Panel 3: Unfavorable or inconclusive results

STREAM Stage 1
FACTS 001

Presented by:
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Challenges

- Dissemination of negative or inconclusive results is hard
  - Publication bias against ‘failed’ trials
  - Participants → individual benefit vs. research → societal/general benefit of better information
  - Experience shows negative results can adversely impact trial participants, communities and the research agenda generally
- BUT, researchers have an ethical obligation
  - Declaration of Helsinki → researchers must disseminate positive, negative and inconclusive results
  - GPP Guidelines → researchers should develop a dissemination plan that manages expectations by preparing for all possible results

Source: Declaration of Helsinki and Good Participatory Practice Guidelines for TB Drug Trials, 2012
Examples from STREAM Stage 1

- Interim results showed similar efficacy for control and intervention
- BUT, results did not meet statistical test of non-inferiority
  - Not conclusive (statistically)
- Disseminated widely to global, national and local stakeholders
  - Challenging to explain what the results meant
Examples from FACTS 001

- Primary analysis indicated that use of pericoital tenofovir gel before and after sex was **not** effective to prevent HIV
- Results disseminated widely to/through scientific conferences, press, CABs, participants, HIV advocacy groups
Concrete tips

Planning is key:

- **Develop scenarios:** it works, it doesn’t work, it’s complicated
- **Plan for data monitoring committees**
  - Share DMC updates with close allies so they aren’t caught off-guard by a quick announcement
- **Gather your allies:** HIV Prevention Communication Working Group – more than 10 yrs preparing for, supporting results dissemination
- **Manage expectations throughout:** Build into comms and community engagement plans for multiple audiences: participants, staff, CAB, communities, policymakers, media, funders...
- **Prepare well:** Tough questions, conspiracy theories, blowback from communities, policymakers, media
- **Plan for media engagement:** before, during, after dissemination
Discussion

• Why is it important to disseminate negative and inconclusive results?

• How can we meet our obligation to disseminate unfavorable/inconclusive results while managing the "fallout" (misinformation/rumors) of what they mean in the community?

• What is the best follow-up with participants and communities after unfavorable results?
Panel 4: Using results to advocate for change

NC-005
STREAM Stage 1

Presented by:
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Challenges

- Ensuring research literacy, working through misunderstandings, misinterpretations and language barriers
- Getting essential high-level stakeholders together
- Research timelines are long, waiting for results, being in suspense is challenging for all levels of stakeholders

Using results to advocate for change through:
- Translated information (study results made simple), and in local language!
- Engaging by previously consulting local researchers and CABs’ coordinators
- Potentialize participants’ and communities affected ownership to the project
- Relay the message through a variety of appropriate channels; meetings, lecture, advocacy briefs, info-graphics
- Always follow up and assess whether the message has been understood!!
Examples from STREAM Stage 1

- Common Dissemination Plan for all STREAM sites
- Provided information to stakeholders, partners (government, NTP)
- Privileged interaction of local research team with communities affected representatives, trial participants and family members
- Results dissemination of the Stage 1 of STREAM trial represented an ultimate practice for STREAM Stage 2, using strategic information to generate common understanding around study results, its applicability and usefulness for the country needs.
Examples from NC-005

• Included Principal Investigator, or other research team members in all engagement with stakeholders where results were disseminated, for clarity

• Incorporated high-level messages made available to explain results to various stakeholders
Concrete tips

Engaging and participating!

• *Understand to whom you are speaking:* clear and transparent language
• *Share data with anticipation with local participants:* they are the ones who matter!
• *Consult and HEAR, consider different perceptions*
• *Document experiences.*
• *Results dissemination with research literacy*
• *Consultation with research team and CAB on local dissemination strategy*
• *Assess understanding, collect FAQs and reinforce information*
Discussion

• Regarding STREAM Stage 1, how participants reacted to the inconclusive results?

• Which were the most common perceptions or comments by dissemination activities’ participants?

• What does the study represent to the communities and the stakeholders?
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