Case Study: Timelines and Tasks for Disseminating the Results of HPTN 035

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HPTN 035 was a multi-center clinical trial that evaluated the safety and effectiveness of two candidate microbicides, BufferGel® and 0.5% PRO 2000, for preventing HIV infection in women. The study was conducted between February 2005 and September 2008 among 3,099 HIV-negative women at seven clinical research sites in Malawi, South Africa, Zambia, Zimbabwe, and the United States by a team of researchers associated with the Microbicide Trials Network (MTN). The MTN is an HIV/AIDS clinical trials network funded by the National Institute of Allergy and Infectious Diseases (NIAID), with co-funding by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health (NIH). Prior to 2006, the study was conducted by the NIAID-funded HIV Prevention Trials Network (HPTN), from which the study gets its name.

Preparations for and discussions about the conclusion of the study and the dissemination of its results were well under way when we formed a communications group to work on developing a formal plan in August 2008. The group comprised NIAID Division of AIDS (DAIDS) leadership, a representative from NIAID's Office of Communications and Government Relations, MTN leadership, the MTN communications director and the study's protocol chair and clinical research manager. Our work revolved around three results scenarios, and we outlined a time line with specific tasks that assumed the study results would be presented as a late-breaker abstract at the Conference on Retroviral and Opportunistic Infections (CROI) in Montreal in early February 2009.

As the sponsor of HPTN 035, NIAID/DAIDS directed overall planning and determined the parameters for stakeholder engagement, which needed to be in accord with CROI's embargo policy and U.S. Securities and Exchange Commission (SEC) regulations. CROI's embargo policy stipulated that the research being presented at the meeting would be embargoed until the date and time of the presentation unless an official CROI press conference occurred first, in which case the embargo would be lifted. A break in the embargo could jeopardize presentation of the study results at the meeting. Because Indevus, one of the study's co-sponsors, was a publicly traded company, the timing of the public release would also need to be dictated by SEC regulations. Indevus would be obligated to publicly disclose the results within 24 hours (excluding holidays and weekends) of it becoming aware of the findings. This meant we would need to calculate precisely when Indevus (and ReProtect, the other co-sponsor) would be told of the results.

At the outset, we understood our plan would require careful orchestration of activities across several different time zones; CROI and the SEC added another layer of complexity. These challenges aside, it was essential that all relevant stakeholders and interested communities—in the United States, Canada, and each trial-site country—receive accurate information in a timely fashion.

For its part, the MTN worked with the trial's staff at each of the sites, helping to guide the development of site-specific plans and providing whatever communications tools and support was needed for successful implementation of these plans. As a first step, we encouraged sites to update their "stakeholders directories" so they would have at their fingertips the names and contact information for government, regulatory, civil society, advocacy, news media, and other important stakeholders, as well as key allies who might issue statements or speak out in defense of the study if need be. The stakeholder directory also required identifying key site-level contacts, including designated spokespersons, members of the crisis communications team, IRB/EC and CAB representatives and superiors within the organization. In addition, sites were asked to update their media relations standard operating procedure (SOP) or to develop an SOP if one was not already in place. A template we provided helped sites define what procedures to follow when responding to media inquiries, including how requests involving participants would be handled.

A template was also provided to guide sites in the development of individual dissemination plans. The template consisted of 11 sections in order to capture in detail the activities, personnel to be involved in these activities, and specific time lines for engaging different groups of stakeholders. Moreover, the template asked sites to identify what steps would be taken for advance notification of certain stakeholders to let them know how and when they could expect to learn the results. Sites were also encouraged to reach out to key journalists as early as possible so they would be better prepared and informed when the time came and, hopefully, be more fair and accurate in their reporting.

To help jumpstart planning at the site level, NIAID prepared draft press releases and messages for each of the three main scenarios. In the meantime, we began drafting a number of documents about the actual results. Clear and concise materials would be required for different audiences (such as media, community, scientific community, and participants) that sites could use as is or adapt as they saw fit. As soon as allowed, we provided study staff with both NIAID's and MTN's final press releases, the final set of messages and a package of materials—some 20 documents in all. These included a "fill-in-the-blank" press release with fill-in-the-blanks for site or local information, internal and external Q&As, PowerPoint presentations, and various fact sheets.

Disseminating the results of HPTN 035 was not without challenges, some anticipated, some not. It required extensive planning and hard work. It was a collaborative effort at every level. Lessons learned will be carried forward.

The following is a time line with many of the activities involved in the planning for and dissemination of the results:

2008

Aug.-Sept.	Sites updated their stakeholder directories and media SOPs
Sept. 8	HPTN 035 team meeting–Cape Town–possible strategies and scenarios were discussed
Nov. 20	Dissemination plan templates sent to sites; sites encouraged to notify keystake holders to expect results (template letter provided)
Dec. 4-5	Data review meeting with study co-chairs, DAIDS–confidentiality agreements in place
December	Ongoing discussions with sites on dissemination planning

2009

January	Ongoing discussions with sites on dissemination planning
Jan. 2	Late-breaker abstract submitted to CROI

Jan. 14	Scenarios, messaging, draft releases sent to sites
Feb. 6	Final materials posted on password-protected portal for internal use
Feb. 5-6 (Thursday-Friday)	NIAID informed primary stakeholders
a) Feb. 5	Gel manufacturers (Indevus, ReProtect), U.S. Food and Drug Administration, Medical Research Council (MRC), South Africa
b) Feb. 6	Other stakeholders
Feb. 6 (Friday)	Sites informed their respective Ministry of Health and IRB/Ethics Committee chair
Feb. 9 (Monday a.m., local time)	Sites informed their in-country drug regulatory agencies
Feb. 9 (Monday, 8:30 a.m. EST)	CROI embargo lifted at conclusion of CROI press conference; sites could issue press releases or media advisories at this time
Feb. 9 and 10	Sites held press events
Feb. 9-onward	Sites continued implementation of their dissemination plans; participants and other stakeholders notified of results