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Improving Dissemination of Clinical Trial Results

Experiences in HIV and TB Clinical Trials

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An introduction to the panel discussion

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Background

- Dissemination of trial results is an ethical obligation
  - 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

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An introduction to the trials

HTPN 052

Question	Does the use of antiretroviral therapy (ART) reduce the transmission of HIV in serodiscordant couples?
When	2007 to 2010
Where	13 sites in 9 countries Botswana; Kenya; Malawi; South Africa; Zimbabwe; Brazil; India; Thailand; and USA (Boston)
Results	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
Results Dissemination	To WHO and National Department of Health in each country; Participants and Community Advisory Boards invited to dissemination event
Other info	Study stopped early because the intervention - early antiretroviral therapy - was so effective (unethical to withhold treatment)

Francesca Conradie; Nombuyiselo Tshandu

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STREAM Stage 1

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

Francesca Conradie; Nombuyiselo Tshandu, Gay Bronson, Helen Platt, Ezio Tavora, Oxana Rucsineanu

FACTS 001

Question	Does pericoital tenofovir gel prevent HIV transmission in HIV non-infected women?
When	2011 to 2014
Where	South Africa
Results	Vaginal use of tenofovir gel, before and after sex, was **not** effective in preventing HIV in a diverse study population of young South African women. Tenofovir gel was found safe for use.
Results 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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NC-005

Question	Phase 2b trial testing the BPaZ and BPaMZ regimens in patients with drug-sensitive and MDR-TB
When	2017
Where	10 sites in Uganda, South Africa, and Tanzania
Results	Both regimens were found to be safe and efficacious, with the BPaMZ regimen in MDR-TB participants resulting in the highest level of bactericidal activity among all treatment arms, including HRZE in drug-sensitive participants
Results Dissemination	Disseminated to trial sites, participants, CE staff and CABs through direct communication, webinars, research literacy and communications trainings
Other info	Results were presented in a poster at CROI 2017 and covered by press including *Science*. Broader dissemination strategies were discussed and developed with CE partners at the TB Alliance's annual CE Forum

Stephanie Seidel; Sarah Mulera

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Panel 1: Communications channels and materials

HTPN

STREAM

Presented by:
Helen Platt
Nombuyiselo Tshandu

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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.