



Handheld devices like GPS and cellular telephones are becoming critical tools in helping to locate participants and enter study data.

Preparing for and Disseminating Study Results

6

Preparing to release your results should begin months before the results of the study are known. Ideally, dissemination should be considered during the strategic communications planning process (see Chapter 3). Planning can ensure that the study's results are understood by all interested parties—your trial participants, the news media, and appropriate national and provincial government health officials.

The time needed for planning will vary from study to study. For smaller single-site trials working with one institution, a basic dissemination plan could be outlined in a few hours and then expanded with input from staff members at the site, sponsors, and trusted partners. For more complex trials—such as trials at multiple sites, conducted by different institutions in several countries—more detailed plans and resources are usually necessary.

Such dissemination activities, and the communications and media planning that are part of sharing research results, are increasingly recognized as essential to the research endeavor. Advocates have become partners in disseminating results, and they are an important bridge between scientists and civil society. Members of community advisory boards (CABs) and even trial participants can help to shape messages, rather than merely receive them. Some sponsors now allocate dissemination funding directly to the sites for communications and media relations.

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Elizabeth T. Robinson/FHI

I The minimum package of dissemination activities

Once your study has been closed—whether on schedule or unexpectedly—the research results should be disseminated to a variety of audiences through appropriate channels, including publication in peer-reviewed journals. This is an obligation of the scientific community and a key element in the collaborative research process (UNAIDS 2007; Emanuel and others 2004).

Depending on the situation, the trial's sites may be responsible for certain dissemination activities, or sponsors and trial networks may dictate how such activities are carried out. A minimum package of dissemination activities includes:

- Information sharing with study participants, CAB members, and staff members at research sites and other related trials in the area
- Formal notification to ethics committees, Ministries of Health, regulators, and other government officials, key partners, and sponsors
- Outreach to leaders in the community where the research was conducted
- Outreach to other key stakeholders (trial networks, health advocates) who are involved in related trials
- Distribution of materials that summarize the results to stakeholders of the trial
- Presentation at scientific conferences
- Publication of the results in a peer-reviewed journal

To achieve impact, research needs to both make the relevant information accessible and promote an enabling environment in which it can be adopted.

—U.K. Department for International Development (DFID), 2005

The contents of the package will be determined by a number of factors, including funding, timing, and human resources. The underlying principle is that stakeholders should be informed as soon as the results are ready to be shared publicly. People should be able to locate your results years later in the public record, whether online or in published archives.

II The dissemination team and plan: compiling the core elements

When planning for the dissemination of the trial's results, you should revisit your initial communications strategy in light of specific needs and any new opportunities:

- Goal: What effect do you hope to achieve or to avoid?
- Audience: Who will be interested in or affected by your research results?
- Approach: What will be the most effective way to reach each group of stakeholders?
- Execution: Who will be responsible for carrying out dissemination activities and when (Center for Interdisciplinary Research on AIDS: Community Research Core 2009)?

Take the following steps to plan for the dissemination of your results.

Step 1. Establish a dissemination planning team and a decision-making policy. Many times, this small group will resemble the team that has been involved in communications throughout the trial, with possible additions of other stakeholders, such as a representative of the organization that is sponsoring the trial or a member of the CAB (see Chapter 2 on choosing your communications team).

Step 2. Determine how your team will make decisions. Once the team is in place, discuss and decide which members of the team will have the authority to make decisions.

- Who should review and approve dissemination materials?
- Who will make key decisions about dissemination?
- Do certain members of the trial's staff have to review and approve communications that target specific audiences, such as government officials?
- What input on decisions will site-level teams have within trial networks?
- How will urgent decisions be made?

These questions may have been answered in your initial communications strategy (see Chapter 3). If not, put them on the agenda for your meetings on the dissemination of results.

Step 3. Discuss how you will release the results of your trial.

Once the team is in place, the members should begin discussing how to disseminate the results. Well before the study concludes and before the team knows the results, the members should weigh the pros and cons of different release strategies, including the presentation of preliminary results at a scientific conference or waiting until the results have been published in a scientific journal. Another strategy is to release the results directly to policymakers, the public, and participants prior to publication or formal presentation at a conference. In such instances, it is wise to seek alternative forms of peer review before the public release of the findings.

When assessing its options, the team should establish its goals and primary audiences, and factor in any special issues related to the timing of the public release. For example, some conferences have strict embargo policies, which may hinder the ability of the trial's sites to inform their participants and local stakeholders until after the public release at the conference. Consider also whether the holiday season or the timing of major events like the international football World Cup may affect your ability to reach stakeholders. (See Box 6.5 for more considerations when selecting a conference for the release of your results.)

Step 4. Develop a written dissemination plan with your team. Some teams prefer to write their plans in a narrative format that follows chronological steps. Others use grids to display—at a glance—specific audiences, activities geared to those audiences, people responsible for each

I recommend that research teams hire a communications staff person other than a study coordinator or investigator of record to manage dissemination. From my experience, the latter are often too busy to do full justice to the communications role.

—Kenneth Kintu, Investigator/
Coordinator, The Makerere University-
Johns Hopkins University Research
Collaboration, Uganda

activity, and deadlines. (See Box 6.1, which provides a template for a narrative plan.) Your team should decide on a format that will work best for your study.

Step 5. Make sure that each site develops its own plan. For multisite studies, each site should develop its own plan based on the local environment, established relationships, and potential for controversy. For example, in preparation for the release of the results of the HPTN 039 study—which investigated whether acyclovir (a drug that suppresses genital herpes) reduces the risk of an HIV infection in someone with genital herpes—each trial site filled in the template shown in Box 6.1. (To download the template, [click here](#).) Although these sites were involved in exactly the same study, the site in Johannesburg, South Africa, and the site in Lima, Peru, developed different plans for the dissemination of their results (see full narrative plans from both sites in Appendices 6.1 and 6.2). Each plan responded to local needs and opportunities, outlined a clear picture of how to proceed, and demonstrated creativity in the approaches that were used. For studies with multiple sites within the same country, all of the sites should coordinate at

Box 6.1. Template for researchers: how to plan for research dissemination

Dissemination Plan for _____

Introduction and background information

Summarize in several paragraphs who is conducting the study, the purpose of the study, study methods, potential outcomes, and any aspects of the research environment that might affect how study results will be understood, interpreted, or accepted by both the community where the study was conducted and other interested parties.

Dissemination activities

Describe which methods you plan to use to reach key stakeholders with information on your study, listing the dissemination activities and enough detail for stakeholders to understand their purpose, timing, scope, and feasibility.

Plan communications that target specific audiences

Briefly outline your plan to identify and communicate with the following groups:

- a) Study staff/the research team
- b) Study participants
- c) Local study community
- d) Ministry of Health and other government or regulatory officials
- e) Public health professionals and the scientific community
- f) Advocates and other relevant civil society groups
- g) Donors
- h) News media

Materials needed to support your plan

List the communications materials that will need to be written and distributed to support dissemination of the results (length, language, target audience).

Staffing considerations

Determine which staff members will be needed to implement the dissemination plan, especially after a trial has ended, when community outreach workers and others may no longer be on site.

Evaluate the dissemination efforts

Describe how you will assess and document the outcomes of your dissemination efforts.

Plan ahead to promote access to and use of findings

If the study's findings have relevance for health care practices, programs, or policies, briefly describe your plans to facilitate access to and use of the results: what will you do, why, with whom, and how.

Box 6.2. Face-to-face meetings at community level are most effective

By Dr. Neetha Morar, Senior Scientist, HIV Prevention Research Unit, Medical Research Council, Durban, South Africa

During past announcements, we tried using toll-free telephone numbers that trial participants could call to receive the results. We were excited about using a new way to communicate, but in the end, few people chose to call. Instead, we found that face-to-face meetings with the trial participants and community stakeholders were the most effective and most appreciated means to communicate results. This included visiting community stakeholders and trial participants who were not able to attend results meetings.

the country level to ensure consistency.

Step 6. Decide in advance how to inform the study's participants—and make this a key element in your dissemination plan.

Consider strategies to prepare participants and stakeholders for various potential outcomes from the outset.

Step 7. When developing your dissemination plan, remember to incorporate any support—especially technical assistance—that you would like from communications staff members who are not at the trial site.

If you are at a site, the communications staff of the network or the sponsoring university or organization can help you determine the type of support you will need to prepare and manage the dissemination. By involving these people early, you allow them to build time and resources into their work plans so that they are ready for you when you are

ready for them.

Step 8. If you are a communications person charged with coordinating dissemination activities from a headquarters or network level, it is equally important to begin collaborating early with staff members at the trial sites. Doing so will make delegating tasks easier later, when time becomes your most limited resource.

If resources allow, network- or sponsor-based communications staff can:

- Provide tailored on-site technical assistance to trial sites and stakeholder groups upon request
- Develop materials that can be adapted for local use by the sites
- Help develop and distribute information packets for specific national or international stakeholders
- Provide logistical support to local advocacy groups to tailor materials about trial results for their constituencies or audiences
- Help partners develop in-depth dissemination and utilization plans targeting the international research community
- Provide institutional mechanisms for stakeholders to use in disseminating information about trial results, such as space for local materials on a sponsor's Web site
- Facilitate the development of case stories that exemplify the value of research processes



Health center, Ahero, Kenya

Silas Achar/FHI

Box 6.3. Review, reflect, revise: updating contact lists, messages, and materials

Most sites will have done a great deal of groundwork for dissemination planning well before they prepare to close the study. Now is the time to revisit and revise all of the materials, outreach event formats, and lists of stakeholders that you have developed and compiled over the years. These resources should inform your dissemination plan. Decide which strategies have worked well in the past and should be reused. Take a hard look as well at which previous communications attempts did not work ideally and should be either improved or left out this time around.

You should assess and update your:

- **Environmental scan**

What did your needs assessment or scan of the research environment (see Chapter 2) tell you about the best ways to share information with trial stakeholders? For some stakeholders, an e-mail message explaining the results may be sufficient. For others, it may be more appropriate to schedule a telephone call or visit.

- **Internal and external audiences** (see Chapters 2 and 7)

Have new players entered the field since your study began? Have new donors become interested? Are new advocacy networks following your research?

- **Key stakeholder lists, including media contacts**

Over the course of a trial, many people change positions. Planning for dissemination provides a good opportunity to update cell phone numbers, e-mail addresses, and other contact information.

- **Key and supporting messages that convey and contextualize the study and key findings** (see Chapter 7)

- **Event reports or other materials used at public events held throughout this or other studies at your site**

Was there a lot of interest? A good turn-out? Did the event provide people the best venue for understanding the trial results? Were there any problems that you could have prevented?

- **Background materials** (see Box 6.4)

and outcomes (National Center for the Dissemination of Disability Research 2001)

Timing, timelines, and time zones

Timing is everything, and with thoughtful planning, timelines can be managed just like anything else. Yet when you are preparing to disseminate the study's results, it can often feel like everything is happening at once. There is an ongoing ebb and flow when rushing to prepare your draft plan to meet internal deadlines and then waiting for the analysis of results before you can finalize the strategy. You will need to develop a detailed timeline, which will become your most valuable tool (and, at times, most despised—as frequent changes are required to be made). Beyond site and sponsor demands, multiple stakeholders around the world and in many time zones will want up-to-the-minute reports and information.

The only reason for time is so that everything doesn't happen at once.

—Albert Einstein

Timing will not dictate everything, but it will determine a lot. Developing and revising your timeline will be an ongoing activity throughout the course of your dissemination planning. (See Appendix 6.3 for a case study of timelines and tasks involved in disseminating the results of a multicenter microbicide trial.)

Here are some major points to consider when developing your timeline.

- Now that you have determined how you want to release your results, consider what is feasible. Your timeline should work backwards from a tentative release date, allowing enough time for each dissemination activity you plan. Remember that your timeline will evolve and change until the last minute. Be flexible.
- If your trial closes prematurely, your timeline for dissemination will be highly compressed. Research institutions sometimes have to close a study early for a variety of reasons—operational problems, safety concerns, or the inability to determine a product's effectiveness ("futility"). In some cases, the trial's independent data and safety monitoring board (DSMB) or data safety committee may recommend early closure because the data show that the product is highly effective, making it unethical to withhold the



Dr. Elisabeth Madraa, Programme Manager at the National AIDS/STD Control Programme in Uganda, presents at the Africa Regional Meeting on "Hormonal Contraception and HIV: Science and Policy" in Nairobi, Kenya, 2005. Participants signed confidentiality statements so that they could discuss study results prior to publication and provide guidance on interpretation to the research team.

Box 6.4. Advice on updating communications products

By Melissa May, Former Director of Public Information, Population Council, New York

Handling the release of the Carraguard microbicide trial results, we learned the hard way about “version control”: managing a document with multiple contributors and reviewers so that one master incorporates everyone’s changes. The difficulties were compounded in that project because of the number of different communications products that we were producing to support the release. Early on, we realized the benefits of giving every document a name that we could use to refer to it, and then to always use that name as the document title, together with a number for version control. By the end we had the “media backgrounder,” the “internal Q&A,” the “external Q&A,” the “South African country handout,” and the “advocates PowerPoint,” among many other documents.

We also learned that it is much easier to have all updates to materials managed by one person, who is responsible for updating all versions, posting them to the Web, and circulating them. In the beginning, we had way too many cooks in the kitchen!

And finally, we realized the benefit of keeping track of where information was repeated. In our materials spreadsheet, we noted which communications products included key bits of information so that we could easily update the materials en masse as new information became available. We even created dummy pages on a password-accessible Web site, which could be completed easily once the final results were known.

TIP



Plan to post all team materials in a central location (a shared drive or other internal, organizational Web portal, or a password-protected bulletin board). This is essential for version control.

product from participants in the placebo arm of the trial. (See Chapter 5 for a more detailed discussion on managing premature trial closures.)

- Allow enough time for coordination between the sponsor or central network and the site-level team. Appropriate members of the research team—perhaps at multiple sites—should have input on the core documents. You will also need to allow time for culturally specific adaptations and translations of the documents.
- Plan for staff attrition and closure of study budgets. Staff members often leave toward the end of a trial to take other positions, knowing that a given study will be closing. In addition, there may be a large time gap between the announcement of the results at an international scientific conference and the timing of a dissemination meeting for community members where the study was conducted. Consider how the loss of staff members and financial resources at trial’s end will affect your ability to carry out appropriate dissemination activities. Budget for adequate staffing to share results locally after the trial has ended.
- If your study team decides to release the results at a conference or in a journal, you should find out the schedule.

For conferences: When are abstracts due for the conference(s) you have chosen for presentation of the trial’s results? Does the conference consider late-breakers, and if so, when are those abstracts due?

For journals: How long can you expect to wait for a decision about manuscript acceptance? Will the journal agree to fast-track your submission? Once accepted, how long before it will be published or available online?

Box 6.5. Choosing a meeting for the presentation of results

By David A. Grimes, MD, Distinguished Scientist, Family Health International, and Professor, Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, NC

Choose early

When possible, both the intended journal for submission and the intended venue for presentation of research findings should be agreed upon by the team before the study begins. As with the journal, the choice of meeting should reflect the intended audience. To whom is your message going? Some meetings draw public health professionals, others include clinicians, some a mix, and some attract lay or professional media as well.

Be businesslike in planning

Deadlines for submission of abstracts tend to occur six to nine months before a meeting. Do not let these deadlines sneak up on you. After you choose your intended meeting, get the abstract submission date on your calendar, with regular calendar warnings in advance of the deadline.

Poster or oral presentation

Meeting organizers are more liberal in accepting abstracts as posters than as oral presentations. Because of limited hours for oral presentations, most abstracts are accepted only as posters. Weigh the pros and cons. Posters are harder to produce than PowerPoint presentations, cost more, are hard to transport, and get less attention. However, posters are still prestigious at some scientific conferences, and may offer the only opportunity to share your findings.

Be cautious about sharing your slides or manuscript

A reporter may ask you for a copy of your full manuscript ("I wasn't able to take notes as fast as you presented; would you mind giving me a copy of your paper so that I can get the facts straight?") Politely decline the request to share any more detail than what was in your public presentation. According to the Ingelfinger rule (Relman 1981), publication of abstracts up to 400 words in length does not constitute prior publication. Should a reporter write a column about your presentation that carries more detail (such as tables) than your oral presentation, you may compromise your ability to publish your work. When dealing with reporters at meetings, be careful about sharing unpublished data. Helping an interested reporter may inadvertently sabotage your publication.

Prior publication

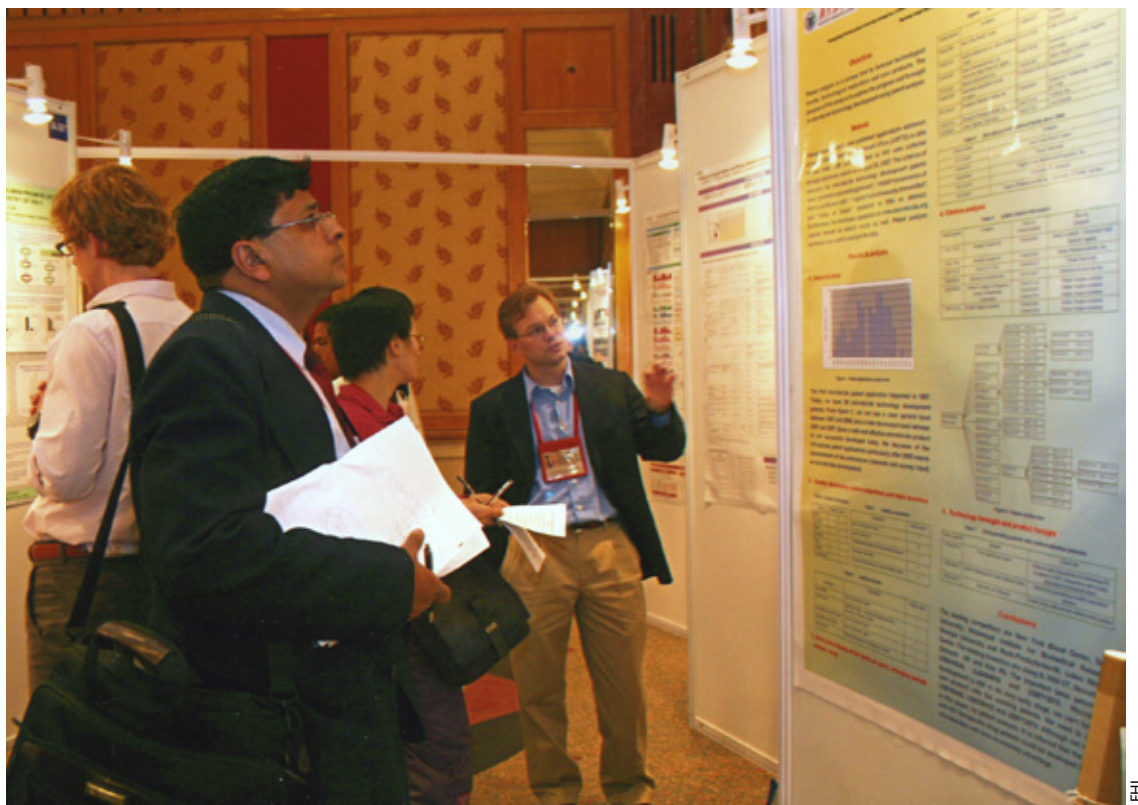
Some meetings refuse to consider research that has been published. If your manuscript is in press at a journal, you have little control over when it will be published. Advise the meeting organizers of this and submit it anyway. Given the long publication queues at many journals, your paper may not appear in print until well after the meeting.

Collaborate with the meeting press

The meeting organizers may hold press conferences. Journalists may ask for an interview after your presentations. These opportunities provide you a chance to share your results with the public via the press, but stay on message regarding your data. Stick to what you presented.

Network with colleagues

Spend time in the lobby, at social functions, and in the exhibit hall. Often more is learned in these settings than in the formal sessions. Carry a stack of business cards with you. Send new contacts a friendly e-mail upon your return to home, saying that you enjoyed meeting them. Networking is important, and those who express interest in your research may appreciate getting a copy of the published article when available.



Dr. David Jenkins of FHI explains study data at a poster session at the 2008 Microbicides Meeting in India, while Dr. Naresh C. Jain, Assistant Editor of the Indian Journal of Medical Research, listens.

Seek to disclose the results to participants as close to the public announcement of findings as possible. A new ethic is evolving to ensure that participants learn of results close to the time they are made public. Given the contribution that participants make to the overall research process, it is respectful to ensure participants learn results directly from the research site rather than hear an interpretation of the results through the media. Informing participants and local officials first also helps to balance the information needs of local collaborators and international audiences, and counters the perception that research is exploitative and controlled by outsiders.

- Some of the factors related to timing involve managing confidentiality requirements. You should decide when to communicate with which tier of stakeholders (e.g., study team, government officials, other interested parties). Do whatever is possible to ensure any embargoes are honored, for example, by asking that recipients sign confidentiality statements that will be in effect until the results are made public. However, you should also plan for the possibility that the results could be leaked before your scheduled release date.
- Take time zones into account when planning. As your team develops its announcement and dissemination strategy, consider your priority target groups and their geographical locations, the number of locations where your announcements may take place, and any logistical limitations that time zones might impose. For example, if your study takes place at sites in Latin America, the United States, and southern Africa, you will need to identify a time for public release that works for all time zones. Do not forget to factor in British Summer Time (BST) for UK audiences and Daylight Savings Time (DST) for groups in the United States.

Box 6.6. Timing the announcement of results: the AIDS vaccine study in Thailand

By Lisa Reilly, Communications Director, U.S. Military HIV Research Program (MHRP), Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD

In the fall of 2009, I coordinated the public announcement of the results of the Thai vaccine study—the largest-ever HIV vaccine trial, led by researchers from the U.S. Military HIV Research Program and conducted by the Thai Ministry of Public Health (MOPH).

We developed a phased announcement strategy to accommodate the three time zones our collaborators were in, which spanned 11 hours. A coordinated and centralized approach to media relations and stakeholder engagement played a critical role in reaching target audiences and mitigating potential issues. This strategy was agreed to months prior to learning the results.

Our initial announcement was made in Thailand on September 24th, 2009, an important Thai holiday and the anniversary of the trial's start date. Thai researchers requested this date and all of the collaborators agreed that the participants should be informed first. The following day, we

held a teleconference with a panel of scientists who discussed the results with members of the media. The study team also submitted a paper to the *New England Journal of Medicine* (NEJM), and planned to present the results at the AIDS Vaccine Conference in October, several weeks after the announcement.

Before the publication and presentation in October, we briefed several groups of HIV researchers about detailed trial data under confidentiality agreements. Some analyses were leaked to the press, and because we were under embargo, we could not address the questions raised before our article was published in the NEJM. In hindsight, the initial announcement to the volunteers should have been planned closer to the presentation and publication date to avoid this gap in public discussion of the full data.

Draft for internal use only

Summary of International Events to Announce the Thai Phase III (RV144) Results:

THAILAND			USA			FRANCE		
Date	Time	Activity	Date	Time	Activity	Date	Time	Activity
THURSDAY 24	22:00		WEDNESDAY 23	11:00	KOL CONFERENCE CALL	WEDNESDAY 23	17:00	KOL CONFERENCE CALL
	23:00			12:00			18:00	
	24:00			13:00			19:00	
	01:00			14:00			20:00	
	02:00			15:00			21:00	
	03:00			16:00			22:00	
	04:00			17:00			23:00	
	05:00			18:00			24:00	
	06:00			19:00			01:00	
	07:00			20:00			02:00	
	08:00			21:00			03:00	
	09:00			22:00			04:00	
THURSDAY 24	10:00		THURSDAY 24	23:00		THURSDAY 24	05:00	
	11:00			24:00			06:00	
	12:00			01:00			07:00	
	13:00	PRESS CONFERENCE		02:00	ISSUES PRESS RELEASE LIVE LINE TO THAI MEDIA EVENT		08:00	PRESS RELEASE ISSUED
	14:00	VOLUNTEER CONFERENCE CALL		03:00			09:00	
	15:00	MOH STAFF CONFERENCE CALL		04:00	HOLD FOR MEDIA INTERVIEWS		10:00	FRENCH PRESS MEDIA MANAGEMENT
	16:00	THAI ADVOCACY CONFERENCE CALL		05:00			11:00	
	17:00			06:00			12:00	
	18:00			07:00			13:00	
	19:00			08:00			14:00	
	20:00	LIVE LINE TO U.S. MEDIA EVENT		09:00	INTERNATIONAL MEDIA CONF CALL		15:00	SANOFI LED EVENT TO MEDIA CONF CALL
	21:00	HOLD FOR MEDIA INTERVIEWS		10:00	ADVOCACY CONFERENCE CALL		16:00	ADVOCACY CONFERENCE CALL
FRIDAY	22:00			11:00	MEDIA INTERVIEWS		17:00	FRENCH KOL/MEDIA INTERVIEWS
	23:00			12:00			18:00	
	24:00			13:00			19:00	
	01:00			14:00			20:00	
	02:00			15:00	1500 MHRP EMPLOYEE BRIEFING		21:00	
	03:00			16:00			22:00	
	04:00			17:00			23:00	

Press Events
 Individual Press Calls/Briefings
 Briefings to Other Key Parties

Finally, try to anticipate other factors that might affect your announcement strategy. For example:

- Does weather affect planning for events during a particular time of year?
- Will holidays or other significant dates interfere with the release of your results?
- Is it important to your institution to inform trial participants in a formal meeting before presenting your findings to the scientific community in your country or internationally?
- Will labor patterns (such as seasonal work) affect your ability to reach participants?
- Will some government officials need to be informed before others?
- What are the possible repercussions of the dissemination of the trial's results?

Box 6.7. Communications timeline and milestones for dissemination of trial results

Revisit your initial communications strategy with dissemination in mind.

- Identify new needs and opportunities.
- Consider your goal, audience, medium, and execution.

Establish a dissemination planning team and a decision-making policy.

- In addition to your existing communications team, you may want to involve additional stakeholders, such as CAB members.
- With your team, discuss and decide which members will have decision-making authority.

As a team, discuss your dissemination goals and develop a written dissemination plan.

- Weigh the pros and cons of different release strategies.
- Establish your goals and priority audiences.
- Plan different activities for each priority audience.

Update lists, materials, and messages as necessary.

- Look over contact lists; ensure they are current and accurate.
- Account for any changes that have occurred since the start of your trial that may affect your dissemination strategy.

Determine the timing of the announcement.

- Choose a tentative release date.
- Decide when to release the results to various stakeholders: staff, participants, sponsors, etc.
- Identify events or other factors that may affect your announcement strategy.
- Plan for various outcome scenarios.
- Discuss and develop key messages for those scenarios (positive, neutral, and negative).
- Share each scenario; meet with site teams and other stakeholders to discuss implications of each scenario.
- Consider the ways each scenario might affect your announcement strategy.
- Determine "top line" (key) and supportive messages for each outcome; translate materials as necessary.

Manage pre-release issues.

- Put systems in place for when the results are known.
- Consider the needs of both global and in-country stakeholders.
- Determine the timing of the results for each group of stakeholders.
- Consider conference or publication embargoes.
- Plan the timing of media embargoes and press releases.

Orchestrate the public announcement.

- Implement your announcement strategy.
- Consider holding a local announcement event.
- Use different approaches for different stakeholders.
- Monitor news media and correct inaccuracies.

Manage post-announcement dissemination activities.

- Continue to monitor media and community concerns; respond when appropriate.
- If you so choose, submit a manuscript to a scientific journal.
- Plan appropriate meetings to involve stakeholders in determining the implications and applications of the results.
- Promote the application of the findings; involve stakeholders in planning, implementing, and evaluating the application of the results.

IV Planning for various outcome scenarios

You can do a great deal of planning and site-level preparation even before you know the answers to your research questions. Scenario planning is an investment of time. It requires a

willingness to commit to a process that by its very nature involves developing some strategies and materials that will never be implemented or used. Yet, such preparation is well worth it.

Preparing for a number of possible outcomes reduces the risk that you will be surprised. With good preparation, the members of your communications and management team will have discussed and determined key messages for every scenario. This enhances the likelihood that all team members and partners will have accurate information and will be able to share consistent messages about your results. Some teams even test the messages with groups of participants to assess the effectiveness of the messages.

Pictured here are local community leaders in Bamako, Mali. When planning dissemination, consider which community groups will want to learn about trial results.



Elizabeth T. Robinson/FHI

Box 6.8. Scenario planning: an investment in capacity building

By Anne Coletti, MS, Scientist, Family Health International (formerly with the HIV Prevention Trials Network)

In late 2008, the HIV prevention field was preparing for the dissemination of results from the HPTN 035 microbicide study. Although a few investigators who were responsible for data analysis knew the study results in early December—about two months before the public announcement scheduled for the Conference on Retroviruses and Opportunistic Infections in early February 2009—most of the site-level study teams and all external stakeholders did not yet know the results.

As the sites and network staff worked on dissemination planning and putting together materials for the possible scenarios (positive, neutral, or negative trial results), the few of us who knew the results had to maintain strict confidentiality. This meant helping the site-level teams articulate the implications of various scenarios, despite knowing which scenario in fact described the real results. At times, it was heartbreaking to send scenarios to the sites, knowing we were sending them extra work.

While those “in the know” felt these scenarios were painful and a waste of time on occasion, others outside the information loop stressed the importance of scenario planning and the role of the exercise as a means to build capacity at the sites and to prepare the broader field.

If I could do it over, I would want to share the scenario-planning materials months earlier, and work out the messaging before anyone knew the results. This would have removed the time pressures from the sites to review and translate multiple materials, and it would have given them more opportunities to think through each scenario as a team.

Take a methodical approach to planning the outcome scenarios. Many people have casual conversations at their site or in conference hallways, asking questions such as, “What will you do if the study results are positive?” “If the results show an effect, will all other studies testing this product be stopped?” “Is there a chance the findings could show harm?”

Although these hypothetical discussions can be stimulating, it is critical to employ strict parameters when your team is doing scenario planning in preparation for the dissemination of your results. Consider the following issues as you plan for various outcomes of your trial:

- Your planning should use the available data and contextualize the situation to address and anticipate possible scenarios: positive results (the product or intervention is proven effective), neutral results (the product or intervention is proven ineffective), or negative results (the product or intervention is shown to cause harm). You should also describe the implications for each scenario. Other considerations in your scenarios may include whether your study will be the first to release results on this intervention or whether it may confirm or dispute data from previous studies. If your study was designed to test a product for regulatory approval, you may need to consider scenarios about the effect of the data on licensure.
- Consider how your announcement strategy varies with each scenario. For example, you may want to actively seek major media coverage if the results are positive, but not for flat results. Keep in mind that external stakeholders will take a greater interest in your results if they are groundbreaking or unexpected—whether the results are good or bad news.

Consider this in your planning and address how the strategy may need to be adapted if your findings were to draw widespread interest.

- Develop key and supporting messages that explain all of the possible scenarios so your audiences will understand the possible outcomes before the final dissemination of your results (see Chapter 7). An easy way to develop your messages is to start by creating a questions-and-answers (Q&A) document. Here's how:
 1. Make a list of the most obvious questions (as well as the hardest) that policymakers, other researchers, news media, or community members may ask you—for all of the possible trial outcomes.
 2. Develop answers to these questions in the form of an internal Q&A sheet (see Appendix 6.4). For example:
 - Is the experimental treatment more effective than current treatment?
 - Is drug resistance a concern? Was drug resistance monitored in the trial?
 - How readily available is this product in resource-poor settings?
 - Do we know if the new treatment is safe for pregnant women?
 - Will trial participants continue to have access to the new drug after the trial is over?Circulate the internal Q&A among the communications team, and revise it as needed to make the answers accurate, clear, and succinct.
 3. Once you have this document revised, review it and highlight the key and supporting messages about the study and the possible outcome scenarios. These should stand out.
- Develop template materials for each of the main scenarios. Once you have your key messages and an internal Q&A, you can use these documents to develop other background materials that will help you contextualize your results. To manage the expectations of others, you must explain your results in ways that are appropriate for each of your audiences.

Prepare and update dissemination materials. Once you have determined your dissemination strategies, including how and when you want to announce the results to your various audiences, you should update all of your materials and develop any new materials you will need.

To stay organized, develop a spreadsheet with interim and final due dates, and assign responsibilities. Pay attention to version control so that you do not inadvertently share the wrong documents. Make sure that everyone who receives the documents is aware that they are confidential drafts. A watermark, such as “draft” or “confidential,” can make this clear.

Most materials will need to be developed as templates, based on your scenarios, with placeholders for when the results and the data become available. Keep in mind that these should be translated and back-translated for accuracy; also, some materials may need to be approved by the Institutional Review Board (IRB). (See Appendix 6.5 for a sample letter to an ethics committee requesting review of materials needed for the dissemination of results.)

You may wish to develop some of the following materials (Center for Interdisciplinary Research on AIDS: Community Research Core 2009). (See Chapter 3 for more on materials development.)

Backgrounder on the results. Concisely summarizes the study and the main findings of your research. The document should be organized by topic areas, and it should include key points in bullet form.

Fact sheets for specific audiences. These one-page fact sheets include the main findings in a short, bulleted format. These key points can be adapted for different audiences. A fact sheet for scientific colleagues might include technical data and numbers, whereas a fact sheet for the news media should focus on the broader context and public health significance of the findings.

Press release. This can be one of the most efficient and effective ways to announce your research results. Depending on what media you target, press releases can help you reach a wide variety of people in different regions. These should be translated for local-language media.

External Q&A sheet. Unlike the internal Q&As described earlier, these Q&As are shared with the public (interested parties) and cover basic questions about why the study was conducted, what the study found, and what the implications are for the participants, for health care programs, and for public health policy.

Flyers, posters, and brochures. Brochures can offer a visually appealing way to release results to a broad audience. Due to their limited space, their use will require considerable simplification of results. This may be appropriate for some studies and highly effective for some audiences. (See Appendices 7.1 and 7.2.)

Letter of thanks to study participants. In addition to meeting with trial participants, you may also want to write a letter to your participants, thanking them for their participation and explaining research findings.

Newsletters about the trial. If you have a regular newsletter, this can be a very effective way to reach certain stakeholders, such as donors and other scientists (see Appendix 3.4).



02 December 2009

To: Community Members/Stakeholders/Gatekeepers

RE: FINAL RESULTS UPDATE ON MDP 301 RESEARCH STUDY

The HIV Prevention Research Unit (HPRU) of the Medical Research Council (MRC) in Durban has been conducting the MDP 301 clinical trial at the MRC research sites based in Tongaat, Verulam and Isipingo since December 2005. To date, we have been working in partnership with community members and provided regular feedback on the research progress and held several community based trainings, outreach and education sessions.

This clinical trial has been recently completed and final results are expected to be available to the public on 14 December 2009.

As an important stakeholder, we would like to share the final results before they become available to the public. We therefore humbly request your presence at this meeting where we will provide the community with the final results of the MDP 301 Trial. The trial would not have been successfully completed without the support, assistance and collaboration of community members and all stakeholders involved. Your participation and input at this meeting will be most appreciated. The meeting details are as follows:

DATE: 14 December 2009, Monday

VENUE: MRC Isipingo Site, 3-13 Police Station Road, Isipingo

TIME: 10:30 -12:30

Yours Sincerely

Yuki Sookrajh
MDP Manager

Cc Prof Gita Ramjee

RSVP: Mduduzi Ngubane
Tel: 031 – 9027494
Fax: 031 – 902 7938

V

Managing embargoes and pre-release issues

After months of planning and sleepless nights, the day will come when the study results become known—to select members of the study team. This is a critical time for studies and site teams, as information disparities, sensitivities around confidentiality, and the potential for leaks become daily realities for your site. Make an effort to discuss and determine how the team will handle this period before the results are disclosed to anyone at the site. This will lessen the tension for everyone and help to maintain a sense of solidarity within your team.

In the weeks leading up to the public announcement, you can expect time to move fast, timelines to change and to-do lists to expand—in other words, expect the unexpected. A tiered distribution system, linked to a timeline, will help you keep track of what groups you need to notify, and in what order.

Consider the following steps to manage this period:

Step 1. Put systems in place to prepare for the results. Often one or two investigators at each site learn the results as soon as they become known and are sworn to strict confidentiality. Meanwhile, the rest of the study staff must wait until just before the public announcement. This is the “crunch” time when dissemination plans and materials need to be finalized. Determine how your site will manage the workload and consider using confidentiality agreements with certain staff members who may need to learn the results to do their jobs. Your site should decide:

- Who will conduct supplementary analysis after unblinding?
- Who will see the documents but not be directly involved?
- Who will finalize all the materials?
- Who will translate them into local languages if necessary?
- Who will arrange pre-embargo briefings with government officials and other key stakeholders, and which staff members will attend?

Step 2. Balance the needs of in-country stakeholders and global stakeholders. Whether your study operates at a single site and works with one institution, or is a multisite, network-driven study, you will have to address the needs of both in-country and global stakeholders. These may include donors, the trial sponsor, scientific colleagues, policymakers, and global advocates.

Step 3. Decide who needs to know what, when, and how. By now, you should have updated the list of your stakeholders and selected the news media you plan to inform. If you have not done so already, it is time to group these people into categories or tiered lists for your internal use.

- Separate out individuals who should be notified before the official results are released publicly and those who can wait for the official announcement.

- Group the people in your “need to know early” list by profession to help you plan any pre-embargo briefings and materials. These lists will often mirror your audiences that you identified earlier in the study.

Although you want to keep a relatively short list of people you need to inform early, remember to think outside of the “usual suspects.” For example, if you are releasing results for a tuberculosis vaccine study in children, remember to include leading pediatricians on your stakeholder list. Even if the pediatricians do not work on tuberculosis, journalists are likely to call these opinion leaders.

Step 4. Account for conference and publication embargoes. Every publication and almost every conference has an embargo policy concerning the timing of public releases. It is important to understand exactly what you may and may not do within the confines of the embargo. Even if you have released findings at a particular conference before, check again, as policies may change from year to year.

- If you are releasing your results at a conference, find out how media relations are coordinated. Most scientific conferences hold press briefings for attending journalists, often selecting the most intriguing abstracts that they think may be newsworthy and then scheduling press conferences around those topics. You may also be able to request a press briefing. In this case, be prepared to “sell” your topic, explaining why it is newsworthy and who will present it.
- If your abstract gets selected for a press conference at a scientific meeting, this may affect your embargo time as well as your announcement strategy.
- If you are publishing the results in a journal, find out the embargo date and when the article is likely to be posted online. Also, find out if you can pre-release any information—under embargo—and under what circumstances.



Imad Ulay/FHI Nigeria

When planning for dissemination of results, remember to inform relevant government officials and donors. In this photo, Carl Hawkins from USAID Nigeria speaks with Dr. Christoph Hammelman, Director of FHI/Nigeria.

Step 5. Carefully plan media embargoes and the timing of your press releases. There may be restrictions on media coverage if you are also submitting a manuscript to a journal or releasing your results at a conference or event. Embargoes are usually respected by professional health journalists. This means that studies may choose to share their press release shortly before the public announcement with certain journalists, under the agreement that the journalists may not publish their story until the embargo has lifted. This strategy allows journalists the time to write accurate and well-researched articles, interview stakeholders, and get quotes so that their stories are ready to be printed the moment the embargo lifts.

If you are planning to share a press release with selected journalists before your embargo lifts, remember these tips:

- Check with the journal or meeting to determine if you are permitted to share a press release or the abstract under embargo with reporters.
- Always include the time zone when the embargo lifts on your press release. For example,

if you are releasing results at a conference in Russia, do not write, “Embargo lifts at 13:00.” Write “Embargo lifts at 13:00 Moscow / 10:00 UK / 03:00 EST.” Include the main time zones where you are sending the release to journalists. Provide this information at the very top of the press release so that it can not be missed.

- List at least two contact numbers, including at least one local mobile number.
- Offer recommendations and contact information of experts who have been informed of the results on a confidential basis prior to public release and who could be available for interviews and to give quotes.
- Check the local culture around embargoes and let that inform your strategy. For example, when communications officers arrived in New Delhi, India, for the Microbicides 2008 Conference, they were surprised to find out that most local journalists did not respect embargoes. It simply was not in their journalistic culture. This information swayed some people to hold onto their press releases until the official embargo ended.

Box 6.9. What is the U.S. Securities and Exchange Commission and how could it affect the timing of the release of trial results?

The U.S. Securities and Exchange Commission (SEC) was created during the Great Depression in 1934 primarily to protect investors. The agency works to enforce laws that require publicly traded companies listed on the New York Stock Exchange to tell the public the truth about their businesses, including products they are developing and the risks involved in investing in them.*

When a research trial is testing an experimental product that is owned by a publicly traded (commercial) company, the company has legal obligations to publicly inform its stockholders of any major findings about the product, whether good or bad news.

The SEC rules state that companies must inform the public within 24 to 48 hours of the trial findings becoming known, to prevent “insider trading” of stocks or securities. However, in cases of sudden closures or unexpected findings, some trial sponsors have been able to negotiate directly with the SEC to delay the public announcement of study results, and thereby gain time to notify Ministry of Health officials or other trial stakeholders directly before they hear about it on the news. (See Chapter 5 for more information.)

For this reason, some trials now strategically time their DSMB meetings to take place on Fridays. This way, if any major change or trial closure is recommended, the trial team will have the entire weekend to notify stakeholders and implement an emergency dissemination plan on Monday morning. This works because the SEC time requirement that the public be informed within 24 to 48 hours excludes Saturdays and Sundays, since the New York Stock Exchange is closed and no trading of stocks can occur over a weekend.

*Source: <http://www.sec.gov/about/whatwedo.shtml#intro>.

VI Orchestrating the public announcement

Your public announcement requires careful orchestration and choreography. It is the day that the curtain goes up and the world comes to know your trial's results.

Consider the following activities as you conduct your plan.

1. You may want to work with an in-country communications firm to implement your announcement strategy. You could consider an international or national communications firm with offices and contacts in the countries hosting trial sites. Such firms can provide vital links to in-country media and logistical assistance to arrange meetings and other activities.

- Be aware of the need to foster close coordination between the firm and local site leaders, especially if the firm is reaching out to opinion leaders of strategic and political importance to local investigators.
- Even if you cannot hire a public relations (PR) firm, consider whom to involve to ensure that stakeholders have appropriate access to trial results and to enhance the use of the findings by health systems.

2. Consider hosting a local announcement event. Many sites host local events for their trial participants and the local community. This is an opportunity to share the study results and thank all of your stakeholders for their support during the study. You may decide to invite media to this event, or you may choose to hold a media briefing separately, perhaps just before the public event. In this case, journalists would be able to receive a briefing on the results targeted for them and ask any questions, but then could stay to participate in the larger event for context. When planning your local event, make sure the timing fits in with the study's larger timeline and any embargo limitations.

3. Use your announcement event to salute your participants, staff, and partners. Regardless of your results, your announcement event is a time to celebrate the completion of a clinical trial. Use your event to acknowledge publicly the participants, staff members, and local leaders who provided support during the study. Consider asking a local leader to take part in the program and a trial participant to speak at the event (see Box 6.10). If you are planning or preparing for future studies at your site, let the audience know that you are staying in the community and you would appreciate their ongoing support with future studies.



The International AIDS Conference is an important venue for dissemination of HIV prevention research.

Box 6.10. Giving voice to trial participants

By Prof. Gita Ramjee, HIV Prevention Research Unit, Medical Research Council, Durban, South Africa and Dr. Nyaradzo Mgodi, University of Zimbabwe-University of California at San Francisco Collaborative Research Program

Individual institutional review boards (IRBs) or ethics committees can sometimes determine the extent to which the research staff may facilitate an interaction between currently enrolled trial participants and the news media. In general, however, IRBs do not allow researchers to proactively promote contact between enrolled participants and news media. Even if an individual participant is willing to speak with a journalist, other enrolled participants may infer that the research team has broken the promise of confidentiality and might do the same to them.

TIP

Getting IRB approval for participants' involvement with the media

- **Speak to your IRB early. Listen to any concerns, such as protecting confidentiality, and find creative ways to address them appropriately in your setting.**
- **Work with your IRB to develop a best-practices policy for allowing trial participants to engage with the media. For example, develop a protocol for selecting potential trial participant spokespersons, including ensuring that volunteers are adequately prepared for the experience of being interviewed. Submit the protocol for review.**
- **Share with your IRB examples of past successful experiences. Bring media clips that include quotes from trial participants of other studies.**
- **Explain the downside if the site does not proactively involve trial participants in media interviews. Media may end up talking to ill-informed or disgruntled participants.**

Once a trial is over, however, ethics committees typically no longer govern the research team's role in such communication. During the dissemination of results of the HPTN 035 microbicide trial in southern Africa, different sites conducting the same study had different views and experiences with linking former trial participants with news media covering the dissemination of results.

In Durban, South Africa, the research team invited a few former trial participants to the local media briefing announcing the results. These women were no longer active trial participants. After the briefing, the former participants did one-on-one media interviews with journalists upon request. The women had agreed to speak with the media before knowing the study results or even which trial arm they were in. They shared their first-hand experience of the research process with journalists and gave interviews in English and Zulu, the local language. Resulting local language and national press coverage included profiles of trial volunteers and quotes that highlighted the human story behind the research statistics.

In Harare, Zimbabwe, HPTN 035 participants did not take part in media interviews when results were disseminated. The study staff had earlier identified some women who could be

interviewed by media personnel if the need arose, but never obtained local IRB permission to do so. Once results were ready for dissemination, some participants were still being followed for various outcomes (such as pregnancy). Ultimately, given the time limitations, and because participant interviews were not included in the master plan for dissemination of results, study staff did not pursue approval for such interviews from the study's IRB.



Mitzy Gafos/Africa Centre

MDP participants from Africa Centre in Mtubatuba, South Africa, prepare songs and dance (with male and female condoms in hand) to celebrate the successful completion of the MDP 301 trial.

Box 6.11. Organizing different meetings for different groups of local stakeholders

By Dr. Ikoma Obunge, University of Port Harcourt Teaching Hospital, Nigeria

In Port Harcourt, we organized a series of dissemination activities to share the results of the cellulose sulfate Phase III microbicide study in Nigeria. This trial had flat results, yielding no evidence that the product helped to prevent HIV or that women using the product were at greater risk of HIV acquisition. We decided to organize separate activities for three different categories of stakeholders:

Study participants. Two outreach workers coordinated with the principal investigator or the site coordinator to contact more than 600 former participants by telephone. Text messages were sent as a reminder to all participants who accepted the invitation. On the morning of the dissemination meeting, a “wake-up call” was made as a reminder. Two sessions were held to accommodate the 120 former participants who attended. These sessions included an overview of the study and a summary of the results, then plenty of time for discussion.

Ministry officials, governmental agencies, regulatory authorities, and civil society organizations. The site team organized a meeting with officials of the Rivers State Action on AIDS Committee to develop a list of relevant stakeholders. The Ministry of Health, National Agency for Drug and Control, Planned Parenthood Federation of Nigeria, and various civil society groups (people living with AIDS, faith-based organizations, youth, and AIDS prevention groups) were invited by letter. The principal investigator presented the study results to the 47 people who attended, then addressed comments and questions from attendees.

The University of Port Harcourt Teaching Hospital community. We notified hospital management and heads of departments of various units of a presentation of the results. Three co-investigators presented the results to 52 attendees, then answered questions from hospital colleagues.

Box 6.12. Disseminating information, demanding information: the dual roles of advocates when trials close

*By Deborah Baron, MMCI Coordinator, GCM and Lori Heise, Former Director, Global Campaign for Microbicides**

The closure of the N-9 study in 2000 and protests about the oral tenofovir PrEP trial in Cameroon in 2005 taught the HIV prevention research field critical lessons in communications—wherever information gaps exist, misinformation and rumor will fill the void.

Less than a decade later, when the cellulose sulfate (CS) trial closed early, no fewer than 27 advocacy and citizen media list servers covered the closures (Robinson 2007). These list servers enabled groups to maintain a steady information flow and dispel any surfacing rumors about the CS study and closure.

In the lead-up to the public announcement, a few long-time advocates were informed of the closure during the pre-embargo period. Early access to confidential information enabled these groups to plan ahead and strategize a public response. The U.S.-based groups Global Campaign for Microbicides (GCM) and AVAC, as well as the African Microbicide Advocacy Group (AMAG), decided to release a joint statement timed with the public announcement of the closure. The key message stressed the importance of continuing microbicides and other biomedical prevention research (African Microbicides Advocacy Group and others 2007).

In addition to the press statement, these groups circulated background materials and an initial Q&A to their list servers, reaching over 5,000 advocates worldwide. The quick availability of easy-to-understand materials helped quell confusion and suspicion among advocates. The AMAG list server and Nigeria AIDS e-forum moderated by Journalists Against AIDS offered online platforms for African advocates to express concerns and ask questions about the scientific and ethical procedures of the closure. Trial sponsors and site staff members were invited and often responded to questions in these e-forum dialogues (Robinson 2007).

Since many people in Africa lack reliable Internet access, the GCM sponsored a series of tele-briefings that gave stakeholders an opportunity to ask questions directly of the investigators and members of the independent data and monitoring committee that made the recommendation to stop the trial. By providing direct access to key decision makers, these calls helped to dispel rumors, reduce suspicion, and disseminate accurate information.

*Lori Heise is currently a Lecturer at the Gender, Violence and Health Centre, London School of Hygiene and Tropical Medicine.

4. Even at the community level, you may need to group stakeholders in different categories and inform them of the results through different approaches. Here are some basic tips on informing stakeholders:

Government stakeholders and policymakers. Do not underestimate the political importance of ensuring that key government stakeholders hear the results directly from you, rather than from others (especially the news media).

- With officials, face-to-face contact is especially important. Appointments for meetings should be made with drug regulatory authorities, ethics review committees, and appropriate Ministry of Health staff, with plenty of lead time.

- If you plan to distribute written materials, keep in mind that busy officials may not have time to read long reports. Include an executive summary explaining what you studied, why you studied it, and what major findings and conclusions your research generated (Ulin and others 2005).

Participants. There are a variety of dissemination activities that can help you inform your trial participants of the study's results. In addition to hosting a community forum or a meeting of participants—speaking at popular forums or local churches—you can send a newsletter or a letter of thanks to participants, explaining the findings of the study. Consider sending SMS (short message service) text messages to participants informing them where they can pick up newsletters.

The local community. In addition to sharing results with trial participants, informing community members near the sites is a recommendation now included in international guidance documents (Heise and others 1998; UNAIDS 2000). You may want to have an open meeting to explain your results and allow members of the community to ask questions about the study. Creative ideas—such as plays and songs—can be very effective in delivering your messages to the community in a way that is understandable to people with little knowledge of science. (See Appendix 6.6 for a sample letter inviting community stakeholders to learn study results.)

Advocacy networks. It is also important to inform other trial networks, as well as both national and transnational advocate networks. Many of these groups can be reached through list servers and targeted press releases. You may also want to consider co-hosting with an advocacy group a toll-free dial-in conference call in order to reach these networks.

5. Determine how to contact health journalists who will not attend your announcement event. When you are announcing study results at a conference, for example, you may also want to telephone or e-mail selected reporters who are not able to attend. A simple grid listing the individual reporters you plan to reach can be a useful tool when you are preoccupied with the details of managing the announcement of your results.

6. Diligently monitor the media so that you can quickly correct their mistakes. If possible, assign a staff member to monitor media during the week of the release. If media coverage spans a few languages in your community, consider assigning one person to cover each language's media. This person should read all articles and have enough knowledge of the study's results to be able to check articles for inaccuracies (see Chapter 9).

7. Take care of yourself and your staff—prevent staff burn-out. No matter how much you plan, the weeks leading to and the week of the release will entail many long hours and late

As members of research communities, advocates often know the best ways to reach their communities, deal with negative media situations, and help research groups develop effective communications strategies.

—Microbicide Trials Network and the Population Council 2007

nights. Make sure you set aside some personal time before the pace picks up and advocate for staff to take a day off in the run-up to the final stretch. This will help everyone to recover their energies and go the extra mile during the week of the announcement.

VII Post-announcement dissemination activities

Dissemination activities do not end after the results are announced to the public. Depending on a variety of factors (the outcome of the study, the size of the trial, the timing of the release), media coverage and inquiries may continue for weeks, and even months, after the results are public.

Continue to monitor the content of the coverage, and the spread of news on list servers, blogs, and similar outlets. Once your study results are covered in the media, you should maintain an archive of articles. This may be helpful for future research.

Community members, government officials, and other interested parties may continue to have questions about the study's results after the trial closes. Make sure you plan for this, and have enough staff on hand to answer questions and maintain relationships with your contacts.

Consider the following steps:

Step 1. Submit your manuscript to a scientific journal for peer review and publication.

Publication in a peer-reviewed journal is one of the most important steps in the dissemination of your study's results to the global scientific community. The peer-review process is in place to prevent the dissemination of irrelevant findings, unwarranted claims, unacceptable interpretations, and personal views. It is the responsibility of the entire team to ensure that study results are published in a journal that offers other researchers and public health professionals access to the findings.

Box 6.13. Dissemination factors that promote the use of research results

- The information needs of specific audiences are considered when designing the study.
- A wide range of stakeholders are engaged throughout the trial (Rogers and Storey 1987; Havelock 1969; Cernada 1982).
- The credibility and reliability of the research findings are accepted by users of the study.
- Findings are disseminated to multiple audiences using a variety of channels and formats.
- Presentation of findings emphasizes the important lessons learned, especially from the point of view of the intended audience, rather than the need for more research.

Source: PR Ulin, ET Robinson, EE Tolley. *Qualitative methods in public health: a field guide for applied research*. San Francisco: Jossey-Bass; 2005. p. 200. Reprinted with permission. Adapted from Sharma 1996.

Step 2. Involve key stakeholders with the dissemination of your results. Research shows that findings are more likely to influence policy and practice if stakeholders are involved in the project from the beginning and if messages highlight the implications of the findings for practice rather than just the need for more research. Also, the impact of research increases when the credibility of the research findings are accepted by the users of the study (see Box 6.13). Because people are more likely to trust those like themselves, it can be helpful to enlist stakeholder allies—such as key advocates, a respected public health physician, or an industry partner—as messengers of your results to their peers.

Step 3. Take advantage of simple ways to increase your reach. In the weeks and months after your announcement, consider ways to multiply your reach, if you deem it appropriate or desirable. Place short articles about your trial results in the newsletters of colleague organizations. Send a short description of the study findings to specialist journals from allied fields and encourage them to highlight the results in their news section. Send reprints of the journal article summarizing the study findings, along with a short personalized note, to key opinion leaders in the country where your study was conducted.

Conclusion

The dissemination of a study's results is an opportunity for researchers to expand their collegial networks, connect with scientists in related disciplines, and establish mutually satisfying relationships with members of the press and advocacy groups.

Elizabeth T. Robinson/FHI



Dr. Leigh Peterson discusses FHI's oral tenofovir trial with news media at the International AIDS Conference in Toronto.

Key points to remember

- Disseminating study results to a variety of local, national, and international stakeholders is increasingly considered an ethical obligation of research and a key element in the collaborative research process.
- Scenario planning—an exercise to prepare for and develop messages for a number of possible outcomes of a study—reduces the risk that you and partner organizations will be unprepared to deal with the implications of study results.
- Dissemination activities continue long after the day you publicly announce your results. Plan to monitor media coverage, respond to inquiries, and include information about your study results in public presentations for weeks and even months after the release. Even years later, stakeholders should be able to easily locate your study results in the public record, whether online or in published archives.