

Sample of a Results Dissemination Plan by a South African Site

HPTN 039 RHRU Results Dissemination Plan

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Overview

The Reproductive Health Research Unit (RHRU) HPTN site is situated inside the Esselen Street clinic, a local municipality clinic in Hillbrow, Johannesburg. RHRU does not anticipate much controversy or media coverage upon the release of the results of HPTN 039. However, if the results show harm, one can anticipate the possibility of negative media coverage, given past reporting on the cellulose sulfate clinical trial (a microbicide). More recently, an HIV vaccine trial was stopped because of futility, and in that case, the media coverage was fair and balanced.

Our results dissemination plans focus around five main efforts:

1. Early communication of results to the IRB/Ethics Committee, the Ministry of Health, and the Community Advisory Board (CAB) just before the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, USA
2. Presentation of results to participants and community members after CROI
3. Press release to present results
4. Distribution of a study summary to local colleagues and other key stakeholders with a presentation of results after CROI
5. Surveillance of local media and community attitudes after CROI to respond to any negative press, rumors, or needed clarifications

Site background

Hillbrow is an urban area in the inner city of Johannesburg characterized by high unemployment and decay. The HPTN site in Hillbrow is housed inside a local municipality clinic that provides services related to sexually transmitted infection (STI), family planning, and voluntary testing and counseling for HIV (VCT).

Approaches for results dissemination to potential results recipients

The RHRU site staff has discussed the possible entities that should be told of the results of the HPTN 039 study based on the template developed by Family Health International (see Box 6.1). A summary of the decisions is provided below:

Tier 1—early results

1. *The chairman of the IRB/Ethics Committee will be informed of the results 24 hours before the CROI announcement. The principal investigator (PI) of RHRU site will e-mail the chairman a summary of the results, including attachments of key messages, a press release, and a frequently asked questions (FAQ) document. The PI will also follow up with a telephone call to the chairman to ensure that he has received the results. We believe that the IRB understands the requirement to keep results confidential until they are announced at CROI.*

2. *The University of Witwatersrand press office and local journalists experienced in scientific reporting* who have worked closely with RHRU in the past will be alerted by the PI 24 hours before the results are announced at CROI.
3. *The National Department of Health* will also be notified through the Chief of the Division of HIV/AIDS and the Head of Epidemiology, 48 hours before CROI, and will be sent key messages, the press release, and the FAQ. The PI will follow up with a telephone call that same day to answer any questions.

Tier 2—results released during CROI or after

1. *Other local researchers, AIDS activist groups, provincial and local government representatives, and other key stakeholders:* The RHRU plans to present the results to these stakeholders about a month after CROI. The site has successfully held a similar meeting for one of the completed herpes simplex virus/HIV clinical trials in August 2007. We will use the same database and list to start inviting all interested parties as early as the second week of January 2008.
2. *Local community leaders, the trial CAB, participants, and community-based media:* The CAB members will be notified 48 hours before CROI, and they will sign a confidentiality document prior to learning the trial results. In mid-February 2008, we will hold a community appreciation event and information session at the site. This will consist of light refreshments and a PowerPoint presentation to discuss the study and its outcome. A one-page summary of the results, provided by FHI, will be distributed to all attendees. A question-and-answer session will be conducted at the end of the presentation.

It will be important to reach as many people as possible for this event, so advertising will begin in early January. Community health workers for the trial will distribute invitations to local clinics and other previous recruitment venues for the trial (churches, community centers, local civic organizations). Community health workers for the trial will also spread the word to participants. Those participants who have phone numbers or who can be contacted through family or friends will be invited directly, and those inaccessible by telephone will be paid home visits, wherein invitations will be delivered at their last known address. The latter activity will be guided by permission the participants granted during the study. The CAB, local AIDS activists, community-based print media, and local radio station will be individually invited by the study coordinator or the Community Liaison Officer (CLO).

Potential problems and post-results activities

As noted in the summary, we do not anticipate any problems from results dissemination, unless use of the study product causes harm to participants. However, if the 039 results are mixed or complicated, we will have a more difficult time with our responses, and the news will be more politicized. If there is likely to be controversy, the site will need three to four days to prepare and communicate with key contacts (Tier one). If the results are not that newsworthy, the team estimates needing 48 hours to inform those stakeholders.

Journalists always ask, “What does this mean and why is it important?” If the news from CROI is that there is no increase in harm, the team estimates that the results will not filter back into news media in South Africa. If use of the study product causes harm, there are two concerns: HPTN 039 participants and government officials especially are likely to be concerned. We will need to have plans in place to deal with this scenario and respond to concerns.

If the treatment causes harm, we will try to allay anxiety of participants at the community appreciation event and through the press releases. We will tell participants at the event that they can come to the clinic at any time to discuss the results or their feelings further. The site will explore whether (a) representative participant(s) might be identified to speak for the participant perspective, if that becomes important. This role might also be assumed by a CAB member who can speak for the participants. We will also encourage participants to return to the clinic when unblinded treatment assignment is available (around April) so we can inform them of their group assignment. We will emphasize that those who did not seroconvert during the trial were not harmed by taking the study product and are not now at any greater risk than if they had not been in the trial.

To counter a possible community backlash against research in this scenario, we will adopt two strategies. First, the study coordinator and the CLO will return to the organizations that helped us in recruitment and answer questions, explaining that very few people who used the study product were put at greater risk of HIV acquisition; that most participants in both trial arms were probably better off from counseling, STI treatment, and free condoms than if they had not been in the study; and other messages to promote research literacy. Second, for the two months after public dissemination of trial results at CROI, the PI or someone senior within the organization will monitor the local press daily for stories about the results and respond to queries as they arise. We will also ask the CAB and community health workers to report any rumors or negative feelings they have heard within the community and among participants in other clinical trials conducted at the site, and we will respond to each situation proactively.

Staff assignments for results dissemination and response to inquiries

Because little reaction is expected in Johannesburg, South Africa, to the results of HPTN 039, the PI will be the primary spokesperson for the site when releasing or presenting results, and when inquiries come in from media (if any). In the event that the PI is not available, the executive director of the RHRU or any other senior RHRU staff member within RHRU may serve as spokesperson. To prepare for general inquiries about the study or the results, the entire staff will have a meeting with the PI a few days after CROI to discuss how to talk to participants and community members about the key messages. Staff will also be trained to direct any media inquiries to the PI or other designated senior RHRU staff member. The CLO or community health workers will serve as spokespeople at the community meetings where results will be discussed. We will also work with the CAB to prepare them to answer questions in an informed way about the results.

Needed resources

- PowerPoint presentations for community and stakeholder presentations
- Press release
- FAQ document
- Study summaries
- Key messages document
- Invitations to promote community event