

Sample of a Results Dissemination Plan by a Peruvian Site

HPTN 039 Results Dissemination Plan for Peru

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Background

The HPTN 039 study of the safety and effectiveness of acyclovir for HIV prevention was initiated in December 2003 in Peru with three sites, one in Pucallpa (Asociación Civil Cayetano Heredia), and two in Lima (Impacta in Lince and Miraflores). By late 2005 and early 2006, two new sites in Peru were incorporated to the study, one in Iquitos (Asociación Civil Selva Amazonica) and another in Lima (Impacta San Miguel). In total, 1,384 men who have sex with men (MSM) have been enrolled in the study in these sites in Peru.

Since there are several individuals involved in three different cities with different Investigators of Record for each site, we will need a plan specifically tailored for each city and will have to consult with and get input on the draft plan from the site investigator of record and community educators at each site.

Dissemination of results

This plan will include:

Tier 1 entities

We plan to work and produce a final report or “Memoria” on the HPTN 039 study in Peru to be printed and distributed to the entities below. This document will present the story of the HPTN 039 study in Peru and worldwide, including its rationale, the trial design and results, major challenges overcome, and lessons learned and outcomes.

The site team plans to have all components of the document—except the results—written and laid out before February 2008, when the results will be publicly announced at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, USA. The dissemination of the report to these institutions can take place immediately after or 24 hours before the announcement at CROI via e-mail. We will also distribute other explanatory, background materials about the trial to these groups:

- Impacta Ethics Committee
- Peruvian National Institute of Health
- Peruvian National Strategy for Prevention and Control of Sexually Transmitted Infections and AIDS of the Ministry of Health
- Directorate of Population Health of the Ministry of Health
- Directorates of Health of Ucayali (for the Pucallpa site) and Loreto (for the Iquitos site)
- General Directorate of Epidemiology of the Ministry of Health
- Country Coordination Committee for the Global Fund to Fight AIDS, Tuberculosis and Malaria
- Congress Health Commission
- Ministry of Health Counselors Committee
- Minister and Vice Minister of Health

Tier 2 entities

- Materials about the 039 study and results will also be distributed to the following entities via the mechanisms and according to the time lines listed in Appendix I:
- Universidad Cayetano Heredia HIV/AIDS research projects
- Scientific societies (Peruvian Colleague of Physicians, Peruvian Society of Infectious and Tropical Diseases)
- Community Advisory Board
- Nongovernmental organizations working on reproductive and sexual health
- Development funding agencies (USAID, the German Cooperation Agency–GTZ, the Dutch Cooperation Agency)
- Peruvian AIDS Network (Red SIDA Perú)
- GLBT agreement forum (all the organizations that belong to the forum)
- Press releases to Web pages for gay Peruvian audiences
- Medical-oriented journal (Gestión Médica)
- Press releases to other media (radio, TV, and press), depending on the city

Dissemination strategy

Public forums. We plan to disseminate results to the community and to participants through public forums in the different cities where the trial took place. We will present the process, the challenges, the lessons learned, and the preliminary results, primarily through interactive slide presentations.

Jorge Sanchez, Abner Ortiz, and Martin Casapia, site investigators from Lima, Pucallpa, and Iquitos, will invite participants to the forums through a formal letter to all above-mentioned organizations.

We will distribute a copy of the final report and a copy of the video “Gracias Perú” to participants of the public forum.

At the public forum, participants will have the chance to ask questions, and these will be answered during the talk.

Inform a wider group of stakeholders. A second step will be the distribution of the brochure to a broader list of organizations in the different cities as noted above and detailed in Appendix I. We will also place a link on the Impacta Web page and the ACSA Web page with the final report and an e-mail link for the public to ask questions. HPTN 039 investigators and community education staff will reply to all questions. Every press release will include the Web page address and an e-mail address for further information.

Prepare participants for results. To prepare participants for the disclosure of results and possible distribution of free acyclovir post-trial, we will discuss these issues during the annual participant appreciation event, scheduled for mid-January, in each of the cities where the study took place.

Other preparatory activities. In October 2007, site staff hosted a general forum on the connections between HIV and HSV-2. The format was a slide presentation with handouts. Attendees included nongovernmental organizations (NGOs), Ministry of Health representatives, and medical colleagues. The site is planning to conduct similar events in Ucayali and Loreto, the districts in which Pucallpa and Iquitos are located.

Media efforts

The site staff will continue to monitor Peruvian news media for reports that could affect perceptions of the HPTN 039 trial. The site has experience responding quickly to stories that do not portray the study in an ac-

curate light by contacting the source of the story to present correct information and by issuing press releases. The site will continue this approach, and will work with colleagues at other sites on stories or controversy picked up in the media, so that we can collaborate in developing a unified response across all study sites.

Staff assignments for results dissemination activities

This will be described in an Excel spreadsheet showing individual responsibilities for communication tasks.

Challenges

At this point, there are a few challenges:

1. **HVTN 502 Step Study:** The decision to suspend vaccination of participants in the HVTN study—a separate HIV prevention trial—has spurred us to disseminate information about it to our Ethics Committee, Community Advisory Boards, participants, and the community at large in the different cities. We have planned forums to inform Ministry of Health staff and NGO representatives about the HVTN study. Following recommendations from the HVTN, we have helped distribute press releases on the vaccination study to different media. Nevertheless, news coverage of HVTN 502 may be affecting community trust in HIV prevention studies in general.
2. **Herpes suppression trial in Tanzania:** Results of this study that were released at the International AIDS Society conference this year have not been broadly disseminated yet in the Peruvian community but may affect perceptions of all HIV prevention research, including our trial.
3. **PrEP study:** The pre-exposure prophylaxis (PrEP) for HIV prevention study in Peru is evolving with no major challenges. However, this project has been so controversial in other parts of the world that we are being very cautious with the potential pitfalls that may jeopardize our study in Peru, including participant recruitment.
4. There is a possibility that neither our HPTN 039 study of acyclovir, nor the Partners in Prevention study will show efficacy. The local community may feel that regardless of their willingness to contribute enrolling in alternative HIV prevention strategies that are being studied, these alternatives do not work. The community may grow tired of volunteering as a result.

Materials/Events we foresee producing for the results dissemination phase of this study include:

- Dissemination of the CROI 2008 abstract, translated to Spanish
- Preparation of a publication as an “HPTN 039 Final Report”
- Bulk production of “Gracias Peru” in DVD format for wide distribution in public forums and to interested organizations
- Press releases
- A Web page on the HPTN 039 results
- Organization of forums in every HPTN 039 city to share results with the community at large
- Appreciation events in every city for dissemination of results to the MSM community
- Appreciation events in every city for dissemination of results to HPTN 039 participants
- Merchandizing to be distributed to HPTN 039 participants at a cost not higher than US\$6 each

These are some of the ideas we intend to work on for the coming months. This proposed plan will be circulated to HPTN 039 site Principal Investigators in a first round for comments, feedback, and input from them and other HPTN 039 staff.

For further comments, please contact Pedro Goicochea by e-mail.