagement Seminar was hosted on November 20, 2015 and was attended by 94 people. The NTP Manager and representatives from the MoH & Sports and the Ministry of Education launched the seminar. STREAM was presented and participants were introduced to the CE rationale and global CAB experiences. Community members delivered results of the four working groups. Participants engaged in a discussion facilitated by local NGO and governmental organizations on settling and supporting the STREAM Mongolia CAB. Final remarks by government officials emphasized that STREAM CE is aligned with the NTP goals of CE and for ownership of the CE process.

The first core CAB meeting was held on November 23, 2015 for nine attendees at the STREAM office, after strategies for supporting the rapid approval of the trial were determined. Outcomes of the previous events and needs of the CE team were discussed. The first general CAB meeting was hosted on December 10, 2015, for 30 participants including facilitators. There was an intense analysis of the questionnaire to patients and the Informed Consent Form. Other details of the trial were discussed among participants.

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