Improving Dissemination of Clinical Trial Results

Experiences in HIV and TB Clinical Trials

Dr. I. D. Rusen
TREAT TB Project Director
An introduction to the panel discussion
Background

• Dissemination of trial results is an ethical obligation
  o GPPs for TB drug trials reference importance of dissemination to:
    ▪ Build trust
    ▪ Ensure respectful partnership
    ▪ Increase ownership of trial results
• Can also be catalyst for program/policy change
• However, often focuses more on peer reviewed publications than communication to civil society, participants and affected communities
Objectives

• Explore dissemination experiences from recent HIV and TB trials through the following topics:
  1) Communications channels/materials
  2) Making complex topics accessible to all audiences
  3) Dissemination of unfavorable or inconclusive results
  4) Using results to advocate for change

• Identify key issues and best practices for dissemination
Panel Discussion Format

For each of the four topics:

• Panelist introduces topic and shares experience on topic
• Discussion questions are open to the panelists
• Main points summarized
• Q&A and discussion open to participants/audience
An introduction to the trials
# HTPN 052

<table>
<thead>
<tr>
<th><strong>Question</strong></th>
<th>Does the use of antiretroviral therapy (ART) reduce the transmission of HIV in serodiscordant couples?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>2007 to 2010</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>13 sites in 9 countries&lt;br&gt;Botswana; Kenya; Malawi; South Africa; Zimbabwe; Brazil; India; Thailand; and USA (Boston)</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>In 1763 serodiscordant couples, there was a relative reduction of 96% in the number of linked HIV-1 transmissions resulting from early initiation of ART, as compared with delayed therapy</td>
</tr>
<tr>
<td><strong>Results Dissemination</strong></td>
<td>To WHO and National Department of Health in each country; Participants and Community Advisory Boards invited to dissemination event</td>
</tr>
<tr>
<td><strong>Other info</strong></td>
<td>Study stopped early because the intervention - early antiretroviral therapy - was so effective (unethical to withhold treatment)</td>
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Francesca Conradie; Nombuyiselo Tshandu
## STREAM Stage 1

<table>
<thead>
<tr>
<th><strong>Question</strong></th>
<th>Is a modified Bangladesh 9-month MDR-TB regimen non-inferior to the 20-month regimen recommended by the WHO in 2011?</th>
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<tbody>
<tr>
<td><strong>When</strong></td>
<td>2012-2017</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>7 sites in 4 countries   Mongolia, Vietnam, Ethiopia, South Africa</td>
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<tr>
<td><strong>Results</strong></td>
<td>Favorable outcomes in the short and the long regimen were both around 80%. The longer regimen performed better than expected under program conditions.</td>
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<td><strong>Results Dissemination</strong></td>
<td>Communications materials developed and tailored to: WHO; International TB CAB; PIs/study teams; Ministries of Health; CABs; participants; family members; other community stakeholders</td>
</tr>
<tr>
<td><strong>Other info</strong></td>
<td>Preliminary results disseminated early</td>
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<td></td>
<td>IDMC thought it was important for NTPs and STREAM Stage 2 (ongoing) to have information regarding ECG monitoring</td>
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Francesca Conradie; Nombuyiselo Tshandu, Gay Bronson, Helen Platt, Ezio Tavora, Oxana Rucsineanu
**FACTS 001**

<table>
<thead>
<tr>
<th>Question</th>
<th>Does pericoital tenofovir gel prevent HIV transmission in HIV non-infected women?</th>
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<tr>
<td>When</td>
<td>2011 to 2014</td>
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<tr>
<td>Where</td>
<td>South Africa</td>
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<tr>
<td>Results</td>
<td>Vaginal use of tenofovir gel, before and after sex, was <strong>not</strong> effective in preventing HIV in a diverse study population of young South African women. Tenofovir gel was found safe for use.</td>
</tr>
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</table>
| Dissemination | To HIV leaders and experts, policy makers, donors  
To participants, CABs, study staff, communities **on day of results release**  
AVAC outreach to advocates  
Media outreach: South African media, US and other global media, press conference art CROI |
| Other info | FACTS 001 was designed as a confirmatory trial for CAPRISA 004, which found modest efficacy among a smaller group of women |

Kay Marshall
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<td><strong>Question</strong></td>
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<td><strong>When</strong></td>
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<td><strong>Where</strong></td>
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<tr>
<td><strong>Results</strong></td>
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<td><strong>Dissemination</strong></td>
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<tr>
<td><strong>Other info</strong></td>
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Stephanie Seidel; Sarah Mulera
Technology, Research, Education and Technical Assistance for Tuberculosis
Panel 1: Communications channels and materials

HTPN
STREAM

Presented by:
Helen Platt
Nombuyiselo Tshandu
Introduction to the topic
The Challenges

Deciding on the appropriate communications channels and materials is influenced by numerous challenges, including:

• There are usually multiple audiences, all with different levels of knowledge, and different levels and types of interest in the work.

• There is a communications life cycle to the project with different messages at each point, from telling people the project has started and recruiting those who will be involved, to disseminating results and advocacy.

• Changing situations – both within a project and from external forces – can mean communications need to be reactive and quick yet usually involve multiple stakeholders and complex messaging.

• Clinical trials can be technical in language and content, yet they need to be understood by every day people – particularly those taking part in the trial. How to deliver information that is accurate can be challenging.
Examples from HTPN

• The need to identify and establish stakeholder advisory mechanisms at the beginning of a trial
• A 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
• Develop material 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.
• When communicating to stakeholders who are not routinely engaged in the clinical research enterprise, ensure that the information is accessible by disseminating through the phases of a clinical trial and patient engagement across the different phases
• Building collaborations with community stakeholders through honest, open dissemination of study results and discussions of future research steps establishes trust between the lay and scientific communities
Examples from STREAM

• Several settings for dissemination activities. Focus group participants, *recognized gate keepers in the communities*, *Local health workers*, *Advocacy groups*

• The media is an important channel for advocacy and reaching the scientific community – in addition to journal publication. For STREAM we use pre-briefings as a way to place key announcements and to control the messaging.

• The website and blogs is a valuable tool for informing stakeholders and the broader research community.

• Sessions at conference are an important channel not only for dissemination and amplification of findings but for building discussion.

• Printed materials have been invaluable for reaching the communities involved with STREAM as well as face-to-face briefings.
Concrete Tips

• Always walk in the shoes of the audience – don’t just tell people what you want to say, consider what is relevant to them and how they will best understand. For example, it is important to translate into relevant languages and for different settings.

• Develop core key messages and communication objectives – don’t try and do everything in one leaflet, have clear messages for the audience and develop materials around that.

• Content is king – develop engaging content, use imagery, use storytelling, theatre, use film, use illustration and good design.

• Listen – don’t just broadcast out. Community meetings and social media make this easier than ever. Good communications should be adjusting to what people say.