Communications Handbook for Clinical Trials

Strategies, tips, and tools to manage controversy, convey your message, and disseminate results

By
Elizabeth T. Robinson
Deborah Baron
Lori L. Heise
Jill Moffett
Sarah V. Harlan

Preface by
Archbishop Desmond M. Tutu

USAID FROM THE AMERICAN PEOPLE
fhi Family Health International
Global Campaign FOR Microbicides
mmci Microbicides Media and Communications Initiative

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Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results

Authors: Elizabeth T. Robinson, Deborah Baron, Lori L. Heise, Jill Moffett, Sarah V. Harlan

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To request additional copies of the handbook, e-mail: handbook@mmci-communications.org.

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Preface

One of the greatest joys and responsibilities of democracy is the freedom of speech. We have the luxury and the burden to communicate our struggles, our hopes, our work, and our passion. In the fight against HIV and the long journey to finding new ways for those most vulnerable to protect themselves, a key challenge is to communicate the logic and the promise of this important work.

Research to find new methods of HIV prevention is a complex and arduous endeavor. It involves building trust across divides of race, gender, culture, and privilege. It demands dedication on the part of scores of counselors, study nurses, lab technicians, outreach workers, and scientists. It requires commitment, honesty, and sacrifice from hundreds and even thousands of participants. And it requires communities to embrace an often foreign enterprise—that of scientific research.

Clinical research is hard to explain to people with little or no scientific background. It is like a foreign language, a different culture—but one that holds great promise for the poor and the rich alike. It is up to us to ensure that the potential benefits of science reach all people and that participants and communities understand and can engage productively as full partners in the research endeavor.

Global guidelines, such as the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* recently published by UNAIDS, in collaboration with AVAC: Global Advocacy for HIV Prevention, are defining new standards for equitable practice between researcher and participant, between donors and community, and between those designing and implementing research and those poised to reap its benefits. This document sets out principles and minimum standards for engaging communities in the conduct of research, including building research literacy, community engagement, and communicating with research stakeholders.

But even the greatest guidelines or constitutions in the world cannot succeed unless we have the practical tools to make them work for everyday people in their everyday lives. For the investigators, study coordinators, and community liaison officers working on the frontlines of these trials, this handbook will serve as one such tool, providing guidance for translating expectations regarding stakeholder communication into concrete practice. The Good Participatory Practice (GPP) guidelines call for a "written communication plan" as an essential element for all future trials. This handbook describes how to develop an overall communications plan, with special plans for research dissemination and crisis communication.

The HIV field is not alone in confronting changing expectations and new challenges when it comes to communicating about research. Across the board, an increasing number of actors now see themselves as stakeholders in the research process. I see this development as a positive one and an evolution we must embrace. As our world gets increasingly complex, the need for science and research literacy becomes ever more acute. This book, and others like it, is an important contribution toward bridging the worlds of science and community—of bringing more and more people into the conversation about research. Increasingly, science is touching all of our lives and we must ensure that even the most marginalized people are part of the dialogue.

God bless you.

Archbishop Desmond M. Tutu

Acknowledgments

The ***Communications Handbook for Clinical Trials*** grew out of the collective experience of scores of individuals who have dedicated themselves to demystifying science and ensuring that both the process and the outcomes of clinical research are communicated clearly. From the beginning, the process of creating the handbook has been a collaborative effort, and the final product reflects the wealth of this input.

The authors would especially like to thank the members of the Microbicides Media and Communications Initiative (MMCI), an ongoing "community of practice" that meets regularly to share strategies for handling the complex communications challenges posed by the conduct of large-scale effectiveness trials of HIV prevention technologies in Africa and other resource-limited settings. Many of the stories and insights contained herein derive from the experiences of MMCI members, who have been incredibly generous in sharing their knowledge, materials, and hard-won wisdom about clinical trial communication. We particularly thank all MMCI Steering Committee members (former and current): Quarraisha Abdool Karim, Centre for the AIDS Programme of Research in South Africa (CAPRISA); Manju Chatani-Gada, AVAC: Global Advocacy for Prevention; Mitzy Gafos, Microbicides Development Programme (MDP), Africa Centre; Yasmin Halima, Global Campaign for Microbicides (GCM); Polly Harrison, AVAC; Lori Heise, London School of Hygiene and Tropical Medicine (LSHTM) (co-author); Neetha Morar, South African Medical Research Council (MRC); Oliver Mweemba, University of Zambia; Patrick Ndase, Microbicide Trials Network (MTN); Pamela Norick, International Partnership for Microbicides (IPM); Elizabeth T. Robinson, Family Health International (FHI) (co-author); Lisa Rossi, MTN; and Deborah Baron, MMCI coordinator, GCM (co-author).

A rich source of learning came from an in-person consultation that we held in March 2009, co-sponsored by the MMCI and CAPRISA. This meeting brought together 45 investigators, trial staff, and community advocates in Durban, South Africa, to solicit feedback on early drafts of the handbook and to collect examples and lessons learned from the lived experience of those working on the frontlines of communicating about HIV prevention trials in Africa. These individuals included:

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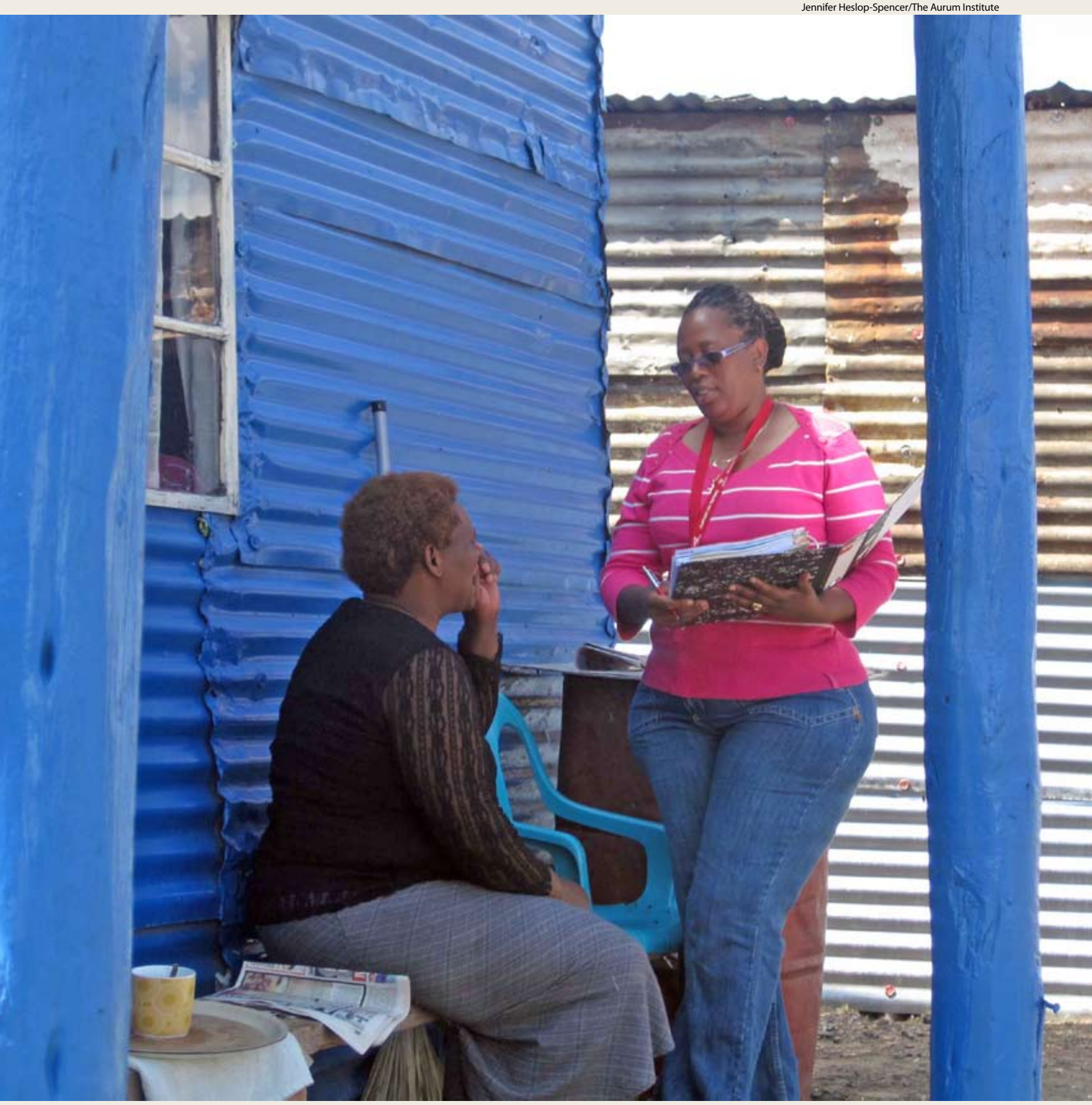
A woman recruits participants from her community for a trial in Africa.

Jennifer Heslop-Spencer/The Aurum Institute



Chapter 1

About This Handbook

How clinical trials are perceived internationally and in communities where trials occur can directly affect support for research, with misinformation and fears of exploitation derailing trials just as easily as operational or scientific setbacks. In 2004, controversy over a planned clinical trial to test oral tenofovir in Cambodia as a potential once-a-day pill to prevent HIV forced the early abandonment of this important prevention trial. Less than a year later, similar controversy, fueled by rumors, misleading media coverage, and communication breakdowns, led to the demise of a second HIV prevention trial in Cameroon. Together, these trials served as a wake-up call to HIV scientists and donors to re-examine the ways they communicate with local and international communities about clinical research.

Expectations for transparency, information sharing, and engagement are rising at the same time that the modes and outlets for communication are multiplying at an exponential rate. The media landscape is changing daily, and international networks of advocates, scientists, and others are linked through the Internet as never before. In addition, an increasing number of people now see themselves as stakeholders in the research process. This brave new world brings both possibility and risk to those engaged in research.

The HIV field is not alone in confronting changing expectations and new challenges when it comes to communicating about research. Clinical research is hard to explain to people with little or no scientific background. Investigators and trial site staff receive extensive training in good clinical practices (GCP) and specific trial protocols but are rarely trained in communications. However, researchers and trial staff are increasingly expected to conduct communications activities at their trial sites.

In this chapter

Jim Daniels

An increasing number of clinical trials are taking place in Africa, Asia, and Latin America. The Comprehensive Care Centre at Nairobi's Kenyatta National Hospital (pictured here) collaborates in a number of multicenter clinical studies.

Communications strategies can help build community and public trust in your research, create an enabling environment for your work, help identify and respond to incorrect information, and encourage the uptake and eventual application of your findings. Failure to attend to this new reality can occasion just the opposite: distrust, sensational or misleading media coverage, and missed opportunities to advance your research agenda.

This handbook is designed to help you navigate these shifting sands and to get the most out of the time and energy you invest in communicating about your study.

1 The purpose of this handbook

This handbook is designed to serve the needs of anyone who conducts, plans, or implements clinical trials—especially trials that evaluate new drugs or interventions in a community setting. We want to make your job easier, whether you are a researcher, a study coordinator, or a communications professional.

Objectives

- Provide practical guidance to clinical trial staff and research partners on how to anticipate and respond to the special communications challenges posed by the conduct of clinical research in resource-limited settings.
- Share lessons learned from case studies of actual experiences running trials in Africa, Asia, Latin America, the United States and Europe.
- Supply hard copy and electronic versions of diagnostic tools, sample templates, and model examples of communications plans and materials that sites can adapt for use in their communications planning and implementation.

Target audience

In writing this handbook, we have prioritized the needs and perspectives of individuals operating at a site level—those actually living and working in the community where the trial is conducted. The handbook will also be useful to people who provide communications support at the trial network or headquarters level. In addition, public health advocates and other partners planning to work or currently working with clinical trials may also find the handbook valuable.

We recognize that individuals may be coming to this issue from a wide variety of backgrounds —as a local investigator, an international principal investigator (PI), a communications officer, a study coordinator, or a staff member. We have tried to make the handbook equally useful and accessible to people working from all of these perspectives.

We also hope this publication will be a practical resource for students of journalism, communications, and public health who wish to learn about the subtleties involved in the communication of complex scientific issues.

What this handbook includes

The handbook addresses the challenges of communicating about clinical trials to stakeholders. Drawing on the collective insights of the many people who contributed to its creation, this handbook uses practical insights and case studies based on the communications activities of actual clinical trials.

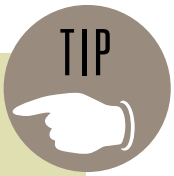
A variety of tools and templates will help readers plan for their own studies, including:

- Sample communications plans for clinical trials
- Communications and crisis-planning templates and checklists
- Scenario-planning tools to facilitate planning for the release of trial results
- Ideas on delegating communications tasks to reduce demands on key site personnel
- Tips and techniques on how to communicate effectively in interviews, in meetings, and with the media

What this handbook does *not* include

Although trial participants are a key stakeholder group that you will need to communicate with, this handbook does not cover protocol-driven communications with trial participants. Communications related to recruitment, retention, counseling, and informed consent are so intimately linked to the conduct of the research itself that they are best dealt with in the protocol and standard operating procedures of the trial.

Community involvement and recruitment and retention activities. Although many of the insights in this handbook apply equally to effective communication with members of the host community where trials take place, we do not cover activities normally undertaken as part of a trial's community involvement, recruitment, and retention programs. Many trials now employ a community liaison officer who is specifically charged with overseeing community outreach and education activities, convening and supporting a community advisory group or board (CAB), and hosting community meetings. Some trials have specific staff members who are responsible for recruitment and retention. These activities are normally supported through a separate budget and involve actions that go beyond communications. Staff members involved in education and outreach may nonetheless find parts of the handbook helpful, especially Chapter 8 on communicating science clearly.



Effective communication serves to:

- **Explain the scientific value of the trial to policymakers, funders, participants, and other key stakeholders in the local and global community**
- **Inform while preventing misinformation and over-reaction**
- **Maintain support for the current study and for future research in the community and country where the research is conducted**
- **Mobilize political will for developing guidelines and national policies and for funding implementation of scientifically proven health interventions**
- **Provide sound sources of information for news media**

Elizabeth T. Robinson / FHI

Article on HIV prevention trial in South African newspaper, February 2007.

II Challenges posed by clinical trials

Communicating about clinical trials can be challenging for many reasons. Trials frequently involve medical procedures that can evoke fear and uncertainty. They often involve complex scientific issues that are unfamiliar to stakeholders. And, they sometimes take place against a backdrop of distrust, born of past abuses real or imagined.

Certain aspects of clinical research also make the challenge more difficult. Some of the research realities that we address in this handbook include:

Gaining the necessary skills and practice to communicate clearly and consistently takes time and energy. This handbook will show you how investing time on communications planning early in your study can save time, energy, and money, especially during an unexpected closure or crisis situation.

Communication requires a collective effort, yet the burden of responsibility often falls to one person at a trial site. The person charged with communications is usually juggling these responsibilities along with their tasks as a study coordinator, a site investigator, or a community liaison officer. This handbook stresses the value of working in teams and taking the time to provide communications and media training to the entire staff.

Clinical trials tend to replicate the hierarchies of power, access to information, control, and prestige that dominate the biomedical sciences. The underlying power dynamics—between clinicians and social scientists, between investigators and community, between headquarters and local staff, between those who control the money and those who implement—can disrupt the flow of information at trial sites and within networks. This handbook highlights practical ways to counterbalance these tendencies and to ensure that information does not become restricted to a small group. We emphasize the importance and benefits of seeking the input and insights of the staff and stakeholders who are closest to the community hosting the trial.

III Origins of the handbook

This handbook emerged from the Microbicides Media and Communications Initiative (MMCI), a multi-partner collaboration housed at the Global Campaign for Microbicides at PATH in Washington, DC.

Founded in 2005, the MMCI is an ongoing "community of practice" that meets regularly by conference call and in person to anticipate and respond proactively to the communications challenges posed by the conduct of large-scale HIV prevention effectiveness trials in Africa and other resource-limited settings. Its members include the communications officers of all the organizations currently sponsoring clinical trials of microbicides and pre-exposure prophylaxis (PrEP) for HIV prevention; research networks—such as the HIV Prevention Trials Network (HPTN) supported by the Division of AIDS (DAIDS) of the U.S. National Institute of Allergy and Infectious Diseases (NIAID); clinical trial investigators; site-level staff; and key advocacy networks working on HIV prevention.

The MMCI's unique contribution has been its ability to facilitate information flow and joint planning across a wide range of trials and to bridge the worlds of science, advocacy, and community. When members review draft messages or consider different strategies, they bring to the discussion a wealth of perspectives and experience: How will this message be understood or interpreted by local community members? Will it raise issues in the blogosphere among advocates? Is it scientifically accurate?

This handbook, written by staff members at the Global Campaign for Microbicides and Family Health International, represents the collective wisdom of this community. Many of the examples and case studies come directly from the experience of MMCI members and their colleagues around the world. We have aimed to capture the rich learning that has emerged from this international, multidisciplinary collaboration.

To make this handbook accessible and relevant to a wide audience, we have included examples and insights from many fields of public health, especially infectious diseases.

IV How this handbook is organized

The handbook includes nine chapters arranged in two sections.

Section 1 (Chapters 2 to 6). This section details the steps typically involved in the implementation of a clinical trial. It takes the reader through the communications tasks that should accompany each milestone in a clinical trial (see Box 1.1):

- Chapter 2: Preparing and Budgeting for Communications
- Chapter 3: Developing a Strategic Communications Plan
- Chapter 4: Communications During the Trial
- Chapter 5: Preventing and Managing a Crisis
- Chapter 6: Preparing for and Disseminating Study Results

Section 2 (Chapters 7 to 9). This section focuses on communications skills that are useful throughout a study:

- Chapter 7: Developing and Using Key Messages
- Chapter 8: Communicating Science Clearly
- Chapter 9: Working with the Media

Case studies and tips. Chapters include case studies from real trials to highlight the information covered in the general text. The case studies illustrate how activities and preparations have worked or failed in real-life situations.

Templates and tools. Sample templates, worksheets, and checklists are included in the appendices and are referenced near relevant text throughout the handbook. These resources are available for users to download from the MMCI Web site where this handbook will be posted. See http://www.mmci-communications.org.

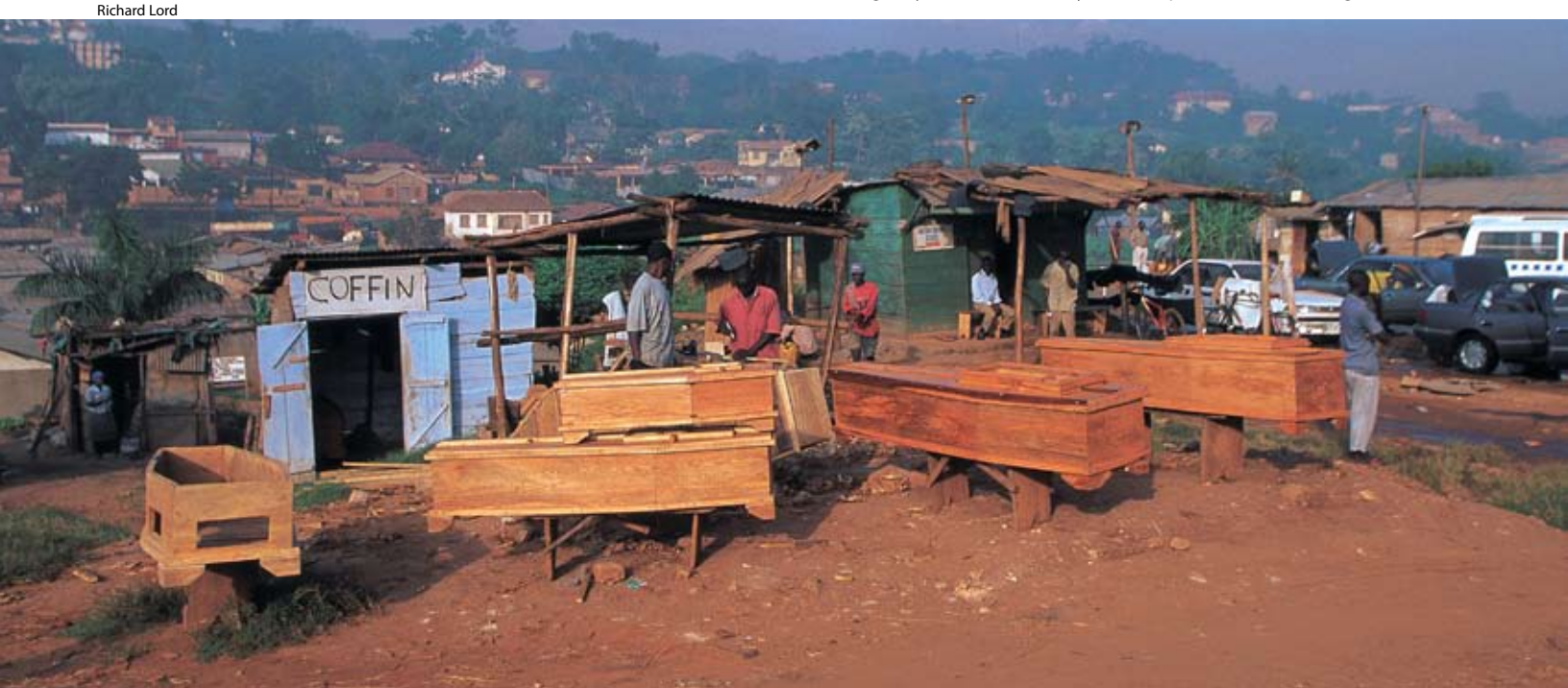
Video. This handbook is accompanied by a 30-minute video (DVD). The video illustrates many topics included in the handbook. It features interviews with trial staff, communications experts, advocates, and others involved in clinical research, and it includes footage to demonstrate the key elements of communications within clinical trials.

A living document

This handbook is a living document. We encourage you to contribute your own experiences and tools to others working in the field of clinical trial communications. An electronic version of this handbook and all of the resources it contains will be available on both the MMCI Web site and Family Health International's Web site (www.fhi.org). We will add new examples of materials and case studies submitted by readers like you. To submit materials or to view the most recent examples of tools and stories submitted by readers, visit: http://www.mmci-communications.org.

The AIDS pandemic has severely affected communities worldwide, especially in sub-Saharan Africa. Research is urgently needed to identify effective prevention technologies.

Richard Lord



Box 1.1. Clinical trial milestones and parallel communications tasks

Clinical trial milestones	Parallel communications tasks	In the handbook
Site identification and development • Establish partnerships • Upgrade facilities and laboratories • Get protocol approved • Conduct formative research	**Communication planning** • Develop your budget • Conduct your environmental scan • Identify your communications team • Orient staff to communication procedures	Chapter 2
Site initiation training • Good Clinical Practices • Ethics orientation • Protocol requirements, etc	**Develop strategic communication plan** (including crisis management and outline of results dissemination plan) **Choose spokespeople; conduct initial media training**	Chapter 3
Trial launch: enrollment begins	**Trial launch** • Inform key stakeholders identified in your strategic plan • Mention enrollment milestones in trial newsletter or updates to key stakeholders	Chapter 4
Interim data analysis	**Data and Safety Monitoring Board (DSMB) meets** • Prepare scenario messaging for all possible review outcomes • Inform research colleagues at closely related trials so they can be alert to possible ramifications of DSMB recommendations • After reviews are conducted, communicate outcomes to stakeholders	Chapter 4
Data collection completed	**Finalize results dissemination plan**	Chapter 6
Release results • Inform authorities • Unblind participants • Submit scientific papers	**Implement dissemination strategy** • Inform key stakeholders • Work with the media	Chapter 6

Key Points to Remember

- Communications strategies can help build community and public trust in your research, create an enabling environment for your work, help identify and respond to incorrect information, and encourage the uptake and eventual application of your findings.
- This handbook provides practical guidance, sample templates, and tools for clinical trial staff and research partners. It is organized to meet the needs of busy people like you. So skim. Bounce between chapters. Relate the case studies to your own situation. Adapt the templates. Make it work for you and your study.

Chapter 2

Preparing and Budgeting for Communications

Planning ahead can help you anticipate challenges and ensure that necessary resources—money, information, and trained staff members—will be available when your team needs them. Taking the time to prepare and budget for communications can strengthen a trial in several ways:

- Alert the study team to previous media coverage and potential controversy
- Pinpoint areas of cultural, political, or scientific sensitivity
- Ensure the wise use of resources
- Identify opportunities for cost-sharing and stretching resources
- Build communications capacity among the study team
- Help delegate and share the workload

In this chapter

Elizabeth T. Robinson/FHI

Physicians discuss maternity cases at the Department of Obstetrics and Gynecology at the Gabriel Touré Hospital in Bamako, Mali.

I Doing your homework—a "desk review"

A "desk review" is the collection of information that can be easily accessed from your desk—through e-mail, Internet searches, academic journals, and colleagues. This information will help you write the communications plan for your trial. To conduct a desk review, consider the following activities.

Review the study documents. Is the trial protocol fully developed? Have other study materials been fully developed and finalized? Does the study have the following materials available: informed consent forms, protocols, participant-information leaflets, and procedures manuals?

Lisa Marie Albert

Many trials have community advisory groups that provide critical input into trial design and implementation. Pictured at left is the collaborative council of the LinCS 2 Durham HIV prevention study in Durham, North Carolina.

Search the published literature for overview materials. What basic information is available on the population(s) who may be involved in the trial—health profiles, languages spoken, ethnic composition, sources of income, basic demographic information, cultural norms? Is there a history of other research in the community, country, or region that could affect the perceptions of your study? This information can be very helpful when you write your communications plan (see Chapter 3) and your crisis communications plan (see Chapter 5).

Review current laws, policies, and practices that may affect the study population. Are there any laws or policies that may affect participants in your study (for example, is homosexuality or selling sex illegal)? Are there local cultural and political norms that may present barriers or challenges to conducting biomedical research?

Conduct a quick analysis of news coverage of similar trials in the same country or region. Does the news media have a history of paying close attention to the topic of your research or to the population participating in your trial? Is the coverage generally positive or negative? A familiarity with previous news coverage can help you prepare for future interactions with journalists.

II Conducting an environmental scan

An environmental scan refers to the process of gathering and analyzing information for tactical or strategic purposes. For a clinical trial, this information will consist of facts and perceptions that can affect your study. Because your trial can be affected from within and without, you will need to conduct "internal" scans and "external" scans. An internal scan assesses the strengths and weaknesses of your team. An external scan covers almost everything else, but in practice it will focus on the communities where the trial is taking place.

One of the most important reasons for conducting an environmental scan is to determine whether your trial is at risk of attracting controversy or negative attention. Misinformation, fear, and prejudice can halt a trial before it even begins. You must consider historical, cultural, and political factors that might influence the perceptions of your study by the trial's participants and by other stakeholders.

There are many ways to conduct an environmental scan, but as the word scan suggests, it is a rapid assessment, not a full-blown investigation. An initial scan can be completed within five to seven days during the trial-planning stages. Shorter scans can be repeated throughout the life of the trial, at regular intervals, or perhaps in response to some event.

A scan's brevity is not an indication of its importance. A properly conducted scan can be vital to the success of your trial—it can help you anticipate opposition, design ways to engage the community, and clarify communications planning (see Chapter 3 on developing a communications plan).

Internal environmental scan: the strengths and weaknesses of your team

Identify your team's strengths and weaknesses as they pertain to communications. This can be done at the site-selection visit or once a site has been chosen for the study. Consider the following factors:

- Does the project have a budget for communications?
- Is the site affiliated with a university or research consortium that has public relations staff or senior managers who should be involved or kept informed?
- Which staff members, if any, have received media training?
- Are there interpersonal dynamics within the staff such as professional rivalries that might impede good communication?
- Do study staff have prior experience working with community leaders?
- Does the organization have a crisis management plan?
- Has anyone on the staff had prior experience dealing with controversy or communications crises? Were these efforts successful?
- How many of the staff speak or read the local language?
- Are there dedicated communications personnel at the site or network level?
- Are there offices or staff in the relevant countries?
- Have resources been dedicated to translating and printing materials?

The answers to these questions should provide you with a good idea of the strengths and weaknesses of the team. Box 2.1 reproduces an abbreviated list of the questions used by the Microbicide Trials Network to assess the communications capacity of different sites in their network. A full copy of their questionnaire is available in Appendix 2.2.

Box 2.1. Questions for conducting an internal environmental scan

1. **Does anyone on your staff have communications expertise?**

   Yes___ No___

   If yes, please describe:

2. **Does your site have experience interacting with news media?**

   Yes___ No___

   If yes, please indicate the level of experience: Extensive ___ Moderate___ Minimal___

3. **Does your site have procedures for dealing with media inquiries?**

   Yes___ No___

4. **Does your site conduct its own outreach and/or training programs with local journalists, or has the site ever considered doing so?**

Yes___ No___

If yes, please describe:

5. **How would you rate your site's relationship with local journalists?**

Excellent___ Good___ Fair___ Poor___ Nonexistent___

6. **Does your site have staff who regularly communicate with advocacy groups and NGOs?**

Yes___ No___

7. **Does your site conduct its own outreach and/or consultations with advocacy groups and NGOs, or do you partner with these groups for any reason?**

Yes___ No___

If yes, please describe:

8. **How would you rate your site's relationships with the following types of groups?**

Women's Health

Excellent___ Good___ Fair___ Poor___ Nonexistent___

Microbicide Advocacy

Excellent___ Good___ Fair___ Poor___ Nonexistent___

HIV/AIDS Treatment Advocacy

Excellent___ Good___ Fair___ Poor___ Nonexistent___

People Living with HIV/AIDS

Excellent___ Good___ Fair___ Poor___ Nonexistent___

NGOs

Excellent___ Good___ Fair___ Poor___ Nonexistent___

Local Government Representatives

Excellent___ Good___ Fair___ Poor___ Nonexistent___

National Governmental Groups

Excellent___ Good___ Fair___ Poor___ Nonexistent___

Health Agencies

Excellent___ Good___ Fair___ Poor___ Nonexistent___

Traditional Leaders/Chiefs

Excellent___ Good___ Fair___ Poor___ Nonexistent___

9. **Does your site have a designated crisis communications team or plan?**

Yes___ No___

Source: Microbicide Trials Network. Communications Planning Survey, 2009. For the full version of the survey, see Appendix 2.2.

Jim Daniels

Some studies that enroll vulnerable populations, such as injection drug users, are more prone to attracting controversy.

External environmental scan: assessing the risk of controversy

A risk assessment helps you to evaluate the likelihood that your research will be misinterpreted, attract controversy, or open itself to sensational media coverage. Consider risks to your institution's reputation and possible communications challenges that could undermine the trial.

Some studies are more prone to controversy than others. For example, a small, Phase I trial among educated participants in a cosmopolitan city will probably not attract controversy, whereas a large multicenter study among injection drug users in a region of the country with ongoing political instability would be more likely to attract attention. Studies that enroll children, pregnant women, or other vulnerable populations—such as prisoners or men who have sex with men—are always more likely to be controversial. Controversial studies might include:

- Research that tests products in sexually active adolescents
- A study that includes injection drug users as trial participants
- An immunization trial that raises religious or culturally sensitive issues
- Research that tests products that are used in the rectum

Does the trial involve topics that might attract the attention of groups that may be motivated to spread negative information? For example:

- Religious or tribal leaders
- Traditional healers
- Anti-vaccine activists
- Local institutions that may be jealous of your funding
- Groups who believe that biomedical research exploits vulnerable people

You might also consider the use of a risk-assessment tool—a systematic way to assess the potential for controversy based on certain characteristics of the trial (see Appendix 2.1 for an example). Understanding the nature of the controversy that might arise can help you determine the type of communications support that might be required. It can also help with the next step in pre-trial planning—budgeting for communications—and it can provide the basis for a more in-depth environmental scan. For organizations that conduct several trials, it can also help to allocate communications resources among the trials.

External environmental scan: identifying factors that might affect your study

You can begin your scan by talking to opinion leaders and others who live and work in the host community. If the trial will be conducted at multiple sites, the scan can be a joint effort between international and site-level staff. Gather information that can help you identify stakeholders, anticipate opposition, and design approaches for community engagement.

Follow these steps:

- Interview colleagues who understand the local context. Talk to the people around you. Begin with those who are readily available. The social structure of the community is often replicated among the local members of the trial's staff. Study nurses, counselors, and others can direct you to opinion leaders in the community. Meet with other researchers or health and development professionals who have worked or lived in the community that hosts your trial.
- Gather pertinent information about the trial community, particularly information having to do with gender and cultural norms, religious issues, and community concerns related to research.
- Review the findings of pilot studies or formative research conducted in the host community (see Box 2.2)—research to understand the interests, attributes, and needs of different populations and persons in the study community. Donors and sponsors often support formative research to help with the design and implementation of large-scale clinical trials. These studies can provide vital insights to your scan of the environment.
- Learn about related trials (see Box 2.3). Identifying other studies that may affect your trial is a critical part of an environmental scan. Develop a simple spreadsheet of all ongoing or planned clinical trials related to your study, especially those taking place in the same region. Your spreadsheet should include dates for the beginning and the end of each trial, and interim reviews that might result in the unexpected closure of a trial.
- Pay attention to political events (local and national) that may affect your trial. Some of this information may have been collected during your desk review.
- Re-examine your desk review of media coverage and information about the site. The Internet can be a valuable tool: Web sites such as http://allAfrica.com and search engines such as Google News and Google Scholar can help you identify information.
- Collect information about groups or individuals who might actively oppose your research, locally, nationally, or internationally. Identify their concerns, including financial jealousy.
- Find out how individuals in your community get information. Where do most people get their news? What are the most popular local media outlets? What avenues are available for those who cannot read?
- Consider whether any group might be threatened by your trial, such as traditional matrons or healers, informal chemists, government health care staff, or others who may lose potential income or status.
- Participate in appropriate community gatherings. Attending community functions—such as health fairs, funerals, or important community events—will help you learn about the

needs of the community. Attending these events is one of the most important ways to establish trust and credibility within the community.

Ask these questions:

- What services presently exist in the community that prevent or treat the disease you are studying?
- What does the community know about the issue or disease you are studying?

Box 2.2. Formative research: Impacta Peru's strategy

By Pedro Goicochea, MSc, MA, Investigator, Communications & Community Relations, the PrEP Initiative, Gladstone Institute of Virology and Immunology, San Francisco, CA

Formative research conducted by social scientists can provide important information that can help study teams plan for better communications. An environmental scan can incorporate information gathered through these systematic studies of the community.

At Impacta—a Peruvian nongovernmental organization that conducts clinical trials about HIV and STIs—formative research is written into all of our study protocols. We do interviews with key informants and conduct focus groups with members of the trial community to find out in-depth information about the people we will be working with.

In planning for a study in a community of men who have sex with men, we started going to the places where these men congregate. We conducted interviews in bars, clubs, and even saunas.

The results of this formative research will help us plan for communications about the trial. Our interviews might demonstrate the need to involve certain civil society groups, or it might point to the importance of sharing information at small community forums. We write these considerations into our communications strategy and our dissemination plan for every study (see Appendix 6.2 for the dissemination plan for the HPTN 039 study).

Formative research also helps us develop and test key messages. Our interviews tell us what information the community wants and where the knowledge gaps are. After developing messages, we have them assessed by clinicians and scientists on our staff to ensure that they make sense from a technical perspective. We then hold focus groups to validate and pre-test messages with the community.

If researchers who are part of your study are conducting formative research, reviewing their results can help you identify and address communications needs in the trial community.

Julio Sandoval

Making information relevant to participants and community members can have enormous impact on the degree to which it is retained and acted upon.

- Are members of the community familiar with other organizations that work on the issue or the disease you are studying? What do they know about these organizations?
- What kind of community-based organizations exist in the area? Who are the leaders? What are their attitudes toward the subject of your research? What does the community think of these leaders?
- Does your project challenge community norms that might prevent people from participating in your study?

Box 2.3. Learn from other trials when planning your own

A review of the media environment in Cameroon showed that several news stories about a previous HIV prevention trial reported that researchers were injecting women with HIV. The study team responded by ensuring that all talking points and messages mentioned that the study product does not cause HIV and that women are never exposed to HIV by researchers.

A scan at one South African site revealed that during a previous trial, a rumor had circulated that the test product undermined the effectiveness of modern contraceptives. The staff members involved in the current trial made sure that all of their communications materials emphasized that the vaccine they were testing did not interfere with fertility or with contraceptive methods.

Conversations with potential stakeholders in Peru revealed that they were concerned about a planned pre-exposure prophylaxis (PrEP) study because similar studies had been stopped in other parts of the world. The investigators immediately invited all stakeholders to an open community forum where they shared the protocol and sought comment and community input. The investigators addressed community concerns and the study successfully started a few months later.

Jim Daniels

Communicating results back to participants and to host communities is an ethical requirement of good research.

III Developing a communications budget

More than 30 national and international ethics policies and guidelines consider the communication of research results to the study's participants and other stakeholders an ethical requirement of good research (Shalowitz and Miller 2008). Although sponsors have historically undervalued this function, they are increasingly supporting the inclusion of communication and dissemination activities as separate line items in research budgets. For example, the National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation now encourage grantees to include communications in their proposal budgets, and most HIV prevention trials funded by the U.S. Agency for International Development (USAID) have a budget for trial-related communications. The United Kingdom's Department of International Development recommends that research networks reserve at least 10 percent of their budget for communication and research dissemination activities (DFID 2005, p. 4).

The budget for a basic communications program

Developing and defending a communications budget is an essential part of successful communications planning. Even the most frugal research budget should accommodate some basic support for communications. Box 2.4 lays out the major line items for a basic communications program. A basic program would be appropriate for small trials with a limited budget.

Box 2.4. Budget template for a basic communications program

Developing a communications plan		
Network/sponsor communications staff		
Name	(XX days)	$_____
Name	(XX days)	$_____
Site staff		
Name	(XX days)	$_____
Name	(XX days)	$_____
Ongoing communications support		
Network/sponsor communications staff		
Name	(XX days)	$_____
Communications associate		
Name	(XX days)	$_____
Site-level communications		
Name	(XX days)	$_____
Name	(XX days)	$_____
Media training (at investigators' meeting)		
Room rental		$_____
Media trainer/facilitator		$_____
LCD projector; video camera rental, tapes		$_____
Travel and per diem, if necessary		$_____
Printing and layout of materials		
Design and printing		$_____
Translation services		$_____
Shipping if necessary		
Dissemination of results		
Telephone, fax, courier		$_____
Travel to sites for communications staff		$_____
Airfare/train		$_____
Hotel/per diem		$_____
Visas		$_____
Community event to disclose results		$_____
Telephone, fax, internet, courier		**$**_____
Overhead		**$**_____
Total		**$**_____

Additional funding will be needed for the development and field testing of materials for the participants' education and recruitment, and for informed consent documents.

Additional community meetings and outreach are usually part of the community engagement budget.

The budget for an expanded communications program

The expanded budget accommodates items that are essential for more complicated, multicenter trials. Trial networks and multicenter trials may need multiple budgets—an overall budget to submit to donors that includes communications costs for the full trial at both the central and the site level, as well as individual budgets for each site.

Box 2.5. Budget template for an expanded communications program

Developing a communications plan		
Network/sponsor communications staff		
Name	(XX days)	$_____
Name	(XX days)	$_____
Site staff		
Name	(XX days)	$_____
Name	(XX days)	$_____
Ongoing communications support		
Network/sponsor communications staff		
Name	(XX days)	$_____
Communications associate		
Name	(XX days)	$_____
Site-level communications		
Name	(XX days)	$_____
Name	(XX days)	$_____
Environmental scan		
Travel and per diem for network/ sponsor staff to visit sites, where possible		$_____
Media training (at investigators' meeting)		
Room rental		$_____
Media trainer/facilitator		$_____
LCD projector; video camera rental, tapes		$_____
Travel and per diem, if necessary		$_____
Trial launch event		
Travel and per diem as needed		$_____
Posters and materials		$_____
Food and beverages		$_____
Community meetings and events		
Flexible budget to be deployed as needed		$_____
Graphics support		
Development of trial logo and Web site/page design for study		$_____
Design of newsletter and brochure templates		$_____
Production and printing of materials		
Printing of promotional materials		$_____
Translation services		$_____

Buttons, T-shirts, carry bags with trial logo, etc.	$_____
Trial newsletter	
Layout and printing	$_____
Mailing and dissemination costs	$_____
Bulk copying of fact sheets, Q&As, etc.	$_____
Dissemination of results	
Retainer for local public relations firm	$_____
Travel to sites for communications staff	$_____
Airfare/train	$_____
Hotel/per diem	$_____
Visas	$_____
Community event to disclose results	
Press briefing/event costs	$_____
Travel and per diem for PI to attend scientific conference	
to present findings	$_____
Telephone, fax, internet, courier	$_____
Overhead	$_____
Total	**$**_____

Additional community meetings and outreach are usually part of the community-engagement budget.

During the dissemination planning for our trial, our site developed a plan and the sponsor knew about our plans. Yet, when it was time to initiate the plan, we were informed that there was no money. And this left us as the site staff in a bad position because we had promised people that we would come back with the results and they were not communicated to. And this indeed caused more harm than good. When we were supposed to start with a new trial, we were forced to start by first disseminating results of the previous trial.

—Trial site community liaison officer

IV Assembling a communications team

At least one staff person—working closely with the principal investigator (PI)—will probably be in charge of managing communications issues during the trial. However, good communications requires a team of people from the site and the sponsor to work together. Ideally, each site should have its own communications team. To establish a communications team:

- Include a variety of staff members. The team should be made up of the PI, study coordinators, the site spokesperson (who may also be the PI), and at least one staff member who works closely with the community, whether as a community liaison officer, the lead recruiter, or a social science researcher.
- Consider including a communications officer and a program manager from the network or sponsor. This is especially relevant if your study is part of a larger network.
- Make sure the team reflects expertise in science, communications, and community engagement. Your team needs to understand and undertake a full range of tasks—scanning, risk assessment, writing, verbal communication, and liaising with policymakers.
- Ask members of the community advisory board (CAB) or the community advisory group (CAG) for their input. They can often provide insight on how results will be interpreted or understood by community members, so they may have valuable suggestions on how best to share trial results and develop messages about the findings.
- Involve technical support staff members—Web-support staff and individuals in the graphics, editorial, or public relations departments at the host institution or university.
- Have a clear leader. The site PI is frequently in charge of the communications team, but other senior staff may also serve this function. If the PI travels extensively, it may be preferable to have the study coordinator manage day-to-day operations of the communications team. If your site team includes a professional communications expert, he or she can fill the role of team leader.
- Be adaptable. As your study progresses or prepares for key milestones, your communications team can and should adapt to meet evolving needs. Remember, however, to keep the team small enough (three to five people) so that it remains manageable.

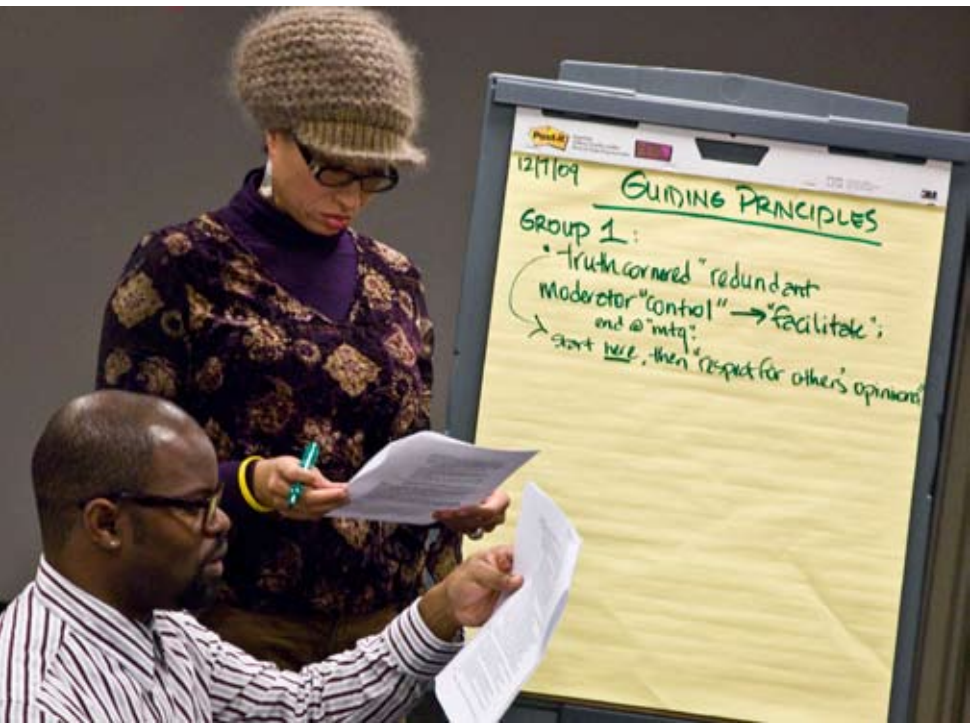
Communication teams should include staff who work closely with the community, in addition to individuals with scientific and communications expertise. In this photo, FEM-PrEP trial staff gather in Nairobi.

Elizabeth T. Robinson/FHI

V Training staff and spokespersons

All staff members have a role to play in communications. Staff members serve as unofficial ambassadors for the study on a daily basis. Not only do clinical staff and outreach workers need to know about the trial, but support staff—the janitor, receptionist, driver, administrative support person, and finance officer—should all be adequately prepared to answer questions about the trial.

If all staff members understand the study, they can alert senior staff to misinformation that might be floating around the community.



Lisa Marie Albert

Communication training for staff should include sessions to practice responding to "hard questions" and communicating the study's three primary messages. Shown here are Randy Rogers and Allison Winfield at a meeting of the LinCS 2 Durham project in Durham, North Carolina.

Train staff members to answer tough questions

Develop fact sheets and "frequently asked questions" (FAQs). Make these documents available to staff members. See Chapter 3 for more on developing materials.

Use the "hat trick." Place hard questions in a bag or hat during site-initiation training, and have all team members answer several questions each over the course of a training session. They can hear each other's responses and see how everyone improves with practice. (See Box 2.6).

Practice stating the study's three main points. Different people will have different ways of delivering the key messages. One staff member will give a different answer from the next, and other colleagues start picking up phrasing, metaphors, etc. For this reason, you can encourage your team to practice saying the three (or so) most important messages of the trial. No matter what happens, and no matter what other information you include, you will get across these main messages.

Explain when someone should refer a complicated or sensitive question to others on the team, such as the communications team leader or the site coordinator.

Distribute certificates. You may want to provide printed certificates to staff members who can accurately answer a set of key questions about your trial during refresher training workshops.

Box 2.6. Answering tough questions: practice does make a difference

By Amy Corneli, Stella Kirkendale, Monique Mueller, and Christina Wong, Family Health International

Before the FEM-PrEP trial launched, we developed fact sheets explaining the trial and major concepts, such as pre-exposure prophylaxis (PrEP). During our regular staff trainings, initial CAB trainings and subsequent refresher trainings at our FEM-PrEP sites, we review these fact sheets as a group. We ask staff and CAB members if anyone can explain certain concepts mentioned in the fact sheets—such as randomization and risk-reduction counseling—and we answer any questions that come up.

However, we have found that reviewing the fact sheets is not enough for staff to truly absorb the material. Therefore, we developed a series of additional training techniques to help them practice answering difficult questions and to get feedback from their colleagues.

Identifying questions, trying out answers. After they review the fact sheets, we give each person a worksheet with a list of difficult questions (e.g., "By giving women this product to use, are you discouraging them from using condoms?"). After writing down their answers on the worksheets, each person reads their answer aloud, while the others in the group provide feedback. The group discusses what was answered well, what may be incorrect, and what information should be included if the same question is asked in the future.

Practicing answers in small groups. The staff divides into groups of three and practices answering questions from our list of "Thirty Tough Questions" (see Appendix 2.3 for the full list). The list of questions is cut into strips of paper, with one question on each strip, and placed in a bag or a hat. One participant chooses a question from the bag and asks the question (acting like a community member), one person answers the question, and the third person observes and provides constructive feedback. The observer refers to the fact sheets to ensure that information on that topic is covered by the person who answers the question.

Perfecting answers in the large group. Staff members practice answering the questions in front of the group. Each individual is encouraged to come to the front of the group at least once to choose a question out of the bag and respond.

After these exercises, the answers improve tremendously. Getting feedback from their peers helps people refine their answers. With practice, all staff and CAB members think about how to break down the complexity of the trial concepts and develop simple ways to remember all the details and answer a question comfortably. Over time, the answers become clearer and more comprehensive.

Discuss communications at investigators' meetings

Most trials bring most members of the staff together before the trial begins. This first "investigators' meeting" is a good time to begin sharing the findings of communications planning, to consolidate how information will flow, and to begin media training. Staff members often have an excellent grasp of the issues that might affect a new study, such as community concerns over storage of blood or other specimens, access to the intervention if it proves to be efficacious, or a perception fostered by national media that research participants are treated like "guinea pigs" by outside interests.

Depending on where and when these meetings take place, consider reserving time on the agenda for the following activities:

- Discuss the lessons learned from the environmental scan (or the media analysis and the desk review, if the scan is not yet underway).
- Gather and share intelligence on any institutional or political factors that could affect the trial and that should be monitored.
- Determine basic processes for internal communications among sites and with the sponsor.
- Identify staff resources to help develop the trial's written communications plan.
- Conduct some basic media training (see Chapter 9).

You may want to summarize your environmental scan in a document that you share with other staff members. Sharing such information provides an opportunity to sensitize the staff to these issues and to seek their input on the challenges you identify.

Discuss communications during your site-initiation training

You should include a session at your site-initiation training that presents an overview of your strategic communications plan (see Chapter 3) to the entire site team and conveys the importance of each person's role in communications.

During the session:

- Seek input about the communications plan.
- Find out what your team knows and what type of training they might need.
- Evaluate your team's communications contacts. Some may have good connections to civil society groups that are interested in similar trials; others may know local religious or women's leaders, or they may be respected by community elders.
- Practice responding to challenging questions that trial members are likely to receive from officials, community members, family, and friends.
- Take note of misunderstandings of concepts or processes: if the staff or the CAB members do not understand something, it is likely that other community stakeholders will have the same misunderstandings.
- Listen for clues and ask staff members about words, in English and in local languages, to use or avoid in key messages about the trial.
- Encourage staff and CAB members to monitor news media, such as community radio programs, list servers (listservs), and local-language publications, for coverage relevant to your study. Review the procedures to follow when they see relevant coverage (see Chapter 9 for more on monitoring the media).

Select and train spokespersons

All sites should have clearly designated spokespersons with the authority to respond to inquiries from officials, news media, advocates, and the public. Team members need to know how to refer questions or media requests to principal investigators (PIs), managers, or others responsible for dealing with such requests. All trial spokespersons should be well informed about the issues of the

trial. It is important that your team always has someone who is equipped to communicate effectively with the media, government, advocates, and others who may inquire about trial issues.

To select and train spokespersons:

- Use the survey in Appendix 2.2 to help you choose the appropriate person(s).
- Provide the spokesperson with media training, whether or not they already have skills and experience speaking with news media. Technical assistance in media training or interview skills may be available from your trial sponsor. Consult Chapters 8 and 9 for tips on communicating science clearly and talking to the media.
- Train more than one spokesperson, so there is always someone prepared to speak when necessary.
- Emphasize that spokespersons should always respond to the media in a timely and respectful manner.

In a lot of instances, our staff comes from the communities themselves. If they get on the taxi or the bus, or they go to shop in the market, people know they work for CAPRISA, they know they're working in AIDS research, and they ask them questions. We've learned our best ambassadors for transmitting correct information is having well-informed staff. . . . It doesn't matter if it's a cleaner, the receptionist, administrative staff, or a finance officer.

—Quarraisha Abdool Karim, Co-Principal Investigator, CAPRISA 004

Key points to remember

- Communications planning and budgeting should begin well before your clinical trial begins enrolling study participants.
- The first step to developing a successful communications plan is to conduct a rapid needs assessment, such as a "desk review" and "environmental scan." These analyses can help you determine your study's strengths and weaknesses, anticipate potential challenges, and identify external factors that could negatively influence your study.
- Understanding the potential threats to your study and the risk of attracting controversy can help you budget appropriately and ensure that necessary resources—money, information, and trained staff members—will be available when your team needs them.
- Ideally, each site should have its own communications team that includes a mix of expertise and perspectives, such as the PI, study coordinator, site spokesperson, and a staff member who works closely with the community. Minimally, each site should designate a communications point person to work with the sponsor and serve as a liaison with any other sites conducting a multisite study.

A health care worker keeps up with the demand in one of the busiest hospitals in the Dominican Republic.

Jim Daniels

Chapter 3

Developing a Strategic Communications Plan

This chapter provides guidance for developing a strategic communications plan for your study. The material in this chapter is presented according to the standard elements of a typical plan (see Appendix 3.1 for an example). A good plan includes strategies for communicating with internal stakeholders (trial staff, sponsors, and funders) and external stakeholders (government officials, journalists, community members, and advocates at the local, national, and international levels).

Your strategic plan should reference a separate "crisis communications plan" for anticipating and managing controversy (see Chapter 5). It should also lay the groundwork for the dissemination of research results (see Chapter 6).

Be prepared to adapt your plan if the circumstances change during the trial. Your activities should be updated regularly to respond to emerging issues or events and to take advantage of new opportunities.

In this chapter

I Background and environmental analysis

In the introduction to your communications plan, describe the topic and the research study in one or two paragraphs. State why your research is important, and why it is being conducted in this particular community. Summarize background information on the trial's purpose, methods, and context. You may be able to adapt language from the study protocol for this purpose.

HIV leaves community members looking to others for care.

Anita Khemka

Anita Khemka

A man living with HIV receives home-based care in Manipur, India. When publishing photos of individuals who are HIV positive, you must ensure that you 1) have obtained permission from the individual to use the image and 2) use captions that avoid stigmatizing people living with HIV.

Identify your study's communication-related vulnerabilities and strengths by summarizing the main findings of your environmental scan (see Chapter 2 for more information on how to conduct an environmental scan). Describe in three or four paragraphs the context in which you will introduce your study, including political or other challenges that could pose a risk to the research project. Opportunities, strengths, or contextual information that could help you achieve your objectives should also be mentioned.

Use all available information sources, including formative research reports, literature reviews, and conversations with colleagues. Briefly note potential issues. Here are some examples:

- Upcoming elections may result in staff changes at the Ministry of Health, possibly introducing a lack of continuity or support for the trial.
- A previous vaccine trial conducted at the same site was the subject of sensationalized reporting that accused the researchers of using local women as "lab rats."
- Formative research among study participants revealed that some of the women think that participants are assigned to study arms according to HIV status—a misconception that could lead to stigmatization of study participants.

II Goals and objectives

The goal of the communications plan is your vision of what you want to accomplish. For many studies, the goal is to explain the research in order to acquire support for the project and to encourage policymakers to apply the findings. Your objectives are the steps that must be taken to achieve those goals.

To develop your communications objectives, you must identify key policy issues, constraints, and problems for which information can serve as part of the solution. Then list your key objectives in relation to the most important issues, such as the dissemination of results, political support for the trial, or visibility for your organization.

The more specific your objective, the easier it will be to determine whether you are on track to achieve your goal. Including a timeline for each objective will help you to monitor your progress.

Sample objectives might include the following:

- To increase understanding among community members of the trial's purpose, its design, and its benefits to the local community.
- To improve the accuracy and tone of the media coverage of the trial and of malaria research by local-language newspapers and radio stations.
- To anticipate and manage controversy related to a tuberculosis vaccine trial by increasing access to balanced information and identifying and responding quickly to misinformation (see Chapter 5).
- To make the results of a meningitis study understandable to influential advocates and policymakers in countries X, Y, and Z, and thereby help inform national immunization policy in those countries.

III The communications team

Before the trial began, you should have identified a team with a range of expertise to develop and implement your communications strategy (this process is explained in Chapter 2). You should list the members of your communications team and their roles in implementing the communications strategy in a chart. Include multiple ways to contact each member of your team.

Your chart should highlight the skills and experience of the team members. For example, has the principal investigator (PI) served as a spokesperson for another trial? Did the community liaison officer receive media training? Have team members responded to communications crises in the past? Does the communications officer meet regularly with counterparts from other trials?

You can organize this section by communications function, as shown in Box 3.1.

Box 3.1. Sample communications team template, organized by communications function

Function	Individuals	Comments	Contact information
Spokespersons	Dr. Suyat Buenaventura, PI	Not available on Wed. afternoons Refer all government questions to Dr. Buenaventura	Cell: 033 758 4665 Home: 037 897 7979 Work: 038 988 4596
	Abay Versola, Study Coordinator	Back-up person Great contacts with local CBOs	Cell: 039 688 4998 Work: 037 832 1919 Home: 038 677 3526
Coordination of issues management, global communications	Lauro Bacani	Leader, Communications Team	Cell: 039 629 2211
	Other team members:		
	Dr. Buenaventura		Cell: 033 758 4665
	Abay Versola		Cell: 039 688 4998
	Usi Abad		Cell: 039 445 8999
Communications support	London office can offer graphics support		ross2@mrc.ac.uk
	Support also available through PR Options, the local media support firm		Jhr78@Prsolutions.com
Subject matter experts	Study and clinical issues: Dr. Buenaventura Socio-behavioral issues: Dr. Quevido Study design, statistical analysis: Dr. Manalo		Cell: 033 758 4665 Cell: 039 687 0675 Cell: 038 756 3984
Government relations	Dr. Buenaventura	Refer all calls from Government directly to Dr. Buenaventura	Cell: 033 758 4665
Media relations	Lauro Bacani	He will direct the caller to the correct spokesperson.	Cell: 039 629 2211
Relations with advocates	Women and AIDS Group		e-mail: info@WAIDS2.org
	Global Campaign for Microbicides		e-mail: dir32@path.org
	Network of Sexwork Women		e-mail: net2@sw.org
Community relations	Luna Balobalo	Lead person on coordinating with community members and CBOs.	Cell: 039 827 9994
	Nurse Flora Acosta	Has strong relations with many church and community groups	
Liaison with donors	Lauro Bacani is in charge of info to donors. Dr. Buenaventura will handle any in-person meetings or calls.		

IV Identification of key stakeholders

Determine who needs to know about your trial; write down each name. Whose views and decisions will affect your ability to implement the trial successfully or to promote the application of its findings in the future?

These stakeholders are the audiences for your communications efforts. Typical primary stakeholders at the individual trial-site level include:

- Study participants
- Trial staff
- Study management and sponsors
- Regulatory authorities and ethical review committees
- Government officials
- Community advisory board (CAB) members and community leaders
- Community-based groups in the host community
- Colleague organizations and the scientific community
- National and international advocacy groups
- Local, national, and international press
- Donors

Silas Achar/FHI

Site staff comprise an important internal audience for communications. Dr. Robert Bailey meets with colleagues involved in male circumcision in Kenya.

In your communications plan, however, you should go beyond these general categories. Instead of defining stakeholders as "Ministry of Health officials," determine specifically whom you need to reach in the ministry. For example, a plan might outline:

> *Primary communications audiences for this trial include the Minister of Health; the Director General for Health Services; the Reproductive Health Commissioner; the national and sub-national representatives for programs, training, and service statistics; and facility-level supervisors and clinicians.*

Recognize that you have colleagues within your organization or university who will want to know about the trial as it progresses. These stakeholders are part of your "internal audience" and may include any of the organizations that are conducting the trial. For example, it could include the president or chief executive officer of the trial sponsor, the country director of the implementing partner where the trial is being conducted, or other staff members in your institution working on similar trials or programs related to your area of study.

Organize your stakeholders into audience groups. Most trials do not have the resources to develop separate messages and communications campaigns for each of the groups or interested parties who make up your audiences. Fortunately, it is usually possible to combine categories according to the kind of information they need or want, their level of scientific sophistication, and the type of messaging that is appropriate.

Community members are important audiences for trials.

Jim Daniels

An example of audience segmentation by general categories, for an HIV prevention trial, might include:

- Policymakers and national opinion leaders
  - Minister of Health
  - Deputy Minister of Health, Northwest Province
  - National AIDS Control Committee members
  - National pharmacy authority
  - Minister of Science and Technology
  - Members of parliament interested in science and health issues
  - Regulatory authorities
  - Ethical review committees
- Sophisticated lay audiences
  - Trial staff
  - Board members, employees, and management of host institutions
  - Funders
  - Advocates and members of nongovernmental organizations (NGOs)
  - Local, national, and international press

- Scientific audiences
  - Sponsors, trial networks
  - Organizational colleagues and the wider scientific community
  - Leadership of related trials
- Community members
  - Trial participants and their families
  - Local community groups and community leaders
  - Traditional healers, health workers
  - Community radio

Figure 3.1 shows another way to group primary audiences for clinical trials.

Figure 3.1. Audience segmentation by external and internal groups

External

- Government officials and other policymakers (e.g., Ministry of Health, regulatory bodies)
- Leadership of related trials or trial networks
- Organizational colleagues and wider scientific community
- Community (traditional leaders and local advocates)
- National and international advocates and civil society groups
- News media (local, national, international)

Internal

- Government officials and other policymakers (e.g., Ministry of Health, regulatory bodies)
- Leadership of related trials or trial networks
- Organizational colleagues and wider scientific community
- Community (traditional leaders and local advocates)
- National and international advocates and civil society groups
- News media (local, national, international)

Box 3.2. Communicating with key stakeholders

By Pam Norick, Chief of External Relations, International Partnership for Microbicides (IPM)

At IPM, communications strategies are designed with our key stakeholders in mind—the donors who support our work, the governments of countries that host clinical trials, the companies that partner with us, the women who volunteer for studies to test our products, and the communities in which they live. This type of communications is about more than just media coverage; it presents different challenges, and requires different approaches—especially on occasions where media outreach is not appropriate.

Our specific approach was put to use when the results for the Carraguard trial were announced in 2008. Although Carraguard was not an IPM product, the results of the trial had significant implications for the field. It was important for IPM to be supportive of the trial sponsor and respectful of their communications activities, while making sure our key audiences were well informed and engaged.

IPM took steps to engage our key audiences before, during, and after the Carraguard announcement. We held calls with our donor community as soon as the data went public, and we sent e-mail updates to key partners. We also provided our clinical research centers with prepared background materials, such as Q&As and fact sheets, that would allow them to keep governments and IPM study volunteers informed. We started with the data and its implications for our product development, and we developed our messages from the inside out.

Communication with our stakeholders is at the core of IPM's comprehensive communications strategies. Without the ongoing support of our donors, partners, volunteers, and others, a female-initiated prevention tool would stand little chance of becoming a reality.

Understanding your stakeholders

Understanding your stakeholders' values, concerns, and needs will help you communicate effectively. Use information gathered during the environmental scan (see Chapter 2) to create a table that summarizes what you know about the key stakeholders for the trial (see Box 3.3).

Create a different table for each study at your trial site to help identify audiences and their interests. For example, although there will be some overlap, a pre-exposure prophylaxis (PrEP) trial testing a product to reduce HIV infection in men who have sex with men (MSM) is likely to have some different stakeholders than a study testing the same product formulated as a vaginal microbicide in women.

People in each stakeholder group are also communicators in their own right. Some may be opinion leaders who influence the knowledge, attitudes, and behavior of others. If you understand this cascade of influence, you can expand the reach and impact of your communications. Through contacts with their peers, well-informed trial participants, for example, may have an affect on the community's understanding of the research. Respected policymakers can be enlisted to use the trial's key messages in speeches and media interviews and to help defuse any controversies that may arise.

Box 3.3. Sample "getting to know your stakeholders" template

Stakeholder group	Level (who do they communicate with?)	Values and goals	Concerns
Members of the host community	Partners, families, local leaders	Varied: Protecting community members, reducing HIV in the community	Safety, community reputation (including stigma), involvement of community in research
Trial participants	Partners, families, local community	Varied: Helping research, earning stipend, reducing personal risk of disease or infection	Safety, burden of trial participation
National policymakers	News media, opinion leaders, constituents	Attaining and maintaining political power, impact on policy	If something goes wrong, they may be blamed for having supported the trial

See Appendix 3.2 for a complete template and possible audiences to consider.

Developing a detailed contact list

Your contact list can be your greatest asset—if it is well maintained. This list is the tool that will enable you to communicate with your stakeholders.

Here are some tips to ensure that your contact list is complete, well organized, and up to date:

Compile a comprehensive contact list. Include all the stakeholders that you have identified for your trial.

Organize your contacts. Use categories to sort and prioritize your list. The categories might include the primary audiences you have previously identified: Media contact, global opinion-leader, donor, advocate, ethics committee member, community leader, friend of the trial.

Jide Adeniyi-Jones/FHI Nigeria

News media interview the former Minister of Health of Nigeria, Professor Babatunde Osotimehin.

Update the contact list regularly. Whether a new government administration has taken over or you have just returned from a conference with 20 new business cards, it is critical to incorporate such new information to keep your contact list current.

Designate and delegate. Assign someone on your team to be responsible for updating the contact list regularly. Remember to notify that person of changes you hear about or new contacts you make. Encourage others on the team to help expand and update the list.

Use a format that works for you. Keep it simple. If your group uses a complicated database that you do not understand, either learn the program or have the information exported into an Excel spreadsheet or Word document.

Box 3.4. Sample contact list entries

Surname	First name	Organization	Title	Address	Phone	E-mail	Category	Comments
Garcia	Roberto	Prensa Libre	Staff reporter	65 Calle Rivera, Puerta Villa	Cell: xxx xxx xxxxxx	name here@ prensa.com	Media	Attended launch event
Media-Rivera	Luiz	Ministerio de Salud	Director de Hygiene y Salud Mental	46 Calle de las Americas, Sector Seis, Lima	Cell: xxxxx xxxx Work: xxxx xxx xxxx	name here@ gov.pe	Govt.	Skeptical but willing to listen. Has asked to be kept updated quarterly.
Chavez	Isabel	Peru Mujer	Director de Salud Repro-ductiva	Prefers e-mail	Cell: xxxxx xxx	name here@ peru.org	Women's health advocate	Linked into international HIV networks; attended launch event

See Appendix 3.3 for a complete contact list template.

V Strategy for ongoing communication with stakeholders

Your plan should describe how you will initiate and maintain communication with internal and external stakeholders throughout the trial. It should include the most important messages you want to convey to each group as well as the strategies you will use to do so. Of course, both your messages and strategies will change over time. Your communications plan should be a living document that evolves as circumstances change and the trial progresses.

Developing messages

List three or four important messages about your trial that you would like to convey to stakeholders. These messages usually address:

- The purpose of the trial and its potential benefits
- The fact that the product or intervention under study is of unknown effectiveness
- The measures taken to protect the safety of participants
- The possible risks and benefits of trial participation

It's helpful to separate out in a communications plan, first the content of what you need to communicate; secondly, the strategy for how you will communicate your messages; third, how to adapt the factual information for different audiences; and fourth being sure to have the right messengers for each audience.

—Manju Chatani-Gada, MPH, Senior Program Manager, AVAC: Global Advocacy for HIV Prevention

See Chapter 7 for more guidance on developing messages. You should refine these messages and develop supporting messages as the trial progresses. More key messages will be needed for specific situations or events and when results are available for dissemination.

Communications channels and approaches

Your environmental scan (see Chapter 2) will provide information about the best ways to communicate with internal and external audiences. During site preparation meetings, for example, stakeholders can be asked how they would like to be kept informed of the trial and how often they would like to receive updates. Some stakeholders may prefer to receive infrequent e-mail alerts or quarterly written reports, whereas others may want to meet periodically with trial staff to ask questions about the trial. This information can be captured in your contact list.

Let stakeholders' preferences—about the type and frequency of information provided and the channels used to convey that information—guide the development of your strategy. You may choose to use different strategies at various stages of the trial. For example, media outreach might be narrowly targeted to educate a few trusted journalists at the beginning of a trial but then gradually expanded to build understanding of the trial among a larger cadre of journalists through media workshops in preparation for the dissemination of results to local, national, and international media.

You may also opt for a staged strategy, where you map out whom you will approach first and the order of subsequent contacts. This may use peer-to-peer networks, or be based on a cascade model of influence. For example, if you are studying a new influenza vaccine and you know of a well-known expert on influenza, you might talk to her first, recognizing that the media and policymakers frequently seek her opinion.

Plan for a regular flow of information instead of one-time announcements, and add activities over time. Be proactive and initiate a dialogue that builds trust.

Monica Wanjiru

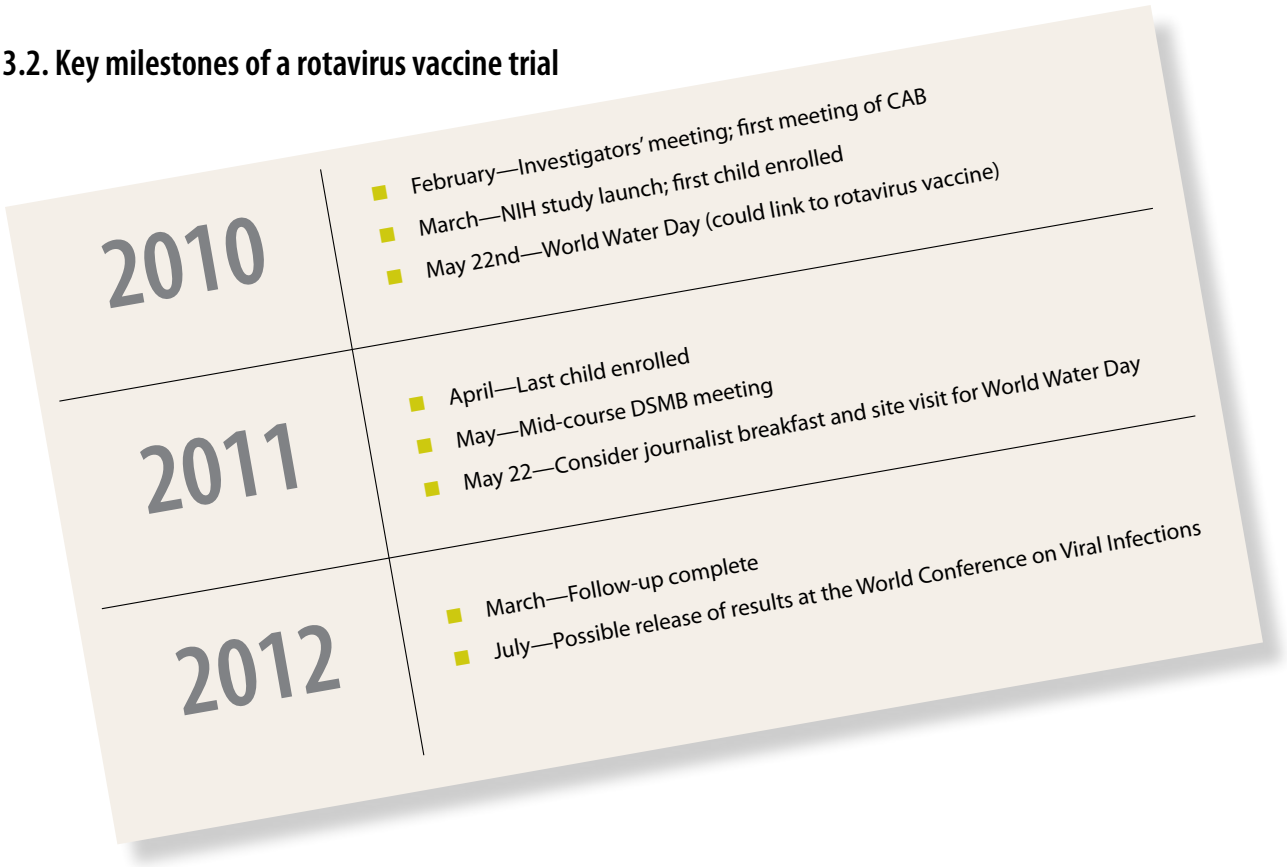
All staff at trial sites are potential ambassadors for their trials. The Population Council in Kenya conducts research in collaboration with many partners.

Activities plan

Translate your communications strategy into an action plan that lists activities, messages, and timing for each audience (Baeyaert 2005).

Identify milestones for your trial and other related trials, and plot these on a timeline. Although regular communications throughout the study are important, there are key milestones that require special attention. These include the launch of the trial, the completion of participant enrollment, interim analyses by an independent data monitoring committee (IDMC) that could recommend modifications or a halt to a study, and the release of the study's results. A timeline of these milestones (see the first item in Box 3.5) can be a useful planning tool.

Figure 3.2. Key milestones of a rotavirus vaccine trial



Consider inviting journalists or other stakeholders to visit the trial site at appropriate milestones.

Remember that important events in related trials—in your region, country, or another part of the world—may still affect perceptions of your own research. For example, the closure of a microbicide or vaccine trial—whether for futility, harm, or benefit—is likely to raise questions about other HIV prevention research.

VI Strategy for managing controversy—crisis communications

Experience shows that at least one problem, controversy, or crisis is likely to occur at some point during your trial. Clinical trials can be difficult to understand, and research on certain topics is inherently controversial—particularly when trials are designed to test unproven interventions in healthy volunteers. Therefore, you must be prepared to respond quickly to misinformation or unexpected events that could jeopardize your trial.

By anticipating which issues are likely to be controversial or misunderstood, and by addressing them early on in a straightforward and comprehensive way, you can prevent potential crises.

Your strategic communication plan should include a short section summarizing your plan for dealing with controversy. If you expect controversy, you will also need to develop a more detailed crisis-communications plan to help you manage emerging issues (see Chapter 5).

VII Dissemination plan for trial results

As you implement your communications strategy, you will build the tools, processes, skills, and resources that you will need to disseminate the results of your trial. Your overall communications strategy should summarize your plan to share results with trial stakeholders. Later, you will need to develop a separate and more detailed dissemination plan.

It is important to outline the basic dissemination plan early in the trial so that you can budget for essential activities such as holding dissemination meetings for community members and other local stakeholders, presenting at conferences, and writing journal articles. As the trial progresses, this plan will evolve.

Chapter 6 offers guidance on developing a dissemination plan that includes strategies for communicating results to different audiences, activities, timelines, and materials to be developed. The scenario planning described in Chapter 6 will help you prepare for the dissemination of the trial's final results by developing strategies and messages for a number of possible study outcomes.

Elizabeth T. Robinson

Dr. Olfa Bahri at the Pasteur Institute of Tunis writes a scientific article on Hepatitis B transmission.

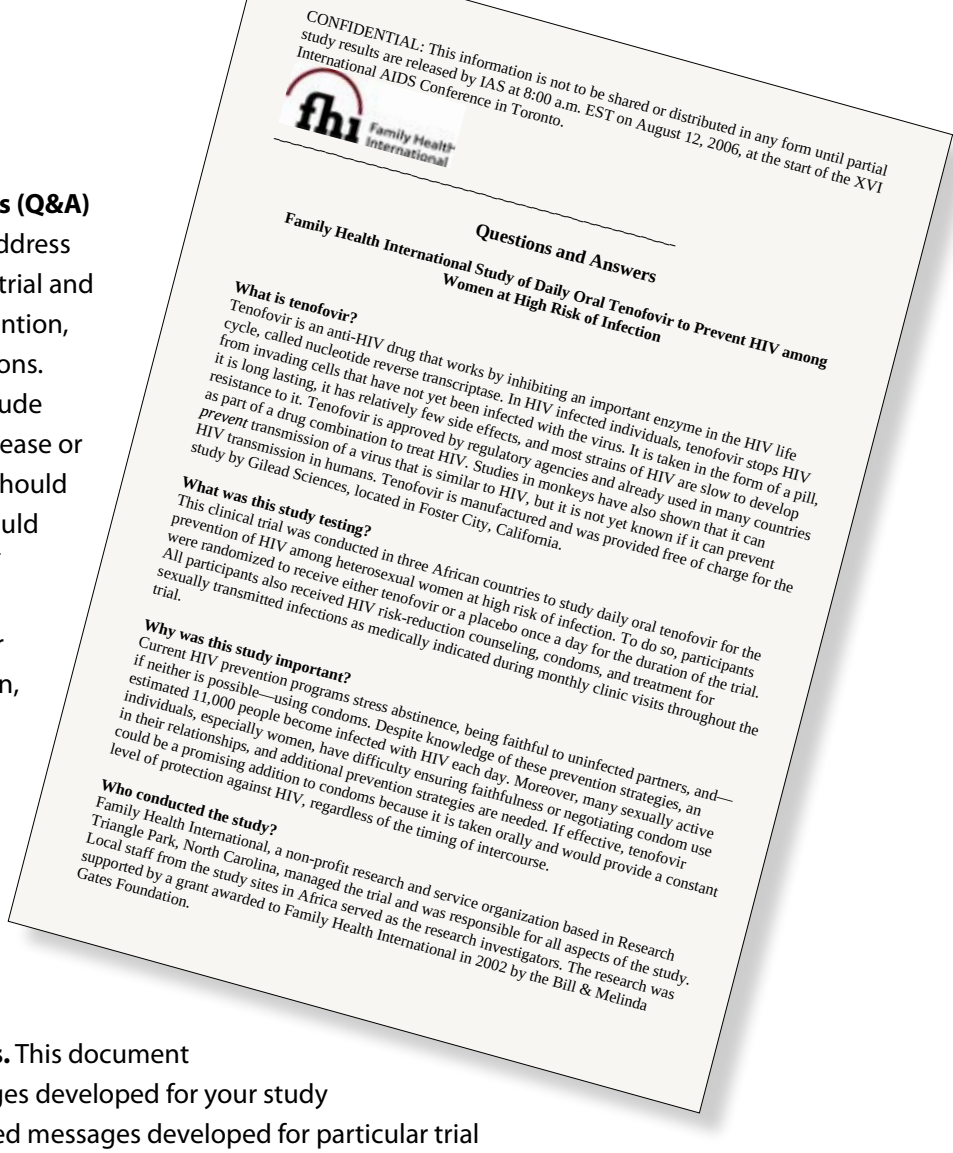
VIII Materials to support the trial

Your plan should include a list of the materials that you will develop to support the trial. Box 3.5 presents a template for tracking the status of these materials. Every study should put together the following core package of materials:

External documents for distribution to stakeholders

Backgrounder. This is a one- or two-page summary of the "who, what, when, where, and why" of the study. It should explain the research questions being addressed in clear language without research jargon. (See Appendix 3.5 for a sample backgrounder.)

External questions & answers (Q&A) document. The Q&A should address common questions about the trial and its design, the research intervention, and the sponsoring organizations. External Q&As should also include general information on the disease or condition studied. Questions should be kept short and answers should be limited to one paragraph. If an answer needs to be longer, consider dividing it into two or more separate questions. Again, use clear language without research jargon. (See Appendix 3.6 for a sample of an external Q&A.)



CONFIDENTIAL: This information is not to be shared or distributed in any form until partial study results are released by IAS at 8:00 a.m. EST on August 12, 2006, at the start of the XVI International AIDS Conference in Toronto.

fhi Family Health International

Questions and Answers

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

What is tenofovir?

Tenofovir is an anti-HIV drug that works by inhibiting an important enzyme in the HIV life cycle, called nucleotide reverse transcriptase. In HIV infected individuals, tenofovir stops HIV from invading cells that have not yet been infected with the virus. It is taken in the form of a pill, it is long lasting, it has relatively few side effects, and most strains of HIV are slow to develop resistance to it. Tenofovir is approved by regulatory agencies and already used in many countries as part of a drug combination to treat HIV. Studies in monkeys have also shown that it can *prevent* transmission of a virus that is similar to HIV, but it is not yet known if it can prevent HIV transmission in humans. Tenofovir is manufactured and was provided free of charge for the study by Gilead Sciences, located in Foster City, California.

What was this study testing?

This clinical trial was conducted in three African countries to study daily oral tenofovir for the prevention of HIV among heterosexual women at high risk of infection. To do so, participants were randomized to receive either tenofovir or a placebo once a day for the duration of the trial. All participants also received HIV risk-reduction counseling, condoms, and treatment for sexually transmitted infections as medically indicated during monthly clinic visits throughout the trial.

Why was this study important?

Current HIV prevention programs stress abstinence, being faithful to uninfected partners, and—if neither is possible—using condoms. Despite knowledge of these prevention strategies, an estimated 11,000 people become infected with HIV each day. Moreover, many sexually active individuals, especially women, have difficulty ensuring faithfulness or negotiating condom use in their relationships, and additional prevention strategies are needed. If effective, tenofovir could be a promising addition to condoms because it is taken orally and would provide a constant level of protection against HIV, regardless of the timing of intercourse.

Who conducted the study?

Family Health International, a non-profit research and service organization based in Research Triangle Park, North Carolina, managed the trial and was responsible for all aspects of the study. Local staff from the study sites in Africa served as the research investigators. The research was supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation.

Stand-by and internal documents for staff use only

Talking points/key messages. This document should include the key messages developed for your study (see Chapter 7), and any tailored messages developed for particular trial sites.

Internal Q&A. This question and answer document is similar to the Q&A listed above, but it tries to anticipate and address controversial issues and common misconceptions about your trial. Its purpose is to provide talking points about such issues for trial spokespeople. This document should be updated to address any issues or misconceptions that arise during the trial. For sample questions to include in internal Q&As, see Appendix 6.4.

Holding statement. This is a press statement that contains basic information about the study, including a contact name and information about your spokesperson(s), study, and organization. It usually includes blank spaces where pertinent information about an unexpected event or situation can be filled in at a moment's notice.

Spokesperson "bios." One- to three-paragraph biographies of all of the trial spokespeople should be prepared and made available to journalists or other stakeholders upon request.

Other materials. You may also want to develop a study newsletter (see Appendix 3.4 for example), brochures, press releases (see Chapter 9), electronic alerts, resource lists, training materials, slide presentations, posters, and flyers.

Box 3.5. Sample list of materials and tools to support the communications plan

Internal: for staff use only	**Status and person responsible**
Timeline of trial milestones and list of other related studies in the country and their milestones (e.g., DSMB meetings)	
Contact list of site staff	
Calendar of relevant meetings/conferences	
Media guidelines/communication SOPs for staff	
Spokesperson training materials	
Internal Q&A addressing anticipated issues	
Talking points/key messages about trial	
Internal Web portal or documents database	
Database with stakeholder contact information	
Annotated list of health advocates	
External: for distribution	**Status and person responsible**
Backgrounder	
Public Q&A	
Study newsletter or brochures	
Bios of spokespersons	
Basic PowerPoint presentation on study	
Web page content (for sponsor or host institution Web site)	

In resource-constrained countries, many stakeholders will need printed materials. Provincial and district health officials, for example, often do not have reliable Internet connections or even access to computers. In such instances it is best to hand-deliver copies of key documents and get signed proof of delivery.

Some national-level decision makers may have access to reliable Internet services and may prefer to receive information about the trial electronically.

All materials should be written in clear, accessible language; nevertheless, messages and materials will need some adaptation for different audiences. For example, a slide presentation at a scientific conference might contain the same basic information about the trial as a presentation to a nonscientific audience, but it might provide extra details and use some technical language. Some materials may also need to be translated into local languages.

Pre-test your materials with members of your target audiences before you produce or distribute them and use the audience feedback to ensure that the materials convey your messages effectively.

Geoff Oliver Bugbee/IPM

Staff at the Reproductive Health and HIV Research Unit (RHRU), an IPM-supported research center in Yeoville, South Africa, demonstrate the flexibility of a vaginal ring being tested to deliver anti-HIV microbicides.

Box 3.6. Respecting cultural sensitivities about wording

By Cheri Reid, Study Coordinator, The Centre for Infectious Disease Research in Zambia (CIDRZ), Lusaka, Zambia

Before our community team started to speak openly about our microbicide trial at public meetings, we first needed to apologize for using words not considered "polite." For example, it is not acceptable in our communities for younger women to speak to older women about sex, or for women to speak to men about sex. Yet, the topic of our research related to things that could not be said in mixed company, such as "vagina" and "anal sex." So we had to say "private parts" for vagina, and pay attention to the cultural rules about what can be said to whom and how. We explained that we needed to use these words so that everyone understood what the research was really about.

It is important to pre-test your materials with members of your target audiences. Show members of each target audience drafts of the materials that have been designed for them and ask them to respond to questions about content, language, and format. This can be done through group discussions and interviews or written questionnaires. Your goal is to determine whether target audiences understand the material and how to make it more useful and relevant to specific audiences.

IX Monitoring and evaluation

Monitoring is essential for the early identification of potential problems and to ensure the effectiveness of trial communications. The information you gather through monitoring can help you refine messages and approaches and measure progress toward achieving your objectives.

> *Monitor results at pre-agreed stages and adjust elements of the plan and the means of measurement if necessary. Ask: What should we continue doing? Stop doing? Adjust?*
>
> —(Baeyaert 2005)

Box 3.7. Monitoring communications and media for a study

The monitoring part of your strategic communications plan should briefly describe how you plan to track stakeholders' perceptions of your trial, relevant media coverage, and the utility of your approach.	
Perceptions of the research among stakeholders	• Outline your regular meetings with stakeholders and how you will track their perceptions. Information sources include meeting reports and periodic interviews with key informants from your target audiences. • Set up a mechanism for staff to report and document rumors or concerns they hear from study participants, CAB members, or other stakeholders; what activities you undertook to respond; and the outcomes of the activities. • Meeting with recruitment staff is a good way to get feedback on what is being said in the community about a research project. Most recruiters are peers of the population of interest for the study and are in close contact with them. Listening to recruitment staff can help you address misinformation that may be circulating in the community.
Relevant media coverage of your trial and related topics	• One or more members of the study staff should be responsible for monitoring media coverage of the trial and related research. Include a standard operating procedure for monitoring media at each site. Be sure to include national and local-language newspapers, radio, and television, as well as religious and community newsletters and Internet list servers (see Chapter 9).
Usefulness of the strategic communications plan and contact lists	• Keeping your contact list up to date will help ensure it remains a useful resource for your team. • Likewise, your overall plan should be monitored and revisited if major changes take place in your study or the field.

Key points to remember

- Start developing your strategic communications plan early, and refer back to it for guidance throughout your study. Your plan will be a living document that evolves as circumstances change, new opportunities arise, and the trial progresses.
- A good plan includes strategies, activities and approaches for communicating with your audiences throughout the trial. Your audiences are the internal and external stakeholders that your team identifies as important to your trial.
- Your overall communications strategy should summarize brief plans for how your study will deal with controversy, disseminate trial results, and monitor and evaluate communication activities.

Chapter 4

Communications During the Trial

By the time you are ready to start your trial, you should have an outline of your strategic communications plan—including details about internal and external communications, crisis management, and results dissemination (see Chapter 3 for details on creating your strategic communications plan). The outline will facilitate a successful launch for your trial and help you to maintain good communications throughout the course of the trial.

This chapter describes how to put your communications plan into action. You will learn how to use your outline and adapt to emerging events so that you can maintain effective communications throughout the course of the study.

In this chapter

I Announcing the start of your trial

There are no set rules for announcing the beginning of your trial. Every study is unique, and a decision on how best to introduce the study to relevant groups and individuals should be made on a case-by-case basis.

The approach you choose will depend on a number of factors, including the information obtained in your environmental scan (see Chapter 2). Some trials send press releases to international media and hold public events. Others choose to invite selected media, advocates, and other researchers to ribbon-cutting ceremonies at trial sites. Some trials simply start to enroll participants without any fanfare, limiting their announcement to an article in an organizational newsletter. The type of launch you select will depend on your study setting, timing, global and local context, budget, and the goals of your study.

Michael Szpir/FHI

Stella Kirkendale (left), in FHI's Behavioral and Biomedical Research Department, meets with Mercy Tsidya, a staff member at the University of North Carolina's HIV prevention research project in Lilongwe, Malawi.

Carlos Vela

Community members march in support of the i-PrEx trial in Iquitos, Peru.

Study launches often focus on government officials and local communities rather than the international scientific community. However, there may be instances where you will want to aim for a wider audience. For example, if the goal of your launch is to increase funding for the study by attracting attention from international donors, you might consider a high profile launch that seeks international media coverage.

What kind of launch should you have?

The following questions will help you determine the purpose of your launch and the activities that may be the most appropriate for your trial. Consider the following questions:

What is the purpose of this launch? What are its objectives? If the purpose is to garner the support of local opinion leaders, perhaps you should have a smaller launch, focusing on activities that acknowledge the value of their input and support. If you are seeking to increase dialogue about a certain health issue on a global level, you might consider a larger launch.

Considering the goal of this launch, should you actively seek attention from local, national, or international media? If you have existing relationships with journalists you trust, consider contacting them, if you choose to seek media attention. Regardless of whether you choose to seek media attention during your launch, you should prepare for it: Orient the study's staff members and spokespersons as needed, and review your standard operating procedures (SOPs) for interactions with the news media (see Chapters 2 and 9). Also, update your directory or contact list of stakeholders, including media contacts, once the trial begins.

Do you have the staff you need? If you are still sorting out the basics for your trial at the time you start enrolling participants, you may not want to have an event. Consider waiting to make a public announcement until you take care of the essentials.

Will there be announcements from the government, the sponsor, or the funder? If so, when? Coordinate with all partners, including the government and your sponsor, and time your announcement appropriately. Do not release anything before any official government announcements go out, and do not release an announcement before checking first with the study sponsor.

Is this a multisite trial? If so, have you coordinated your strategy with the other sites and the headquarters staff? Multisite trials require a lot of centralized coordination because sites will often have different launch dates. If you are part of a multisite trial, you will likely work closely with the staff members at headquarters. They may provide you with a generic press release that can be adapted for your specific context. They may will also work with each site to ensure that each site-specific launch is coordinated with the sponsor's press release, if applicable.

Are there upcoming conferences or other events that could provide an opportunity to release the news of your study's launch? You may want to consider timing your announcement around a scientific conference, since such events provide excellent access to the wider research community as well as news media interested in public health.

Use your judgment to determine the type of launch that would be best for your trial. Keep in mind your study's setting, objectives, and budget.

Materials

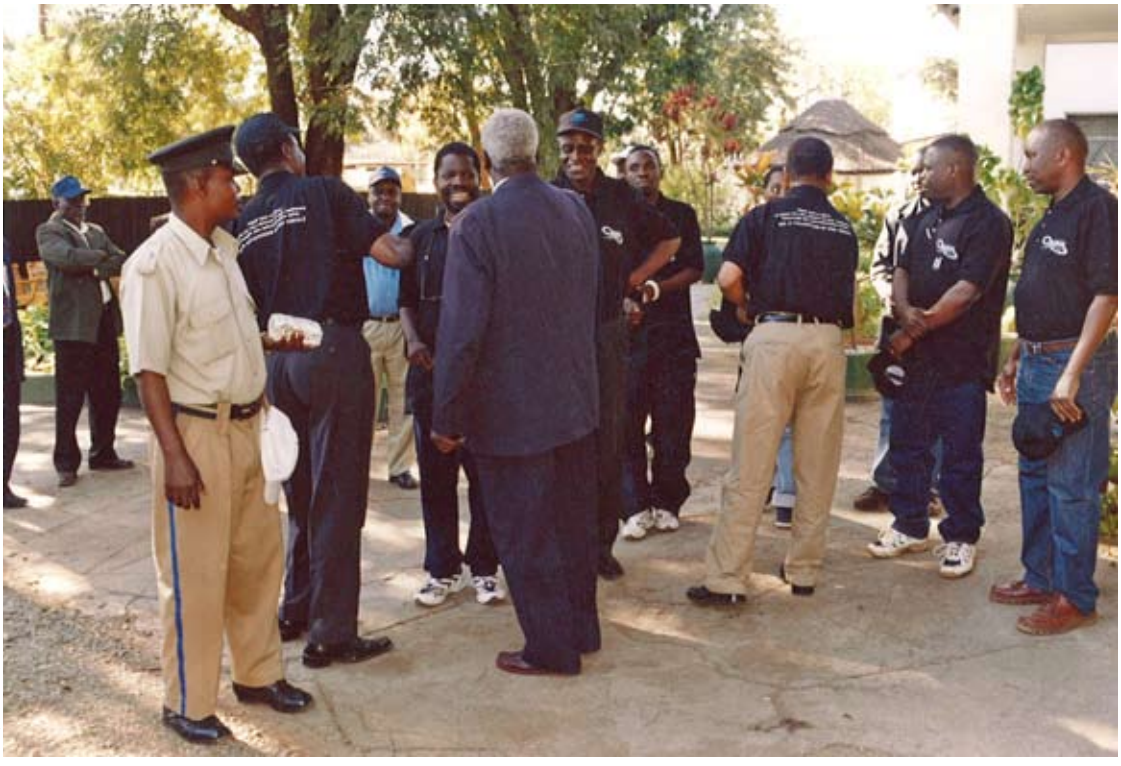
The strategy for launching your trial publicly will determine the type of supportive materials that might be necessary. Basic materials you may need include a press release (see Chapter 9) and study backgrounders and Q&As (see Appendices 3.5 and 3.6).

In addition, large study launches often print additional promotional materials, such as brochures, posters, bags, and T-shirts. For more on developing materials, including pre-testing, see Chapter 3. For information about budgeting for these items, see Chapter 2. To read about incorporating key messages into materials, see Chapter 7.

Sample strategies for trial launches

Tailor your release to the needs of your trial. Be creative—draw on the ideas and suggestions of others. Here are some examples of trial announcements that were tailored to opportunities that arose during the planning phase.

Early government involvement. In Mazabuka, Zambia, the early involvement of the government helped to ensure successful communications during the launch of the Microbicides Development Programme's (MDP) 301 study. The MDP 301 trial was a Phase III study that evaluated the safety and effectiveness of the vaginal microbicide PRO 2000 for reducing HIV infection in women. As they were planning the launch, MDP staff members called the office of the Minister of Health to invite him to participate in the public launch of the study. He agreed after the first call, and then met with the principal investigator to discuss the launch and the details of the trial. According to that study's staff members, his presence at the launch was important for the public perception of the trial during the launch phase, especially since this was the first trial of its kind in Mazabuka. The fact that the Minister of Health was launching the trial led to a wide



Jossy Phiri/National Food and Nutrition Commission of Zambia

In Mazabuka, Zambia, the involvement of the government helped ensure successful communications during the launch of the Microbicide Development Programme's MDP 301 study.

Box 4.1. Sample spreadsheet for trial launch announcements

Plan for announcing the launch of X trial					
Group	**To be contacted**	**Activity**	**Date**	**Who will contact them**	**Materials needed**
Government officials					
Regulatory agencies					
Leadership of host institution					
Leadership of related trials					
Partners					
Donors					
Advocacy groups					
Community					
News media					

representation of media—including journalists from government and private media sources—at the event. In the end, most coverage of the MDP 301 launch was positive.

Tiered strategy. For the multi-country VOICE (Vaginal and Oral Interventions to Control the Epidemic) study, the Microbicide Trials Network (MTN) developed a tiered announcement strategy in which they released information about the trial in waves. Such a strategy ensured that by the time the trial was under way, basic information about the trial had already been communicated—via public presentations at local, national, and international meetings—which gave news media, the scientific community, and civil society advocates access to accurate information. Although the VOICE team was not ready to officially announce the study until August 2009, the staff distributed a press release at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in July 2009, stating that the trial would begin the following month. The MTN released a study backgrounder and a Q&A document at the same time. In September 2009, two further statements were released: one from the sponsor, the U.S. National Institute of Allergy and Infectious Diseases (NIAID), stating that the trial was under way; and another from MTN announcing that enrollment had begun at the Zimbabwe site. To launch the trial in Zimbabwe, site-level staff issued their own press release, a modified version of the larger MTN release. The other sites followed. In the end, MTN's strategy—informing the international research community that the trial was coming, even years before the study began to enroll participants—paved the way for a smooth launch when the time came to release the official trial announcement.

Box 4.2. Advantages and disadvantages of drawing attention to a study launch: "First South African-developed HIV vaccines begin testing in SA"

When the leadership of SAAVI 102/HVTN 073, a small Phase I vaccine study in South Africa, decided to organize a public launch for the study, their announcement attracted a lot of media attention. In general, Phase I trials do not seek much publicity (this trial would enroll only 36 participants). But there was something unique about the vaccine study: the candidate products were developed by local South African scientists. The study team decided to launch the trial publicly and invited high-profile speakers.

The launch received considerable, positive media coverage, especially as it coincided with the 2009 International AIDS Society Conference being held in Cape Town. It provided an important opportunity for the many stakeholders involved in the study to strengthen their connection to the study. Participants at the launch included government officials, researchers, leading advocates, and community stakeholders, as well as staff from the South African AIDS Vaccine Initiative (SAAVI), partners, and sponsors—the HIV Vaccine Trials Network (HVTN) and the U.S. National Institute of Allergy and Infectious Diseases (NIAID)—who were in town for the conference.

This type of public launch can have many benefits, but it also has potential drawbacks. Media attention can increase public pressure and heighten expectations for positive results from the trial—something that no study team can promise. Moreover, the larger and more prominent the event becomes, the more likely it is that stakeholders who were not invited will feel left out. In selecting a launch strategy, trial teams need to determine what is best for their study, given the context, the timing, and other factors.

Jennifer Heslop-Spencer/The Aurum Institute

Communications materials and approaches must be adapted to suit the needs of different audiences.

II Maintaining good communications

Courteous and respectful communications is an important element to ensuring the success of any trial. Another key element is continuous communication. Your team must develop ways to communicate openly and with appropriate frequency with stakeholders who have concerns or questions. You and your staff should maintain ongoing connections with key stakeholders and opinion leaders, or delegate this work to someone who can manage these responsibilities.

Regular communication needs to happen at many levels: with participants, sponsors, the protocol team, site teams, community advisory boards (CABs), the Ministry of Health (MOH), the general public, regulatory bodies, selected news media, and others.

Approaches may include:

- Responding promptly and respectfully to e-mailed inquiries
- Accepting invitations to give overview and update presentations on your study at local and national meetings and consultations
- Proactively arranging meetings with community leaders, parliamentarians, or news media to explain or discuss scientific concepts relevant to your trial
- Developing explanatory fact sheets and other documents targeted to different audiences

Over time, the research team's willingness to engage in dialogue—and the respect shown in such communications—builds trust that will help you manage controversies that may emerge.

As a rule, it is better for a research team to focus on the low-key education of their stakeholders than to engage in highly visible publicity.

Internal communications

It is essential to establish systems to maintain good internal communications throughout the course of a trial. Try to include individuals and organizations that are involved in the study, such as the trial's staff, participants, the host organization, and funders or sponsors. Each member of the internal team has a role to play. When all members are informed and able to contribute to a feedback loop, the team works more efficiently and can respond to unexpected events that may arise.

Keeping staff informed. Staff can be ambassadors for your trial and should be appropriately informed during every stage of the trial. Team members should be provided appropriate levels of detail, depending on their role in the organization.

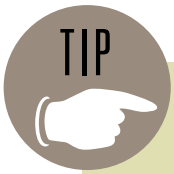
To keep your staff informed, you should hold regular meetings with senior staff members and other relevant, key staff members. Some sites meet every week to exchange information, including any concerns or misconceptions that were raised by participants.

Box 4.3. Implementing our plan: ongoing communication at multiple levels is key

By Quarraisha Abdool Karim, PhD, Regional Director, Center for the AIDS Programme of Research in South Africa (CAPRISA), Durban, South Africa

When we started to prepare for the CAPRISA 004 tenofovir gel trial, we first had to assess the community and the preparedness of potential participants to be in trials. Would microbicides be acceptable to women and their partners in the communities? Would it be acceptable for community members to participate in a microbicide trial? Would potential participants be able to understand their rights and the basic principles of informed consent? We had to figure out how to establish structures for dialogue between the community and the researchers, and to set up cohorts and see if there were sufficient incident rates of HIV to allow the trial to be completed. That went on for about two years before we enrolled the first participant. All of these steps involved communication, which was important for both information-gathering and building trust. We used many fora to share what the trial was about and the rationale and justification for doing this work.

I've never taken an approach of "flying below the radar screen," but I instead aim for openness and transparency. In the almost 25 years of doing AIDS research, I've learned that the public interest in HIV/AIDS research is very different than it is in other types of research. You need to share information as much as possible, with all of the stakeholders. This includes participants, the sponsors of the trial, the site teams and protocol teams, and community advisory boards or research support groups. Other groups we talk to include the Department of Health, regulatory bodies, and our ethics committee. It is important to keep of all these players in the loop, up to date, and engaged in the process early on. This means providing regular updates, as opposed to waiting for when you have a study milestone. Ongoing communication at multiple levels is key.



Ensuring an ongoing dialogue with trial stakeholders

- **Use your staff as communicators, and ask them to contribute when developing messages about the trial.**
- **Keep all stakeholders informed and engaged from the beginning of the research process—don't wait for a milestone in the study.**
- **Show concern for all members of the community; be careful not to show preference for one group or political party over another.**
- **Be considerate of various learning styles, and use a range of techniques to ensure communication on multiple levels.**
- **Keep your materials updated, especially as new information or concerns emerge.**
- **Use available opportunities, venues, and mechanisms to ensure consistent communications with stakeholders.**
- **Initiate meetings with trial stakeholders when necessary. Be flexible about the meeting's location: Some meetings are more appropriate at the trial site, whereas others may be more appropriate in a church, a government building, or another public place.**

Staff meetings may include:

- Status reports from the past week: You can discuss new staff hires, participation in meetings or conferences, site events, operational updates, information, misinformation or rumors heard from study participants and others, and so on.
- Media and communications update: Discuss media inquiries about the study, interviews that were conducted, and the status of any materials that are being developed or used by the study.
- An update from each site (for multisite studies): This will allow sites to learn about emerging challenges from each other.
- Scientific updates for the team: Provide news about technical publications and news reports (and their implications for your trial). Also, discuss information about related trials or even political concerns that may affect the trial.
- Community meetings: If an important community issue arises, the community liaison (who should attend community meetings) can quickly arrange a meeting with traditional and local government leaders.

As your study proceeds, use opportunities during all-staff meetings (such as annual investigator meetings) to provide refresher training in communications, including media training for any

trial spokespersons. For any meetings you hold, be sure to take meeting minutes and to save them in an archive for future reference.

Communications log. You may want to keep a communications log (multisite trials may want several—one per site plus one central log). Staff members can fill out simple paper templates or forms to record events that happen throughout the week. For example, the site may have a visitor or may be receiving inquiries on a certain topic. These events could be recorded in the log for later analysis.

The principal investigator (PI) can review the log regularly and can contact the relevant team member if something needs to be addressed. Logs can be reviewed and referenced during weekly, monthly, and joint site meetings, as well as meetings with other groups within your institution or externally.

Communications logs can be important for catching potential communications issues early on. Some events may not be a concern at the time, but a trend may become apparent later. These logs provide a record of progress, challenges, and collaboration. They may also provide information that can help you to document your impact and report back to the sponsor (see Box 4.4 and Appendix 4.1).

Box 4.4. Internal communications within the Male Circumcision Consortium: monthly updates

By Silas Achar, Communications Officer, Family Health International, Kisumu, Kenya

For the Male Circumcision Consortium in Kenya—a research and capacity-building project that works with the Kenyan Ministry of Health and other partners—we have a monthly update system that helps to facilitate internal communications among our team.

We use a communications log in the form of a simple grid (see Appendix 4.1) that each project partner fills out and brings to the monthly meeting. Each partner notes which communications activities have been implemented and which are planned, whether misinformation or rumors are emerging, among whom, and whether any materials have been planned or completed. These updates are discussed during monthly meetings, allowing partners to plan ahead and collaborate in a coordinated fashion to develop key messages, responses to misinformation, or other issues.


MALE CIRCUMCISION CONSORTIUM

MCC MALE CIRCUMCISION CONSORTIUM News

MCC News

An e-newsletter about male circumcision for HIV prevention in Kenya

March 2010
Issue 12

In this issue:

Strategy Aims to Enhance Demand for Male Circumcision

Road Show Spreads the Word about Male Circumcision for HIV Prevention

Male Circumcision in the News

Resources

ew Kitheka, a clinical mentor with APHIA II Nyanza in Rongo ict, shares a word with Peter Owino, a male circumcision client at the wa Health Centre in Awendo.

Photo courtesy of FHI

Strategy aims to enhance demand for male circumcision

Over 30 days in November and December, 35,000 men in Nyanza Province sought

As the project's communications coordinator, I then take the filled-out forms and use some of the most salient items to compile a project e-newsletter which gives prominent credit to the individuals and organizations it mentions. The newsletter also provides a venue to share links to new publications on male circumcision for HIV prevention and local news articles on the procedure.

These updates help us track our progress over time and help to ensure collaboration and communication between all partners. We also share these updates with our sponsor and use them during the reporting process.

Communications that require ethics committee review. Research regulations and norms primarily address communications related to recruitment, enrollment, and keeping participants informed about any issues that may affect a volunteer's decision to participate in a trial. Site teams should refer to the specific protocol and site-specific SOPs on communications with participants; these communications would also be referenced in trainings on Good Clinical Practices (GCP) for the site staff members.

In the Carraguard trial, the ethics committee asked to see the slides that would be used when briefing government entities on the release of the results. This is something we didn't expect.

—Melissa May, Former Director of Public Information, Population Council

Institutional Review Boards (IRBs) generally want to review and approve any communications product that reaches potential and enrolled participants during the period of active recruitment or study implementation. Ethics committees have considerable latitude in setting their own standards about the materials they want to review and approve, and policies can vary across sites.

Some—but not all—IRBs prefer to review all materials developed for potential participants, including flyers, advertisements, posters, and brochures specifically designed for recruitment, as well as educational materials (such as PowerPoint presentations) for community meetings where potential trial participants may be present. Generally, any written material that includes contact information is considered a potential recruitment tool, and therefore must be reviewed and approved by the IRB that oversees the trial.

Consult your research ethics committee at the beginning of the study about its expectations for the review of materials for participants.

Social scientists often have critical insights that can help craft messages and have useful skills for helping to field test communication materials. Consider making them a part of your communications team. Pictured here are Dr. Ariane van der Straten, Director of the Women's Global Health Imperative, RTI International (left) and Dr. Cynthia Woodsong, Director of Social and Behavioral Science at IPM in South Africa, discussing a microbicide protocol.

Elizabeth T. Robinson/FHI

Box 4.5. Lessons learned regarding ethical clearance for communications efforts

By Mitzy Gafos, Co-investigator of the MDP 301 study at the Africa Centre site, South Africa

Research Ethics Committees (RECs—as IRBs are called in South Africa) are required to review study-related information sheets. The REC for the Africa Centre reviewed all participant information relating to the MDP 301 study, a multicentre trial that investigated the safety and effectiveness of the candidate microbicide PRO 2000. However, our REC wanted to review all information that the study team disseminated in the community even if it was not directly related to the study—for example, talks about World AIDS Day or the No Violence Against Women campaign. The Africa Centre had to get REC approval for all forms of media; this included study updates in community magazines and drafts of talks for radio shows, even a draft Q&A sheet that would be used during radio phone-in shows.

The turnaround times for the review and approval of the materials proved to be a real challenge. For example, when the cellulose sulfate (CS) microbicide trial closed unexpectedly, the Africa Centre MDP team immediately produced a leaflet explaining why the CS study had closed, reinforcing that the products being tested in the two trials were different and that the MDP study testing PRO2000 would continue. We submitted the CS information sheet to the REC in early February 2007 but only received approval, with no recommended changes, three months later despite regular requests for approval. By then, our research team had already verbally informed all of the participants about the closure of the CS trial and its implications for the MDP 301 study.

Following the CS closure, we adopted various strategies at the Africa Centre to reduce the time between review and approval of communications resources, including:

Flagging urgent communications needs. When the 2% PRO 2000 gel arm of the MDP 301 study was unexpectedly discontinued, we built on the lessons from the CS closure and were better prepared in terms of managing the turnaround time of communications. As soon as we were informed of the Data and Safety Monitoring Board (DSMB) recommendation, I contacted the chair of the ethics committee and informed him that we would be submitting an information sheet about the discontinuation within 24 hours. I stressed the urgency of being able to inform the community and requested an urgent approval by the chair to use the materials, pending a full review by the committee. This time the materials were turned around within seven days, and we were able to support verbal explanations about the protocol change with written materials, which helped participants further explain the discontinuation to partners and family members.

Getting materials pre-approved. We put together a series of documents with standard messages about the study, which we submitted for pre-approval by the ethics committee. These materials were not used regularly but could be utilized immediately if needed.

Scenario planning for upcoming results. Two months before the investigators were aware of the MDP 301 trial results, we submitted three separate information sheets to the ethics committee for review: all with a standard background section, then three different scripts based on the possible outcomes of the trial—not effective, marginally effective, and effective—and the related implications of each scenario. All of the information sheets were pre-approved by the ethics committee, so the minor changes that were required once the results were known could be addressed within 24 hours by e-mail. This enabled the site to disseminate the information sheet on the day of public release.

Get it in writing. Different ethics committees and chairs interpret international and national regulations differently. We learned that asking the committee to put in writing what they expected of the study, and proactively asking for updates if committee members changed, helped enormously in streamlining the ethics review and approval process.

Keeping participants informed. Since communication with participants is regulated by the study protocol, it is not covered in detail in this handbook. However, research literacy should be emphasized throughout the course of your trial. Trial staff should be well equipped to explain to participants (and their partners, when relevant) why and how research is done in simple, easily understood terms (in all official languages used at the trial site).

Depending on emerging events, you may need to share information with participants about the trial you are conducting and about other trials. What goes on in related trials is often conveyed through local media or word of mouth to community members, so such news may have an impact on your trial. Keep your participants informed, and listen to and respond to their questions. This will ensure that your participants understand their roles and their contributions throughout the course of the trial.

Jossy Phiri/National Food and Nutrition Commission of Zambia

Helping community members understand the logic of research can help alleviate fears and prevent misunderstandings.

Keeping funders and sponsors informed. Communicate with your sponsor regularly by sharing status reports. This can be done by e-mail. It will probably be beneficial to also conduct conference calls on a monthly basis. If your study has a newsletter, ensure that it is sent to the sponsor. If you are organizing an event at your site, send the invitation to your sponsor regardless of where they are based—even if only as a courtesy. Other reporting requirements will depend on the sponsor. If your study is part of a network, these communications may be streamlined through a coordinated effort.

Keeping CAB members informed. You should have regular meetings with your CAB, or local research support groups, following any sponsor- or protocol-mandated requirements related to trial communications. The individuals on these committees can then provide regular feedback to you about the study and community perceptions or concerns. Regular meetings provide the opportunity for the study's staff and CAB members to collaboratively address emerging issues. You should also ensure that newsletters are sent to members of the CAB or other research support groups.

External communications

Communicating with external stakeholders—including the trial community, advocates, the media, the wider scientific community, other researchers, and national policymakers—is essential from the time you launch your trial to the time you complete your trial and release your trial results.

Box 4.6. Suggested steps for review and approval of educational materials

By Pedro Goicochea, MSc, MA, Former Co-investigator, HPTN 039, Asociacion Civil Impacta Salud y Educacion, Peru

When we started to produce items for the different communities we were working with at Impacta Peru, a non-profit HIV research organization, all educational materials were submitted for review and approval from our ethics committee.

However, during one of our monthly meetings with the Community Advisory Board (CAB), CAB members raised concerns and asked the investigators to consider their input on the kinds of materials that were produced, as well as the content—especially with regard to terminology and use of jargon.

To be responsive, our research team decided to share the materials for review—not for approval—with the CAB *after* they were approved by the ethics committee. The CAB viewed this gesture as "rubber stamping," because no modifications could be made after the materials had already been approved by the ethics committee.

We then decided to adopt a more participatory process for the production of any material developed for potential or current study participants. The process now follows these key steps:

1. Conceive and write the contents.
2. Validate contents with the study's staff members.
3. Design the graphics and the layout.
4. Pre-test the materials in focus group discussions.
5. Adjust the materials in response to the pre-test.
6. Revise the design and layout.
7. Conduct a second pre-test.
8. Submit materials to the CAB. Explain to the CAB that the materials have been pre-tested with the different communities and brief them on the process.
9. Incorporate CAB comments into a final version.
10. Submit materials to the ethics committee for approval.
11. Produce the final versions.
12. Distribute the materials based on a plan that includes training the staff members who will use the material, such as counselors, outreach workers, and physicians.

Based on the strategic communications plan you developed before your trial began (see Chapter 3), you can develop systems and use routine methods to ensure regular communication with external stakeholders.

To reach multiple external groups, you might:

- Send out an e-newsletter or e-mail updates about your trial, including milestones, events held, and links to news coverage or informational resources. Always include some description of the trial's specific public health purpose, as e-mails and e-newsletters are often forwarded by recipients to others less familiar with your trial.

- Depending on staff capacity, you might aim for monthly or quarterly distribution of such updates. Frequency is important to keep the lines of communication open and to convey that you care that stakeholders stay well informed.
- Make your newsletter as visual as possible, including photographs and other graphic elements. For example, if your site has produced new low-literacy graphics to help participants adhere to the product, consider using them to highlight an article.

- Invite small groups of stakeholders—including study sponsors, policymakers, journalists, or community members—on tours of your study site.
  - A tour could include a visit to the clinical exam facilities, the document storage room, and the laboratory. Such visits can be very instructive to individuals unfamiliar with research implementation. Visitors can be walked through a mock counseling session for participant screening, shown how blood is drawn, or meet with nursing staff to ask questions about participant care and referral systems.
  - Consider taking photographs of the visit. If you receive permission from those on the tour, use a photograph in your next newsletter with a caption explaining which groups or policymakers were involved.
- Community media, including radio, can be an effective way to communicate with a wide range of stakeholders during a trial. Some trials have trained producers and announcers on various topics. These individuals host community radio programs where issues are raised and information about the trial is communicated directly to the listeners.

Photographs at trial sites. Photographs can be a very effective way to show community members, sponsors, and other stakeholders what research looks like, where it takes place, and why it is important. Photographing a study tour is a great way to document a visit and put a human face on your trial.

Elizabeth T. Robinson/FHI

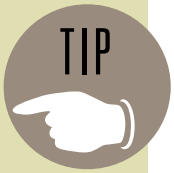
Study tours are an important way to educate opinion leaders about your trial. FHI scientists visit the Durban-based Lancet/Bio Analytical Research Corporation laboratory, which supports the CAPRISA 004 trial.

Nevertheless, be aware that it is unethical to show trial participants in photographs without their explicit permission. In fact, many ethics committees do not allow current participants to be photographed during a trial, even if a participant gives his or her permission. It could be unintentionally stigmatizing to the participant, causing social harm. For example, community members might assume incorrectly that the participant in the photo is HIV positive, or a husband might become angry that his wife has joined a study without his knowledge. For the trial participants who eagerly want the opportunity to be photographed and to tell their stories, it is advisable to wait until they have completed their study visits and are no longer officially enrolled in the study.

Keeping the trial community informed. Just as it is important to hold regular internal meetings, it is also essential to engage community members through regular meetings. A wide range of trial staff members (not just the PI) should be visible to the community on a regular basis at community meetings and events. Community engagement demonstrates to community members that you care not only about your trial but also about their general health and welfare.

Building trust is an ongoing process—one that should begin before the trial even starts (see Chapter 2) and should continue throughout the trial. Community staff members, especially when equipped with the proper information, can facilitate lasting relationships between the community and the trial.

Keeping the community informed



Provide regular community education.

- **To provide ongoing education to the community about research and the research process, a community education plan should be developed and facilitated by the research team, including the community educator at each site. This will also establish and maintain open pathways of communication from community members to the research team.**
- **In addition to your area of research, you can identify other health areas that the community wants to know about and provide education in these areas as well (family planning, HIV/AIDS, nutrition, infant health, etc.). Such activities help to develop trust between the study site and the community, and the meetings also help to reinforce or create a sense of community.**
- **Regular education sessions will allow you to monitor emerging concerns, build relationships of trust with key community members, and identify opportunities to pass messages about the trial to local community members and opinion leaders. Depending on the context, you may need to start with traditional leaders, and then go from there (this will be determined by the information gathered in your environmental scan—see Chapter 2).**

Be visible in the community.

- **Throughout the clinical trial, the trial team should maintain relationships with civil society groups during and after the site preparedness phase.**
- **Community education forums and community meetings can be initiated by your study and held either at the study site or at a well-known community site (such as a school or place of worship).**
- **You should consider participating in established local events, celebrations, and community health forums. Each community event could be an opportunity for you to communicate with the local public, not only about your trial, but about health issues more generally.**

Include civil society groups.

- **While you conduct general community outreach, you should also target specific civil society groups.**
- **You may want to invite individuals to your meetings, or arrange one-on-one meetings with well-known community members, faith-based leaders, advocates, heads of other nongovernmental organizations (NGOs) or research organizations, and others.**

When working with the community, be creative and take advantage of opportunities that may arise. You may even want to combine some form of entertainment with your educational techniques. The following are some creative ideas that different research sites have used to keep communities informed:

- Appear on community radio shows that provide scientific messages to the community and offer them the opportunity to ask questions of researchers.
- Perform songs or plays at community events to share messages about the study with the community.
- Organize a theater group with people from the community.
- Organize contests that motivate community members to be an active part of the process.
- Publish a quarterly column in a local newspaper, explaining the trial's progress.
- Arrange information booths at local health forums or other community events.
- Share photos of trial-related events to promote your trial's visibility.

Keeping the larger scientific community informed. A wide range of individuals and groups within the larger scientific community should be regularly informed about the progress of your trial. These include:

- Other researchers and public health professionals
- Researchers working on related studies in your institution, town, province, or country
- Government or health authorities, regulatory authorities, and IRBs or ethics committees who reviewed and approved the study protocol
- Professional associations that focus on your research topic

To communicate with these groups, you might:

- Develop a trial newsletter to communicate to other scientists in the field and other interested parties (see Appendix 3.4).
- Update your mailing lists continuously to include new scientific colleagues, individuals you meet at relevant conferences, or opinion leaders whom you want to keep informed.
- Participate in working groups that hold regular meetings with scientists from other pivotal trials to share information on emerging methodological or scientific issues, trial updates, and communications needs.
- Contribute written updates to electronic venues (such as list servers) that promote dialogue among communities of practice for the disease or health area in which you work.
- Present updates on your work at scientific meetings whenever possible.

Keeping the government, MOH, and other officials informed. You may want to organize regular briefing sessions, perhaps quarterly, for MOH officials to keep them up to date with the study and any emerging scientific issues related to the topic. One study in South Africa, for example, has a quarterly meeting with provincial-level officials in the Department of Health, giving updates and reports on the trial. Alternatively, you may want to schedule individual

face-to-face meetings with key government officials. You may also want to provide written information on a regular basis.

Keeping media contacts informed. As you develop your strategic communications plan (see Chapter 3), you should identify a small group of journalists with whom you will share information about the trial. These journalists should be selected based on previous balanced and accurate health coverage that they have written, knowledge of the issues in your field (such as HIV/AIDS), and the relative importance of their media outlet.

When your study begins, consider contacting a few of these journalists to explain the study goals and the basics of clinical trials. A low-key introduction to study goals and methods may help to preempt future misunderstandings. From that point forward, exactly when you contact the media will depend on the needs of your study. Just as with other trial stakeholders, it is important to maintain regular contact with selected journalists throughout your trial. This fosters relationships based on trust and aims to ensure that they (and the audiences they serve) are adequately informed.

You can also consider using national holidays, anniversaries, or other events to engage with journalists. In Peru, for example, one research team organized a luncheon event on their national "Day of the Journalist," with the goal of keeping local journalists aware of the type of health information that research staff can provide. At the luncheon, the team acknowledged the work of journalists and highlighted their contribution in keeping the population informed. The trial staff also awarded a prize to the journalist who had published the largest number of articles on HIV/AIDS in the preceding year, and took the opportunity to brief luncheon attendees on the status of the HIV/AIDS epidemic and the efforts to combat it, including the HIV/AIDS research being implemented by the team.

For more on building relationships with media during your trial, see Chapter 9.

Silas Achar/FHI Kenya

Prime Minister Raila Odinga of Kenya (front left) arrives in Kisumu to address a community meeting on male circumcision for HIV prevention. Involving key officials in events can increase the visibility of the health issue you work on.

Communications etiquette

The manner in which you communicate with participants, staff, partners, and external stakeholders will have an important impact on how information about your trial is perceived and understood. Notably, the emotional tone of your communications matters, particularly in contexts where any research may be considered potentially exploitative of vulnerable populations. Of course, the style or approach you may use to communicate with various groups will differ, depending on the group. But if proper communications etiquette—respectful communications—is practiced by all staff members from the beginning, it will benefit the trial as a whole.

Why is etiquette important? Because it opens the way for candid dialogue. For example, when the university provost who serves as one of the authorized spokespersons for your trial treats a local advocate dismissively, it might be more difficult to count on the advocate's support later on. On the other hand, when a principal investigator takes the time to sit, unhurried, with community opinion leaders and answer all questions that are posed, this helps ensure that local community members will understand the trial. The relationships one builds through respectful communications can help stakeholders to feel comfortable going directly to the principal investigator—for example, should they have a concern during the course of the trial—instead of taking their complaint to the media. Manners and basic civility matter. Respectful communications and a willingness to listen are paramount.

III Tracking and responding to emerging issues

Jennifer Heslop-Spencer/The Aurum Institute

Use available opportunities and venues to ensure consistent communication with trial stakeholders. Vaccine outreach workers with the Rustenberg Research Center work during an event in South Africa.

Monitoring media, community voices, and stakeholder views throughout your study will help you stay abreast of any situations or issues that need to be addressed. In order to prevent misinformation and to ensure that your trial runs smoothly, address any problems as quickly as possible. Be sure to use proper communications etiquette as you handle these situations. For information and tools for handling crisis situations (for example, unexpected trial closures, or negative or sensational media coverage of your trial), see Chapter 5.

Monitoring media

At least one staff member at your site should pay close attention to media coverage as a formal part of their job duties. However, *all* staff members who consume news can be asked to alert the site's point person responsible for media monitoring whenever they hear a local-language broadcast or come across news coverage in local papers about the trial or that might affect the trial.

The staff member assigned to monitor the media should pay attention to negative tones conveyed in local media reports on clinical trials or other opposition to some aspect of the research. Track local and national media (print and broadcast), and whenever possible, monitor media in local languages as well. It is also important to look at international media sources, which give your trial staff some context; your review of the media should include larger dialogues and international trends.

See Chapter 9 for more on how to monitor and respond to media when necessary.

Monitoring and responding to community voices and stakeholder views

Check with community outreach workers regularly to see what questions community members are asking and what concerns are being voiced.

- Develop expectations and methods for community outreach workers to report arising issues immediately to the PI or the community liaison officer (CLO).
- Any findings should be documented to track actions and resolutions and to inform future trials.
- Regular staff meetings will allow you time to keep abreast of any community issues that arise.

Responding to community concerns is not always a question of finding a better message or adapting your communications strategy. Sometimes, it requires addressing the cause of the concern. Stakeholder objections sometimes identify real problems with how a trial is being implemented. In such instances, correcting the problem is a more effective strategy than trying to "manage" it away.

—Lori Heise, Former Director, Global Campaign for Microbicides

Monitor community rumors.

- Regular community meetings may provide an opportunity for you to hear any misinformation or rumors circulating in the community.
- In addition, participants often reveal concerns during their clinic visits that may reflect larger community concerns.
- It is important for the study's staff members to notify the PI of any "social harms" reported by participants, so issues can be tracked and problems averted.
- Another good strategy is to have a staff member (sometimes an outreach worker or peer educator) in the study waiting room. Not only can he or she address unhappiness that participants may express about the trial (such as long wait times), but the staff member can attend to budding rumors and misconceptions that participants discuss. (See Box 4.7.)
- You can also place a suggestion or feedback box in the waiting room.
- When you attend local and site meetings, listen for hallway chatter that may reveal concerns or issues with the trial (internally or externally).

Box 4.7. Monitoring community voices through participants: CAPRISA 004

By Bernadette Madlala, Nurse, CAPRISA 004 study, Durban, South Africa

The concerns and views of trial participants often mirror those in the larger community. When a participant expresses a concern to someone on our staff, the staff member addresses this concern immediately, to prevent it from migrating into the community and becoming a larger issue.

To do this, we have a variety of systems in place. For one, we have identified the clinic waiting room as an important source of information. Participants talk about anything and everything in this room, and sometimes, when participants come in for their appointments, while waiting to be seen by the study staff, they will ask us about rumors they heard. As a result, our staff has started taking turns sitting with participants as they are waiting for their appointments. We also have a suggestion box in the clinic waiting room. Staff members working on a microbicide gel trial encourage participants to write whatever issues or concerns come to them during their visits. These concerns are also taken into consideration, and the concerns noted in the suggestion box are regularly addressed.

We know that if participants leave the clinic without getting proper information, there is the possibility that rumors and false information will spread. These systems ensure that our participants have the information they need to be ambassadors for the trial, correcting any misinformation that they might hear outside the trial site.

Pay attention to signs of disquiet among stakeholders.

- Watch for expressions of concern by government officials that support for the trial could cause them political embarrassment or signs that a stakeholder is using criticism of the trial as an opportunity to push his or her own agenda.

Monitoring and communicating about other trials

All stakeholders should receive the information they need about any related studies that may affect your study in a timely way. For example, senior management should notify stakeholders about the future release of results from related trials. When the results are made public, staff members should be briefed on what to say to participants and community members who ask about the related trial, since participants often hear about other trials through the media. To ensure that the site's staff are providing consistent and accurate information on the related trial, it is a good idea to write down and share the key points you want to convey.

For some external stakeholders, such as government officials or local NGOs, it may be adequate to simply forward an e-mailed copy of a well-written article that provides some background on the related trial. A personal note from you explaining how you interpret the news can help provide some context for the recipients. Alternatively, you could provide links to news summaries of the related trial in your next e-newsletter.

News from other trials may also present an opportunity for you to provide a refresher on research literacy to interested parties.

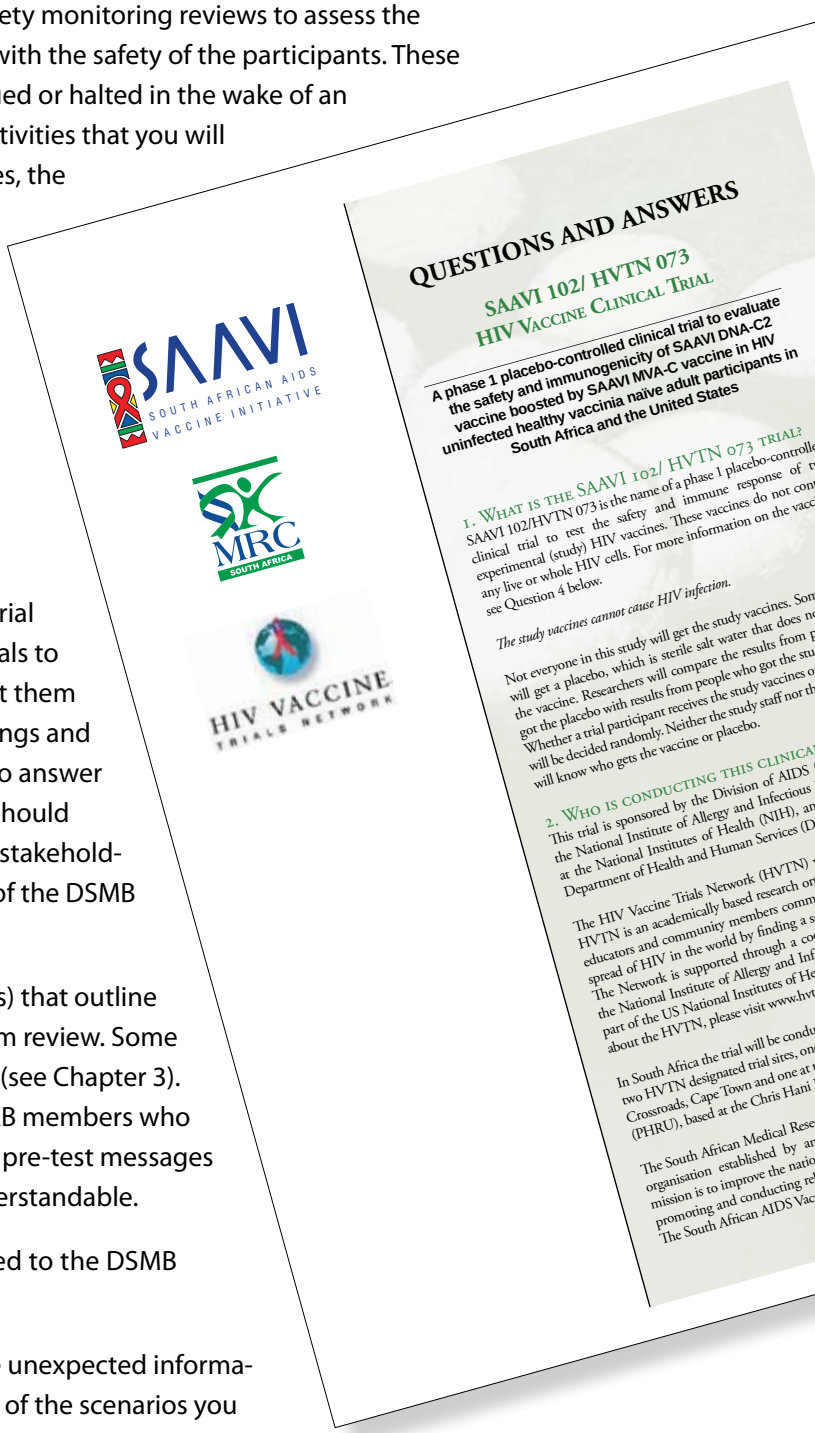
IV Preparing for interim analyses

Most large-scale studies undergo interim data and safety monitoring reviews to assess the product's efficacy and to uncover potential concerns with the safety of the participants. These are significant events because a study could be modified or halted in the wake of an interim review. Plan ahead for the communications activities that you will need to implement for these reviews. In most instances, the initial review of a trial does not have enough data to justify the modification of a trial, but early closures can happen. Trials are usually well under way before a review board has enough data to identify an efficacy or safety issue that could affect the study.

Once the first Data Safety and Monitoring Board (DSMB), sometimes referred to as a data monitoring committee (DMC), meeting has been scheduled, you should:

- Contact appropriate regulatory bodies, your IRB, trial sponsors, and other investigators doing similar trials to inform them of the upcoming, planned review. Let them know that you will inform them of the DSMB findings and recommendations and that you will be available to answer any questions. A short note, as shown in Box 4.8, should suffice. Briefly outline possible outcomes for your stakeholders, so they can be alert to possible ramifications of the DSMB recommendations.
- Prepare materials (such as Q&As or backgrounders) that outline questions that might be asked following an interim review. Some of these materials may have already been written (see Chapter 3). Get help from site staff and individuals such as CAB members who understand the local languages and can help you pre-test messages or materials to ensure that they are clear and understandable.
- Prepare messages for all possible scenarios related to the DSMB review.
- Develop a tentative plan for how you would share unexpected information with key trial stakeholders, according to each of the scenarios you have identified (see Chapter 6 for more on scenario planning).

If the DSMB recommends a halt to the study, you will need to follow procedures related to unexpected closures (see Chapter 5).



When preparing for interim DSMBs, revisit materials used earlier in your study, such as this Q&A prepared for the launch of a SAAVI HIV vaccine trial.

Box 4.8. Sample e-mail alerting stakeholders to upcoming DSMB meeting

Dear Colleagues,

The independent Data and Safety Monitoring Board (DSMB) for the Bangkok Tenofovir Study will meet October 26 and 27 in Atlanta, GA, for its planned interim review of trial data. This clinical trial is a joint collaboration of the U.S. Centers for Disease Control and Prevention, the Bangkok Metropolitan Administration, and the Thailand Ministry of Public Health, and is examining the safety and efficacy of once-daily tenofovir as pre-exposure prophylaxis (PrEP) for HIV prevention among injection drug users in Thailand.

At the upcoming meeting, the DSMB will conduct a regular review of the safety data and will review the HIV infection rate in both arms of the trial for the first time to determine if there is enough evidence to determine efficacy at this point. While the most likely outcome of the meeting is that the DSMB will recommend the trial continue to its planned completion, it is possible that the panel could recommend that the trial be stopped. CDC and our Thai colleagues are therefore preparing for all possible outcomes.

The DSMB could make four possible recommendations:

1) That the study continue as planned.

2) That the study be stopped early because data show strong evidence that once-daily use of tenofovir significantly reduces the risk of HIV infection among injection drug users.

3) That the study be stopped because the data suggest that once-daily tenofovir will not prove effective in reducing the risk of HIV infection among injection drug users and continued study is not warranted.

4) That the study be stopped due to concerns about participant safety.

We hope this information is helpful to you in your own planning and will continue to keep you abreast of developments in this trial, including the outcome of the DSMB meeting.

Sincerely,

Source: U.S. Centers for Disease Control and Prevention. Reprinted with permission.

V Disseminating results

Once your trial closes, you should disseminate the results to all of the stakeholders you identified in your strategic communications plan. Since planning for the dissemination of results is a lengthy process, you should begin to develop your plan while the trial is still in progress. Your dissemination plan will include specific objectives, identify audiences interested in the results, and outline a feasible strategy for releasing information to both internal and external parties. For more on results dissemination, including a timeline on the steps involved, see Chapter 6.

YouthNet/FHI

While essential, communicating results at scientific meetings is only one aspect of disseminating results. See Chapter 6 for how to develop a full dissemination plan.

Key points to remember

- Consider your goals, budget, setting, timing, global and local context, and the benefits and risks of attracting public and media attention when deciding which type of launch is right for your study.
- Maintaining ongoing communication with interested parties throughout your study is essential to building trust.
- Good communication starts at home—with strong internal communication. Internal stakeholders are important ambassadors for your trial and should be appropriately informed during every stage of the trial.
- Monitoring news media, community voices, and the views of opinion leaders throughout your study will help you stay aware of emerging issues that need to be addressed. In order to prevent misinformation and to ensure that your trial runs smoothly, address any problems as quickly as possible.
- Never underestimate the power of emotional tone in communications. Respectful, transparent, and courteous communications are paramount, particularly in contexts where any research may be viewed as exploiting vulnerable groups.

Dr. Nuon Sarith pauses for a moment while caring for AIDS patients in Phnom Penh, Cambodia.

Jim Daniels

Chapter 5

Preventing and Managing a Crisis

By their very nature, clinical trials routinely deal with issues of risk and uncertainty. When a trial enrolls children, takes place in poor or disadvantaged communities, or involves controversial topics such as sex, drugs, or infectious diseases, it can evoke strong emotions. As a result, managing controversy and dealing with sensitive information is a routine, almost daily task at many trial sites.

But some issues have the potential to blow up into major incidents that can undermine community trust and threaten the entire research endeavor. It is these issues—where strong emotions combine with rumor and inflammatory media—that the need for crisis communications comes into play. Often done ad hoc at the height of an unraveling situation, a response to a crisis seeks to enact "control in the face of high uncertainty in an effort to win or restore audiences' and publics' confidence" (Heath 1997, p. 295). Crisis communications is the process of managing the strategy, messages, timing, and distribution channels necessary to communicate effectively with the media, employees, core constituents, advocacy groups, opinion leaders, stakeholders, and policymakers in a highly charged atmosphere (Shepherd 2005).

What is predictable in a crisis?

- There will be an immediate need for complete and easily understood information.
- Media interest will intensify.
- Issues will often change with time.
- Scientific evidence on the issue is often evolving.
- The quality of the communication itself could be open to scrutiny.
- Organizational credibility can quickly shift (Shepherd 2005).
- Some people and organizations will see an opportunity to promote their own agendas.

In this chapter

YouthNet/FHI

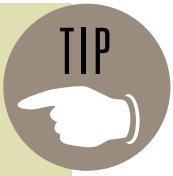
Regularly inquiring about community concerns or issues can help prevent false rumors from circulating about a trial.

This chapter provides guidance on developing and implementing a formal crisis communications—or rapid response—plan to help sites anticipate, mitigate, and manage emerging issues. It will be especially helpful to research teams that need to manage an unexpected, premature trial closure or deal with negative media allegations that threaten to stigmatize trial participants or undermine support for a trial from the government, donors, regulatory agencies, and civil society groups. This crisis communications plan supplements the overall strategic communications plan (see Chapter 3).

I What is a crisis communications plan?

A crisis communications plan:

- Outlines the communications steps that trial staff and partners should follow at the local, national, and possibly global level *when a situation or event threatens to negatively affect a clinical trial*
- Outlines the policies and procedures for rapidly assessing and responding to an evolving situation
- Identifies who must be involved, at what time, and in what manner in order to diffuse or minimize the potential crisis quickly, efficiently, and compassionately



Crisis communications basics:

- **Identify, analyze, and prioritize the issue.**
- **Formulate a strategic plan.**
- **Implement the strategy quickly to manage the issue.**
- **Evaluate the results of communications efforts and update the plan as needed.**

Many crises can be prevented with good preparation, following the steps suggested for developing your trial's strategic communications plan (see Chapter 3). Remember, a crisis communications plan can be useful even when the event is not caused by or attributed to your trial.

II Why is a crisis communications plan needed?

An unexpected situation may arise that threatens the integrity or reputation of the trial community, the study, the partners, or the intervention(s) being tested. Such situations are often precipitated by negative attention from in-country stakeholders, community members, organizations in other countries, or by the media. They could include:

- Safety concerns (including an unexpected concern on the part of the Data and Safety Monitoring Board [DSMB])
- Allegations of exploitation

Box 5.1. The value of having a systematic way to reach out quickly to site teams

By Theresa Gamble, PhD, Scientist, Family Health International

Working as a senior clinical research manager in the HIV Prevention Trials Network (HPTN) at Family Health International, I am involved with managing many complicated, multisite studies. In the summer of 2009, a situation arose that made my team realize the importance of having a communications plan.

One of the ongoing HPTN studies is enrolling serodiscordant couples (one person is HIV positive and the other is HIV negative) and has two outcomes. The first outcome is to determine if treating the infected person with antiretroviral therapy (ART) can prevent the spread of HIV to a sexual partner. The second outcome is to identify the best time to start ART with regard to CD4 cell count (early versus late initiation). If successful, the results of this study could have significant impact on the way that ART is used for both treatment and prevention.

A similar study—not part of the HPTN—was being simultaneously conducted in Haiti. The Haitian study divided HIV patients into two groups. The first group started on ART according to the current guidelines of the World Health Organization (WHO), and the second group started treatment earlier. When the Data and Safety Monitoring Board (DSMB) for the Haitian study did their interim review, they found that more people in the group receiving ART according to WHO guidelines had died or developed tuberculosis. They recommended that the team halt the trial.

Because of the Haitian data, our study's sponsor, the U.S. National Institutes of Health (NIH), asked that the DSMB for our study convene a special meeting to look at the Haitian data more carefully. The examination of the Haitian data confirmed significant differences between the two studies, such as the participants in the Haitian trial were much sicker than the participants in our study and had higher rates of co-infection of HIV and tuberculosis. The DSMB decided to allow our trial to continue. Because of the importance of these developments, we needed to let all our study sites know about the results of the Haitian study and also inform them about our DSMB's recommendation. In turn, all of the HPTN sites needed to quickly inform their own Institutional Review Boards (IRBs).

Jim Daniels

A community coordinator (center) stands outside the HIV clinic at the hospital in Les Cayes, Haiti, after helping to admit a man living with HIV.

Although we were able to inform everyone who needed to be contacted, we did not have a systematic way of doing so at the time. What would have happened if the recommendation from our DSMB had been different and we had to change our study? That would have involved informing a much wider audience.

Since then, we have developed a communications plan for the trial. It lists the people and organizations that need to be informed of important developments and states how we will contact them. We also developed a sample letter that can be used to share results from other studies or other information the team should disseminate to keep all sites informed. Finally, we created a one-page document with background information on our study that can be used as a stand-alone document or as a supplement to other communications materials.

- Legal disputes
- Political issues or personal vendettas
- Disgruntled staff members or participants
- Incidents or problems attributed (rightly or wrongly) to the study, the trial network, or sponsors

Crises can be triggered at a national or local level or may involve global issues that require an in-country response. A crisis can also include situations where, in the eyes of the media or general public, the project did not react to a situation in an appropriate manner or project staff members were disrespectful.

When such situations arise, it is vital that the study staff, partners, and spokespersons respond quickly and compassionately to minimize harmful fallout. Each site needs a tailored plan, including standard operating procedures (SOPs) for media communications, and designated team members and spokespersons prepared to take appropriate action. In cases where several different groups in the same country are working on related studies—for example, vaccine trials—the groups might meet to coordinate a national response for expected issues. Each site could still tailor its own plan in relation to the national plan.

III Preventing crises

If you find out what matters to people and what causes concern, you can develop a plan to prevent crises. It is better to prevent a crisis than to spend your time in continual crisis management. It follows that the central element of effective communications is to establish and maintain relationships with groups that have a direct or indirect interest in your study or program. This involves the effective management of issues that may evolve into crises—a field known as "issues management" (Heath 1997, p. 295).

The key to effective issues management is to build relationships and trust ahead of time.

—Lori Heise, Former Director, Global Campaign for Microbicides

The practice of issues management—a proactive approach to anticipating and diffusing situations before they escalate into crises—ensures a reliable *outward* flow of information and a reciprocal flow *into* and around the organization (Jackson 2004). This process is based on the principles of stakeholder engagement (see Chapter 3). A principal aspect of this approach is that expert and lay perspectives inform each other as part of a two-way communication process.

Stakeholders must be identified, communicated with, listened to, understood, and accommodated (Jackson 2004). Researchers working on a study are responsible for ensuring that formal networks of reporting, consultation, coordination, and advice are in place. This will likely engage individuals or groups, such as:

Box 5.2. Overarching principles for crisis communications

Focus on trust

The overriding goal of crisis communications is to interact in ways that build, maintain, or restore trust. This is true across cultures, political systems, and levels of economic development.

Communicate early and often

You are always better off being the first to communicate bad news. It puts you in control of the message. In the absence of information from a credible source, people will look to the media for information or draw their own conclusions.

- Communicating *early* shows you are not hiding anything.
- Communicating *early* ensures dissemination of accurate information.
- Communicating *often* diminishes the information vacuum.
- Communicating often establishes *you* as the primary source for credible information (thereby diminishing the potential for misinformation) (Shepherd 2005).

Listen for others' concerns

- Even if a concern is misplaced or inaccurate, acknowledge the emotions behind it and then address the concern directly. "I hear how concerned you are for your child's well-being, so let me share what we know. . . "
- Always communicate with compassion and empathy.
- Connect with those affected by the issue.
- Avoid being arrogant or paternalistic.

Share information, exhibiting honesty, candor, and openness

Transparency in communication is essential. Research shows that people are more likely to overestimate risk if information is withheld.

Simplify

- Speak in plain language (do not use jargon or complex medical or public health terms).
- Do not preach.

Acknowledge uncertainty and ambiguity

Reporters and the public do not like to be "spun," "managed," or put off. Most people can accept uncertainty if they are told the process that is in place to resolve outstanding questions.

Adapted from: Heath RL. Best practices in crisis communication: evolution of practice through research. J Applied Communication Research. 2006;34(3):245–48.

- Trial participants
- Trial staff
- Officials at the university where the study is being implemented
- Local and national regulatory and coordination bodies (ethics committees, drug regulatory authorities, health departments, national AIDS committees, etc.)
- Colleagues and other research organizations conducting similar studies
- Officials at the donor or sponsor organization and their relevant technical and communications officers
- Local health care workers (such as those with local HIV care and treatment programs)
- Professional associations
- Relevant civil society, women's advocacy, or health activist groups
- Local and national media and journalists

Wise crisis management begins before a crisis occurs.

— Robert L. Heath (1997, p. 301)

Dick Hill/Hillstudio

Teleconferences are useful for coordinating with multiple partners during a crisis, as well as for daily communication. Here, FHI staff confer with HPTN trial partners.

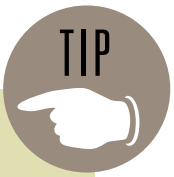
IV Preparing for potential controversy

Contingency planning requires proactive steps to prepare people and set up systems for crisis situations before they occur.

Define your crisis communications team

The crisis communications team is responsible for anticipating and diffusing controversies. This includes:

- Monitoring emerging issues
- Assessing the potential for a situation to develop into a communications crisis
- Identifying appropriate communications strategies and actions
- Briefing spokespersons
- Developing materials to respond to the situation
- Engaging media, advocacy, and community channels as necessary and appropriate
- Keeping partners informed of the situation
- Evaluating responses and adjusting strategies as needed



The roles and responsibilities of each member of the crisis communications team should be clearly defined and explained. It is especially important to clarify who has final authority to approve materials, messages, and strategies.

The role of most other people associated with the trial is strictly to relay information to the crisis management team and refer inquiries to the designated spokesperson. The spokesperson must be aware of his or her part in relaying information and know how to handle inquiries.

Ideally, the crisis communications team is drawn from the project's overall communications team and includes three to five people, with members added as needed. Minimally, a crisis communications team should include:

- The team leader who serves as the communications lead for the overall study (the communications point person)
- The lead investigator of the study
- Other technical and communications staff, as needed
- One or more designated spokespersons
- Ad hoc members based on the issue that arises, such as a community liaison officer, or a social scientist familiar with the project

It may also be appropriate to add outside representatives, such as an official from the local Ministry of Health (MOH), a liaison to an industry partner, or a trusted community representative.

Orient your crisis communications team

- Identify your presumptive crisis communications team, recognizing that membership may need to evolve to fit the needs of a particular situation.
- Ensure that members understand the overall purpose of the team and their own roles.
- Brainstorm various potential crisis scenarios (such as an adverse event following immunization, a rumor in the press, a political disagreement, or an unexpected outcome of the trial's DSMB meeting).
- Convene the team for an orientation meeting and run through possible scenarios, thinking about the types of situations that may arise and the appropriate steps to handle them.
- Formalize a rapid response procedure for handling negative or potentially explosive situations (see further guidance and sample procedures in the next section and Box 5.3).
- Develop and update a detailed contact sheet, listing all team members and including their home and mobile numbers. Not all crises happen during working office hours.

Develop a list of people to be kept informed

- Identify the key group of people to be kept informed in the event of a crisis, including:
  - Senior management of the sponsoring organizations
  - Research teams at the site level
  - Ministries of Health, local government officials, and ethics committees, where relevant
  - Partner organizations (including both clinical and communications coordinators)
  - Health advocacy groups at relevant levels (community, national, and international, depending on the scope of the crisis)
  - Community leaders, if appropriate
  - Donors, if appropriate
- Develop and update contact lists of these people and identify point people from within the crisis team who will be responsible for keeping others informed. Make sure to note the most suitable way to reach the point people, as some may not check e-mail frequently.

Identify trusted media contacts and resources

- Review your list of media contacts (local, national, and international) and identify a small number of trusted health reporters known for accurate and balanced reporting. Consider local radio or other local media that community members use and trust.
- Consider briefing these journalists on your study when appropriate opportunities present themselves.
- Maintain up-to-date contact information for these reporters at all times.

Orient all project staff on the crisis communications process

- All staff should know how to identify warning signs of issues that may develop into a potential crisis.
- Staff members should have clear instructions on how to report such issues to management, including when an event causing harm has occurred.
- They should understand the procedure for crisis communications, especially how to direct inquiries and how information will be communicated to outside stakeholders during a crisis.

Identify spokespersons and external experts

- Identify one primary spokesperson for responding to media inquiries. In a crisis situation, it is usually best to limit the number of spokespeople authorized to speak to news media.
- If appropriate, identify technical experts and government officials who may be called by news media to respond during a crisis. Ensure that such colleagues have appropriate background information and adequate knowledge of current events related to your research. At some point you may want to refer media inquiries to such individuals, so make sure they have the proper authorization to speak on behalf of their respective institutions.
- Remember that advocacy groups and activists voice issues in the public arena for individuals who otherwise may have little power to influence change. Consider informing and briefing key spokespersons at advocacy organizations about the issues in your field, because these people may be called on by news media during a crisis. Such groups often have important communications channels and resourceful tactics to advance issues that concern them.

Prepare spokespersons and other key staff

- Ensure that trial spokespersons and other key staff have the skills needed to fulfill their roles, including media training or crisis communications training, as appropriate. Some sites provide media training to members of the trial's Community Advisory Board (CAB). Media training can include formal training with role-playing and videotaping, or one-on-one mentoring by skilled staff (see Chapter 9).
- If you do not have internal resources for this, consider asking other institutions that conduct media training to include your staff person in their next training event.

Tips for trial spokespersons

Designated spokespersons should be forthright when dealing with media questions. However, there are some questions that should not be answered without prior consultation with trial decision makers, such as sponsors or their legal departments. This includes questions related to causal speculation, allocation of blame, insurance coverage, or financial damages.

Even in times of crisis or extremely negative press coverage, it is important to share information through accurate and clear messages. Avoid the "ostrich in the sand" approach—do not close doors or stop answering the telephone!

Provide updates when new information is available. Some people believe that once the story is over in the press, everyone forgets. In fact, many stakeholders have long memories. When the next trial closure or similar situation arises, questions will resurface. Be prepared.

Source: Melissa May and Annette Larkin. Message Delivery Strategies Media Training. Cape Town, South Africa, 2006.

V Developing a rapid response procedure

The general process for handling a potential communications crisis is to identify in-house decision makers, convene a discussion, and use risk-assessment criteria to determine whether a given issue needs to be managed. Consider these criteria:

- Is the issue critical to your organization, your trial, trial participants, or your mission?
- Is your organization or your trial associated with the issue, or do key stakeholders hold you accountable for it?
- Do characteristics of the issue make it potentially high impact?
- Does the issue attract opposition stakeholders with the capability and credibility to propel its development? Are current opposition stakeholders likely to influence more credible stakeholders to take up their cause?
- Does the issue raise opposition from opinion leaders—media, columnists, community leaders, members of regulatory bodies, or policymakers—who are in a position to stir up discontent (Shepherd 2005)?

In addition to addressing these questions, your team should gather useful information from professional and informal networks (Jackson 2004).

Developing good relationships with a few trusted reporters is an important strategy for ensuring that you have avenues for countering misleading media. Inaccurate media coverage can inflame a controversy and magnify its effect.

YouthNet/FHI

Box 5.3. Sample procedure for rapid response to crises

Each site should develop a site-specific procedure that identifies the steps that should be taken if an event or rumor threatens to undermine community trust or trial credibility. The sites should work in partnership with networks and collaborating institutions (when appropriate) before the study begins (or as soon as feasible). The procedure should clearly identify the roles and responsibilities of key staff members and the steps that should be taken in the event of a communications crisis.

1. Staff learns of a problem or a potential problem and reports it to [***name of designated management contact***].
2. Management shares information with crisis communications team by telephone or e-mail.
3. Site coordinator or principal investigator (PI) investigates and shares findings with crisis communications team and with upper management as appropriate.
4. Crisis communications team convenes an urgent conference call, does a rapid assessment of the situation, and prepares an appropriate plan of action. (This may include deciding to take no action.)
5. The team prepares an internal Q&A or holding statement, if necessary, and shares it with relevant staff members. For example, "A ___ at ___ involving ___ occurred today at ___. The incident is under investigation, and more information is forthcoming."
6. If the situation has not resolved, the crisis communications team outlines and shares a communications plan that is devoted to the situation. This plan will designate a spokesperson and include recommendations on whether and when to issue a holding statement.
7. The team's plan and prepared documents are shared with primary stakeholders (to be identified, case by case). These may include ministry of health officials, donors, or investigators who lead studies that are testing the same product.
8. The crisis communications team implements the situation-specific crisis communications plan—including a more substantive statement, Q&A for reactive use, media scan, and a log of media inquiries and coverage.
9. The crisis communications team and senior management agree on which external experts to brief and refer journalists to and what, if anything, to tell other key people in the wider community (including other researchers or key people in the field) who are likely to be contacted for comment. The communications team notifies experts and other key persons by telephone. An e-mail advisory might be necessary if the situation is complex.
10. The crisis communications team ensures that spokespersons rehearse tough questions.
11. As the situation unfolds, the crisis communications team "meets" regularly to discuss progress, media reports, inquires received from news media or influential trial stakeholders, how inquiries are being handled, and additional steps needed to keep others, including the public, informed.
12. The crisis communications team holds a debriefing meeting once the situation is resolved, then documents what happened and what was learned from it (for internal use and to share lessons learned with the field, as appropriate).

Source: PATH, Rotavirus Vaccine Program. Clinical trial communication planning to manage risks. Washington (DC): PATH; 2007.

Box 5.4. The Malaria Vaccine Initiative's crisis communications card

Despite current control efforts, malaria still kills approximately 900,000 people every year, with most deaths occurring in Africa among children under the age of five. In 2009, the PATH Malaria Vaccine Initiative (MVI) partnered with GlaxoSmithKline (GSK) Biological to launch a Phase III trial of the vaccine candidate RTS,S—the first malaria vaccine to demonstrate sufficient safety and efficacy to justify a major Phase III trial. The trial is expected to enroll up to 16,000 children and infants in a subset of countries across sub-Saharan Africa.

"We especially wanted a good crisis procedure in place for this trial because it involves children and infants," says David Poland, the communications officer at PATH working with the trial. "It is so easy for parents to attribute any negative outcome that a child might experience to the vaccine, even if the vaccine has nothing to do with it."

As part of their communications planning, MVI and GSK developed a rapid response procedure that outlined what should happen if a potential controversy erupted during the trial. "Also, together with GSK, we created a moisture-resistant card that has the MVI and GSK contact information on one side and a nine-step checklist for crisis communications on the other," notes Poland. "We issued copies of the card to all staff involved with the trial to carry in their wallets."

Building from the card idea, Poland revised the MVI issues management training for the sites from a fairly complex presentation to a format that mirrored the checklist on the card. "Keeping it simple became more important than ever after our observations on the ground suggested that with all the activities that engage the attention of PIs and the staff, communications work of all kinds will rarely come to center stage."

"The biggest thing I have learned," concludes Poland, "is to keep issues management simple and easy to follow. If you want busy people to implement something, it has to make sense to them and fit within their work realities."

VI Implementing your crisis communications plan

When new issues or problems arise that require a communications response, they must be referred immediately to the site PI (or the most-senior manager available) and the communications team, following your rapid response procedure. These people will discuss:

- What happened, and its significance
- Who should be informed
- Actions to be taken to remedy any matter that has serious implications for the organization or the trial
- Everyone's role and responsibilities

Your response should include the following actions:

Be proactive. Be the first to frame issues, including bad news. Speak to the stakeholders directly, telling them what you do and do not know. Never communicate that you do not know something without also clearly stating what you are doing to find the answers.

Make sure that spokespersons are available to reporters. Rumor loves an information vacuum. If you do not make experts available to answer questions, people will reach their own conclusions or seek information from less informed and perhaps adversarial sources. Ensure that the trial spokesperson at the site level has the mandate and training to talk to local news media.

Choose communications approaches that suit the situation. The more hostile the group your research team is dealing with, the greater is the need for face-to-face communications. Meeting with people in person shows that you care about their concerns and take them seriously.

Do not forget to communicate "in the family." Inform stakeholders—including participants—before they hear about it from the media. Communicate with allies in your field, opinion leaders, and other credible third-party spokespeople who can reinforce your messages.

Use the crisis as an opportunity to demonstrate your organization's commitment to engagement and transparency. For all the stress they create, crisis situations provide an important opportunity to demonstrate the integrity and values of your organization. How you respond can frame the image of your organization far into the future.

Monitor the crisis. As events play out, be sure to keep a close watch on the temperaments of the community and the stakeholders. Determine whether the issue is gaining momentum or settling back to normal. The frequency of inquiries by news media, the amount of space devoted by media to the issue, and the degree of outrage expressed in media stories, on advocacy list servers, and by trial stakeholders are important indicators to watch (Heath 1997, p. 304).

Ensure that you follow up on commitments you made to share information. Keep your word if you told stakeholders that you will send them written information or that you will let them know when the trial's results are published.

Debrief once the situation has been resolved. Do not lose the opportunity to learn from any crisis situation. Always schedule a meeting after the situation settles down to discuss what worked and what did not work. You can use this as an opportunity to review your plan, document experiences, and retain institutional memory. If another crisis arises, take a few moments to reflect on what did and did not work in your previous situations.

VII Managing unexpected trial closures

One of the most common situations requiring a rapid response is an unexpected closure of a trial because of scientific futility or concerns for the participants' safety. An important part of crisis communications planning is to anticipate such possibilities and to plan for them accordingly. It is especially important to track upcoming DSMB meetings for your own and other related trials and to consider options for responding under different scenarios. (See Chapter 4 for more about DSMB meetings, and Chapter 6 for information about scenario planning.)

There are a variety of things that the communications staff can do to manage expectations and to prepare stakeholders for the possibility of premature closures—whether such closures bring good or bad news.

- Track the planned DSMB meetings to stay informed on the status of the trial.
- Update materials before major milestones to prepare for the possibility that the team will not have time for lengthy planning for dissemination of results.
- E-mail or call key stakeholders to alert them to regular DSMB meetings, so that they can consider the potential implications for their agendas and prepare accordingly.

Box 5.5. What to do if safety concerns lead to an unexpected trial closure

Sample announcement plan for unexpected closure

Group	To be contacted	Activity	Date	Who will contact them	Materials needed
Sponsor	Senior staff	Initial internal communication following DSMB		DSMB liaison	E-mail explaining DSMB decision and reminder about confidentiality prior to public announcement
Research team	Principal investigators	E-mail and phone call			1) Closure statement; 2) Q&A; 3) Letter with timetable, milestones, and process information, per usual study closure procedures; 4) Copy of letter to the FDA
Ethical review	Local IRBs	Official notification to local IRBs			1) Closure statement; 2) Official letter etc.
Regulatory agencies					
FDA		Official notification			
National AIDS Committee (NAC)		Official notification			
NAFDAC		Official notification			
Partners					
					Statement and Q&A
Donors					
					Statement and Q&A
Advocacy groups					
Local advocacy groups					Statement and personal e-mail
Community					
	Study participants	Study participants will be informed by local research team as they return for follow-up visits			Guidance to staff
News media					
	Key journalists who have been following the trial	Inform of closure, share statement, respond to questions			Statement
List server postings					
	AIDS-Africa, etc.				Press release

The checklist on the opposite page summarizes what should happen if the management decides to stop a trial after a recommendation by the DSMB to suspend the trial for safety reasons. In multicenter trials or those that have international sponsors, some of these actions may be coordinated and implemented centrally. It is important to establish a clear division of labor for those who will alert the various stakeholders listed below. Prompt and open communication with all stakeholders is essential in such situations.

- Following the DSMB's recommendation to close the trial, you should inform:
  - Trial leadership—all principal investigators for multisite trials
  - Trial sponsors and donors
  - Ministries of Health and government officials
  - Relevant ethics review committee(s)
  - Regulatory authorities and national food, drug, or poison control boards
  - National and international health organizations, such as the World Health Organization (WHO) and national AIDS councils
  - Manufacturer of the pharmaceutical product or device
- Convene a meeting of key trial staff members to discuss an action plan. Engage the communications team to update and implement the crisis communications plan.
- Conduct outreach to key stakeholders (internal and external).
  - Communicate personally with clinical trial partners and the funding agency
  - Coordinate with study staff in charge of informing participants
  - Organize a meeting with the trial's CAB
  - Conduct teleconferences with the drug or device manufacturer
  - Contact the leadership of other related trials or trial networks
  - Contact leading local and global advocacy and civil society stakeholders
- Seek agreement from major health organizations (such as WHO) to issue statements, if appropriate.
- Draft a press release. Check whether you need IRB approval to issue a statement to news media.
- Distribute messages to key allies. Organize teleconferences with communication officers of all sponsoring groups, key advocacy networks, and allied scientists.
- Monitor media coverage of closure.
- Collect information from the community on an ongoing basis as the situation evolves.
- Respond and follow up as needed.

Even with advance planning, the condensed time frame of unexpected closures puts considerable pressure on the trial's staff. This can be exacerbated in situations where the product being tested is owned by a company that is publicly traded, such as on the U.S. Stock Exchange. In such instances,

U.S. financial regulations by the Securities and Exchange Commission (SEC) apply, further narrowing the time available for communicating with stakeholders (see Box 6.9).

To limit opportunities for insider trading, SEC regulations require that sponsors promptly disclose to the public any information that may substantially change the value of a stock. This means that once a company becomes aware of a safety issue, it has a legal obligation to inform investors of this finding (often via a press release). Not surprisingly, this legal obligation can pose conflicts with the investigator's desire to ensure that in-country officials are informed of any concerns before the information is released publicly.

The closure of the cellulose sulfate microbicide trial in 2007 demonstrated many of the challenges of managing the unexpected closure of a trial. Box 5.6 summarizes some of the main lessons learned from this example.

Box 5.6. Lessons learned from the cellulose sulfate trial about emergency trial closures

What worked

- Negotiating with the SEC directly for a 24-hour delay in release of the sponsor's press release on the business wire.
- Opting against holding a press conference, and instead contacting a few trusted health journalists respected for writing balanced and accurate stories.
- Intensely monitoring the media and correcting inaccuracies.
- Collaborating with the wider field through the Microbicides Media and Communication Initiative—a field-wide collaborative effort to coordinate communication issues across prevention trials.
- Coordinating the press releases of the research groups and the product developer.

Lessons learned

- Contextualize the situation. Use local HIV prevalence and incidence estimates among people both within and outside of the trial to paint a picture of the trial communities and countries.
- Specify the numbers of individuals affected (such as the number of women who became infected during the trial) in statements.
- Coordinate closely with all trial sites in the area and ensure they have communications support on the ground.
- Mind the time zones. Schedule strategy and urgent response calls at times amenable to in-country staff and those most in need of support.

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Always communicate with compassion and empathy.

Key points to remember

- The best way to manage a crisis is to prevent it in the first place. Use the practice of issues management—a proactive approach to anticipating and diffusing situations before they escalate into crises—to build relationships and trust before a situation unfolds. This approach is based on the core principles of stakeholder engagement and two-way communication processes where expert and lay perspectives inform each other.
- Don't wait for a crisis to occur to make a plan. Take proactive steps to develop a rapid response plan that identifies members of the crisis communication team. The plan should outline the steps that the designated point person, management, spokespersons and others should take in the case of a potential crisis.
- When a negative situation with the potential to undermine community trust or threaten the integrity or wellbeing of your trial arises, your rapid response or crisis communications plan should be put into action immediately.
- Trust, transparency and truthfulness are essential to effective communications for crisis management.

Study staff/SIDI

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

Chapter 6

Preparing for and Disseminating Study Results

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.

In this chapter

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.

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

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

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. Although these sites were involved in exactly the same study, the sites in Johannesburg, South Africa, and 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 they used. For studies with multiple sites within the same country, all of the sites should coordinate at the country level to ensure consistency.

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 activities and enough detail 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 were 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 and 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 are 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.

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

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

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

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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.

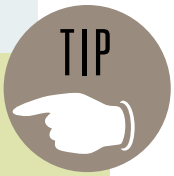
Box 6.4. Advice on updating communications products

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 material updates managed by one person, who was 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.



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.

- 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.

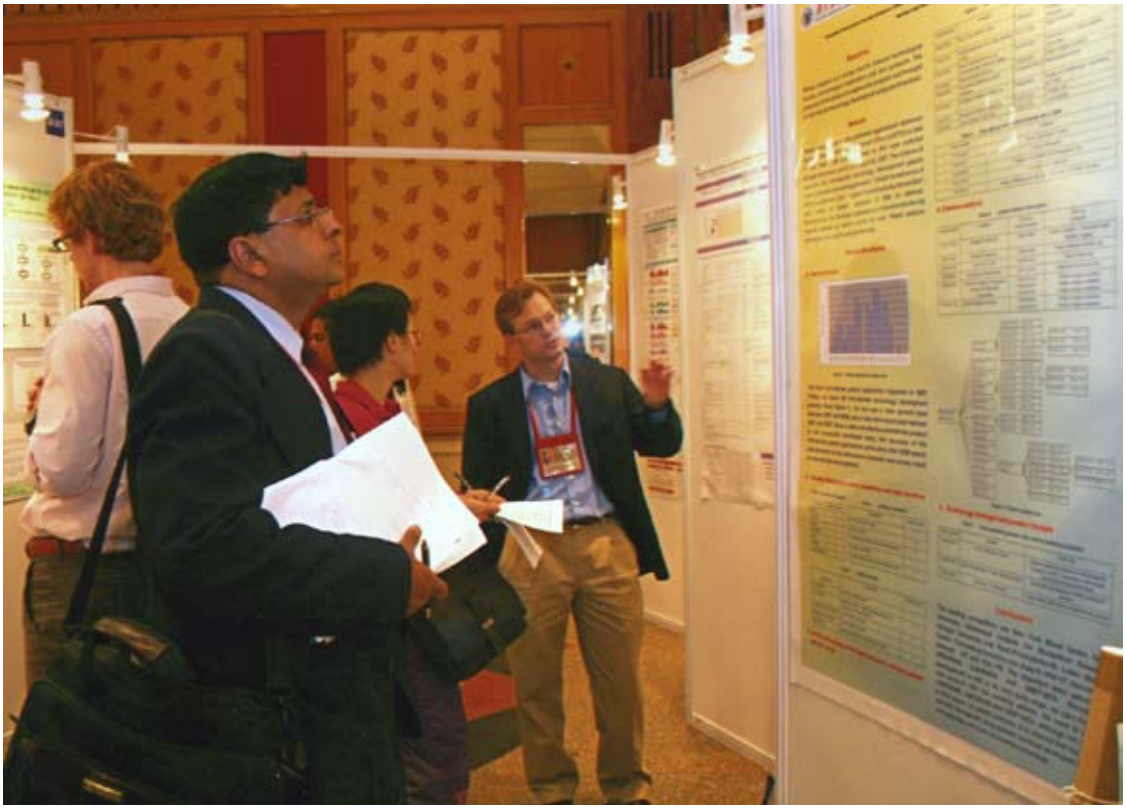
Poster or oral presentation
Meeting organizers are more liberal in accepting abstracts as posters than as oral presentations. Because of limited hours for oral presentations, most abstracts are accepted only as posters. Weigh the pros and cons. Posters are harder to produce than PowerPoint presentations, 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.



FHI

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 with 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
	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	
THURSDAY 24	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		THURSDAY 24	01:00	
	07:00			20:00			02:00	
	08:00			21:00			03:00	
	09:00			22:00			04:00	
	10:00			23:00			05:00	
	11:00			24:00			06:00	
	12:00		THURSDAY 24	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	HOLD FOR MEDIA INTERVIEWS		09:00	FRENCH PRESS MEDIA MANAGEMENT
	15:00	MOH STAFF CONFERENCE CALL		04:00			10:00	
	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
	22:00			11:00	MEDIA INTERVIEWS		17:00	FRENCH KOL/MEDIA INTERVIEWS
	23:00			12:00			18:00	
	24:00			13:00			19:00	
FRIDAY	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.

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

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.

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.

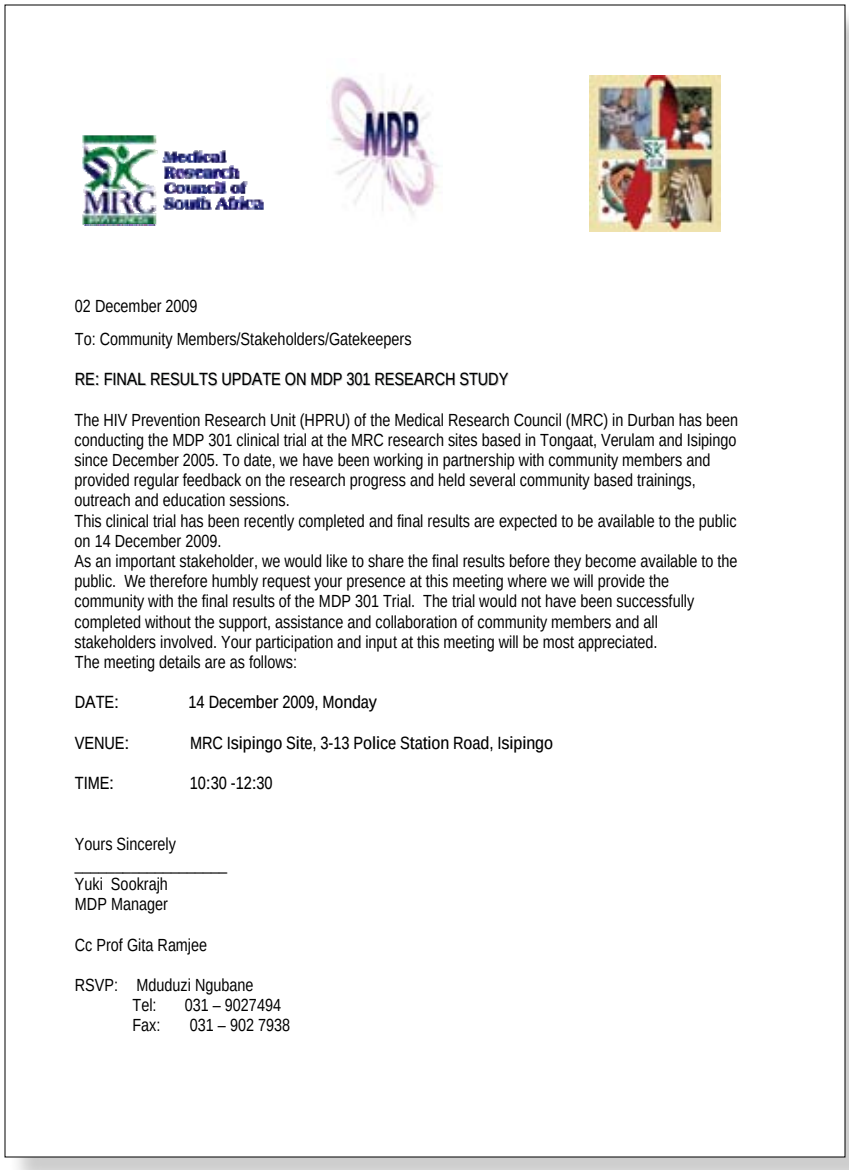
Press release. This can be one of the most efficient and effective ways to announce your research results. Depending on what media you target, press releases can help you reach a wide variety of people in different regions. These should be translated for local-language media.

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).



Medical Research Council of South Africa

MDP

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 they coordinate media relations. 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 Ulayi/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 with reporters under embargo.
- 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.

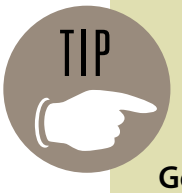
YouthNet/FHI

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 (ECs) 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.



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.

> *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

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

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.

Elizabeth T. Robinson/FHI

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

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.

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.

Dr. Kawango Agot, Director of the Impact Research and Development Organization, speaks to policymakers and community leaders at a 2008 meeting on male circumcision in Kisumu, Kenya.

Chapter 7

Developing and Using Key Messages

Key messages are short statements that explain your study or address an issue related to your research. They are the main points you want people to remember. Effective key messages do not contain technical details or focus on complexities. They provide straightforward, clearly worded information that seeks to engage people and gets them interested in your work.

A good key message is:

- Concise—it uses accessible language
- Simple to say aloud
- Focused on one idea
- Easy for people to understand and remember
- Persuasive
- Nonjudgmental
- Relevant to the intended audience

This chapter will help your research team create, refine, and use key messages. It will be useful to all members of the research team who have a part in this process: researchers and their assistants, community liaison officers, community advisory board members, administrative staff and others.

Your key messages provide the groundwork for your communications activities and the materials you'll use throughout your study. If you invest the time and effort to develop effective key messages that address the needs of your audience, you will have built a strong foundation for the rest of your communications work.

In this chapter

Elizabeth T. Robinson/FHI

Sarah Harlan and Brad Tytel provide feedback to a participant at MMCI's communication booth at the Microbicides 2008 Conference in Delhi, India.

Family Health International

I Why key messages are important

Key messages provide a strong foundation for your communications work. During the course of your trial, you will probably develop several sets of key messages: some to provide basic information about your study, some to respond to specific issues or questions that arise, and some to help communicate and contextualize your findings.

Well-developed key messages facilitate interactions with the media, the public, and with stakeholders by:

- Helping you stay organized when speaking with the media or with stakeholders
- Providing you with the information you need to maintain your composure and professionalism in stressful situations
- Ensuring consistency and continuity of information, especially for studies with multiple sites or partners
- Improving the public's understanding of your trial

Key messages help the study team convey consistent, accurate information. For example, a principal investigator preparing to speak with the department of health, a research associate writing an editorial for the local newspaper, or a community liaison officer giving an interview about study results could all consult the trial's key messages. Key messages can help ensure that the study team communicates reliable information, no matter what situation is presented.

Key messages also provide a "frame" to help the listener interpret the information. In other words, your key messages should provide some context for the information you convey. A frame is an emphasis, an angle, or a broader context that provides a more complete understanding of the issue. As the examples below show, it is often helpful to frame a study in terms of the ultimate benefits it could provide.

> *Our study is testing whether doctors in remote regions can safely use a simpler, less-expensive blood test to monitor the well-being of patients who are taking potent anti-HIV drugs. If so, we could ensure that more people have access to these life-saving drugs.*

> *In our vaccine study, fewer children in the group that received the oral vaccine for rotavirus became infected, compared to children who received the "dummy" vaccine that contained no active ingredient. This is good news, as it shows the vaccine is effective in preventing diarrhea and saving children's lives.*

> *Microbicide trials help to save women's lives in two ways: by advancing the search for new HIV prevention tools and by bringing needed health services to trial communities. Our trial provided women and their partners with state-of-the-art prevention services, including HIV testing, access to male and female condoms, supportive counseling, and quarterly screening and treatment for any sexually transmitted infections.*

II How to develop key messages and supporting messages

You should consider developing your key messages with a group of people. The following steps outline one possible approach to developing key messages and supporting messages for your study.

Step 1. Decide what you need to communicate.

- Begin with the basics: Why are you doing the study? What do you hope to learn? Who could possibly benefit?
- Determine defining characteristics: How is this study unique? How does this study advance the larger public health issues?
- Brainstorm a list of probable questions and concerns from each of your target audiences.
- Discuss the answers to these questions.
- Prioritize the most important things to say.

Remember, all of the questions and answers that you come up with can generally find a home in one of your communications documents—your Q&A document, your study's backgrounder, or the materials you prepare for the community. But the task of developing key messages is to choose the three most important messages that you want to communicate to each audience. People generally absorb only three key points in any single exchange—your job is to decide what those points should be.

Step 2. Write down the three or four most important points you want to convey.

- Write short sentences that summarize your main points.
- Use simple, jargon-free language.
- Use active rather than passive voice.

Pictured here is a mother with her baby in a health facility in Thailand. Worldwide, women are disproportionately affected by HIV/AIDS.

Jim Daniels

For example, a trial that is evaluating the safety and effectiveness of the drug tenofovir in women for use as pre-exposure prophylaxis (PrEP), might consider the following key, or "top-line," messages:

> *Key message 1: We are conducting a research study to see if taking a pill every day can safely protect women against HIV infection.*
>
> *Key message 2: This study is committed to safeguarding the well-being of all study participants and will strengthen HIV prevention and care services in the community.*
>
> *Key message 3: If the pill proves safe and effective, it could provide women and couples a new way to prevent HIV infection that does not interrupt intimacy.*

Anita Khemka

Pills to be given out at a medical camp in Tamil Nadu, India.

Step 3. Develop supporting messages for each key message. The next step is to develop a short list of supporting messages for each of your key messages.

Supporting messages provide the facts, examples, and simple explanations that reinforce your key messages. The supporting messages can also vary in detail and scientific sophistication, depending on the different audiences you wish to reach.

For the example described above, the supporting messages for a lay audience might read as follows:

Key message 1:

We are conducting a research study to see if taking a pill every day can safely protect women against HIV infection.

Supporting messages:

- The pill, called oral tenofovir or TDF, is currently being used to treat people already infected with HIV.
- We know that the pill is safe to use and slows the progression of HIV in people already infected.
- We do not know if the pill can be taken regularly to help prevent HIV infection in people at high risk. This is why we are conducting this study.

Key message 2:

This study is committed to safeguarding the well-being of all study participants and will strengthen HIV prevention and care services in the community.

Supporting messages:

- The study has been reviewed and approved by our national ethics committee, regulatory bodies, and the Ministry of Health.
- An independent Data and Safety Monitoring Board (DSMB) will meet regularly to review the trial and monitor the well-being of participants.

- The study will provide all participants with high-quality health services, including HIV testing and risk-reduction counseling, family planning services, access to male and female condoms, and testing and treatment for sexually transmitted infections.
- Because of these services, women in the trial will likely have a reduced chance of becoming HIV positive compared with other women in the community. Despite access to counseling and free condoms, some women may not be able to negotiate condom use 100 percent of the time and will become infected during the trial. That is why it is so critical to continue research to find effective HIV prevention methods that women can use.
- We are working closely with the local antiretroviral (ARV) clinic to set up a referral system and help strengthen its services both for women in our trial and for the wider community.

Key message 3:

If the pill proves safe and effective, it could provide women and couples a new way to prevent HIV infection that does not interrupt intimacy.

Supporting messages:

- Although condom uptake has risen dramatically among casual sex partners, a majority of couples in long-term relationships report that condoms interfere with intimacy. A once-a-day pill would overcome this obstacle.
- Currently less than half of all couples in this community report using a condom the last time they had sex, even though almost one in three people are infected with HIV. People need more options to help them avoid infection.

Informed consent materials reviewed by your Institutional Review Board (IRB) may be good sources of well-developed, simple messages appropriate for other lay audiences, such as community leaders or local radio stations.

Step 4. Tailor your key messages and supporting messages to different groups of stakeholders. The best communicators adapt their style of communication, their language, and their supporting arguments for each target audience. When adapting your supporting messages for different audiences:

- Consider what information is potentially most useful or compelling to different groups. For example, emphasize the "big picture" when addressing lay audiences, and the implications for policy when addressing policymakers.
- Try to use locally relevant analogies (such as sports if you are talking with men's groups or farming if you are in a rural community) to help explain your point. This can help people relate to your research by drawing on familiar experiences.
- Be sure to adapt your language and the level of detail provided to suit your audience's needs.

For example, in the PrEP trial described above, you might choose to provide more technical detail in your supporting messages when communicating with a scientifically sophisticated audience.

A re-worked version for message 1 for a scientific audience might read:

Re-worked key message 1:

We are conducting a study to test the safety and effectiveness of oral tenofovir, taken once a day, to prevent HIV infection.

Re-worked supporting messages:

- The concept of using therapeutic agents as a prophylactic (known as pre-exposure prophylaxis, or PrEP) has proven effective with other infectious diseases such as malaria.
  - Several studies suggest that the use of antiretrovirals (ARVs) before exposure to HIV may prevent HIV infection.
  - A single dose of the ARV drug nevirapine—given to the mother during labor and given to her newborn after birth—cuts the HIV infection rate by 50 percent.
  - Giving tenofovir to a monkey just before and just after exposure to simian immune virus (SIV) can prevent an infection.
- Tenofovir's excellent safety and resistance profile, along with convenient dosing, make it an ideal candidate for PrEP.

If you are talking to policymakers, you might emphasize a slightly different set of messages, focusing less on the potential benefits of tenofovir for individuals and more on its potential role and impact in a national HIV prevention program.

A re-worked version of key message 3 for a policy audience might read:

Re-worked key message 3:

If the pill proves safe and effective, it could provide a new way to prevent HIV infections and reduce the incidence of HIV.

Re-worked supporting messages:

- One in every three adults in our country are infected with HIV.
- Despite national prevention programs, thousands of people are infected with HIV in our country every year.
- New HIV prevention approaches that can be used and controlled by women (and also used by men) are urgently needed.
- Use of tenofovir could provide an important new prevention strategy for our national HIV prevention program.

One excellent resource for evidence-based health information tailored for different audiences is http://www.cdc.gov/DiseasesConditions/, the U.S. Centers for Disease Control and Prevention (CDC) Web site. The site provides information in a question and answer format for a variety of

users: health professionals, researchers, parents, travelers, and others. The CDC Web site is a good place to glean information for supporting messages and to see how information can be adapted for different groups. The *British Medical Journal* (BMJ) also publishes excellent key messages alongside clinical papers, helping journal readers absorb what is new and what is important about study results. Box 7.1 provides examples of messages and supporting information that have been adapted for different audiences.

Box 7.1. Sample messages adapted for patients and providers

This excerpt is based on materials prepared by the CDC on heart disease and heart failure. Notice how the content and style of the messages is tailored differently for patients and professionals.

Key messages about heart disease—for patients

- Heart disease is the leading cause of death in the United States. Around 630,000 Americans die of heart disease each year. That's more than one in every four deaths in this country.
- The term "heart disease" refers to several types of heart conditions. The most common type is coronary artery disease, which can cause heart attack.
- Having high cholesterol, high blood pressure, or diabetes also can increase your risk for heart disease. Ask your doctor about preventing or treating these medical conditions.
- Your doctor can perform several tests to diagnose heart disease, including chest X-rays, coronary angiograms, electrocardiograms (ECG or EKG), and exercise stress tests.

Adapted from: http://www.cdc.gov/heartdisease/docs/ConsumerEd_HeartDisease.pdf.

Top-line message and supporting data on heart failure—for health professionals

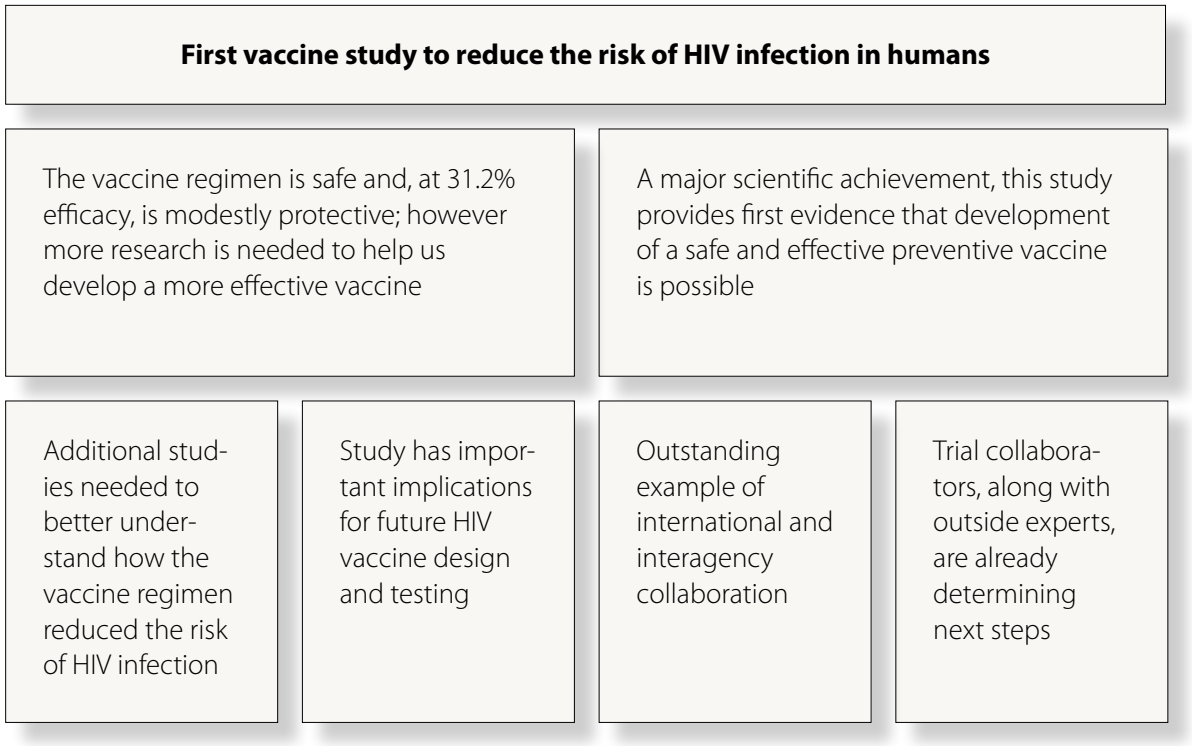
- Around 5 million people in the United States have heart failure. About 550,000 new cases are diagnosed each year. More than 287,000 people in the United States die each year with heart failure.
- The most common causes of heart failure are coronary artery disease, hypertension or high blood pressure, and diabetes. About 7 of 10 people with heart failure had high blood pressure before being diagnosed. About 22 percent of men and 46 percent of women will develop heart failure within 6 years of having a heart attack.
- Heart failure is the most common reason for hospitalization among people on Medicare. Hospitalizations for heart failure are higher in black than white people on Medicare.
- The quality of life and life expectancy of persons with heart failure can be improved with early diagnosis and treatment. Treatment usually involves three to four medicines. Medicines used to treat heart failure include ACE inhibitors, diuretics, digoxin, and beta blockers.

Adapted from: http://www.cdc.gov/dhdsp/library/fs_heart_failure.htm.

Step 5. Consider organizing your messages graphically. It can be useful to organize your messages graphically in a table or a message grid (a matrix-like arrangement of messages on a page). Graphic treatments can guide the user through the logic of the messages and provide a one-page, easy reference that he or she can review before talking to a stakeholder or the media. The grids themselves are not shared with people outside of the trial.

One way to organize your messages is to present them hierarchically as in the message grid below (see Figure 7.1). In this example—developed to explain the results of an HIV vaccine trial in Thailand—the overall topic of the message grid is described in the first box and the two key messages are summarized directly below it. There are two supporting messages for each key message.

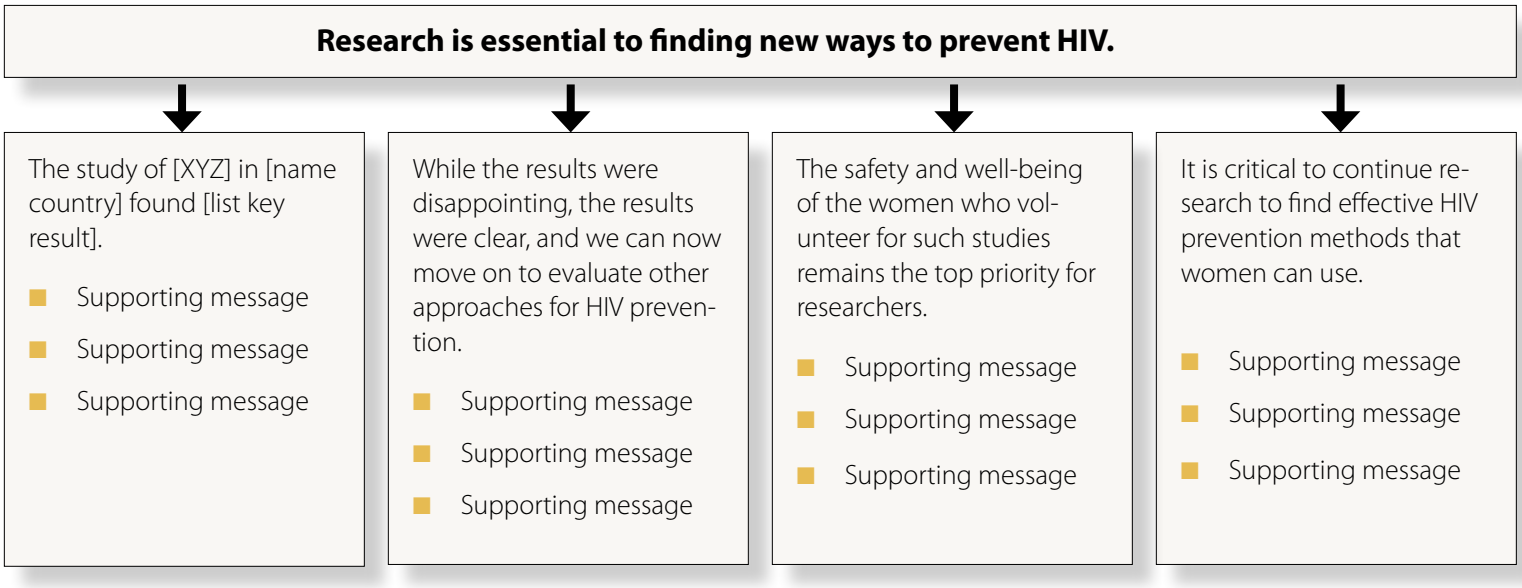
Figure 7.1. Sample grid of key messages



Source: U.S. Military HIV Research Program. 2009. Reprinted with permission.

A similar way to summarize your messages is to use a table with an introductory top-line message with four key messages underneath, as shown in Figure 7.2. For a complete copy of this type of message grid, see Appendix 7.3. An alternative type of grid—organized with sections for connecting with your audience, overcoming barriers, encouraging your audience to take action, and demonstrating the benefit of taking action—is presented in Appendix 7.4.

Figure 7.2. Sample grid to outline introductory and key messages



III Creating tailored messages for any situation

In addition to the regular key messages, you may need to develop other messages to address situations that arise during the course of your study. Perhaps your research institution has a new organizational mission that you want to publicize, or you wish to respond to a new discovery that is related to your study.

For example, when microbicide researchers at the Microbicide Trials Network (MTN) and CAPRISA discovered that some participants were enrolling in two different microbicide studies at their sites in Durban, South Africa, at the same time, the researchers needed messages to address concerns about how such co-enrollment (which was a protocol violation) might affect the two trials.

The steps below follow this example to explain how to create key messages in response to a problematic situation.

Step 1. Identify the situation. It is important to know exactly why you want to communicate. Is there a crisis that you want to address? A rumor you want to quell? Misinformation you need to correct? New details or changes you seek to make public? Clearly stating the situation will be one of your key messages.

> "The MTN leadership became aware of a serious situation concerning the co-enrollment of approximately 96 HPTN 035 participants into the CAPRISA 004 study."

Step 2. State clearly how you are addressing the situation. Demonstrate your concern.

> "We are working diligently to better understand exactly how this occurred, and we are actively considering measures to prevent future co-enrollment of participants in HIV prevention trials."

Step 3. Provide information for the future.

> "The impact of these co-enrollments on the scientific integrity of HPTN 035 is likely to be minimal."

"On April 24, 2008 the MTN leadership became aware of a serious situation concerning the co-enrollment of approximately 96 HPTN 035 participants into the CAPRISA 004 study. I can assure you that we are working diligently to better understand exactly how this occurred, and we are actively considering measures to prevent future co-enrollment of participants in HIV prevention trials. Although some questions still remain unanswered, based on the information we have to date, the impact of these co-enrollments on the scientific integrity of HPTN 035 is likely to be minimal, resulting in a loss of less than 1 percent of the total follow-up time for the 3100 women on the HPTN 035 study."

—Sharon Hillier, MTN Principal Investigator

When you put all the steps together, you have developed a set of messages that form the foundation for your communication, in this case a letter from MTN, the HPTN 035 sponsor, to their stakeholders. (The CAPRISA 004 leadership also released its own statement to stakeholders to address the situation.)

Jim Daniels

A man listens intently to a skit on HIV prevention at a village near Jacmel, Haiti.

You must be an active listener to develop a well-tailored message. Paying attention to conversations that are relevant to your research will help you develop messages that are relevant to the needs and concerns of your audiences.

For example, in one microbicide study, community liaison officers reported that some people in the community believed that the study was intentionally infecting people with HIV. The team took these rumors seriously and developed key messages to dispel this belief.

In another instance, religious leaders voiced concerns that a trial studying a vaccine to prevent a sexually transmitted infection might encourage young girls to be promiscuous. The study team developed messages about these concerns and hosted a tea hour to discuss the study with members of three local congregations.

Being an active listener helps you pick up on potential cues around you. Ask yourself:

- Do local staff members voice any concerns about trial procedures?
- What questions are raised in community meetings?
- What words do people use to describe relevant concepts?
- What questions or arguments have the media posed about the trial?

IV Refining and testing your messages

Refining and testing your messages is an important step in making sure they are effective.

To refine your messages:

- Read the message out loud. Does it sound conversational? If not, edit until it does.
- Simplify the language. Try to reduce complex technical language. Remember that key messages are broad statements; they do not include many details.
- Check the length. Keep it short.
- Make sure your key messages frame the issue.

Julio Sandoval

Designated spokespeople can benefit greatly from media training.

Test your messages with representatives of your intended audience.

If possible, test your key messages with the following people:

Internal staff. Share the messages with staff members—especially those who work closely with your intended audiences. For example, if the messages are targeting donors, have the person who liaises with your funders look at the messages. If the messages are for local leaders, make sure the community liaison officer provides input.

Technical experts and researchers. Your colleagues will have a wide range of perspectives—they can comment on accuracy, candor, and transparency.

Intended audiences. To see if your messages are clear and easy to understand, try them with people who fit the profile of your intended audience. Choose independent outsiders who are not familiar with the topic—someone from another department in your institution, a family member, or even a teenager.

Members of your community advisory board, and local and global advocates. CAB members, advocates, and civil society representatives are often well informed. They can help you ensure that your messages are responsive to the questions and concerns of their respective communities.

V Delivering key messages

The following guidelines can help you with the delivery of your messages. Some general tips are also summarized in Box 7.2.

Guideline 1. Your key messages should form the foundation of your communications strategy. Use your message grid when developing materials to ensure that you are focused and succinct. You can incorporate key messages into a range of communications products including:

- Q&A fact sheets
- Text for your Web page or newsletter
- Media materials (see Chapter 9)
- Correspondence
- PowerPoint presentations

Whether you are writing an article for a local newspaper or an e-mail inviting community advocates to attend a social gathering, remember to use your key messages. Even stakeholders who are well acquainted with your study should be reminded why the study is important and why they should continue to stay engaged and support the research.

Guideline 2. Take every opportunity to reinforce key messages with the study's staff. Share your key messages with the entire study team, including the administrative staff and others who are not directly involved in the research. Encourage everyone to learn and to use the key messages.

- Review key messages at staff meetings.
- Provide regular in-house trainings.
- Engage them in role-play activities.
- Write the messages on a small laminated card or brochure that staff members can refer to if needed.

Guideline 3. Update your messages as needed. At some point you will need to update your key messages. For example, if your messages say that your study is the only large-scale trial testing a certain product, and then a year later another large-scale study testing the same product is launched, you should revise and update the messages in all of your materials. Remember to share updated versions whenever you revise them.

Box 7.2. Five things to remember when delivering key messages

1. Make sure that the key messages are communicated by a well-prepared spokesperson who has credibility with the audience.
2. Speak in an open and sincere manner that projects care and compassion, using a respectful, nonjudgmental tone.
3. Use "bridging" to stay on message and to bring the conversation back to the messages you want to deliver (see Chapter 9).
4. Follow up with frequent and consistent communications that are repeated by others with influence.
5. Include clear recommendations for action, as appropriate.

Source: Shepherd MB. Emergency risk communication. Presentation at Family Health International, Research Triangle Park, NC; May 2005.

Guideline 4. Share your messages with others. Share your messages with other sites, with the trial network, and with colleagues who are conducting similar studies. Your colleagues may want to adapt your messages for their own studies. Welcome such requests: consistent messages across a scientific field can help manage expectations and promote accurate media coverage.

Jim Daniels

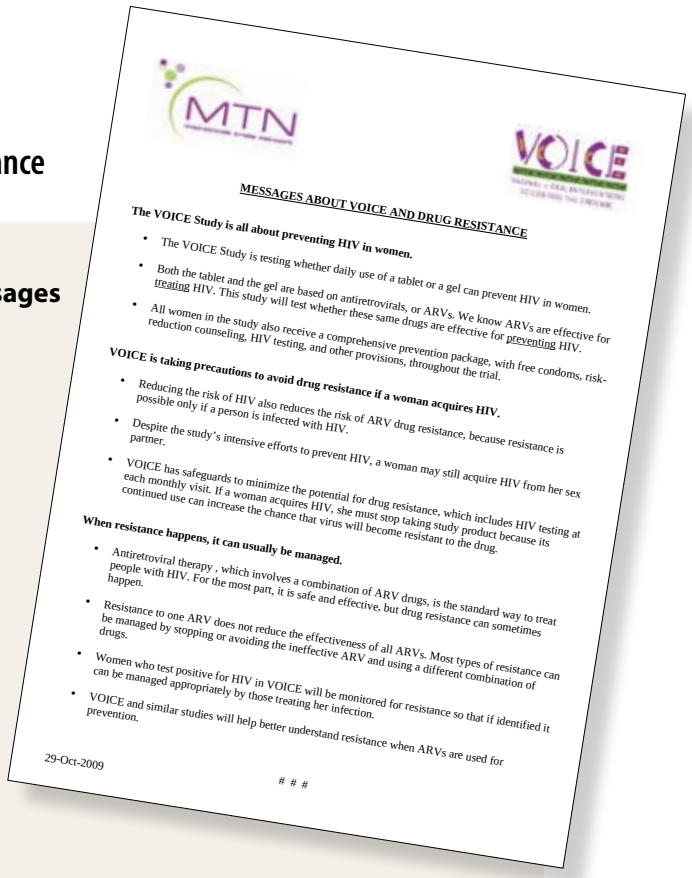
Community meetings can serve as an effective means to communicate key messages.

Figure 7.3 illustrates how the Microbicide Trials Network (MTN) incorporated messages into a variety of their communications materials that they developed on possible drug resistance associated with using ARVs to prevent HIV. They had three main messages on resistance: One explained how and why drug resistance develops; a second described how the study plans to limit the chance that a participant will develop resistance; and a third explained how drug resistance can be managed if it does develop. They included these messages in study-related fact sheets, adapted them with simple graphics for PowerPoint presentations, and reinforced them in materials available on the MTN Web site.

Based on these messages, the Global Campaign for Microbicides (GCM)—an international civil society advocacy organization—used this information to develop even simpler messages to describe drug resistance. They used the simplified information in their public trainings on ARV-based prevention strategies (see Figure 7.4).

Figure 7.3. VOICE study: explaining drug resistance

Key messages



MESSAGES ABOUT VOICE AND DRUG RESISTANCE

The VOICE Study is all about preventing HIV in women.

- The VOICE Study is testing whether daily use of a tablet or a gel can prevent HIV in women.
- Both the tablet and the gel are based on antiretrovirals, or ARVs. We know ARVs are effective for treating HIV. This study will test whether these same drugs are effective for preventing HIV.
- All women in the study also receive a comprehensive prevention package, with free condoms, risk-reduction counseling, HIV testing, and other provisions, throughout the trial.

VOICE is taking precautions to avoid drug resistance if a woman acquires HIV.

- Reducing the risk of HIV also reduces the risk of ARV drug resistance, because resistance is possible only if a person is infected with HIV.
- Despite the study's intensive efforts to prevent HIV, a woman may still acquire HIV from her sex partner.
- VOICE has safeguards to minimize the potential for drug resistance, which includes HIV testing at each monthly visit. If a woman acquires HIV, she must stop taking study product because its continued use can increase the chance that virus will become resistant to the drug.

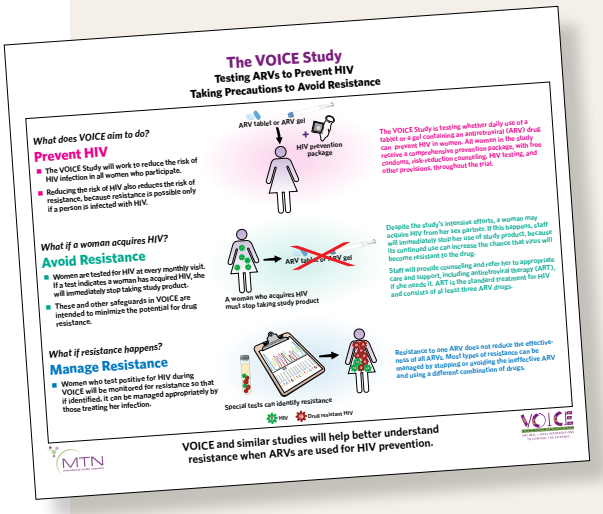
When resistance happens, it can usually be managed.

- Antiretroviral therapy , which involves a combination of ARV drugs, is the standard way to treat people with HIV. For the most part, it is safe and effective, but drug resistance can sometimes happen.
- Resistance to one ARV does not reduce the effectiveness of all ARVs. Most types of resistance can be managed by stopping or avoiding the ineffective ARV and using a different combination of drugs.
- Women who test positive for HIV in VOICE will be monitored for resistance so that if identified it can be managed appropriately by those treating her infection.
- VOICE and similar studies will help better understand resistance when ARVs are used for prevention.

29-Oct-2009

# # #

Simple PowerPoint slides for public presentations



Q&A with more detailed scientific explanations of drug resistance for those seeking in-depth information

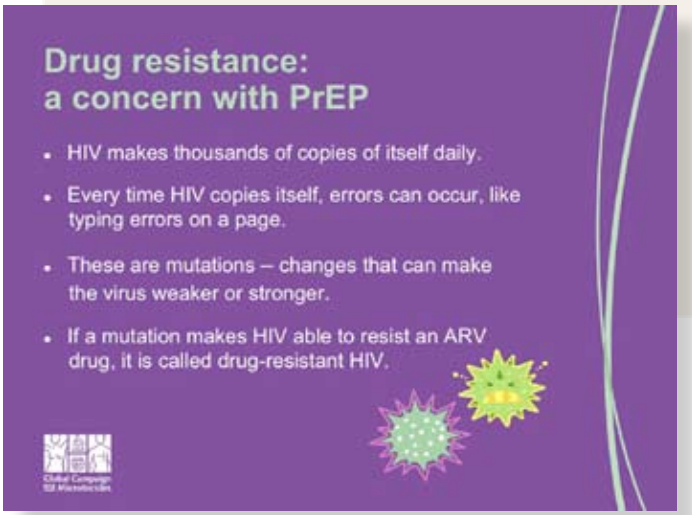


Figure 7.4. GCM training slide on drug resistance

Such key messages provide a foundation for communication activities and materials throughout a study.

"Preparation is everything in communication," says FHI President for Research, Dr. Ward Cates. "Know your audience. Decide what you want to say and what you want to ask before you begin communicating at any level—on a conference call, at the podium, or in media interviews. Simpler is better."

Family Health International

Dr. Ward Cates, FHI President for Research, observes that, "With communications, simpler is better."

Key points to remember

- Key messages are short and straightforward statements that include the main points you want people to remember. Supporting messages provide the facts, examples, and simple explanations that reinforce your key messages and help you connect with your audience.
- Listening is just as important as writing when developing key messages. Effective messages are tailored, refined, and tested to ensure they respond to the needs and concerns of different audiences.
- Your key messages provide the building blocks for your materials and communications activities throughout your study.

Chapter 8

Communicating Science Clearly

Misunderstandings about scientific research can happen for many reasons.

For example:

- Scientists often use technical jargon.
- Some words—such as significance and trial—have different meanings in a scientific context than they do in everyday usage.
- Fundamental concepts—randomization, double-blind trial, efficacy—are not commonly understood.
- Some terms—like hazard ratio—cannot be easily translated into other languages.

Fortunately, whether you a researcher, community liaison officer, or advocate, there are ways to make sure you are communicating scientific concepts clearly.

Research teams can reduce the chance of a misunderstanding by paying attention to how communities talk about these issues and by following some simple guidelines to communicate more clearly. This chapter provides guidance on how to talk to different audiences about clinical research.

In this chapter

Anita Khemka

A health worker in Tamil Nadu, India, speaks to men at a train station about HIV testing.

I Why research is necessary

As someone involved in clinical trials, you may take it for granted that medical research is important. But many people do not have a clear understanding of why clinical and behavioral studies are needed. Explaining the need for research is crucial for the clear communication of scientific information.

Geoff Oliver Bugbee/IPM

Clinical trials often strengthen local laboratory capacity. A lab technician works in the lab at the Mvita Clinic, an IPM research center, in Mombasa, Kenya.

Consider these guidelines when you convey scientific ideas:

Guideline 1. Emphasize the health impact of your research. How will your study potentially benefit the health of the general public? Clearly stating the potential health impact of the research is one way to show how studies provide necessary evidence for health interventions. For example:

- This study is exploring how to develop an easy way for women to protect themselves against HIV.
- Currently, there is no malaria vaccine on the market. This study could help create a vaccine that could save millions of lives each year.
- Our research is trying to find out how well a new drug can reduce respiratory problems in children with chronic asthma. If we find out it works, this could help thousands of young people participate more fully in daily activities.

Guideline 2. Show how your study fits into the bigger picture of public health needs and research. Explaining the connection between your work and the big picture of public health can help others to see your team as part of the global community of scientists. People will come to appreciate that their involvement in the study has value.

For example, if you are about to start an HIV prevention trial, you will need to talk about HIV/AIDS in the community—perhaps by providing a simple explanation of prevalence and incidence.

- Begin by asking, "How have people in your community (or town, district, country) been affected by the virus?"
- Respond to their stories with information about the numbers of people locally, nationally, and globally who were infected with the virus in the past year, are living with HIV, or have died of AIDS.
- Explain how research has helped to find better ways to care for people who are infected with HIV by, for example, ensuring the safety of drugs that are used for treatment.
- Discuss how your study might address the epidemic in the community and worldwide.

Guideline 3. Explain that all research asks a question. Whenever you talk about a research study, point out that the research team does not know what the results will be. All research tests a hypothesis, and no matter what the result, the study will add to our knowledge about how to prevent or treat the disease. When communities understand that no one has the answer, researchers and community members can appreciate their shared purpose and feel solidarity with one another.

For example:

- We do not know if this medicine works, so we are doing this study because we want to find out whether it can help protect children from diarrhea.
- We know this vaccine protects mice against influenza. Our study is trying to find out whether the vaccine can also protect humans.

Anita Khemka

To see if your messages are clear and easy to understand, try them with people who fit the profile of your intended audience. Pictured here is a peer educator conducting a group discussion on HIV in New Delhi, India.

Guideline 4. Explain why the study is being conducted in that particular community. Provide an honest explanation of why their community was chosen. It is important to explain that the scientists are trying to solve a problem in the community. Communities that are provided with a specific explanation are less likely to feel that they are being exploited by the study.

In the case of HIV prevention trials, for example, one might say:

- Large-scale HIV prevention studies must take place in settings where the HIV incidence is high and where prevention is most needed.
- We must ensure that products work in this community and are acceptable to residents.
- Studies must be conducted in areas where there are scientific institutions and trained research personnel.
- Communities and countries hosting studies are contributing to worldwide progress in preventing HIV infections.

Guideline 5. Provide some background information about your field. Whether you are drafting a press release or preparing a talk for a Ministry of Health, you should be able to explain quickly the purpose and context of your research, including the studies that came before. For example:

> "Scientists have been studying microbicides for the past 20 years. We have been getting better at determining what might work, and we recently discovered problems with certain approaches. This study is the latest step in this process."

Guideline 6. Outline the process of clinical research. Few people understand how much effort, cost, and preliminary research is required before investigators launch a large-scale clinical study. Although it is not necessary to explain the details about the phases of research, it can be

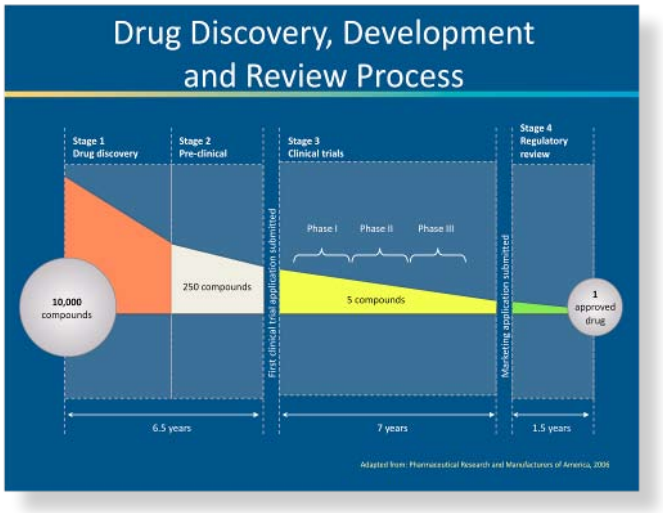
helpful to mention that extensive lab work, animal testing, and studies involving small groups of people are conducted for safety and side effects long before a product or intervention is tested on a large group of people.

Most people intuitively understand that a treatment must be shown to be safe before it can be shown to be effective. Pointing out that this principle is integral to the structure of all clinical studies helps people to understand that scientists strive not to harm anyone who volunteers for a study. The research process itself is designed to minimize risk to participants and maximize the chance of success.

As you explain clinical research, consider the scientific literacy of your audience. The same information can be presented in many different ways. The graphic examples below (Figures 8.1 to 8.5), which explain the phases of drug development and clinical research, assume different levels of reader sophistication.

A sophisticated audience can apprehend a great deal of information in a single image. For example, Figures 8.1 and 8.2 explain the process of drug development, including the phases of a clinical trial, the success rates of products as they advance through each phase, and the development timeline.

Figure 8.1. Explaining the process of drug discovery to a scientifically literate audience

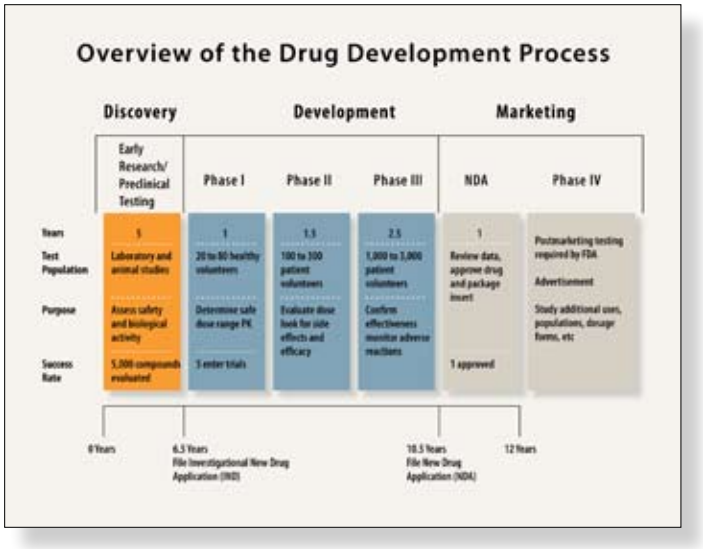


Reprinted with permission from the International Partnership for Microbicides, Silver Spring, MD, 2010.

The International Partnership for Microbicides adapted the chart above to explain the process of drug discovery to their donors, a relatively sophisticated audience. It highlights the number of candidate microbicides that are tested at each phase, illustrating that only the most promising products move forward and only one safe and effective product may emerge.

Figure 8.2 explains the stages of research more fully.

Figure 8.2

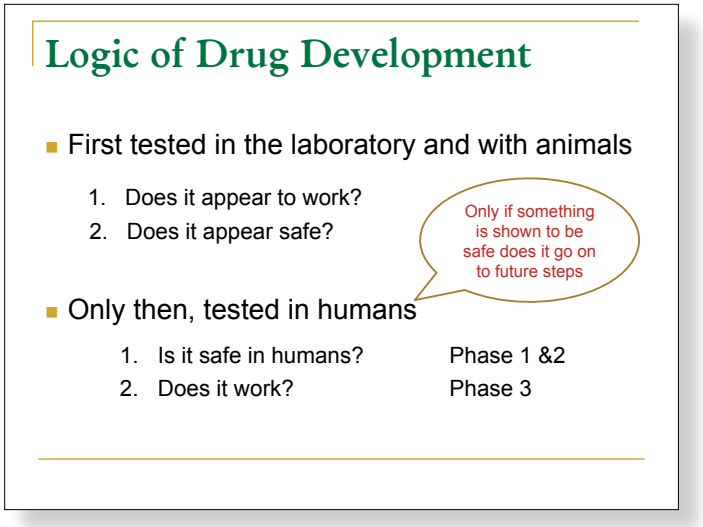


These figures might be too complicated for many audiences. But similar information can be presented in a much simpler way.

The Global Campaign for Microbicides (GCM) uses a series of "mix-and-match" slides to simplify these concepts for nonscientific audiences. The GCM slides demonstrate simple ways to reinforce key concepts, such as the duration of drug development, and illustrate some options for providing more or less information depending on the audience's scientific literacy.

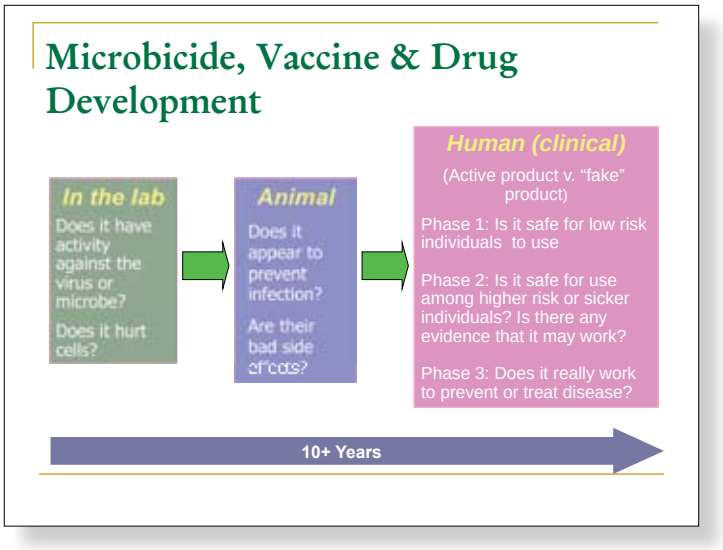
GCM's first slide (Figure 8.3) emphasizes that all experimental products are tested in the laboratory and in animals before they are considered for testing in human beings.

Figure 8.3.



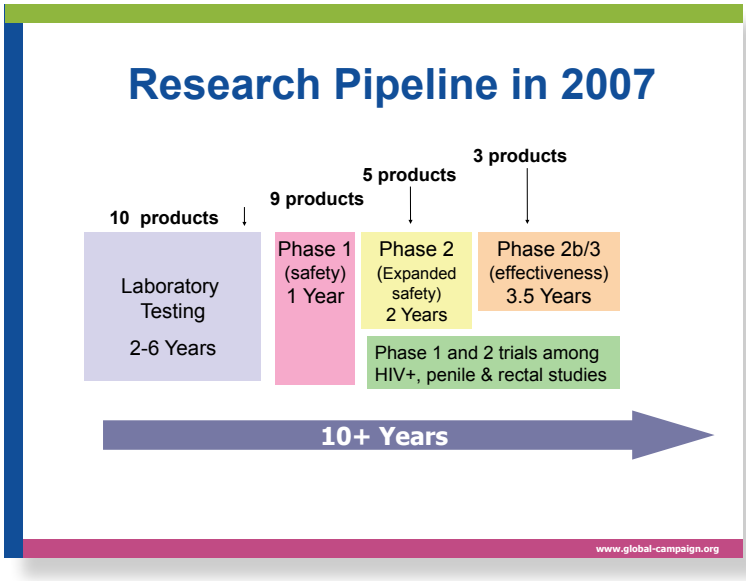
The second slide (Figure 8.4) reinforces this notion and provides a little more information about different the phases of a clinical trial.

Figure 8.4.



An alternative slide (Figure 8.5) provides additional information on the duration of each phase and the reduction of viable products with each successive phase.

Figure 8.5.



Guideline 7. Frame research as serving the common good. Whenever you talk about your study, emphasize the positive outcomes of medical research. For example, flu shots, medications to treat HIV, contraceptive pills, tetanus shots, and the eradication of smallpox are all public health successes of medical research. Emphasize that your study also hopes to find answers to health problems.

Remind listeners that public health research has always been a global effort. Highlight that the same product may be tested in numerous safety studies in the United States and Europe and then tested in Asia, South America, and Africa in later-stage trials before it is approved for use and implemented at a country level.

II Translating the language of clinical studies

> The key to writing easy-to-read materials is to get outside of your own head and stop thinking about what you know and what you think is important, and try to think of it through somebody else's eyes and what they will think is important to know—and then write your materials with this audience in mind.
>
> —Anna Forbes, former Deputy Director, Global Campaign for Microbicides

Researchers sometimes fear that simple explanations dilute important scientific concepts. However, it is essential to communicate clearly and credibly with nonscientific audiences so that potential participants, trial communities, politicians, and others will understand why their support is needed.

Listen to the language used by your audience. Pay attention to the patterns of speech used by people who live and work where your study is being conducted. How do local staff members and journalists discuss the health issues you plan to study? What words or analogies do they use? Journalists care about readability, and they are careful to use language to suit their audience.

In Kenya, for example, journalists often refer to "the cut" when they write about male circumcision because that is what Kenyans call it. Scientists who are conducting research on male circumcision can take this into account when they explain their work to community members.

Jim Daniels

A clinician at a clinic in Cambodia handles blood specimens. Drawing and storing blood has raised issues in some communities. Communicating clearly about how blood is handled in a clinical trial can be an important way to allay community concerns.

Box 8.1. Replacing jargon with everyday words

Jargon	Everyday language
vaginal intercourse	sex
coitally dependent	when you have sex
disinhibition	take more risks
transmission	infect
acquisition	become infected with
concentration level	strength
systemic toxicity	side effects
seroconvert	become HIV positive
accrual	participants joining the study
retention	participants staying in the study
terminate	end

Translate scientific terms into everyday language. You can keep it simple without sacrificing the meaning of a concept. Some people follow the two-syllable rule (Forbes 2009): questioning the use of all words that have more than two syllables. Try to replace complicated words with shorter terms or with language that is more familiar. (See Box 8.1 for an example of how to replace jargon with everyday words.)

You should also be alert to double meanings. Even the most commonly used terms in clinical studies can be misinterpreted. Sometimes a seemingly neutral scientific word or phrase can have negative connotations to others or different meanings in a local language. This can create stumbling blocks that interfere with the implementation of a study. Box 8.2 demonstrates three such instances that may require a further explanation from you.

Consider the use of images to tell your story. An illustration can do much to explain a concept. Graphics can help you transcend language differences and cultural barriers and can make complicated ideas easier to grasp. Of course, the same visual tool may not be effective for every audience. See Box 8.3 and Figure 8.6 for examples of visual aids that are appropriate for lay audiences.

Anita Khemka

Performing plays is an excellent way to illustrate scientific concepts. In this photo, young women in New Delhi, India, act out "The Immune System Dance," an activity to help understand how HIV is transmitted.

Box 8.2. Everyday words that can mislead

Come join our trial!

You hold a *trial* to decide if someone is innocent or guilty of a crime. Am I in trouble?

This is a Phase I safety trial of a new HIV product.

Oh good, the trial will help keep me *safe* from HIV!

We have censored 30 participants.

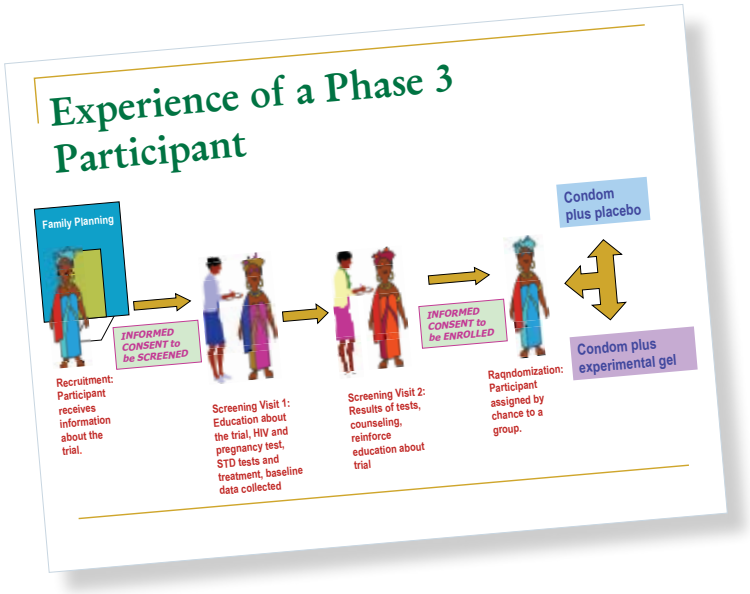
Why were some participants *censored* and not allowed to speak?

Box 8.3. Baobab trees used to explain serodiscordance

The Partners in Prevention (PIP) HIV/HSV Study enrolled people who were in serodiscordant relationships (where one partner in the couple was HIV positive and the other was HIV negative). The PIP team needed to explain the concept of serodiscordance in a way that could be understood by the study's participants in eastern and southern Africa. The team used an image of two baobab trees (left), one of which is infested with termites that can destroy one or both trees. Partners in Prevention used the illustration to show how HIV can infect one or both partners, but that it cannot be diagnosed without testing.

You should also consider the use of software, such as PowerPoint, which allows you to use compelling photographs, drawings, and simple, colorful charts. A good slide has a minimal amount of text. If you use a graph or a chart, make sure that the axes and the data are clearly labeled. Do not read aloud from a slide; use it as an outline, not a script.

Figure 8.6.



This slide from GCM provides a visual introduction to civil society stakeholders of the notion of a randomized controlled trial from the perspective of a trial participant.

Use props when you present scientific information. Props can help you explain concepts in an engaging way. Props make a presentation more interesting and memorable (see Box 8.4).

Katie West Slevin/GCM

Tabita Mahlangeni, community educator with the Aurum Institute of South Africa, participates in an interactive exercise, "Understanding the HIV Life Cycle," with a group of trial site staff, CAB members, and advocates during a prevention research literacy training conducted by the Global Campaign for Microbicides in Johannesburg, South Africa.

Pay attention to local context and culture. The tools you use to explain your study must be relevant to the community. Multisite studies may need to adapt materials to the needs of each site (see Box 8.5).

Box 8.4. Using props to explain clinical trial concepts

Concept	Prop	Exercise	Lesson
Placebo	Two glasses of water, salt	Bring out two glasses of water. Stir salt into only one glass. The glasses will look the same, but one now has an "active ingredient"—the salt.	A placebo is a word that refers to something that looks like medicine but isn't, and has no effect on the person who takes it.
Double-blinded	Two glasses of water, sugar	Bring out two glasses of water. Ask someone from the audience to pour the sugar in without anyone else seeing them do it. Ask the audience to guess which glass has sugar in it.	Neither the participants nor the researchers know which participants are receiving the test drug and which are receiving the placebo.
Randomization	Paint a cardboard box to look like a die, each side with a different number of dots from 1 to 6.	Ask each person to roll the die and remember the number that appears on top of the box. Divide the group according to these numbers: 1 to 3 on one side of the room; 4 to 6 on the other.	When people are randomly assigned to either the intervention group or the placebo group of a study, the only determining factor is chance.

Box 8.5. The importance of field-testing materials: lessons learned from Orange Farm

When staff members of the Bophelo Pele Male Circumcision Project at Orange Farm, South Africa, began a research study to determine whether adult medical male circumcision would help to reduce the risk of HIV transmission, they were surprised to find that many men did not know whether they were circumcised or not. The staff quickly printed brochures with photographs of a fully circumcised penis and an uncircumcised penis, so that men could see the difference.

Some community members were disturbed seeing photographs of penises in materials. "We asked for suggestions of other ways to explain the differences, and community members suggested that we use drawings, which were less offensive to them," said Dirk Taljaard, project manager at the Bophelo Pele Male Circumcision Project. The team immediately revised the materials, and now uses drawings to show the anatomical differences.

Use stories and analogies to explain scientific concepts. Years after people forget facts and statistics, they will remember a good story, especially if it sparked a moment of understanding. Make sure that the analogies you provide are culturally and politically appropriate. Here are some examples of narratives that explain certain scientific concepts:

> *Hypothesis testing.* Farmer Batayan has grown maize for five years, and he now wants to begin growing millet instead. He is not sure if the fertilizer that helped to grow his maize will increase his millet crops. The fertilizer might harm the millet or have no effect on the millet. To find out for sure, Farmer Batayan must test the fertilizer on his fields. Farmer Batayan decides to plant two separate plots of land with millet seed. He adds the fertilizer to the first plot and nothing to the second plot. He can now compare the plots directly and determine if the fertilizer helps the millet grow. If it does, he will apply the knowledge he has learned and add fertilizer to both plots next season.
>
> *Monitoring by a Data Safety and Monitoring Board (DSMB).* A mother asks her daughter to make a meal. As the daughter cooks the meal, the mother opens the pot to check if all is going well. When the food is ready, the mother tastes the food before serving the family. Although the daughter (the research team) is cooking the meal (running the study), the mother (the DSMB) is there to make sure the food is cooked properly.
>
> *Different strengths of the same product.* When one part of a trial that was testing a higher strength of the PRO 2000 microbicide gel was stopped, many people could not understand why a lower dose might work, when a higher dose was ineffective. Investigators began using the analogy of brewing a good pot of tea—a popular beverage in most of Africa. They explained that four tea bags will make the tea taste bitter, whereas tea made with one bag tastes better.
>
> *Protocol.* A study protocol is like a recipe. Just as a recipe provides a list of ingredients and the instructions for preparing a dish, research protocols provide all the elements (product, population) and the plan (study design) for carrying out a study.

Translate scientific concepts into local languages. Even high-level stakeholders who speak English will appreciate hearing news in their own language. When briefing national government officials, consider providing background materials not only in the official national language, but in the main local language. When translating technical terminology into local languages, allow enough time for the translation and back-translation of important materials.

III Demystifying statistics

The use of numbers can be challenging when you want to communicate scientific information. Statistics are often misreported or misinterpreted by journalists and the general public. Follow these rules to help them understand your study:

- Simplify numbers. Instead of saying "51.2 percent," say "about half."
- Be careful with fractions and proportions. For example, if you say, "A vaccine reduced risk by one-third," many people jump to the conclusion, "That must mean that two-thirds of people in the study got infected!"
- Use numbers and numerical comparisons that people can relate to their own lives. For example: "Three out of four women of childbearing age in Province Z told us that they currently do not want to get pregnant but they have no way to control their fertility."
- Know how to explain common statistical terms.

Consider these examples:

Statistical significance
Short description: If a result is reported as "not statistically significant," it means that the finding could be due to chance rather than a real difference between groups.

Longer explanation: When researchers say that the difference between two groups is not statistically significant, they mean that, given the number of people in the study, they cannot be confident that any difference observed reflects a true difference between the two groups.

This does not mean that there was no difference. It means only that any difference observed in the sample might be the result of chance. Scientists tend to say that a difference is not statistically significant if the possibility that the difference is merely due to chance is greater than 5 percent.

Confidence interval
Short description: the range of values within which the true value is likely to be; the margin of error for a result.

Longer explanation: Because a trial must limit participation to a subset of a much larger populace, it can only provide a result that is an estimate of what the true effect would be in the broader population. To assess the accuracy of this estimate, one must look at the confidence interval, which provides the range within which the true effect is likely to lie. The narrower this range, the more certain researchers are that the estimate is close to being accurate and that the same result would be seen again if the trial were repeated. As such, confidence intervals

are important for fully understanding the strength and reliability of the result, even one that is statistically significant.

Trials typically use a 95 percent confidence level (95% CI), meaning that there is a 95 percent chance that the true result lies within the interval. For example, if a trial demonstrates that a product reduces HIV infections by 40 percent, and the 95% CI is 22 percent to 68 percent, there is a 95 percent chance that the true effectiveness of the product is somewhere within that range.

Elizabeth T. Robinson/FHI

Explaining statistical concepts in a clear way is one of the greatest challenges of communicating about science to lay audiences.

Incidence and prevalence
The difference between these terms can be confusing.

Incidence refers to the number of **new cases** of a disease or condition in a specified time period—for example, the number of people who acquired an illness in a certain region within the past year. Incidence is often expressed as a percentage. The term is usually used for comparisons, to describe whether the new cases of a disease are increasing or decreasing.

A researcher might say that the incidence of malaria in community X has risen because over the past 12 months there were 500 new cases of malaria in the community, whereas there were only 400 new cases in the previous year. If X community has 10,000 people, the incidence of malaria would be 5 percent (500/10,000).

Prevalence refers to the total number or proportion of **old and new** cases in a specified time period—for example, the total number of people in a region who have an illness at the moment. For a chronic infectious disease, it would include people who are newly infected and people who have been infected for several years.

Prevalence is often expressed as the number of cases per 100,000 people. A researcher might say that the prevalence of HIV in a city of 1 million people is 5,000 per 100,000 (or 5 percent) because their estimates suggest that 50,000 people in the city are currently carrying the virus.

It should also be noted that the incidence and prevalence in a community can be very different. For example, a community may have a high prevalence (i.e., many people living with HIV) but a low incidence (i.e., very few new infections are occurring, perhaps because of successful prevention and treatment programs).

Box 8.6. Present scientific results in simple, clear terms

By Dr. Kawango Agot, Director, Impact Research and Development Organization, and Principal Investigator of the Bondo, Kenya, site of the FEM-PrEP trial

It is so important to convey research results clearly and simply. Concepts like partial efficacy can be particularly confusing. This is something I have witnessed many times. People are very creative in the way they apply math! For example, if a given treatment is found to be 50 percent effective, some people might interpret this to mean that all they need to do is take double the recommended dose and they would be fully protected.

In 2007, I was part of a research team that published a scientific paper showing that medically performed male circumcision is safe and can reduce men's risk of HIV infection during vaginal sex by about 60 percent (Bailey and others 2007). Our study was one of three that found similar results. The findings were exciting, but explaining them has been a challenge. Everyone talks about male circumcision providing 60 percent protection, but not everyone understands what it means. Our attempts at explaining this statistic have revealed gross misunderstandings. One interpretation we often hear is that if you have unprotected sex with an infected partner ten times, six of these times you will not get HIV. Another interpretation is that once a man is circumcised, it is okay to have sex with infected women as long as he stops or uses a condom after the sixth one.

After we announced the study results, our research team held numerous dissemination meetings with the media. We found in one media training workshop that the slides we were using were difficult for journalists to understand. One journalist dismissed the results as invalid because the percentage of protection was not exactly the same in all of the studies—reducing the risk by 51 percent in one, 59 percent in the second, and 60 percent in the third. To correct this misunderstanding, we took great care to emphasize that even though the results appeared slightly different in each of the three countries where the research was conducted, the difference was negligible and could be explained by differences in populations targeted by the studies, not differences in the effect of circumcision on HIV infection.

Michael Stalker/FHI

After three randomized clinical trials showed that male circumcision provides men partial protection against HIV infection, the Government of Kenya decided to expand male circumcision services.

How we train our community educators to explain partial protection can also be useful when explaining it to journalists: Everyone who engages in unprotected sex has a chance of getting HIV whether they are circumcised or not, but men who are circumcised have a lower chance of getting HIV than do men who are not circumcised. We explain that in the research studies, circumcision prevented 60 percent of the infections that would have occurred if the men remained uncircumcised. In other words, 60 percent of all the infections that occur in men who are not circumcised would be prevented if those men were circumcised. For me, this experience with drastically inaccurate interpretations of scientific research has emphasized how important it is for researchers to take the time to make sure they are communicating their results simply and clearly.

IV Five ways to avoid misunderstandings

No one can guarantee that all audiences will understand your trial. However, here are five things you can do to limit misunderstandings or misinterpretations of your study:

1. Limit the use of acronyms.
Most people will not be familiar with the acronyms you use in your work. If you must use an acronym, be sure to spell out the complete term on first use.

2. Use respectful language.
Research protocols often use terms that carry scientific value but may seem dehumanizing to nonscientists. For example, scientists sometimes refer to people who participate in a clinical trial as subjects. Use the words participants or volunteers to describe people who enroll in trials. These terms honor their willingness and effort to be involved in the trial.

3. Use neutral, straightforward language.
Terms such as target group and control arm can be confusing or trigger negative responses. Other terms—such as seroconversion—are too technical for lay audiences. See Box 8.7 for alternatives.

Box. 8.7. Speak in ways that emphasize the human face of trial participants

Our study targets sex workers. ▶	Our study enrolls sex workers.
Fewer infections were found in the experimental arm. ▶	Fewer infections were found among community members who received the experimental drug.
Many subjects were noncompliant and deviated from the study protocol. ▶	Not all participants used the study product as directed.
Ten percent of subjects seroconverted during the trial. ▶	Ten percent of the participants became HIV positive during the study.
We censored women who became pregnant during the trial. ▶	The analysis of HIV infections did not include participants who became pregnant during the trial.

4. Use consistent language.
Many study products and interventions have multiple names, which can cause confusion. For example, the drug Viread is also known as tenofovir, and some people refer to pre-exposure prophylaxis (PrEP) as an oral microbicide.

When introducing a new product or concept, it is important to refer to it consistently with the same name to avoid confusing people. It may also be helpful to point out the other terms that may be used to describe the same thing (such as Viread and tenofovir).

5. Avoid promising more than you can deliver.
Research has no guarantees, so you should present realistic timelines and expectations.

Use the conditional tense—with words such as could and might—when you communicate timelines and possible scenarios. Temper your description of the study's goals with the realities of scientific research. Be positive about your research without overstating its potential.

For example:

- We hope to release our results next December.
- If this product works, it might help to save millions of lives.
- If the government approves this intervention, we will be ready to launch a new program.

Similarly, be conscious of the many interpretations of the terms you use. In everyday language, we tend to use many terms interchangeably—and words can mean different things to different people. For example, when talking about prevention, it is important to make a clear distinction between absolute protection—a product that prevents infection 100 percent of the time in 100 percent of the people—and partial protection—a product that reduces the risk of infection in some people.

Key points to remember

- The first step to communicating clear information about your scientific research is to take a step back and explain the big picture. Remember to outline the public health benefits and process of clinical research, contextualize the need for your study, explain its purpose, and address why this research is taking place in your particular community and country.
- Consider the scientific literacy, learning styles, and cultural context of your audiences when explaining clinical research. Incorporate creative techniques to connect with your audiences. Images, graphs, props, theater, analogies, stories, PowerPoint slides, role-plays, and songs are powerful communications tools that can help you explain and simplify complex scientific concepts.
- To limit misunderstandings, translate scientific terms into everyday language, avoid jargon, simplify numbers, and do not promise more than you can deliver.

Jennifer Heslop-Spencer/The Aurum Institute

Media strategies are an important part of your overall communications plan. Decide how you will involve news media before, during, and after the trial.

Chapter 9

Working with the Media

Media coverage can shape public opinion about a clinical trial and about medical research in general (Grimes 1999). Scientific research about HIV and other infectious diseases is often newsworthy, so you should expect media interest in your trial. In today's globalized world, a small story in a local paper can quickly escalate into national and international coverage through Web sites, online media, international television, and new social media formats. Similarly, international news is instantly available at the community level, where it can contribute to knowledge or cause confusion, concern, and misinterpretation.

The media can also influence funders, policymakers, and ethics review committees. Accurate media coverage of an issue can educate and inform potential participants and partners, bolster public support for your trial, and advance the public health agenda. Inaccurate or inflammatory news coverage, on the other hand, can spread rumors, sideline research, and even scare government officials away from approving research that might attract controversy.

Your overall communications strategy (see Chapter 3) should include a component that describes how you plan to work with the media before, during, and after completion of your trial. It is important to build relationships of trust with key members of the media and to understand their role in translating science to the public.

In this chapter

Julio Sandoval

Wila Frias (left), lead counselor at the Asociación Civil Selva Amazonica, is interviewed about the iPrEx trial and HIV prevention.

I Understanding the media

Most people—be they politicians, policymakers, funders, or trial participants—get much of their news and information from the popular press. An understanding of how the media operates is the first step to learning how to communicate clearly and effectively with

journalists. This, in turn, increases the likelihood that the reports about your research will be accurate and informative, and it helps to frame the public discussion in a constructive way (Kampen 2000).

Guideline 1. Researchers and journalists have different goals. Journalists need to come up with stories that will grab public interest and often must publish them within days, if not hours. Researchers ask a question and typically spend years systematically looking for evidence—possibly finding an inconclusive answer. As a scientist, you can help journalists meet their needs and yours by helping them to write accurate stories about your trial. (See Box 9.1.)

At CAPRISA we involve the media in whatever we are doing, so the media can be one way of disseminating information. We know that if you don't involve the media, it may be difficult for you. They might think that you are hiding something… What can I say? Bad stories sell better. People like to read bad stories.

You have to involve them from the beginning. They have to understand what is happening. What is happening when these people enroll in this study? What drug is being tested? How is it going to be conducted? They have to have correct information.

—Mukelisiwe Mlotshwa, Research Nurse, CAPRISA, Vulindlela, South Africa

Effective media relations begin with understanding the goals and limitations of journalism. Professional journalists are bound by:

- Autonomy (journalistic independence)
- Media deadlines, extreme time pressures
- The use of multiple sources for balanced reporting
- A need to attribute facts and quotes
- A need to check the facts
- A need for information to be condensed
- Competition among media—they need to be first with the news or get an exclusive

Desmond Ajoko/FHI Nigeria

Former U.S. President William Clinton has been instrumental in helping reduce prices for HIV drugs in Africa.

Box 9.1. News media goals versus trial site goals

Media goals/functions	Trial site goals	How to reconcile
Report the news and inform the public; entertain and persuade	Educate communities about the issue, product being studied, or the trial	Write materials showing the human face of the issue, provide a news hook that brings in a community perspective
Sell papers or advertizing time	Undertake a trial efficiently and ethically; gain visibility for the institution or the issue studied	Offer compelling quotes, an interesting angle, and eye-catching photo opportunities from your site or an event
Reflect the views and opinions of society	Change society by developing new tools to prevent or treat disease, or new public health interventions	Demonstrate that research teams and opinion leaders care about big issues like justice, ethics, and health
Focus on short-term or high-profile events	Focus on longer-term health goals; build long-term research literacy in the community	Suggest story angles that link your research or main message to a current event or to a timeless health issue such as maternal mortality
Present a number of varying opinions	Present accurate messages that convey the importance of the research and the issue studied	Listen to concerns; calmly but directly address misinformation or misrepresentations; communicate science clearly
Seek the truth	Provide an accurate view of a continuously changing trial or evolving scientific issue	Contextualize research to promote understanding of complex issues

Source: Contrast between mass media and public health goals. In: Nelson DE, Brownson RC, Remington PL, Parvanta C, eds. Communicating public health information—a guide for practitioners. Washington (DC): American Public Health Association; 2002.

There are many reasons why the press may want to talk to you. For example:

- They need background information on a subject.
- You work on issues that are currently making the news.
- They need to quote an expert to add credibility to their story.
- They are looking for details about a crisis situation related to your organization (Hurt 2004).
- They may even want to write a negative story and use your comments to legitimize their perspective.

Box 9.2. Have a clear message to tell us

By Kanya Ndaki, Deputy Editor of PlusNews, Integrated Regional Information Networks (IRIN), United Nations Office for the Coordination of Humanitarian Affairs

There is definitely a hunger for information about clinical results among the public. Researchers sometimes mistakenly assume that their work isn't necessarily of interest to the average person. But trials are conducted on the ordinary man on the street. Trial participants are ordinary people. So it's important to know how these trial results affect us, what the implications are.

As a researcher, however, you have got to have a very clear message. It's no use inviting a journalist to a clinical site to speak to participants if you're not clear about what it is you want the journalist to take away with them. You've got to communicate your message effectively or else the journalist can come in, see these women as "guinea pigs," and interpret the trial completely differently.

Why you may want to talk to the press

Media play a critical role in your communications efforts. Responsible journalists, like responsible scientists, take their role very seriously. Scientists and journalists both seek knowledge and want to communicate their findings to the public.

Journalists can help scientists:

- Demonstrate the benefits of particular public health policies
- Encourage health policymakers to take new data into account when revising practice guidelines
- Reassure the public and address rumors (Shepherd 2005)
- Increase community access to information on health innovations
- Encourage community members to participate in a study or health program
- Articulate obstacles to health services
- Model healthy behaviors such as responsible parenthood (Smith 1995)
- Spur greater allocation of funds or government support for research on the topic you study

For these reasons, researchers should look for opportunities to work with the news media.

Guideline 2. Scientists can help to frame stories about clinical research. All stories are "framed" in a particular way. When a journalist writes a story, he or she takes a particular angle and frames the story to reflect certain themes. For example, a story about research on childhood immunizations could have a public health frame (immunizations save lives), an exploitation frame (outsiders are experimenting on our children), or an economic frame (preventing illness saves money in the long run).

Remember that how you frame a story should be grounded in reality. Learning how to frame a story is a valuable skill, but if your frame is merely spin—telling the story in a one-sided way to promote yourself or some agenda—your story will lose steam fast. For example, if your highly anticipated study results show that a promising new vaccine did not work, professional reporters will see through efforts to frame the results in a positive light.

The community of Vulindlela, South Africa, one of the sites of the CAPRISA 004 tenofovir gel trial.

Elizabeth T. Robinson/FHI

Box 9.3. Giving journalists the right information at the right time

By Salim Abdool Karim, MBChB, PhD, Director of CAPRISA, Nelson R Mandela School of Medicine at the University of KwaZulu-Natal, South Africa

I did my first microbicide clinical trial in 1994. Fifteen years later I'm still learning. One thing I've gained in my experiences is that the media—particularly print media and the radio—are amazingly powerful allies. They really have such an important role to play in informing and in educating people about HIV/AIDS.

We shouldn't let the occasional blip sully any of that relationship. They do a superb job. Our task as researchers is just to ensure that we provide them with the kinds of information that contribute to improving the public's understanding of what we're trying to do and where we're trying to go.

As a scientist, I know we have breakthroughs all the time, but they are often miniscule. They are barely a single step of one of the four legs of a tortoise. You can't be going around all the time to the newspapers and saying 'This is really newsworthy.' Rather, you have to wait for there to be big news and something worthwhile putting in the news.

Be aware of the underlying narrative in media coverage about the health issue you are studying. Position yourself so that you can guide journalists toward frames that will help them portray your study accurately, while satisfying media criteria for newsworthiness (see Box 9.4).

Box 9.4. What makes a story newsworthy?

Journalists and editors use a set of criteria to help them decide what is newsworthy—information, topics, or events that are interesting enough to report to the public. A subject is often considered newsworthy only if it meets at least two of the following criteria:

- **Timing:** Is the story providing brand new information? Is it current?
- **Proximity:** Is the story local?
- **Uniqueness:** Is the information distinct or unusual?
- **Significance:** Are many people affected? Does the information concern people personally?
- **Timeliness:** Is the material being released at a conference or some other event?
- **Permanence:** Is it timeless or enduring (topics such as adolescent pregnancy)?
- **Prominence:** Is the event or person well known?
- **Context:** Does your story relate to bigger issues, such as national health priorities?
- **Human interest:** Does the material inspire human interest, sympathy, or humor?

Guideline 3. Be alert for negative coverage. Pay attention to the emotional content—especially fear, anger, skepticism, or dread—of recent media coverage on your research subject. For example, if you were about to begin a trial and saw this quote in a local paper, consider how it would it affect your approach to the local media:

> "The prostitutes of Cameroon live like dogs, but some of them have been offered something that's worse: the life of a laboratory rat, without much compensation, without much explanation, and, above all, without any guarantee that they'll come out of it alive or at any rate as healthy as they were before they were recruited (Ramazzotti 2005)."

The exploitation frame employed by this reporter plays on readers' emotions and sense of outrage. The specific messages conveyed are that research is inherently exploitative, and that voluntary participation in clinical trials among vulnerable populations is impossible (Mack and others 2010).

To counter a negative frame, one must address the audience's underlying feelings, while providing an alternative perspective. You might point out, for example, that scientists who are dedicated to improving public health are working with the community to prevent HIV and save lives among those most affected by the pandemic.

Guideline 4. Reporters can be important sources for scientists. Although scientists can be sources for reporters, sometimes the roles are reversed. You can glean important information by paying attention to the questions that reporters ask.

For example, if a reporter starts probing about rumors that blood draws (such as samples taken for HIV tests) are being sold or used for satanic rituals, it could prompt you to explore whether similar ideas are circulating in the community where you are recruiting participants. Likewise, if a reporter's question indicates confusion about basic scientific concepts, it can alert you to pay special attention to explaining those concepts clearly in future interviews with local reporters, as well as in discussions with community stakeholders.

YouthNet/FHI

Reporters' questions can provide insight into issues that need clarification in the wider community.

Box 9.5. Beware of the media's trigger vocabulary

By Natasha Mack, PhD, Linguistic Anthropologist, Family Health International

Repeated messages do not need to be supported by evidence to be believed by the public. Once people have formed a strong opinion, new evidence is generally made to fit, contrary information is typically filtered out, ambiguous information is interpreted as a confirmation, and consistent information—even through the repetition of inaccuracies or misinformation—is seen as "proof positive," making such messages virtually impossible to correct later (Shepherd 2005).

Words and phrases used repeatedly to talk about a given theme can help frame or shape the perception of a trial's ethics, often tapping into an underlying cultural narrative or discourse on research exploitation. Media persistently use science exploitation and negative discourses on HIV as "frames" for their stories, drawing on familiar stereotypes, interpretations, and storylines in ready-made formulas (Kitzinger 2000).

For example, media coverage in 2005 on the oral tenofovir trial in Cameroon tapped into public emotions about exploitation through the use of trigger phrases such as "guinea pigs" that instantly tell audiences to interpret a news story as yet another exploitation narrative. Our search of the term "guinea pig" in PubMed (1950 to present) and other databases located academic and news articles laced with similarly charged vocabulary, including "torture," "Nazi Germany," "conspiracy," and "Tuskegee." In using trigger vocabulary, the media and the HIV activists it quoted aligned the news stories of the Cameroon trial with other narratives about global exploitation in clinical research (Jones 1993).

Researchers who work in places where the media use negative frames or trigger words should make it clear that they are working for the benefit of trial participants and others at risk. Speaking with candor and integrity about their motivations for improving public health is a powerful antidote to negative messages.

Adapted from: N Mack et al. The Exploitation of "Exploitation" in the Tenofovir PrEP Trial in Cameroon: Lessons Learned from Media Coverage of an HIV Prevention Trial. Journal of Empirical Research on Human Research Ethics (JERHRE). In press, June 2010.

By speaking with reporters on a regular basis, you can stay current on what the media are paying attention to. Their questions often reflect society's latest interests and trends. You can strengthen your communications by adapting your key messages to address issues or draw comparisons to topics that are of interest to reporters.

Whenever I do media trainings with our researchers, I prepare our team to answer questions in the context of what's happening currently in our field. For example, when we released trial results just after the former South African Health Minister passed away, we anticipated that media would ask questions about this timely event. We prepared messages that linked her legacy to the need for ongoing HIV research, allowing us to respond to current events while staying focused on our key messages about the study results.

—Will Mapham, Communications and Advocacy Director, Reproductive Health and HIV Research Unit, the University of the Witwatersrand, South Africa

II Developing a media strategy

Your media strategy addresses how and when you deliver your key messages and other information to members of the press. A media strategy is just one part of the overall communications plan for a trial (see Chapter 3). Your media strategy will:

- Identify how you plan to involve news media before, during, and after the trial, and which approaches you plan to use (see Box 9.6).
- Outline standard operating procedures (SOPs) for interactions with the media (see section III of this chapter for more on media SOPs).
- Identify key messages to convey to different types of media.
- Specify plans for monitoring media coverage.
- Outline processes to respond to misinformation in media coverage.
- Establish when to proactively seek news coverage.

Lisa Rossi/MTN

Prof. Salim Abdool Karim addresses news media at the Microbicides 2008 Conference in New Delhi, India.

Box 9.6. Approaches for sharing information through news media

Approach	Purpose	Tips
Press conference/ media briefing	• Announce a new discovery, publication, or launch of a major new program. • Draw attention to an urgent situation.	• Invite journalists from many different outlets, including community radio, print publications, Internet sites, and television programs. • If the press briefing is at your study site, consider including a tour of the facilities after the briefing. Visuals are important, especially for television news media. • Identify key spokespersons available for interviews, since many journalists will want to do follow-up interviews. If your site community speaks multiple languages, make sure to include spokespersons fluent in those languages who can speak with local media. Consider including respected community members and other third-party validators.
Press kits	• Provide short materials and background information for a story. The press release is the main document, which can be supplemented by fact sheets, Q&As, visual aids, reports, and biographies of experts.	• Prepare press kits for journalists whenever you do a press briefing or invite journalists to attend an event. Keep the information concise and easy to scan. If you are launching a lengthy report, include copies of the executive summary only. • When possible, translate key materials (press release, fact sheets) into the local language. This can prevent misinterpretation of scientific terms and sensitive issues. • Include contact information for spokespeople in case reporters have follow-up questions.
Telephone calls to reporters or editors	• Alert reporters to a breaking news story, such as upcoming trial results or other announcements. • Follow up on a press release or invitation to an upcoming event. • Inform reporters or editors of errors and ask for a correction to be printed.	• If possible, give reporters adequate notice. For example, do not wait until the day before your study releases results to contact journalists. • Do not assume that because you sent a press release the reporter has seen it or has had time to read it. • Always leave a telephone number where they can reach you, preferably both an office and mobile number. • Start by asking if they have time to talk. If they are on deadline and busy, ask when you can call back. • Be prepared to say everything you need to say very quickly—get right to the point.

Press release/press statement	• Provide the key elements—What, Why, When, Where, and How—of a story. • Offer reporters a news hook, as well as compelling quotes, statistics, or concepts to help frame the story. • Use proactively for announcing new published data, trial results, or a surprising development that affects the field as a whole. • Use to support or respond to an announcement or situation in the field. • Promote transparency of the research, especially when an unexpected change or trial closure takes place.	• You can distribute press releases many different ways depending on whether and how much media you are seeking. Consider using a wire service if you want to make sure many media outlets see your statement, or opt to post it on your organization's Web site if you are not actively seeking coverage. • A press release should be factual. Never overstate or oversell. • Always be sure to proof read your press release for grammatical mistakes or misspelled words.
Opinion pieces/ op-ed columns	• Express a strong opinion about an issue with local impact. These are typically written and signed by a prominent person or expert or by a group of organizations.	• News editors are looking for op-ed pieces that say something new or provide a fresh perspective.
Letters to the editor	• Reinforce the importance of a published story. • Present an alternative opinion than the one put forward by the person quoted in a story • Point out and correct an important mistake.	• Keep letters short, concise, and fresh. Do not repeat and reinforce negative information. • Be professional, especially if you are responding to an inaccuracy or inflammatory accusation. • When correcting an error, consider whether a telephone call would be more appropriate and effective or if both responses are necessary.
Social media	• Reach out to new influencers and global stakeholders through online media tools and sites, including blogs. • Share information, especially on topics where you would like feedback or to engage in an online dialogue. • Provide short updates that do not require much detail or explanation.	• Social media, such as Facebook and Twitter, make it easy for readers to share your content with others in their networks. If your stakeholders are online, you may want to be as well. • Be aware of the risks involved and be careful to monitor any social media tools you use, as naysayers are just as likely to engage as supporters.

To develop a media strategy:

Step 1. You need to know how the people you might want to reach receive information. Reviewing your environmental scan should provide you with this information and can inform your media strategy. You should seek to answer the following questions:

- How do most people in your trial community get news—from local sources (such as newspapers or community radio shows) or from other media outlets (such as national or international television news)?

Clinical trial sites are increasingly using social media to help reach potential participants and other stakeholders involved in the research movement. For the HIV Vaccine Trials Network (HVTN), sites such as Facebook are valuable tools for keeping their constituencies informed and engaged.

Tweets (at left) from the Twitter Web site are used to convey information on the Conference on Retroviruses and Opportunistic Infections.

- Which newspaper do national policymakers read?
- Do international advocates who follow your study rely on Internet blogs and postings for updates?

Step 2. Identify health journalists and keep an updated media list. Identifying the journalists who write about issues relevant to your trial is very important. To do so:

- Read the local and national newspapers, and take note of which journalists cover health and related issues.
- Review the journalists and media outlets in your stakeholders' lists and identify any gaps.
- Identify local radio and television reporters who cover health issues on their shows.

Step 3. Know which media outlets can best address your communications goals. For example, if you want to update policymakers, a national newspaper may be the best way to spread your message. On the other hand, if you are targeting young people, you may be better off approaching a television program or an Internet source. To reach a rural community in local languages, you might try grassroots media (see Box 9.8). Consult Box 9.6 for general guidance on what type of media approach might be best suited for a particular situation.

Box 9.7. Characteristics of different types of media

Type of Media	Characteristics (reach, audience, accessibility)
Print media—newspapers and magazines	• Influential people, such as politicians and policymakers, will often turn to print media for their news • General public
Radio	• Available to a broad audience • Suitable if you want to communicate local information • Has an entertainment function but is also a venue for serious discussions • Strong ability for interaction with call-in shows
Television	• May be a medium for serious news or for entertainment, depending on the outlet; some talk shows and news broadcasts are intended to entertain rather than to inform • Not as accessible as radio • Requires strong visuals to be effective
Internet—online media, blogs, and social media	• Limited accessibility in developing countries • Can quickly disseminate (accurate or inaccurate) information globally

Step 4. Adapt your media strategy to each milestone in your study. Your media strategy will vary at different stages in your study. For example, the team may decide to post a press statement on your Web site for your study launch. The same team may implement a broader, more proactive media outreach effort to announce trial results, including contacting key media allies one-on-one or hosting a press conference.

Respect local circumstances when deciding on media strategies. For multisite and network-sponsored studies, remember that different sites may share a communications plan but decide on different media strategies. Coordinate, collaborate, and communicate with partners throughout the process—not only when you respond to a crisis.

Adapt your materials to fit your strategy—not the other way around. For example, if your site decides to invite local-language media to visit your site, make sure you have materials in the local language that are ready and available for them.

Dr. Morenike Ukpong, Coordinator of the New Vaccine and Microbicide Advocacy Society (NVMAS), uses a mix of approaches to communicate with advocates in Nigeria and elsewhere.

Elizabeth T. Robinson/FHI

Box 9.8. Using grassroots media

By Junaid Seedat, Former Senior Program Officer in Communication, Information and Education for the International AIDS Vaccine Initiative

Scientists don't always spend energy talking to the media closest to the people and the communities we're working with. South Africa has an incredible history with community radio, and yet rarely do you see people in new prevention technologies actually engaging community radio, community theatre, or community media. I think that if we want to have the media support our efforts, we need to focus on community media as well as mainstream media. As researchers, our focus tends to be on journalists we can take for coffee or out to dinner, those who are close to our homes and don't cause us any inconvenience. I think that the whole issue around guinea pigs and other sensationalist issues is based on the community members who just weren't well informed. Research teams need to train media spokespersons who speak the local language and invest in developing materials that are simplified while remaining accurate and respectful to community audiences. The best way to fight against sensationalism originating in communities is to use community-based media.

Step 5. Choose your messengers wisely. We trust news from people we identify with—make sure to use the right spokespeople for each audience and each situation.

Take context into account. In many circumstances, the site spokesperson can deliver a statement and talk with media directly. However, there may be times when it is most appropriate for an announcement to come directly from the sponsor or the trial's principal investigator, who may not be based at your site.

Recruit third-party spokespeople who have high-level standing in the community or who are unusual sources, so that people pay attention.

Box 9.9. Sample media monitoring grid

News outlet	Piece published/date	Comments
Nairobi Star (Kenya)	Nurses set to join circumcision team (4 Aug 2009)	Written by a reporter who attended media training event we organized.
Daily Monitor (Uganda)	Cost of male circumcision prevents wider use in Uganda (29 July 2009)	Balanced coverage, discusses our trial and quotes local leaders.
PlusNews (international)	Male circumcision brings Swazi men to clinic (5 Dec 2009)	Positive tone. Says 92% of men who seek MC agree to HIV testing

Step 6. Incorporate media monitoring. Monitoring the media coverage of your study and of the field in which you work is an essential element of any media strategy.

Each site should establish a process for tracking, monitoring, and sharing media coverage.

Monitor relevant local, national, and international media daily. Delegate someone to track information about the field in general, not only your study or specific area of research. Remember that all trials can affect each other, particularly if negative media coverage appears.

Keep in mind that editorials and letters to the editor are among the most often read sections of newspapers. If a highly inaccurate or negative piece is published, consider responding directly or ask colleagues with credibility in public health circles to do so.

Monitor a variety of sources, including list servers, social networking sites, and blogs. Ask close colleagues who read this type of media to alert you to any coverage of your trial. Although these sources generally have lower circulation than other types of media, inaccuracies can still circulate and spread misconceptions about your study.

Radio and TV can be challenging to monitor. At times, media interviews are only used days after being recorded, or they can be used multiple times for different stories. Whenever pos-

sible, try to get the full transcript or recording. This will assist in situations that may require a response, especially if you think you were misquoted.

To monitor international coverage of related research, consider setting up a Google News Alert (see Box 9.11). Subscribing to high-quality news digests, such as the Kaiser Daily HIV/AIDS Report, is another option for people with regular Internet access.

Your team should intensify monitoring efforts during times of announcements or major events in the field. Some days, few articles appear in the press, and the monitoring only takes a few minutes. However, when results are released, the press may be filled with stories about your trial or relevant trials. During these times, you should consider assigning more than one person to the task of monitoring media and pointing out inaccuracies. Another increasingly common option is to hire a local media firm to coordinate these efforts.

The local staff can be an invaluable resource in the effort to track coverage. For example, one clinical trial site investigator kept hearing about articles her staff had noticed in the newspaper. She implemented a policy that anyone who saw an article about the study should buy a copy of the newspaper, get a receipt, and bring both in for reimbursement. By offering to reimburse people, staff members became willing to bring in articles. This helped the study to improve its media monitoring efforts.

YouthNet/FHI

In many countries, community radio is a key source of information for community members.

Learn about the news cycle—the amount of time between the release of editions from a news outlet. The most common example of a news cycle is the daily newspaper, which is typically released early each morning. That 24-hour period between daily editions constitutes a news cycle. Pay attention to reprinted articles or the dissemination of adaptations of previously distributed material. Although a newspaper or radio story might originally appear in one source, it will likely travel to other sources if it is a compelling piece. For example, a story in a local newspaper may eventually show up in national newspapers, radio, television, or the Internet. This kind of redistribution occurs with both positive and negative coverage.

Respond to inaccuracies in the media, as needed. If you find inaccurate coverage of your trial in the media, contact the source and politely correct the information, without being condescend-

ing or defensive. Ask them to print a correction; if the article is online, have them remove any inaccurate information from their Web site.

Correcting information in a professional manner will help establish a relationship between you and the media source. Eventually, the journalist may start going directly to your research team for information.

Box 9.10. What every site should know about responding to Internet media

International online media coverage has quickened the pace and broadened the circulation of news about clinical trials, especially announcements about study results. While your site's main communications activities will be largely interpersonal in nature, you should pay close attention to online media coverage of your study. Start setting aside resources and time to monitor and respond to Internet postings. Here are some tips to get started:

Gear up. Sensational news coverage on the Internet can occur at any time of day or night. The communications and media point person for your trial site should have reliable access to the Internet, both at the trial site and from home. This may mean budgeting to purchase a laptop or telephone with Internet access, or identifying other ways to stay connected, such as having a reimbursement policy for using an Internet café during weekends and holidays.

Use your global networks to monitor media around the clock. When announcements or results are expected, make a plan with your partners across the world. Designate point people to make sure that media is being monitored 24 hours a day and that news coverage is quickly shared with your communications team.

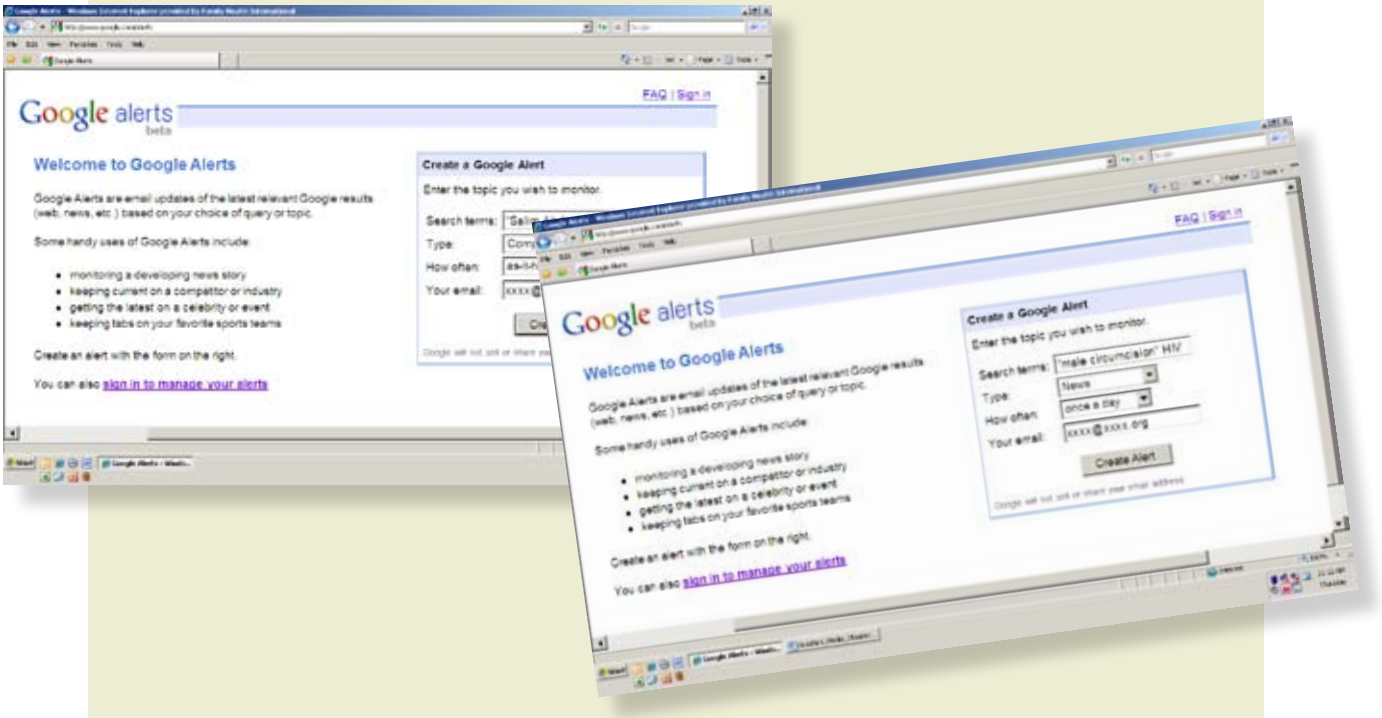
Respond quickly. Be prepared to respond swiftly to inaccurate or inflammatory coverage online on major Internet sites. Do not lose time writing something new. Adapt your key messages and prepared materials to quickly compose an online correction or response. Typically, it is not feasible or advisable to respond to small-circulation blog postings or defamatory Web sites—for example, to AIDS denialists or anti-research groups. However, if a negative blog has possible links to local news outlets, it is important to take these posts seriously. Even if you do not respond to the blog, you might want to consider what could be done locally to counteract the false claims being made. When negative postings are picked up by other online news outlets and spread widely, you will likely need to respond.

Call and correct errors. If an article is posted on a legitimate online news Web site, there should be an editor's contact e-mail and telephone number available. At first notice of an inaccuracy, fallacy, or breach of embargo, call the editor and ask for a correction or removal of the link, if appropriate.

Avoid character debates. If the coverage is a blog, social media, or list server posting, be careful about seeming defensive or engaging in a personal debate. Even if you or your professional work is personally attacked, remain formal and professional in your written correspondence. Refute the inaccuracies, use the facts from your existing materials, and direct people to your Web site or other high-quality resources for more information.

Box 9.11. How to set up a Google news alert

It is easy to set up "Google Alerts" that tell you of any new online media coverage. By entering key words, you can have Google automatically generate a list of current articles that are relevant to your study and deliver them to your e-mail in-box. You can set up multiple alerts if you want to be informed anytime there is news on the topics you select. Here is what to do:



1. First, go to www.google.com/alerts.
2. Under "Search terms," type in the name of the topic, person, trial site, or other item about which you would like to receive news. (Tip: When searching for a term with more than one word, use quotations for more accurate searching, such as "cholera vaccine.")
3. You can select "News" if you would like to receive only things posted to proper news Web sites. For other online sources of information, you can select "Blogs," "Web," "Video," or "Groups." Selecting "Comprehensive" will ensure that you receive notification when your search term shows up on any of these online sources.
4. Select how often you want to receive notification.
5. Enter your e-mail address. (Note: you do not need to have an account with Google to set up Google Alerts.)
6. Log in to your e-mail account to verify the request from Google Alerts. You will start receiving news immediately.

Communicating via broadcast media is a skill that requires cultivation and practice. Reviewing tapes of practice interviews can be very helpful.

Jennifer Heslop-Spencer/ The Aurum Institute

III Responding to media requests

Your team should establish a basic protocol for handling media inquiries. Some teams may find it helpful to create a media SOP to make sure that the staff handles media inquiries in a consistent manner (see Appendix 9.2). Other teams may prefer to have a less formal policy regarding media inquiries.

Keep the following things in mind when developing your media SOP:

- Designate one or two site-level staff members to handle all media inquiries. Identify a back-up person for times when the designated staff members are not available.
- Assign roles and responsibilities of those who will be responsible for interacting with the media. List the steps that the administrative staff should take if a reporter calls. Decide whether the designated contact staff member or spokesperson will schedule media inter-

views. Determine who will facilitate interviews with external allies and third-party experts when journalists ask for sources they can contact.

- Clarify your site's policy on media interviews with trial participants and Community Advisory Board members and your position on allowing reporters to access the site for tours.
- Create a checklist of questions to ask journalists. This short list should help the spokesperson gather relevant information about the reporter and the article to be written, such as the name of the publication, details about the interview, and the deadline. In some cases, the spokesperson may want this information before agreeing to commit to an interview.

Box 9.12. Questions to ask journalists

About the journalist

- ☐ Name? _____
- ☐ Who do you work for? Publication? _____
- ☐ Office number / mobile number? _____
- ☐ Email? _____

About the story

- ☐ What's the story about? _____
- ☐ Who do you want to interview? [*Investigator, community member, participants*] _____
- ☐ Who else are you interviewing? _____
- ☐ Do you have/need backgrounder information? _____

Logistics

- ☐ What's your deadline? _____
- ☐ What times are good for you? [*If scheduling for someone else, get a few options*] _____
- ☐ If TV or radio, what's the format? Live or recorded? _____
- ☐ Call-in questions? _____

- Use Google to find out information about the journalist. Google is a good tool to help you find out some quick background about the journalist and his or her publication. By conducting a simple search, you can often find articles the journalist has written, the reputation of their publication, and other relevant details (see Box 9.13).

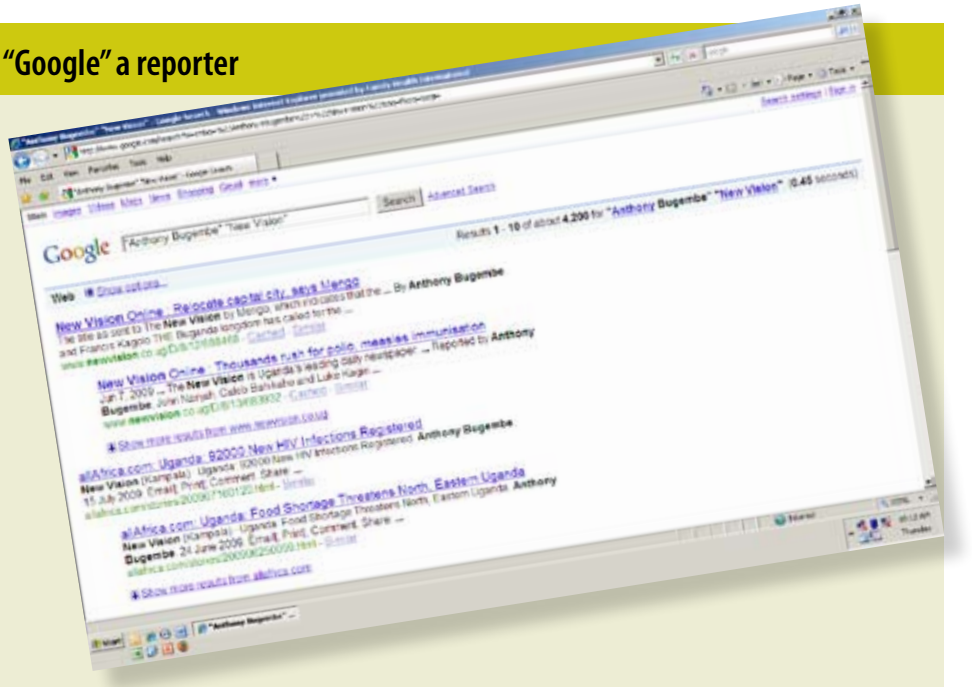
Once you have written your SOP for media requests, put it into action whenever requests come in.

Brief the spokesperson. If the person who handles media inquiries is not the official spokesperson, make sure that he or she provides background information about the journalist to the spokesperson.

Inform the sponsor or network communications team about media inquiries. Determine whether your site has a protocol in place that explains when to notify network- or sponsor-level communications staff members. Some sponsors want to be informed when international journalists contact a site, whereas others may wish to be notified about all media inquiries.

Learn the lingo. Just as scientists have a specialized vocabulary, journalists have a language of their own. Knowing some of this terminology can help you communicate with reporters, especially when they call with a request for a quick "sound bite" or ask you to speak "off the record." (See Box 9.14.) If you do not fully understand what the journalist is saying, ask for a clarification before you respond.

Box 9.13. How to "Google" a reporter



Follow these steps for using Google to find information about individual journalists:

1. Go to www.google.com. If your country has a local Google home page, use that instead. For example, if you are based in Zimbabwe, use www.google.co.zw.
2. Enter the name—in quotation marks—of the reporter who just called to request an interview. If the first results are not returning news stories, try also entering the name of the journal.
3. Click on recent entries to get a sense of the journalist's general tone, accuracy, and command of scientific language. This will help you know how much you will need to simplify explanations of research processes or concepts.

Box 9.14. Important terminology related to news media

B-roll	This is film footage that can be used as background images for television news or films. It is useful to have high-quality film footage of your clinic or project available, especially in the case of a major announcement when a television news program may request b-roll to accompany a story on your study for the nightly news.
Deadline	Deadlines in journalism are strict and final. Unlike other fields, there are no extensions or second chances as the deadline means that the paper is going to print or the news is going on the air. When journalists say they are on deadline, respect their time frame.
Embargo	Scientific journals and medical conferences often have strict embargo policies that stipulate the date and time when information issued to the media may be released to the public. If news is under embargo, journalists cannot publish or air the news until the stated time. Embargoes can be useful for both journalists and scientists, because they allow key journalists to access information prior to its public announcement. This provides them enough time to do a good job reporting the story without ruining the surprise. Reporters who regularly cover science and medicine generally respect embargoes. Embargoes are a professional standard in certain contexts, but mean little in other settings.
Exclusive	An exclusive interview or story means that you have established an understanding with a particular journalist to not share the story with any other journalists, at least until after the story is published. Providing journalists with exclusive information can be useful in certain situations and help foster relationships based on mutual trust and respect.
Frame	How the story is presented—who defines the issue and what views are expressed.
News hook	Hooks are the components of a news story that make it interesting to the reader, such as immediacy, timeliness, controversy, effect on a local population, or dramatic human interest. When considering whether to pursue your story, reporters consider whether there is a news hook.
"No comment"	This is a dangerous phrase said to reporters in moments of panic—try to avoid it. Saying "no comment" often suggests that you are either hiding something or you are uninformed and incompetent. Instead, turn a question around and respond with a key message or simply say, "This is not my area of expertise . . . I can only speak about my work on . . ."
On/off the record	These terms can mean different things to different reporters. However, you should assume that everything you say to a reporter is on the record, meaning that it could be used in an article and attributed to you. Do not be tempted to say things off the record. If you cannot say it on the record, you really should not be saying it.
Pitch	To suggest a story idea to news reporters, producers, or editors.
Sound bite	Short, attention-getting quote that communicates the gist of your message.

Adapted from: Bray R. 2000. SPIN Works! A Media Guidebook for Communicating Values and Shaping Opinion. San Francisco, CA: The Spin Project, Independent Media Institute.

There are times when a reporter may catch you off guard, for example at an event or conference. If a reporter asks to interview you, do not feel pressured to do the interview at that time. To manage an impromptu encounter:

- Determine the journalist's deadline and see whether you can arrange to be interviewed at another time, even if only 20 minutes later, so that you have time to organize your thoughts.
- Identify the topic of the story.
- Ask if the reporter has conducted any other interviews and with whom.
- Take some time to organize your thoughts and jot down your key messages.
- If possible, talk to others whom the reporter has interviewed and find out what questions the journalist asked.

IV Getting your message across

Several techniques can help you convey your message even when you are asked a difficult question. In these situations, take a deep breath and remember that you are the expert and that you alone control what you say (see Chapter 7). The following strategies can help you stay on message:

Bridging. Bridging is a transitional phrase that allows you to move the direction of the interview into your territory. Bridging words include: and, but, however, in fact, for example, because, and on the other hand. The following sentences provide some examples of the bridging technique:

- "That may have been true in the past; however, this is the way we are doing it today . . ."
- "We are very committed to involving people with HIV/AIDS in Community Advisory Boards. In fact, in the trial X, nearly half of our CAB was made up of HIV-positive women."
- "This new trial will break new ground in the field. For example . . ."

ABC technique. This technique builds on the bridging technique and can help you change the direction of the interview without completely ignoring the tough questions being asked. To use this technique, follow these three steps:

- *Answer* the premise of the question.
- *Bridge* to the most important issues.
- *Communicate* key messages.

By addressing the question even briefly, you will help move the interview on to other topics—where you guide it. (See Box 9.15 for an illustration of how to use this technique.)

Box 9.15. Interview techniques: using the ABC approach

A study testing Product X showed the product barely worked. Why do we need another study on it?

Answer the premise of the questions	**Bridge to the most important issues**	**Communicate key messages**
The previous study on Product X took place in two Asian countries and only included men who have sex with men.	It's important to test Product X in a number of settings and among different populations to determine if it can protect people.	Our study is testing safety and effectiveness of Product X in women who live in several of the countries in Africa most affected by HIV.

Flagging. Flagging uses phrases that emphasize the importance of your messages. They tell the reporter—your audience—what should be highlighted.

Box 9.16. How to get your message across using flagging

By Annette Larkin, Public Relations Consultant, CONRAD, Washington, DC

When conducting media trainings, I always tell people that if they learn nothing else, they need to take away how to effectively flag key messages during an interview. Why? Because there's nothing more important in an interview than getting your three or four key messages into a story, whether it's print, radio or broadcast. Despite what the reporter is asking, if you do almost nothing but repeat your key messages in a way that forces the reporter to listen, your messages will likely be included in the story.

Follow these guidelines before and during your interview:

- First, tailor your messages to your audience—think about who will read or listen to the story and make sure your messages are what they need to know, with the appropriate language.
- Make sure your messages are concise—if they are too long and hard to understand, the reporter may have difficulty using them in the story.
- Limit yourself to three or four key messages.
- Repeat these messages several times, throughout the interview. Repetition helps drill your messages in.
- Finally, use these phrases to introduce your messages:
  - "Let me tell you the three most important things you need to know . . ."
  - "The key issues are as follows . . . 1, 2, 3"
  - The main points are . . ."

V Being interviewed by the media

An interview is not a conversation. It is an opportunity to deliver a carefully crafted message about your work. Preparation is essential.

Prepare for interviews ahead of time.

- Familiarize yourself with the journalist and the media outlet. Do some research to learn about the other news stories they have written for print, radio, or television (see Box 9.13).
- Determine the format of the interview. If you are doing a radio and TV interview, find out whether the interview will be done live or recorded, and how long it will be. Short, live interviews do not allow for any retakes, while longer interviews that are recorded can be edited and, therefore, be much more forgiving.
- Know your key messages. Be prepared to reiterate these messages in as many answers as you can. Briefly respond to the question, then bridge to your key message (see Chapter 7).
- Know what you want to say in advance, and prepare compelling quotes. Reporters look for quotes from scientists that summarize the impact of a research finding or policy decision and why it is important. Describe in short sentences what is at stake. Explain in easy-to-understand language what this discovery means for our understanding of the disease, the causal agent, and public health.
- Do a mock interview with a colleague. Being able to practice your message before the interview can boost your confidence and help you feel prepared to answer any question that may come your way.
- Check the news to make sure you know about any late-breaking events that might affect your remarks.

Give a clear and memorable interview.

- Be direct. Keep your answers short, simple, and to the point.

Media training can help prepare trial spokespersons to communicate effectively with reporters in crisis situations.

Trial staff from the Africa Centre in Mtubatuba, South Africa, practice communications skills during a media training.

Deborah Baron/PATH

- Do not use jargon or acronyms. Describe your project in language that anyone can understand. Assume that the reporter and his or her audience know very little about clinical trials.
- Use active language. "More than 3,000 women participated in the study" is stronger than "The study had more than 3,000 women." Drop the passive language and make your language move with active verbs.
- Stay professional. Your undisciplined remark can and will make news. If you do misspeak or have an outburst, deal with it immediately. You might say, "Let me clarify that . . . " Always appear confident and friendly. Never become angry or attack a reporter who is asking you questions. It is his or her job to dig for an interesting story.

Media training is important, and as scientists, we don't have enough of it. During the Phambili HIV vaccine trial, a colleague sat with me and grilled me about the details of the study. It was incredibly helpful. The questions she asked me were far harder than those really asked by journalists, so I felt prepared when it came time to talk to a reporter. Training and support of scientists is important, and individual coaching is incredibly useful.

—By Dr. Glenda Gray, MBBCH, FCP, Co-director, Perinatal HIV Research Unit, University of the Witwatersrand, South Africa

- Stay honest. Bluffing, exaggerating, or lying is a recipe for disaster. Do not say more than what you had planned. If you are asked a question that you do not know the answer to, you can say, "That is a very important question, but not within my area of expertise. What I can say is . . . " You can also suggest another source that may be able to respond to the question, or offer to find out and get back to the reporter.
- Represent your organization. Make sure that what you say is your organization's public position.
- Avoid accepting or confirming a negative question. For example:

  Q: "Don't you care about whether the women become HIV-positive?"
  This question implies that the questioner suspects you might not care. Negative questions are often asked when a negative answer is suspected. They are used to seek confirmation and agreement.

  A: "The safety and well-being of the women who volunteer for trials is our top priority. That is why we are conducting this HIV prevention research."
- Remember that the microphone or camera is always on. Do not use the phrases "no comment" or "off the record." If you do not want to see it on the front page of tomorrow's paper, then you probably should not say it.
- Talk to your audience, even if you cannot see them. If you are doing a radio interview in a studio or you are talking into a telephone and have never met the interviewer, stay animated and engaged with the conversation. People can "hear" a smile as well as a yawn.
- Pay attention to body language. Much of your message is conveyed through body lan-

guage, emotional tone, and attitude. Therefore, it is important to know when smiling is appropriate, and to avoid appearing smug, arrogant, defensive, or negative.

Follow up with the reporter. This is just as important as performing well during the interview. After an interview, you should:

- Send the reporter an e-mail, thanking her or him for the opportunity to talk about your study and offering to help clarify any remaining questions. Be sure to include your contact information.
- Report back to your communications team. Send a brief summary of the interview to the person on your communications team who is keeping track of media coverage. Include the reporter's contact information, any lessons learned from this interview, or tough questions you were unprepared to answer.
- Send news clips to the study coordinator, communications person, or principal investigator when the article is published. Consider sharing media clips with external stakeholders, such as donors.

React quickly to inaccurate information. This is critical, regardless of the type or size of the media outlet. If you do not address inaccuracies, the same misinformation may continue to resurface in unexpected places.

Box 9.17. Avoid being misquoted

By Dr. Daniel T. Halperin, Lecturer on Global Health, Harvard University School of Public Health

Many scientists are reluctant to talk to reporters for fear that they will be misquoted. This is a valid concern. Sooner or later, it will happen to everyone. However, this is not a reason to avoid talking to the media. There are several things you can to do reduce the chance of being misquoted:

- Conduct interviews over e-mail. This is becoming increasingly common, and it reduces the chance that you will be misrepresented, since your words are provided in writing and you can go back and check what you said.
- Ask reporters how you can help them be sure they get their facts right. Some reporters may offer to send you a draft, or the section that quotes you, or they may call and read to you parts of the story to be sure they have understood the topic correctly.
- Speak slowly and clearly so that you can be easily understood.
- Provide handouts with written information to make sure that the reporter is not relying only on the interview.
- If you think a reporter is not following your points, try to determine if the cause is confusion or deliberate misrepresentation. If you think a reporter is trying to spin your messages in a negative way, you could suggest credible allies in the field to talk with—who will support your work and back up your messages.
- After the interview, follow up by e-mail to reiterate points you think the reporter may not have understood.

Although these tips may not guarantee that you are never misquoted, they will go a long way in preventing misrepresentations.

To correct inaccuracies:

- Call the reporter or editor to request a correction. Online journals can be changed almost immediately. When you find a mistake in an online version of an article written for newspapers or magazines, contact the journalist quickly to request that the article be revised for purposes of accuracy before it goes to print. If it is printed, ask the journalist to print a correction in the next publication.
- Prioritize your corrections. If the article has more than a few inaccuracies, consider selecting the most important factual errors and highlight only those to the journalist. Many journalists will respond to a few errors but may choose to ignore a long list of things to change.
- Write a letter to the editor, or post a comment if the publication is online. Letters to the editor are typically among the most read items in a newspaper. When responding to misinformation, do not repeat the inaccuracy in your letter. Take a positive tone, and keep your letter short—about 150 words if possible. (See Appendix 9.3.) Sometimes it is a good idea to discuss matters with the reporter first.
- Call the paper and ask if you can write an op-ed piece. This is often a good strategy if the article is negative in tone but still factual. The editors may welcome the opportunity to publish a piece that takes a different approach to the same topic.
- Go on local and community radio shows to spread accurate information. Radio news often picks up inaccuracies from print media. Call the station and inform them of the error. They can change their script immediately, so the mistakes are not repeated. Additionally, you can ask for opportunities to speak on the morning or evening news program, where you can share correct information and take call-in questions from the community. This is an excellent chance to address rumors and misinformation, and to set the record straight.

Help reporters put a human face on research.

Pictured here is a young woman and child in Kibera, Kenya.

Jim Daniels

VI Helping journalists write good stories

Knowing what it is that journalists need to get a story published can help you get your views into print. The more you understand the objectives, limitations, and challenges that journalists face, the more you can help a journalist do his or her job better to write accurate and compelling stories.

Here are some tips to help journalists write stories that editors will want to publish.

- Provide an interesting story. Remember that journalists get many press releases everyday. Make yours stand out. Do you have an angle that will make reporters want to cover your story?
- Supply the reporter with several sources. One of the main principles of professional journalism is to provide accurate and balanced coverage of a story. At the same time, journalists are usually on tight deadlines and often appreciate any help with additional contacts who

can confirm a story, give them background information, or offer quotes as independent experts.

- Provide photos or ideas for visuals. Competition for space in newspapers and television news is becoming increasingly fierce. Think about the picture you want to see on the front page of the newspaper or on the nightly news. Try to frame your story with a powerful image that will carry a news article. For example:

  When the Global Campaign for Microbicides hosted an HIV Prevention Summit for Women and Girls in Johannesburg, South Africa, attended by the Deputy President, they wanted to make sure the media did not cover the story only from the government's perspective. To help frame the story, they invited 30 teenage girls from a local high school to attend and ask the Deputy President questions about how they could protect themselves as young women. The image of these young women gave the journalists powerful photographs and video footage for their media coverage.

- Provide sound bites. The more you can speak in catchy, short sentences, the more likely you will be quoted. Also, the journalist's job is much easier if she or he does not have to edit

Box 9.18. The importance of reacting quickly to inaccuracies in the media

If you respond to media inaccuracies quickly enough, you can ensure that online versions are corrected by the next day's edition. See below for an example of an overnight change in a story picked up by the Dow Jones Newswire. The "Repeat and Correct" version was published after the trial's communications team contacted an editor at Dow Jones Newswire, which then ran the correction.

Original headline: "AIDS Prevention Drug Fails Wider Tests"

"Repeat and Correct" headline: "AIDS Prevention Drug Studies Inconclusive"

your long sentences. Sound bites are usually one-liners that can include a quick metaphor, example, or a new analogy. They are not clichés, technical statistics, or quotes from other people.

- Provide a well-written and informative press release. A press release should be used only when the content meets news criteria (see Box 9.4). Put your most important information in the headline and the first few paragraphs. If reporters do not see a story immediately, they will stop reading before finding the news you wanted to share. (See Appendices 9.4 and 9.5).
- Consider adding a training component to your press events. Some sites have found it useful to invite journalists to attend a half-day briefing and information session before a press conference where an announcement will be made. These training opportunities give scientists the chance to provide an overview of how clinical trials work, background on specific interventions or research in the field, and context for the announcement to come. Likewise, it gives journalists, especially those new to health issues, opportunities to ask general questions about research and strengthen their scientific understanding more broadly.

VII Nurturing relationships with the media

Scientists can take an active role in communicating with the press by building relationships and becoming a trusted source. All reporters have sources—people who keep them informed so they can do their job. Becoming a reliable source should be one of your priorities with the media.

By developing a working relationship with a reporter, you create an open channel to update journalists on research in your field. This could include drawing attention to a new trial, providing context about policy developments, or providing updates on the microbicide field.

Your ongoing contact with reporters will help make sure they have the information they need to do their job. However, do not confuse being friendly with the media with being friends. Building trust with a reporter is founded on a healthy respect for our different roles.

> *I've developed a relationship with certain researchers and advocates in the country. So when something happens, they fill me in. They take time to brief me because they know I'm interested and they know I'd like to cover the issues. Building these relationships has taken a lot of time, but it's very important to cultivate a relationship with researchers because as a journalist, you have the challenge of trying to keep the story fresh and keeping it on the agenda.*
>
> —Kanya Ndaki, Deputy Editor of PlusNews (IRIN)

To become a source for reporters:

- Return calls quickly and respect deadlines.
- Make yourself available—call reporters, provide positive feedback when you read an insightful story, and create opportunities for the press to learn about your study.

- Know the issues, both about your study and the field.
- Provide written background materials that summarize your key messages.
- Be a resource—put reporters in touch with other experts and suggest ways they can find more information about the issue.
- Stay in touch. Keep journalists up to date on new developments in the field.
- Do not make promises you cannot keep, such as providing an exclusive story.

Box 9.19. Understanding media constraints is a key to being a trusted source

By Dr. Francois Venter, President of the Southern African HIV Clinicians Society, Clinical Director of the University of Witwatersrand's Reproductive Health and HIV Research Unit, South Africa

I cultivate relationships with reporters, and I usually have a good relationship with at least one journalist at each major paper, television station, and radio station. When I interact with them, I make sure they know I understand the media constraints. I do not provide long-winded comments, because I know they will not be easy to incorporate into an article. I make sure that the stories I suggest are actual stories, not just dry press releases or bragging about my fabulous project. If I put out a press statement, I am prepared to be phoned that same day and am ready to give off-the-cuff comments. I also make sure to provide context information to help the journalists add depth to their reporting. For me, making sure that I am familiar with the media constraints is key to being a trusted source. It is what keeps the journalists coming back to talk with me.

A "trusted source" has a proactive relationship with one or more journalists and may be called on for their opinion about many aspects of the health field. If you have cultivated a good relationship with a journalist, you may become one of their regular sources. Trusted sources respond promptly to inquiries, stay well informed and updated on the latest developments in the field, and give clear and accurate information and facts.

Box 9.20. Communicating your passion for the issue

By Mitchell Warren, Executive Director of AVAC: Global Advocacy for HIV Prevention, New York

So much of being a trusted source for reporters comes down to your passion for the issue. Does it make your juices flow? Are you committed to it? As soon as that passion is gone, you are no longer a good communicator, no matter how well trained you are. Training can help you say smart things to the media. But at the end of the day, it's about being accessible to the media, and being open to them. It's being able to say articulate things in a language that they can understand. If you are open to their requests, and if you tell them the truth as best you know it, they will come back to you. A lot of it is just being able to explain your study in a way that makes sense to them and that helps them explain it to their readers.

Box 9.21. When key spokespeople become statesmen for the field

By Pam Norick, Chief of External Relations, International Partnership for Microbicides, Silver Spring, MD

IPM is fortunate to have a Chief Executive Officer, Dr. Zeda Rosenberg, who is one of the recognized spokespersons for the microbicide field. Zeda is often asked to speak or comment on the latest developments in microbicides and HIV prevention research.

Zeda is successful because she is open-minded and recognizes the value of effective communications; yet she is disciplined about sticking to the data she knows to be true. She is supportive of research conducted across the HIV prevention community, and she is careful only to comment on science relevant to microbicide research and development. The HIV prevention community is small, and Zeda's first rule is to do no harm and be respectful.

We on the IPM team support Zeda's role as spokesperson by providing her with two essential tools: data and contextual background. Each time Zeda is asked to speak, we prepare talking points, messages, and background materials on the specific topic as well as the publication or venue. We ensure that she has the information she needs to tell the right story in the right way to the right audience. Along the way, we take time to translate the science for general audiences. Translating science for the public represents a cornerstone toward fostering public support.

Entering an interview with facts and clarity not only makes journalists' lives easier, it makes our spokespeople more relatable, quotable, and popular among all of IPM's audiences.

Key points to remember

- The more you understand how the media works and the challenges reporters face, the easier it will be for you to communicate clear and accurate information about health research to the public.
- Media strategies are an important part of your overall communications plan. Decide how you will involve news media before, during, and after the trial. Select appropriate spokespersons. Adapt approaches and messages for various study milestones. Determine when to proactively seek news coverage.
- Outline a standard operating procedure for how your site will respond to media inquiries, interact with journalists, and share news reports with your team and other internal and external stakeholders.
- For successful interviews, make sure to prepare in advance. Deliver your key messages clearly and consistently. Provide background and facts to support your messages. Give examples and analogies that frame your story in a public health context. Follow up with the journalist after the interview.

Appendix 2.1

A Risk Assessment Tool

PATH, an international nonprofit organization that studies vaccines for infectious diseases in developing countries, developed a simple risk-assessment tool to determine the expected level of communications risk for each of its vaccine trials. The tool does not evaluate the technical or scientific risk that may be involved with a trial; instead it looks at the potential for controversy, the risks to PATH's reputation, and expected communication challenges that could affect the trial. A similar approach can easily be adopted for other types of research and clinical trials.

All PATH vaccine trials are checked against the indicators below. Each indicator is given the appropriate number of "flags" (0, 1, or 2) depending on the risk. The tally of flags for that particular trial determines the trial's overall "communications risk factor" (see below), which in turn indicates the level of communication effort and financial resources required.

Determining the risk factor is an internal process at PATH—the results of the assessment are not shared with partners or other external groups. In principle, this tool should provide more consistent judgments and planning for communication related to clinical trials.

Below is the chart filled out for an imaginary Phase III trial in India evaluating the safety and efficacy of an experimental pediatric vaccine (as tested by a "challenge") against pneumonia.

Indicators		One flag	Two flags	Total flags per
Type of trial	Phase	Phase I	Phase III	🚩🚩
	Challenge/non-challenge and inpatient/outpatient	Challenge or inpatient	Challenge and inpatient	🚩
Location	Geographic location	Resource poor setting	Possible social or political issues of concern; high background mortality rate	🚩
	PATH presence	No PATH office/staff		
Population	Age (*Descending age trials get two flags)	Children/toddlers	Infants	🚩
	Health	At-risk (includes pregnancy)		
Product	Route of administration	Nose spray, patch, or injection in the arm	Subcutaneous/intramuscular	🚩
	Suspected safety issue(s) (e.g., Reiter's syndrome, intussusception)	Any suspected safety issue(s) with this or similar products		
	Type of vaccine	Live attenuated and/or adjuvant not yet licensed		
	Disease target	Deadly/high mortality rate (e.g., meningitis, HIV)		🚩
Communications capacity	Staff and experience		No communications contact(s) or experience	
Total Flags				7

🚩

Total Flags

0-3 = Low risk

4-6 = Moderate risk

7+ = High risk

This trial is at relatively high risk for controversy

Microbicide Trials Network: Communications Planning Survey

Name of Site:_____ Date:_____

I. Site Capacity and Experience

1. Within the last year, which of the following audiences have you proactively engaged? What were your primary aims for communicating with these groups?

Important Audiences Within Last Year		
Audience	**Y/N**	**Aims**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		
NGOs		
Media		
Local Government		
Regulatory Bodies		
(other)		

2. Are there particular methods of communication or engagement that you find preferable for these audiences? Methods may include telephone contact, written correspondence, face-to-face meetings, community meetings, briefings, flyers, drama, radio programming, etc.

Methods Of Communication Or Engagement		
Audience	**Y/N**	**Method**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		

NGOs		
Media		
Local Government		
Regulatory Bodies		
(other)		

3. Does anyone on your staff have communications expertise?

Yes____ No____

If yes, please describe:

4. Does your site have experience interacting with news media?

Yes____ No____

If yes, please indicate the level of experience: Extensive____ Moderate____ Minimal____

5. Does your site have procedures for dealing with media inquiries?

Yes____ No____

6. Does your site conduct its own outreach and/or training programs with local journalists, or has the site ever considered doing so?

Yes____ No_____

If yes, please describe:

7. How would you rate your site's relationship with local journalists?

Excellent____ Good____ Fair_____ Poor____ Nonexistent____

8. Does your site have staff who regularly communicate with advocacy groups and NGOs?

Yes____ No____

9. Does your site conduct its own outreach and/or consultations with advocacy groups and NGOs, or do you partner with these groups for any reason?

Yes____ No_____

If yes, please describe:

10. How would you rate your site's relationships with the following types of groups?

Women's Health

Excellent___ Good___ Fair____ Poor___ Nonexistent___

Microbicide Advocacy

Excellent___ Good___ Fair____ Poor___ Nonexistent___

HIV/AIDS Treatment Advocacy

Excellent___ Good___ Fair____ Poor___ Nonexistent___

PLWHA

Excellent___ Good___ Fair____ Poor___ Nonexistent___

NGOs

Excellent___ Good___ Fair____ Poor___ Nonexistent___

Government Groups

Excellent___ Good___ Fair____ Poor___ Nonexistent___

Health Agencies

Excellent___ Good___ Fair____ Poor___ Nonexistent___

11. Does your site have a designated crisis communications team?

Yes___ No___

12. Who is likely to be the primary media spokesperson or spokespersons for your trial?

Name: _____

Name: _____

13. Who is likely to have primary responsibility for organizing outreach efforts with the following?

Does he/she have previous experience interacting with these groups?

Who Will Be Talking To Whom?		
Audience	**Primary Responsibility**	**Done Previously?**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		
NGOs		
Media		
Local Government		
Regulatory Bodies		
Health Agencies		
(other)		

14. Has your site ever involved former and/or current trial participants in outreach activities?

Yes____ No____

If yes, please describe:

15. Have current and/or former trial participants ever been interviewed by the media?

Yes____ No____ Not certain____

16. If yes, was the site involved in making arrangements?

Yes____ No____

17. Does your site have a process to obtain consent for media interviews or photographs?

Yes____ No____

18. Does your site oppose the idea of current and/or former participants engaging in outreach or media activities?

Yes____ No____

If yes, why?

II. Communications Challenges and Needs

1. Locally or elsewhere in your country, are there HIV prevention trials that are ongoing, have been completed, were stopped prematurely, or are being planned that could shape perceptions of your trial?

HIV Prevention Trials Landscape				
	Microbicide	**PrEP**	**Vaccine**	**Other**
Ongoing				
Completed				
Stopped				
Planned				

2. When do you anticipate being ready to start enrolling participants in your trial?

3. Are there any significant local or national-level events that might take place between now and the time you expect to begin enrolling participants? Events may include government elections, the launch of another trial, etc.

Yes____ No____ Not Certain____

If yes, please describe:

4. Looking back, what communications issues have been the most challenging for your site? These may include rumors in the community, negative media coverage, or situations that have stoked common misperceptions about clinical research.

1.

2.

3.

5. What do you perceive will be the most difficult communications challenges for your trial?

1.

2.

3.

4.

5.

6. What aspects of your trial do you anticipate will be of greatest concern or most likely to generate misconceptions for each of these audiences?

Potential Concerns	
Audience	
Participants	
Male Partners	
Community Groups	
Microbicide Advocates	
HIV Treatment Advocates	
NGOs	
Media	
Local Government	

Regulatory Bodies	
Health Agencies	
IRBs or ECs	
(other)	

7. Which of the above audiences do you expect to be the most challenging to deal with in regard to your trial?

8. On a scale of 1 to 5, how would you rate each audience's awareness of your trial at the current time, with 5 being extremely aware and 1 signifying having no awareness?

Community Groups___ Local Government___

Microbicide Advocates___ Regulatory Bodies___

HIV Treatment Advocates___ Health agencies___

NGOs___ IRBs, ECs___

Media___ Other (Specify) ___

9. Which audiences do you consider the most critical for the success of your trial?

10. In the event of a communications crisis, are there individuals or groups within the community you think would show public support on behalf of the site?

11. Please list any key messages about your trial that you anticipate the site may wish to emphasize.

1.

2.

3

4.

12. On a scale of 1 to 3, which of these materials would you find most useful for communicating with external stakeholders, with 1 being the most useful and 3 being the least useful?

___Study Q&A

(with questions such as: What is the aim of this trial? What is a microbicide? What is PrEP? What happens if a participant acquires HIV?)

___Study backgrounder (2-3 pages)

___Site-specific study Q&A

(with questions addressing study procedures, potential community concerns, etc.)

_____Products fact sheet

_____PrEP backgrounder/fact sheet

_____Microbicide backgrounder/fact sheet

_____Role of DSMBs and interim reviews for this trial

_____PowerPoint presentations

_____Biographies of investigators

_____Other (specify):

13. Have you begun to consider or to plan specific outreach activities for your trial?

Yes___ No___

If yes, please describe:

14. In which areas or for what types of activities would your site potentially request planning assistance, direct on-the-ground support, or capacity building?

___Media training for key site staff

___Planning consultations or briefings for journalists

___Preparing materials for consultations or briefings with journalists

___Conducting consultations or briefings for journalists

___Planning consultations or briefings with advocacy organizations

___Preparing materials for consultations or briefings with advocacy organizations

___Conducting consultations or briefings with advocacy organizations

___Planning consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Providing materials for consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Conducting consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Other (specify):

Thank You!

Source: Microbicide Trials Network. Communications Planning Survey. 2009.

"Thirty Tough Questions" for Trial Staff

This tool can teach staff members about the scientific basis of the research and help them learn how to explain the research clearly. Staff members can cut the following questions into strips so that each one appears on a separate strip. They can put the individual questions in a hat and practice answering them at staff meetings or workshops. Over time, their answers will improve, and they will have the opportunity to see how their colleagues manage challenging questions.

1. Has the product you are studying been proven to be safe?

2. What are some of the side effects?

3. Why are you doing the study in this community, not in the United States or Europe?

4. If a participant gets HIV while in the study, what treatment will she have access to and for how long?

5. How does the community benefit from the research?

6. Why is this study potentially exposing healthy women to HIV?

7. Is it the first time that this product or drug is being tested?

8. By giving women this product to use, are you discouraging them from using condoms?

9. What if women become pregnant during the study?

10. If you are encouraging people to use condoms, how are you going to find out if the product or drug is really effective?

11. Why are you only focusing on women?

12. Is the trial taking advantage of a vulnerable population that is in need of help and cannot say no?

13. What kind of participants are you looking for?

14. What is the purpose of this study?

15. How well does this product work in preventing women from becoming infected with HIV?

16. What HIV prevention methods are offered to women throughout the study?

17. What does risk-reduction counseling mean?

18. What are the benefits of participating in this study?

19. What are the risks of participating in this study?

20. Why can't everyone get the product or drug, since researchers think it might work?

21. What does randomization mean?

22. Won't participating in the trial ultimately put women at higher risk than if they had not participated?

23. If proven to work, will the product or drug be available and affordable to the people in the settings where the trials are taking place?

24. If you think the drug will be effective, is it ethical to give some women a drug with nothing in it to prevent HIV when you could be providing protection for all women in the study?

25. Why do the participants have to use a modern form of contraception?

26. Why are pregnant women excluded from the clinical trial?

27. I have heard that the doctors take a lot of blood. How much blood will they take from participants and why?

28. If the participants and researchers are blinded, how does anyone know who is getting the placebo or the treatment?

29. How will the researchers protect participants who are at risk of partner abuse for participating in this trial?

30. Will participants who seroconvert (get HIV) receive free ARVs for the rest of their lives?

Source: Family Health International, 2009.

Appendix 3.1

Sample Strategic Communications Plan

Below is a sample plan developed by Family Health International to guide trial communications in one country. It has been left partially filled out to show what a written plan contains.

Strategic Communications Plan for X Trial

Below we describe the study's major vulnerabilities (issues, groups, individuals, or community concerns that could limit the success of the study) and our plans to address these issues before they become problems (what we will do, why, with whom, and how). The key elements in the plan include:

- Environmental scans
- Partnering and networking
- Ongoing communication with stakeholders
- Engagement with activists
- Public information and research dissemination
- Selective outreach to news media
- Good internal communications
- Research dissemination

Introduction/background

[Fill in here]

Team/roles

[Fill in here]

Environmental scan and analysis of vulnerabilities

[Fill in here]

Objectives (internal/external)

[Specify objectives clearly, as shown in examples below.]

1. *Improve how scientific information is disseminated within the network.*
2. *Improve dissemination of scientific information to the community where trials are conducted.*
3. *Improve the utility, accessibility, functionality of the Web site.*
4. *Increase visibility of the network among interested stakeholders internationally and locally to facilitate community and stakeholder engagement.*

Existing relations and outreach to key research partners and stakeholders

The study team will continue making contact with researchers and community members at various levels. The two PIs are well recognized in their areas and will be quite useful in keeping contact with the network of researchers in their site. Existing communication with partners and stakeholders includes the following: [List as appropriate for your trial.]

1. *Relations with government officials and other decision makers*
2. *Relations with the local study communities*
3. *Relations with local, national, or regional advocacy groups*
4. *Donors active in supporting HIV programs: USAID, DFID, WHO, Gates Foundation, Clinton Foundation, EGPAF, UNAIDS*
5. *Health professionals*

Strategy for rapid response to controversy

As a controversy emerges, the communications team will work with appropriate individuals from the groups listed above to identify: [Write down what is relevant for your trial.]

1. *Possible steps to change the course of the issue's progression: This may include communication intended to inform, advise, demonstrate due diligence, demonstrate caring, etc.*
2. *Other communications activities will be implemented to build consensus or support among opinion leaders and key stakeholders, such as meetings, press briefings, and the placement of op-ed pieces by prominent colleagues with credibility in health and human rights.*
3. *Site-specific communications: In all network sites, we will depend very heavily on local CABs to acquire information and to respond to community concerns, rumors, and other misinformation within the sites. CAB members will be trained on the importance of their role. The PIs will be the project's spokespeople at the sites, and the network can assist them to prepare responses to issues as they emerge.*

Ongoing communications that target specific audiences

[Write down key groups you will need to inform on an ongoing basis, and how you will do that.]

1. *News media: The network can stay in touch with a small group of journalists through whom communications about the network will be made. These journalists will be identified through their previous work on covering research and HIV/AIDS and through their media affiliation.*
2. *Local community: Community education forums will be conducted by site teams.*
3. *Government or ministry officials: Quarterly briefing sessions will be organized for Ministry of Health officials to keep them up to date with the site-level activities. They will also receive regular information through the newsletter.*
4. *Public health professionals will receive updates through the newsletter.*
5. *Study staff/research teams: Staff members will be trained in the area of research literacy and will learn how to answer tough questions that may be asked by community members during community education forums.*
6. *Activists or other civil society groups.*

Materials needed to support communication and dissemination plans

We will identify the communications materials that will need to be written and distributed (including language and target audience) and determine who is responsible for each of these materials. These will include: [List materials you need to support your plan.]

1. *A statement about the network*
2. *A list describing other HIV prevention studies being conducted in each country and key events for these*
3. *Annotated lists of activists in each country*
4. *Calendar of relevant meetings and conferences, nationally and globally*
5. *Q&A*
6. *Contact list of site staff*
7. *Media guidelines governing coordination and procedures for media inquiries*
8. *Materials to include in training of study team: presentation on communications, research literacy issues (including research concepts and study procedures as well as issues pertaining to prevention trials) and how to answer difficult questions*
9. *Rapid response plan*
10. *List of key resources*
11. *Internal Web portal/Basecamp site with network materials*
    - *Protocol*
    - *Community assessments*
    - *News clips*
    - *Photographs*
    - *Backgrounders and Q&As*
    - *Contact lists*

"Getting to Know Your Stakeholders" Template

Stakeholder group	Level (who do they communicate with?)	Values/goals	Concerns
Host community members			
Trial participants			
Local leaders			
Religious leaders			
Local health care workers (including traditional healers)			
Ethics committee(s)			
Community advisory board			
National policy makers			
National/international advocates			
National policy and opinion makers			
Employees and management of host institutions			
Funders/sponsors/network			
Leadership of related trials			
Local/national media			
International media			
Wider scientific community			

Contact List Template

Surname	First name	Organization	Title	Address	Phone	E-mail	Category	Comments	Staff contact

Samples of Newsletters for Clinical Trials

FEM-PrEP

Trial Update

Pre-Exposure Prophylaxis for HIV

Putting HIV in its Place in Pretoria

FEM-PrEP scientists use an innovative strategy to recruit participants

A few years ago, the massive metropolis that includes Pretoria, South Africa, was renamed *Tshwane*—a word that means, "we are the same," according to city officials. The name change, and even the meaning of the word *Tshwane*, are controversial subjects in South Africa. What remains uncontroversial is that the HIV epidemic has not affected the two million residents of Tshwane in the same way.

For various reasons, the virus has affected some communities more than others. The FEM-PrEP researchers need to identify these communities because an HIV-prevention trial can only be effective in places where there is a high incidence of HIV. In other words, the women who volunteer for the trial must be at "higher risk" of acquiring the virus.

Finding and recruiting these women is often a significant challenge for HIV-prevention trials. However, FEM-PrEP's socio-behavioral and community (SBC) team is taking a novel approach to recruiting participants for the clinical trial. "The approach combines a method called *Priorities for Local AIDS Control Efforts* (PLACE) with computer-based mapping strategies to identify promising recruitment areas to focus recruitment efforts," says Amy Corneli, the SBC principal investigator.

The PLACE method was originally developed to improve the reach of AIDS-prevention programs. The SBC researchers are using modified PLACE questionnaires to interview members of the community, asking them about the places where people go to meet potential sex partners. The researchers visit these places—*shebeens* (informal taverns), guesthouses, and even bushes by the side of the road—where they talk to the people who go there to socialize.

Business owners are asked about the clientele and about the busiest times at the establishment. The interviewers also collect information from the patrons about their alcohol consumption, sexual practices, and risky behaviors.

Local research staff based at the Setshaba Research Centre conduct these interviews. Among them is Dimakatso Molete, who has extensive knowledge of the social networks in the area. Molete, who is known as *Aus Maki*, has conducted hundreds of interviews with establishment owners and patrons. It's a task that has its challenges.

"Establishment owners are difficult to get in touch with," says Aus Maki. "This takes much of our time as we may visit the place several times before we can find them. At first, their staff are suspicious of people they do not know," she says.

(continued on page 4)

Stella Vivienda/FHI

Interviewers, Dimakatso Molete and Ross Malamatsho, use a global positioning system device to map the coordinates of a recruitment area.

USAID
FROM THE AMERICAN PEOPLE

fhi Family Health International

Issue No. 2 July 2009

Source: Family Health International. FEM-PrEP Trial Update. 2009.

Source: Pre-Exposure Prophylaxis Initiative (i-PrEx). Global i-PrEx Update. 2009. Reprinted with permission.

NÚMERO 12 – DICIEMBRE 2009

Unidad de Educación Comunitaria e Involucramiento

En este número

Difusión del servicio de diagnóstico de VIH de Impacta a través de la guía Gay Epicentro.

Diálogo entre investigadores y comunidad respecto a los estudios

"Para el mejor papi del mundo! Te amaré por siempre, con cariño: Muñequita"... mensaje exhibido en una de las mantas de amor

1. Notas Breves

El 09 de Diciembre **participamos** en el II Encuentro de Lucha contra el VIH-SIDA organizado por el Congreso de la República y la Asociación Hogar de Vida. En dicho evento se hizo una revisión sobre los últimos hallazgos en prevención, así como se brindó un reconocimiento al doctor Alberto La Rosa Domínguez entre otros, por su dedicación y aporte al tema del VIH-SIDA. ¡Felicitaciones al Dr. La Rosa!

El 12 de Diciembre se presentó el **Plan Anual de Educación Comunitaria e Involucramiento** de la unidad de ensayos clínicos peruana para los estudios de la red de vacunas. Dicho plan ha sido elaborado por los miembros del equipo y describe las estrategias de reclutamiento y retención a ser implementadas durante el año 2010 con el objeto de alcanzar la cuota de reclutamiento programada en el tiempo establecido.

El servicio de diagnóstico de VIH que nuestra clínica Impacta ofrece, se sigue difundiendo a través de la Guía Turística Gay de Lima de Epicentro, quien quincenalmente actualiza y extiende los puntos de distribución.

El **centro de llamadas** ha atendido a través de la línea SIDA, 181 contactos telefónicos de los cuales 139 (76.8%) corresponden a participantes de TARGA principalmente.

2. Reclutamiento

El 1 de Diciembre se realizó en el Centro de Salud Cuartel General (Pentagonito) un encuentro con la finalidad de informar y sensibilizar a la población militar acerca del estudio de investigación en vacunas contra VIH e identificar potenciales voluntarios. La convocatoria estuvo a cargo del personal de salud del Pentagonito, Lic .Patricia Vilchez y Lic Paola Coahila, alcanzando la asistencia de 80 personas aproximadamente entre personal militar de tropa y administrativo.

De igual forma, el 10 de diciembre se presentaron los estudios de la red de tratamientos en reclutamiento activo a las profesionales enfermeras de la Región de Salud del Callao. 42 profesionales de los establecimientos participaron del mismo.

La red de salud revisó y aprobó la implementación del sistema de referencia Plus de los establecimientos de sus respectivas jurisdicciones los estudios presentados: a) Lima Sur: A5259, A5253 Y A5255; b) Lima Este: A5253 y c) Callao: A5259.

3. Retención

59 visitas domiciliarias han sido efectuadas, de las cuales 30 corresponde al estudio EBV, 15 corresponden a estudios de vacunas y 14 a estudios de tratamiento. Los participantes que no fueron recuperados (8) corresponden en su mayoría a participantes del HVTN 504, quienes se han mudado (6) o han viajado fuera del país (2).

Sample of Study "Backgrounder"

Family Health International

Backgrounder

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

Since 2004, Family Health International has been working in Africa to study whether a widely used HIV treatment drug, called tenofovir, can also prevent HIV in women who are at high risk of HIV infection. In particular, researchers have looked at the drug's safety and effectiveness in preventing HIV infection in these women.

This study is important because a new HIV prevention approach, such as using a drug like tenofovir to prevent infection, could be used with other prevention strategies such as condoms to substantially reduce the number of people who become infected with HIV worldwide. It could make an especially large impact in Africa, where more than 70 percent of all HIV infections occur, and would be of particular benefit to people who have difficulty negotiating condom use.

The FHI study involved heterosexual women from the African countries of Ghana, Cameroon, and Nigeria who had multiple sex partners. Because the women were at high risk of being infected with HIV, they were also the most likely to benefit from tenofovir if it can be shown to safely and effectively prevent HIV.

Tenofovir is not a new drug. It has already been tested in thousands of HIV-infected people, it is approved by regulatory agencies, and it is being used in an oral form in many countries for HIV treatment. The FHI study is among the first to begin testing the oral form for both safety and effectiveness in preventing HIV infection.

The study was designed according to the most rigorous international ethical standards. It was approved by institutional review boards at Family Health International and by regulatory authorities in the countries where the study took place.

Half of the participants received daily oral tenofovir and half received a daily placebo, which is a pill that looks and tastes like tenofovir but does not contain any drug. At monthly visits during the study, participants received HIV prevention counseling, were given condoms to use during all sexual acts, and were provided treatment for any symptomatic sexually transmitted infections, all actions which have been shown to reduce the risk of HIV infection.

Liver and kidney functioning were evaluated every three months to confirm the safety of tenofovir for HIV-uninfected individuals and to identify any possible side effects of the drug. Participants were also tested for HIV each month to determine the drug's effectiveness at preventing HIV. Those who became infected with HIV during the study were provided enhanced referral to care and support services in their communities, including

access to care that involves antiretroviral drug provision when needed. Local investigators identified facilities within each country that offer low-cost, HIV-related psychological, social, and medical services. Infected participants were counseled and referred to those sites. Those who experienced medical problems that were directly related to their participation in the trial received medical services free of charge.

If this or other tenofovir studies conclusively demonstrate that tenofovir is safe and effective for preventing HIV, then Gilead Sciences, the U.S.-based manufacturer of tenofovir, has agreed to provide the drug at a no-profit cost to HIV prevention programs in resource-poor countries. Gilead has provided tenofovir free of charge for the FHI study, which is being supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation. Preliminary results will be available August 17, 2006 at the International AIDS Conference in Toronto. Final results will be submitted for publication in 2006.

For more information on Family Health International, see http://www.fhi.org.

Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention, care, and treatment. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems. FHI has a staff of 1600 and offices in nearly 40 countries.

Sample External Questions and Answers (Q&A)

Family Health International

Questions and Answers

August 10, 2006

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

What is tenofovir?

Tenofovir is an anti-HIV drug that works by inhibiting an important enzyme in the HIV life cycle, called nucleotide reverse transcriptase. In HIV infected individuals, tenofovir stops HIV from invading cells that have not yet been infected with the virus. It is taken in the form of a pill, it is long lasting, it has relatively few side effects, and most strains of HIV are slow to develop resistance to it. Tenofovir is approved by regulatory agencies and already used in many countries as part of a drug combination to treat HIV. Studies in monkeys have also shown that it can prevent transmission of a virus that is similar to HIV, but it is not yet known if it can prevent HIV transmission in humans. Tenofovir is manufactured and was provided free of charge for the study by Gilead Sciences, located in Foster City, California.

What was this study testing?

This clinical trial was conducted in three African countries to study daily oral tenofovir for the prevention of HIV among heterosexual women at high risk of infection. To do so, participants were randomized to receive either tenofovir or a placebo once a day for the duration of the trial. All participants also received HIV risk-reduction counseling, condoms, and treatment for sexually transmitted infections as medically indicated during monthly clinic visits throughout the trial.

Why was this study important?

Current HIV prevention programs stress abstinence, being faithful to uninfected partners, and—if neither is possible—using condoms. Despite knowledge of these prevention strategies, an estimated 11,000 people become infected with HIV each day. Moreover, many sexually active individuals, especially women, have difficulty ensuring faithfulness or negotiating condom use in their relationships, and additional prevention strategies are needed. If effective, tenofovir could be a promising addition to condoms because it is taken orally and would provide a constant level of protection against HIV, regardless of the timing of intercourse.

Who conducted the study?

Family Health International, a non-profit research and service organization based in Research Triangle Park, North Carolina, managed the trial and was responsible for all aspects of the study. Local staff from the study sites in Africa served as the research investigators. The research was supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation.

Where did the study take place?

The study was conducted in the three African cities of Douala, Cameroon; Ibadan, Nigeria; and Tema, Ghana. These sites were selected because their populations have high rates of HIV infection, which is an important factor for determining the effectiveness of possible HIV prevention drugs. If tenofovir is shown to be safe and

effective, HIV prevention programs that provide tenofovir can be established at these sites, so that women at risk for HIV can be reached and can benefit from this intervention.

Who participated in the study?

Nine hundred thirty-six heterosexual, HIV-negative women were included in the study. Four hundred were from Ghana, 400 from Cameroon, and 136 from Nigeria. To be eligible, all volunteers had to be sexually active HIV-uninfected women between ages 18 and 35 years.

How were participants evaluated throughout the study?

Participants were tested for HIV at a screening visit, an enrollment visit, and once a month during follow-up. With each HIV test, pre-test and post-test HIV prevention counseling was also provided. Side effects and any reported changes in health, whether considered by the study investigators to be potentially related to the study drug or not, were evaluated, treated if necessary, and recorded each month. In addition, liver function and kidney function were evaluated every three months to identify other possible reactions to the drug.

What precautions were taken to help participants prevent HIV?

Women were counseled monthly on safer sexual practices such as reducing their number of sexual partners and using condoms during every sexual act. Male condoms were also provided to them. In past prevention trials, these services have been proven to reduce the risk of HIV among participants. For example, results of a microbicide trial conducted by Family Health International in Cameroon, which used similar HIV prevention strategies, showed a 50 percent lower incidence of HIV among trial participants than among community members tested before the trial.

How long did the study last?

Enrollment began in June 2004 and ended in March 2005. After enrollment, each woman was to be followed for up to 12 months. Follow-up data available differed by trial site. Because of early withdrawal of the study drug from Cameroon and Nigeria, women there did not complete the trial as planned.

When and why was the study drug withdrawn in Cameroon and Nigeria?

The study drug was prematurely withdrawn in Cameroon in February 2005 and in Nigeria in March 2005. In Cameroon, the study was closed after the Ministry of Public Health suspended provision of the study product to participants to allow review of study procedures in the wake of media controversy over oral tenofovir research there and elsewhere. However, follow-up of women already enrolled in the trial continued until September 2005. In Nigeria, FHI closed the study due to operational issues.

What did the safety data from the study show?

No statistical differences were found in severe liver or kidney abnormalities between women in the tenofovir group and women in the placebo group. The numbers of other side effects and health changes were also similar between the two groups. The most common reported events for both groups were malaria, vaginal yeast infections, stomach pains, and headache.

How many women became infected with HIV during the study?

Eight women on study drug or placebo became infected with HIV. Two of the infections occurred among women receiving tenofovir, and six occurred among women receiving placebo.

How do the HIV data break down by country?

Of the two women in the tenofovir group who became infected with HIV, one was from Ghana and one was from Cameroon. Of the six in the placebo group, two were from Ghana, one was from Nigeria, and three were from Cameroon.

What can we conclude from the results?

These results provide no evidence that short-term use of oral tenofovir for HIV prevention causes harm, since the women receiving tenofovir and those receiving placebo did not differ substantially in terms of liver and kidney function or other health changes. However, not enough data are available to determine whether tenofovir protects against HIV infection.

What happened to participants who became infected with HIV?

Those who became infected were referred to HIV care and support services. Local investigators identified facilities within the study countries that offered HIV-related psychological, social, and medical services, and participants who become infected were counseled and referred to those sites.

What procedures are in place to ensure that the women who became infected with HIV are receiving the services they were promised?

All of the women who became infected with HIV during the study were referred to a health counselor who referred them to local hospitals for HIV care and support services. The health counselor also offered to accompany each woman to her first visit to help her register for services. Family Health International has also been in contact with study staff, local hospitals, and local nongovernmental organizations to ensure that the women will have continuing access to such services. In Cameroon, for example, Family Health International has signed a contract with a local hospital to provide 15 years of care and treatment to the 10 women who became infected there, and a nongovernmental organization has agreed to provide additional psychosocial support. Similar negotiations are under way in Ghana. In addition, the one woman from Nigeria who became infected was enrolled in the President's Emergency Plan for AIDS Relief program there.

What are the implications of this study?

Daily oral use of TDF in HIV-uninfected women was acceptable and was not associated with increased clinical or laboratory adverse events. Although the effectiveness data are inconclusive, the trial strongly supports the need for additional studies to test the effectiveness of oral tenofovir in preventing HIV infection in humans. Now that tenofovir has been demonstrated to be safe and acceptable for HIV-negative individuals at risk, it is crucial to determine if this approach can effectively reduce risk for HIV infection.

What similar studies of oral tenofovir are being conducted?

The Centers for Disease Control and Prevention is testing tenofovir among diverse populations in two countries: injecting drug users in Bangkok, Thailand, and men who have sex with men in Atlanta and San Francisco, USA. The Centers for Disease Control and Prevention is also studying tenofovir in combination with another drug, emtricitabine, in heterosexual men and women at high risk of HIV infection in Gaborone and Francistown, Botswana. Finally, the National Institutes of Health and The University of California at San Francisco are planning to study the same combination of drugs in men who have sex with men in Lima, Peru.

Does Family Health International have any plans to continue studying tenofovir for HIV prevention?

Family Health International is identifying and preparing potential sites for future studies of tenofovir alone or tenofovir plus emtricitabine among both men and women at high risk of HIV infection. A protocol is also being developed in conjunction with the CAPRISA Project of Mandela University in Durban, South Africa, to study whether a topical gel containing tenofovir, used as a microbicide, can also prevent HIV infection.

What is Truvada? Why study two different drugs?

Truvada is the name for the fixed-dose combination of tenofovir and emtricitabine, described above. Family Health International and others are interested in studying this drug combination because there are significant data suggesting the promise of both tenofovir and tenofovir plus emtricitabine. Because we don't yet know for certain how the animal data will correlate to human protection, we believe it is essential to move forward as quickly as possible to evaluate both of these promising interventions.

Template for a Monthly Summary Report on Communications

Nyanza Provincial Task Force on Male Circumcision (Communications Subcommittee)

Monthly summary report on communications

District (specify):	Month (specify):	
Communication activities (performed by staff that involve or target these groups)	Type of activity (summary of activity or channels used to reach the target groups, such as interpersonal meetings, sensitization forums, newsletters, presentations, media, others)	Outcome of activity (summary of the outcome of the communication activity,such as concerns, issues raised, how your team handled situation, lessons learned)
Community groups (FBOS, CBOs, youth groups, women, elders; specify other stakeholders)		
Health providers (Describe the cadre of providers, e.g., DHMTs, MDs)		
Policymakers (PHMTs, provincial administrators, etc.)		
News media (Reporters, editors; specify others)		
Others (Please let us know about any issues or themes that you think are important in the meetings or other communications activities that you have been involved in or helped organize in the last month. Describe any meetings or problems that do not fall into the categories above.)		

Communication concerns (Describe the concerns gathered during these forums, e.g., rumours, myths, misconceptions, misinformation)		
Future communication activities planned (e.g., meetings, outreach activities, personal visits, brochures, development and testing of key messages to use with specific communities/ stakeholders)		
Other progress or comments		

Prepared by: Date:

E-mail completed form to: xxxx@fhi.org, Secretary, Provincial Task Force on Male Circumcision

How Unexpected Closures Can Affect Other Trial Sites: The Cellulose Sulfate Trial Closure in South Africa

In January 2007, a study in South Africa on cellulose sulfate (CS), a potential microbicide, closed prematurely after its Independent Data Monitoring Committee identified a safety concern during a review of preliminary results and recommended that enrollment stop at trial sites. The research team at the HIV Prevention Research Unit at the South African Medical Research Council (MRC), which managed several sites around Durban, and CONRAD, the trial sponsor in the United States, worked quickly to plan how to share the news with local, national, and international stakeholders, including trial participants. In South Africa, the MRC released a press statement and contacted a well-respected South African health journalist, hoping her article on the closure would set a balanced tone for press coverage to follow.

Meanwhile in Mtubatuba, a small town in KwaZulu-Natal 200 kilometers north of Durban, a research site affiliated with the Africa Centre for Health and Population Studies was conducting a separate large-scale microbicide study testing a different product called PRO 2000 gel. On Friday of the week of the MRC's public announcement of the CS study closure, the Africa Centre contacted members of its community advisory board (CAB) in Mtubatuba to invite them to an urgent meeting. The Centre's staff planned to brief CAB members the following Monday about the sudden closure of the CS trial and reassure them that their PRO 2000 microbicide study was not affected.

That weekend, however, a journalist from Durban posing as an insurance official with the health department traveled to Mtubatuba, hunting for the inside 'scoop' on the closure. He located a CAB member for the Africa Centre's PRO 2000 trial in Mtubatuba who—convinced by this guise—took the journalist to the home of a PRO 2000 trial participant. Other participants joined and were encouraged by the undercover reporter to share their perceptions, unaware that they were being interviewed by a journalist (Gafos 2009).

The next day, the City Press, a national newspaper, ran the headline, "Women used as AIDS guinea pigs" (Hlongwa and others 2007). The article claimed that hundreds were feared to have contracted AIDS during the CS study and that women were selling their gels in the townships as AIDS cures. More articles by the same journalist followed, accusing the CS study of unethical conduct and claiming that women were instructed to have promiscuous unprotected sex and that the researchers had purposely infected participants with HIV. Not only were these assertions not true, the article was based on interviews with participants from a completely different trial than the CS trial that was prematurely halted.

While coverage of the CS trial closure remained balanced and accurate in the United States, a wave of negative press and sensational headlines followed in local press in South Africa as well as in Uganda (where another CS trial site was located). These articles painted a picture of poor, uneducated, and vulnerable women taken advantage of by researchers and duped into participating in clinical trials.

The closure of the CS study in South Africa and related concerns about safety had snowballed into a narrative of exploitation, affecting perceptions among the community and the entire microbicide field of the ethical conduct of microbicide trials. The research organizations directly involved in the South African CS study and a related CS study in Nigeria implemented intensive communications efforts to respond to the events. Other research and stakeholder groups also offered technical assistance and support behind the scenes, both locally and internationally, including the Microbicides Media and Communications Initiative, which set up teleconferences and worked on coordinating messaging.

Advocacy groups, such as the Global Campaign for Microbicides and the African Microbicide Advocacy Group, facilitated civil society calls and online discussions, while South Africa's Treatment Action Campaign and Gender AIDS Forum wrote articles and statements of support to refute the rumors and myths.

These combined efforts were successful in calming the waters and promoting more accurate news coverage. The participation of local groups introduced African voices into the media coverage. While these "damage control" efforts improved the situation, the experience highlighted for all that what happens in one trial can easily affect other trials. Investigators, research groups, and communities in this area have put these lessons learned into action. They now plan ahead to avoid controversy, develop integrated communication strategies, and work collaboratively to discuss messaging for trials and results.

Illustrative Crisis Communications Plan

In 2005, India saw one of the country's most severe outbreaks of Japanese encephalitis (JE), a mosquito-borne illness that occurs in Asia and the Western Pacific. More than 6,500 cases and close to 1,700 deaths were reported—the majority of them children. Widespread coverage of the outbreak—including photos of dying children— in local, national, and international media led to a public outcry.

The government of India rapidly launched a national JE vaccination campaign and PATH, an international health nonprofit organization, was asked to provide technical assistance. A few weeks into the campaign, news broke of severe adverse reactions and even deaths among some children receiving the vaccine. The vaccine had an excellent safety record, so most technical experts felt that the deaths did not result from the vaccine, but rather from another cause among this very vulnerable population.

Local and national media ran speculative stories questioning the vaccine's safety. The communications and management team gathered to determine the best approach to dealing with the situation. Weighing their options, they considered a formal institutional response that could have helped get accurate information out to the public and set PATH up as a reliable source for future media inquiries. But given that the investigation into the deaths had not yet concluded, PATH initially decided not to respond directly, but to help the government of India respond appropriately.

However, when a national television network decided to film a panel discussion on the issue, PATH's lead technical officer in India recommended to the U.S.-based program director that PATH should participate despite the initial strategic decision not to engage. This example highlights the importance of being flexible and the need to account for specific country considerations in developing and adapting a communications strategy.

The following year, PATH helped the government of India develop its communications strategy with an emphasis on the lessons learned from 2006. They encouraged early engagement with the media and placed a greater emphasis on the buy-in of local officials. For example, one district health minister brought his son for vaccination at a launch event, illustrating his confidence in the program.

Finally, they revised their internal Q&A, including the results of an investigation into the deaths, which found no relation between the vaccine and the deaths. If reporters brought the issue up again, spokespersons now had clear messages to use to correct the false accusations and instead communicate positive messages about the campaign.

(See below for a copy of the full crisis communications plan for the Japanese encephalitis project.)

Japanese Encephalitis (JE) Project Crisis Communications Plan

Overview

This plan describes the process by which PATH will address any inaccurate and/or potentially negative press coverage or other misperceptions associated with activities conducted under the PATH JE project. This plan is specific to activities related to the Government of India's (GOI) 2009 JE vaccination campaigns.

A communication crisis is a situation that threatens the integrity or reputation of the partners or partnership, usually brought on by adverse or negative attention from community members or the media. This includes any rumor, adverse event, legal dispute, accident, or manmade disaster attributed (rightly or wrongly) to the project or partners. It can also include situations where, in the eyes of the media or general public, the partnership did not react in an appropriate manner.

Routine activities

The communications associate for the JE project monitors daily media coverage addressing JE disease and vaccines, keeping a related log and copies of media clips. This monitoring is particularly acute and intensified following outreach to media generated by PATH or GOI regarding the 2009 Indian campaigns.

Process for preparation and response following concerning media report or crisis situation

- Upon learning of an inaccurate or concerning news media report, the communications associate forwards a copy of the article with relevant questions to the Management Team. The senior communications officer from PATH External Relations is copied on this e-mail.
- The management team responds to the communications associate with their initial read of the situation and appropriate plan of action (or inaction).
- The communications associate summarizes the team's reactions and proposed strategy and e-mails this summary, along with a link to the associated media report, to the PATH Senior Management Group and Strategic Program Leader. The involvement of the SMG is to keep leadership aware of the report, as well as the team's plan for response.
- The communications associate works with the management team to prepare a holding statement and/or internal Q&A. (Example of holding statement: "On [date], at [health center], the death of a [#] year old child who had been given JE vaccine was recorded. This incident is under investigation. Additional details will be provided as they become available.")
- The team's plan, holding statement, and Q&A documents are shared with primary partners (to be identified case-by-case), which may include Ministry of Health officials, funders, and others. These documents are shared via e-mail, but the management team may also contact partners via telephone when appropriate.
- A primary spokesperson is assigned to respond to media inquiries, and technical experts identified as potential media contacts are notified via e-mail or telephone.
- Note: A designated spokesperson should be forthright in dealing with media questions. There are, however, some questions he or she cannot answer, including those related to financial estimates of damage, insurance coverage, causal speculation, allocation of blame, or anything "off the record."
- The communications associate provides regular updates to SMG and broader PATH team.
- When the situation is resolved, all related parties are asked to debrief and document lessons learned.

Relevant team members

I. Communications team

The primary role of this team is to help assess the potential for a situation becoming a communications crisis. The team routinely monitors media coverage and provides initial notification of a potentially concerning or inaccurate report. Communications team members also assist in drafting and collecting technically accurate and up-to-date materials in response to the situation.

Senior communications associate, JE project

Senior communications officer, External Relations

Media relations officer, External Relations

II. Management team

The management team is responsible for providing initial reactions to the inaccurate or concerning news report and for developing an appropriate plan of action. (It must be noted that sometimes the appropriate plan will call for no response from PATH.) The management team is also responsible for notifying relevant partners and funders and designating appropriate spokesperson(s), either internal or external, depending

upon the particular situation.

JE project director

JE project deputy director

Senior program manager, India

Country office director, India

Country partners – to be contacted as needed by management team representative

Assistant Commissioner, Immunization

Ministry of Health & Family Welfare

III. PATH Senior Management Group and Strategic Program Director
Involvement of the PATH Senior Management Group (SMG) and the Strategic Program Director is to ensure that leaders are aware of potentially harmful reports about PATH and PATH activities. Following notification according to the process outlined above, SMG should be regularly updated on the team's plan for response. If no response is warranted, SMG should also be notified of this approach. Senior management may also provide input on decisions that could affect the overall organization.

IV. Other staff and partners to keep informed
Additional senior members of the JE project team and PATH External Relations may be notified throughout the process, as determined by the management team.

JE project vaccine development advisor	
JE project administrator	
JE project health policy and economics officer	

Notifying the project funder
The JE project director or a member of the PATH Senior Management Group (whomever is most appropriate in a given situation) will keep the responsible program officer of the project funder informed. As noted in the process above, the funder should be contacted after initial reactions and the planned response are summarized.

Key JE project partners
Representatives from partner organizations, including but not limited to national governments or Ministries of Health, may need to be notified if a situation requires specific clarification and it falls within their area of expertise or capacity to respond. Internal documents may also be shared with external partners at the discretion of the JE project director, in order to prepare for potential contact by journalists.

External statement or response
When appropriate, as determined by the JE project director, a response to or statement regarding negative press coverage may be drafted and posted to the following online forums:

Forum	URL	Instructions
ProMED	www.promedmail.org	Submit post to [e-mail here], include full name, affiliation, and country.
TechNet	www.technet21.org	
Other listservers TBD		

Source: PATH. 2010. Reprinted with permission.

Sample of a Results Dissemination Plan by a South African Site

HPTN 039 RHRU Results Dissemination Plan

By Sinead Delany-Moretlwe, Reproductive Health Research Unit (RHRU), University of the Witwatersrand, Johannesburg, South Africa

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 inquires 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

Sample of a Results Dissemination Plan by a Peruvian Site

HPTN 039 Results Dissemination Plan for Peru

By Pedro Goicochea, MSc, MA, Former Co-Investigator, HPTN 039, Asociación Civil Impacta Salud y Educacion, Lima, Peru

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 a "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.

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

By Lisa Rossi, Director of Communications and External Relations, Microbicide Trials Network, University of Pittsburgh, Pittsburgh, PA

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

Sample Questions to Include in an Internal Q&A for Trial Results, Based on Three Outcome Scenarios

Below are examples of questions that might be included in an internal Q&A, for each of three possible outcome scenarios. Preparing answers for these allows you to think through in advance how to respond to challenging questions.

Positive effect

- When did researchers first observe positive results (such as a protective effect) with use of this product, and why did they not immediately halt the study and begin making it available to all of the study participants?
- Are you now providing all study participants with the product at no cost? If not, when?
- How can you be sure that your results are accurate, especially since they contradict the results of a similar study completed earlier by another research group?
- Is this study conclusive or are more studies needed to confirm the results?
- What are you doing to help the participants who may have acquired HIV during their participation in this study?
- Now that you have positive results, what are you doing to ensure that public health authorities can quickly begin to develop policies and implement strategies that support widespread distribution and use of the product?
- Can enough of the product be manufactured fast enough to meet the demand?
- What are you doing to ensure that persons who can benefit from use of the product have easy access to it free or at low cost?

Minimal or no effect

- Why did researchers continue this study after results from a similar study showed that the use of the product did not reduce the risk of someone becoming infected with HIV?
- Given that a higher dose of the product might have reduced the risk of participants becoming infected with HIV, are you going to provide them with a free supply of the appropriate dose?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Why should donors continue to fund studies of products that do not work?
- What more must researchers do to ensure that all studies are well designed and no study becomes a missed opportunity to prevent the spread of HIV?
- What impact do you think the failure of these studies to find effectiveness will have on how public and private donors evaluate research proposals?

Negative effect

- When did researchers first observe negative results and why did they not immediately halt the study to protect study participants?
- What are you doing to get the word out about these findings and prevent harm to all persons taking this product who may be at risk of becoming infected with HIV?
- What caused the negative results?
- If you do not know definitively what caused the negative results, what are you doing to find out?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Are there other studies under way of use of this product for HIV prevention that should be halted?
- Who is to blame for what happened?
- Why was this study conducted on humans in the first place? Why in developing countries?
- Why should donors continue to fund HIV prevention studies?
- How can you expect anyone to participate in HIV prevention studies if they know that such participation may harm them?
- Are these negative trial outcomes having a negative impact on recruitment for HIV prevention studies?
- Why did you do this study here and harm our people?
- Did you have any indications from other research that the product is harmful?

Sample Letter to Ethics Committee Requesting Review of Materials Needed for Dissemination

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

HIV PREVENTION RESEARCH UNIT

1st and 2nd floors, Westville Village Market,
123 Jan Hofmeyr Road, Westville, 3630, Kwazulu Natal.
PO Box 70380 Overport 4076, South Africa
Tel: + 27 31 242 3600; Fax: + 27 31 242 3800

05 November 2009

Chair: Biomedical Research Ethics Committee
Westville Campus
University of KwaZulu-Natal

PROTOCOL: An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection (MDP 301). G Ramjee, MRC
MRC Ref: T267/05
Africa Centre Ref: T111/05

RE: Approval of Trial Results Dissemination Presentation, Q & A Document and MDP Backgrounder

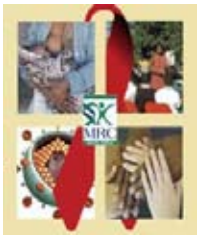
Dear _____,

The above-mentioned trial is now closed to participant follow-up and data has been locked. We are expecting the results to be released sometime in December 2009, depending on the review of the data analysis in late November 2009.

As we have done in the past, please find enclosed a Powerpoint presentation, which will be used to provide the information to communities and trial participants. We would appreciate your feedback on this. We also enclose the Q & A document and study backgrounder for your information.

As we are blinded to the data and we have no results, we have some slides which do not have final data and there are three outcome scenarios each with a possible explanation. Once the trial results are available, this data and the final outcome scenario will be added for your expedited review at a later stage.

Sample Letter Inviting Community Stakeholders to Learn Study Results



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

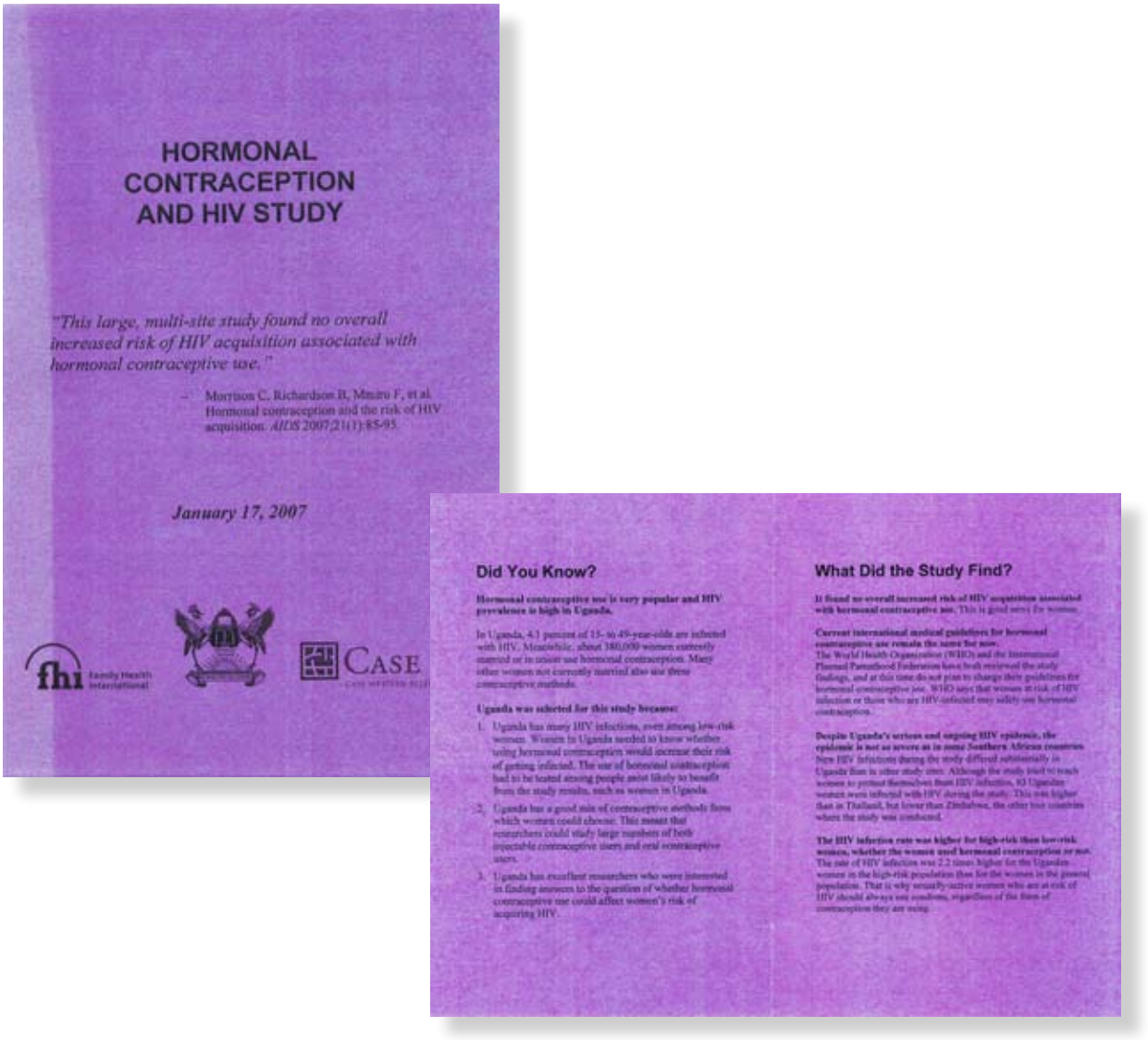
_____
Yuki Sookrajh
MDP Manager

Cc Prof Gita Ramjee

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

Sample Brochure to Share Study Results with a Community

Messages in this FHI brochure were written for an audience of community members.



HORMONAL CONTRACEPTION AND HIV STUDY

"This large, multi-site study found no overall increased risk of HIV acquisition associated with hormonal contraceptive use."

– Morrison C, Richardson B, Mmiro F, et al. Hormonal contraception and the risk of HIV acquisition. *AIDS* 2007;21(1):85-95.

January 17, 2007

fhi Family Health International

CASE

Did You Know?

Hormonal contraceptive use is very popular and HIV prevalence is high in Uganda.

In Uganda, 4.3 percent of 15- to 49-year-olds are infected with HIV. Meanwhile, about 380,000 women currently married or in union use hormonal contraception. Many other women not currently married also use these contraceptive methods.

Uganda was selected for this study because:

1. Uganda has many HIV infections, even among low-risk women. Women in Uganda needed to know whether using hormonal contraception would increase their risk of getting infected. The use of hormonal contraception had to be tested among people most likely to benefit from the study results, such as women in Uganda.
2. Uganda has a good mix of contraceptive methods from which women could choose. This meant that researchers could study large numbers of both injectable contraceptive users and oral contraceptive users.
3. Uganda has excellent researchers who were interested in finding answers to the question of whether hormonal contraceptive use could affect women's risk of acquiring HIV.

What Did the Study Find?

It found no overall increased risk of HIV acquisition associated with hormonal contraceptive use. This is good news for women.

Current international medical guidelines for hormonal contraceptive use remain the same for now.
The World Health Organization (WHO) and the International Planned Parenthood Federation have both reviewed the study findings, *and at this time do not plan to change their guidelines for* hormonal contraceptive use. WHO says that women at risk of HIV infection or those who are HIV-infected may safely use hormonal contraception.

Despite Uganda's serious and ongoing HIV epidemic, the epidemic is not as severe as in some Southern African countries.
New HIV infections during the study differed substantially in Uganda than in other study sites. Although the study tried to reach women to protect themselves from HIV infection, 83 Ugandan women were infected with HIV during the study. This was higher than in Thailand, but lower than Zimbabwe, the other two countries where the study was conducted.

The HIV infection rate was higher for high-risk than low-risk women, whether the women used hormonal contraception or not.
The rate of HIV infection was 2.2 times higher for the Ugandan women in the high-risk population than for the women in the general population. That is why sexually-active women who are at risk of HIV should always use condoms, regardless of the form of contraception they are using.

Sample Brochure to Share Study Results with a Ministry of Health

Messages in this FHI brochure were written for an audience of health professionals and policymakers.

Study of Hormonal Contraception and the Risk of HIV Acquisition

"This large, multi-site study found no overall increased risk of HIV acquisition associated with hormonal contraceptive use."

– Morrison C, Richardson B, Mmiro F, et al. Hormonal contraception and the risk of HIV acquisition. *AIDS* 2007;21(1):85-95.

January 16, 2007

fhi Family Health International

STUDY SYNOPSIS:

A recent study funded by the U.S. National Institute of Child Health and Human Development (NICHD) has found **no statistically significant overall association between the use of either combined oral contraceptive (COC) pills or depot medroxyprogesterone acetate (DMPA) and HIV acquisition**. A total of some 6,100 HIV-negative women participated in the four-year study, which was led by Family Health International (FHI) in conjunction with seven other institutions, and conducted in Uganda, Zimbabwe, and Thailand. In this prospective, cohort study, women were equally divided among the three groups (users of COCs, users of DMPA, and women not using hormonal contraception). The primary finding of this study provides the best reassurance to date for women in need of highly effective contraception in settings of moderate to high HIV risk.

The study also explored whether sexually transmitted infections (STIs) modified the relationship between hormonal contraceptive use and HIV acquisition. Among STIs included in the analyses were vaginal infections (trichomoniasis, bacterial vaginosis, and candidiasis), cervical infections (chlamydia and gonorrhea), and infection with herpes simplex virus-2 (HSV-2). The African data found only one relationship between hormonal contraceptive use and STIs: Surprisingly, among the approximately half of African study participants testing *negative* for HSV-2 at enrollment, those who used either COCs or DMPA had a statistically significant increased rate of HIV acquisition compared to non-users. This finding was unexpected and has no clear biological mechanism. Thus, as is often the case with unexpected study findings, further research must evaluate this potential association. Of note, the study found that participants who were infected with HSV at the beginning of the study had higher rates of HIV infection than did those women who were HSV-negative at the start.

The results from the study do not indicate that any changes should be made in the provision or use of DMPA or COCs. Neither the World Health Organization nor the International Planned Parenthood Federation, which have reviewed the study results, plans at this time to change its guidelines for hormonal contraceptive use by such women.

Besides no overall increased risk of HIV acquisition associated with hormonal contraceptive use, what else did the study find?

The HIV epidemic is serious and ongoing in Uganda.
Of 3,654 women screened in Uganda, 601 (16.4 percent) were already HIV-infected. This observed HIV prevalence observed was substantially higher than the prevalence of 4.1 percent among all 15- to 49-year-olds in Uganda reported in 2005 by the United Nations. This may have been because all of the women in this study were sexually active at the time of study enrollment and because women were recruited several years before the UN data were collected.

HIV incidence (new infections during the study) differed substantially in Uganda than in other study sites.
The HIV incidence rate among *all* study participants in Uganda was 1.55 per 100 woman years. (A total of 63 Ugandan women were infected.) This was higher than in Thailand (0.15 per 100 woman years), but lower than Zimbabwe (4.03 per 100 woman years). Despite Uganda's serious and ongoing HIV epidemic, the epidemic is not as severe as in some Southern African countries.

Hormonal contraceptive users in Uganda, and especially DMPA users, when compared to women not using hormonal contraception had a somewhat higher risk of acquiring HIV than did such women in Zimbabwe.
Possible explanations include chance, measurement differences in potential confounders by country, or that the effect of hormonal contraception differs by HIV subtype. In Uganda, the HIV subtypes are predominantly A and D. In Zimbabwe, the predominant subtype is C.

The HIV infection rate was higher for high-risk than low-risk women in Uganda, whether the women used hormonal contraception or not.
The rate of HIV infection was 2.2 times higher for the Ugandan women in the high-risk population than for the women in the general population. That is why sexually-active women who are at risk of HIV should always use condoms, regardless of the form of contraception they are using.

HPTN 039 Acyclovir Study Results: These are important results that challenge us to explore further.

Based on previous research linking herpes as a risk factor for HIV, this study answers key questions but clearly tells us we need to know more about how these viruses interact.

Multiple studies showed a 2-3 fold increased risk of HIV acquisition among persons with HSV-2 infection:

- It is thought HSV-2 creates an easier portal of entry recruiting immune cells that are "targets" for HIV entry
- Learned that suppression of HSV-2, with a standard dose of acyclovir (400mg twice daily), did reduce genital ulcers but did not prevent HIV infection among men & women infected with HSV-2
- The study answered primary and secondary objectives
- Surprises from this study included:
  - 37% reduction in visible genital ulcers (substantially lower than in past studies in the US & Europe)
  - In 2 of the 3 regions, less reduction in amount of HSV-2 in breakthrough ulcers
- Next steps to explore from HPTN 039: 1) acyclovir absorption/ pharmacokinetics in different populations, 2) HSV-2 susceptibility to acyclovir from different populations, 3) other etiologies of genital ulcers
- The door is still open to evaluate HSV-2 interventions for HIV infectiousness and transmission

Previous research suggested that acyclovir, the successful treatment for herpes, might be a pathway to HIV prevention.

- Acyclovir has been a safe and effective treatment for HSV-2 for more than 20 years
- Researchers theorized that acyclovir's ability to suppress HSV-2 and prevent genital outbreaks could block HIV infection in people infected with herpes

This well-designed, conducted, and monitored study reinforced proven prevention strategies and provided safeguards to protect the well-being of study volunteers.

- Volunteers were provided with condoms, regular exams, episodic herpes treatment, and extensive counseling on how to reduce their risk for HIV infection throughout the study
- Largest trial of its kind:
  - 3,172 HSV-2 infected people
  - 9 sites, 5 countries
- Sites achieved high volunteer recruitment and excellent retention
- No serious adverse events related to the study drug
- Full disclosure and full consent
- Participants who became infected with HIV during the study have been referred for appropriate medical care and treatment in their community
- Grateful to volunteers

Millions with genital herpes are at risk, so studies to determine the effect of HSV-2 on HIV are essential along with other initiatives.

- 1/3 of new HIV infections in Africa are estimated to be due to HSV-2 infection
- 20% of adults in the U.S. and ~ 50% of women in Sub-Saharan Africa and men having sex with men (MSM) in Latin America have HSV-2 infection
- Although HSV-2 is common, it is often unrecognized in spite of frequent reactivations
- Partners in Prevention study is determining whether HSV-2 can reduce HIV transmission and delay the rate of progression to AIDS
- Need research on:
  - Biology of HSV: factors related to HSV-2 activation
  - Treatment of HSV: effect of higher doses of current drugs, new drugs, combination therapy on clinical and subclinical HSV
  - HSV vaccines
- Clinical trials are needed to move from epidemiologic and biologic observations in order to identify effective interventions

Adapted from: materials developed by Dr. Connie Celum, Principal Investigator, HPTN 039.

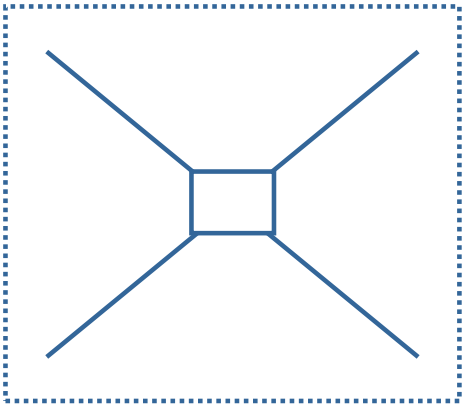
Alternative Sample Grid to Create Compelling Messages

Spitfire Strategies

Messaging Tip Sheet: Create compelling messages

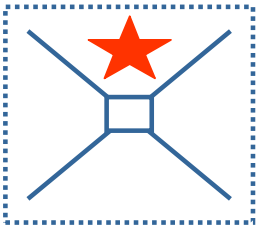
Developing Message Points
Once you know who you want to reach and have determined what they care about, you can create message points that will resonate with this audience. Good messaging has no more than four main points. These points need to be both concise and compelling. It is that easy, and that hard.

To help you think through your message points, try using a message box. The message box is in this shape for a reason. The circular nature of it reminds you that you can start at any message point and hop around to your heart's desire in a speech, during an interview, in a press release – any time you are communicating about your issue. Just stay in the message box. If the messages were presented in a linear fashion, the inclination would be to start at the top and work down. Instead, messages should remain flexible so you can deliver the ones that best fit an audience's knowledge and interest.

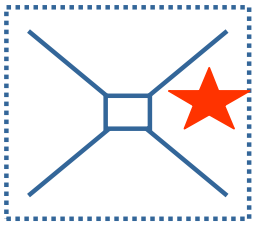


For each different target audience that you are trying to reach, you should have a different message box. This is because every audience has different values and your messages will be most effective if they are tailored to each of your target audiences. Tailoring your messages doesn't mean starting from scratch, but rather adjusting each of the points as needed for the new audience.

Once you have filled in the four core messages in your box (described below), you can develop supporting points for each message including compelling facts, stories and statistics.



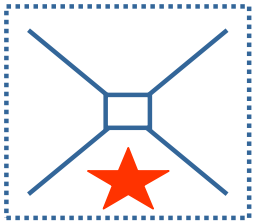
The Value Message – Top (North) Section
This is where you connect with your audience and tap into a specific value that your audience has. This message point reminds them of your common ground, or says something that will get them to agree or at least nod their heads. For newcomer audiences this is a point that you may spend a great deal of time on when making a speech or preparing materials. For the choir this is more of a touch and move on point. Remind them quickly and move to other points that are more pressing.



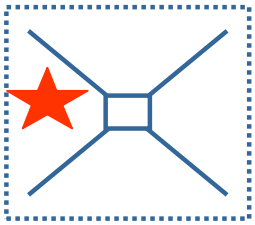
The Barrier Message – Right (East) Section
With so many different opinions out there, the chance for misconception is high. People may not realize the extent of a problem – or they may not realize they are basing all their decisions on an incorrect fact.

Think about all the seemingly credible stories you have heard that have ended up being urban legends. It took a lot of people passing around false information before the story made its way to you and countless others. It doesn't take long to take an incorrect fact and circulate it as the truth. The barrier message point addresses this challenge by countering your audience's key misconception about your issue.

The key to a successful barrier message is that you do not repeat your audience's misconception. Rather, you provide new or unexpected information to overcome this barrier to your audience buying in to your message.



The Ask – Bottom (South) Section
At least one message point should be focused on getting the target audience to do something. What's the point in getting their attention if you don't use it to reach your goals? This is where the ask comes in – the more doable it is the better. Asking someone to save the children isn't helpful – it's overwhelming. People have no idea how to do this. Increasing a school budget to allow for more qualified teachers, however, is something people can get behind.



The Vision Message – Left (West) Section
This message point echoes the value message point. It says to people: If you do what I ask you to do, then you get what you want.

Testing Your Message Box
Once you have finished your message box, pat yourself on the back. Then find a way to test your messages among some audience targets. This could be as simple as asking three or four members of your audience what they think, or it may mean fielding a national poll. Either way, try it out on someone who can evaluate the messages from a neutral standpoint – this rules out you and anyone who helped you complete your message box.

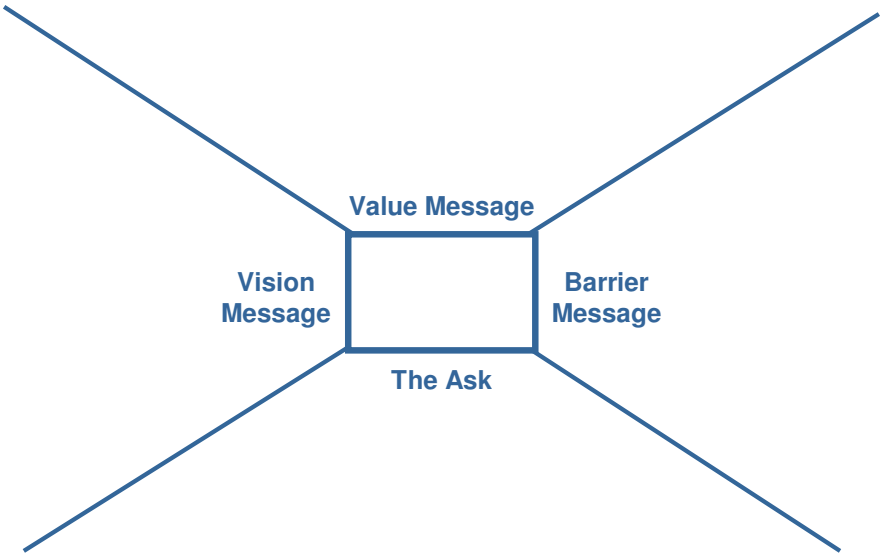
Creating Compelling Messages Worksheet

Who are you trying to reach with this message? *(Remember to keep your audience as narrow as possible. And only select one audience at a time – different audiences need different message boxes.)*

_____

Brainstorm a list of values that your audience has. Circle the one that is most important that you will tap into with your message.

Now fill in the four sections of your message box.



Managing Media Inquiries: Worksheet for Media Calls

Worksheet: When the media calls
Collect the following contact information from the journalist:
Name of journalist:
Publication:
Office number:
Mobile number:
E-mail address:
Ask the journalist the following questions:
What is the story about? What is your angle?
Who else are you interviewing?
If the interview is for radio or television, what is the format? Will it be broadcast live? Will it include call-in questions? What time is it scheduled for and for how long?
What times are good for you? Please give a few options so I can check with the spokesperson's schedule. (What is the deadline?)
Deliver information to the spokesperson:
Brief the person to be interviewed, including all the information gathered above.
Find a few articles the journalist has written on the topic and provide them to the person who will be interviewed.

Sample Standard Operating Procedures (SOPs) for Media Inquiries

SOP for Media Inquiries

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedures that need to be followed on site and off site (within catchment areas and the community) with the media and management of any events that occur and are of concern.

2.Introduction

It is important that we have mechanisms for ensuring that there is effective communication with the media and community. Responsible persons have an obligation to ensure that the media and community receive accurate and relevant information about the study and the study procedures at all times.

3.Responsibility

Principal Investigator (PI)

Sub-investigator

Project Co-ordinators (PC)

Community Educating Officer (CEO)

Reception staff

Any staff member who might be in contact with media

Communication with the Media:

- The primary media point person shall be the Site PI. In the absence of the Site PI, the back-up point persons shall be the study coordinators (clinical trial and socio-behavioral component).
- All study staff will refer media inquiries to the primary media point person (the Site PI) or in her absence, the back-up (study coordinators). For international media inquiries, the Site PI and study coordinator should contact XXX) as well as the PI and clinical monitors.

4.Equipment And Materials

Internal documents (not to be distributed outside the study team and Community Advisory Board [CAB]):

- Internal Frequently Asked Questions (FAQs) about the study
- Tips on how to deal with the media
- Media Call Log Sheet
- Media Visit Log Sheet

External documents (documents that can be distributed to the community):

- Backgrounder on trial
- Frequently Asked Questions about clinical trials

5. Procedures

5.1. Media-Initiated Telephone Calls or Visits

5.1.1. When a caller or unexpected visitor asks to speak with someone about the trial, determine whether the person is a member of the media. Ask: "May I have your name and the name of your organization? What is the reason for your call? What is your phone number and your e-mail address?"

5.1.2. If the person is from the media, request and write down all the information you can get on the Media Call Log sheet. Tell the caller that the site PI would be the best person for him or her to talk to. Make sure you have the reporter's phone number and inform him or her that you or the PI will call back shortly (to give the PI time to prepare). The PI should then be reached and should consider whether to accept doing an interview. (In some cases, it may be best to postpone or decline an interview. In some cases, it would be a mistake not to accept an interview. Seek advice if in doubt.)

Call the reporter back to schedule or decline the interview.

5.1.3. If the PI is unavailable, connect the reporter to the PI's designee while informing the designee that you are doing so. The PI or spokesperson should always have background information on the reporter's request and consider the advisability of discussing the trial at that time before scheduling the interview. If the reporter is unknown to the spokesperson, inquire among colleagues about the reporter's reputation for fairness, or Google the reporter's name to get a sense of his or her knowledge of research, accuracy and tone, and attitudes toward HIV prevention trials. If the reporter has a reputation for inaccuracy, it is best to conduct the interview by e-mail so that quotes cannot be distorted. The PI or spokesperson can say, "I'm busy at the moment but would be happy to answer questions if you send them to me by e-mail."

5.1.4. If all the people responsible for media communication are unavailable, please take a message on the Media Call Log Sheet. Ask "When do you need this by?"and assure the reporter that the appropriate person will call back quickly with a response to the request, one way or the other. Inform the media person when he or she should expect to hear from the PI or designee. If the media person is a visitor, schedule an appointment and say that you will call to confirm or reschedule after you have talked to the PI. Be respectful of the reporter's deadline.

5.1.5. Call the PI immediately and inform her of the media interest, the topic, and any necessary action. If the PI does not answer, leave a message and call a designee.

5.1.6 Send an e-mail copying the PI, the SBC site specialist, the clinical monitors, and the communications point person to inform them of this contact from the media.

5.1.7. If the media call or visit needs to be responded to, the PI or designee should return the call within 24 hours and in time for the reporter to meet his or her deadline, whether accepting or declining the interview.

5.1.8. Document what has been done (such as call to PI, or e-mails) and the responses received from the PI or designee on the Media Log Sheet.

5.2. On-Site Media Visits

5.2.1. If an unexpected visitor asks to speak with someone about the trial, follow the steps outlined in section 6.1.

5.2.2. If the person is from the media, seat him or her in the staff dining area and inform all staff in the

area that a reporter is visiting. Assign someone to ensure that that the visitor does not communicate with anybody while waiting and does not take photographs of participants without permission. Because of the need to protect the confidentiality of study participants, the reporter must not tour the center during hours of operation.

5.3. Communicating with the Media Off Site

In instances where the community outreach team or any other staff are involved in activities within the community and there are media people present, the following must be done:

5.3.1. The preferred procedure is to invite the media staff to visit the center and meet with the PI. If this is not possible, and if the person responsible has received media training, he or she can answer the reporter's questions.

5.3.2. If the person responsible is not media trained, he or she must set up an appointment for the reporter to visit the site for full information from the people trained in communicating with the media.

5.3.3. Record all necessary details about the reporter: full name, name of the organization, contact details, and the topic of interest or angle of the story.

5.3.4. Inform the PI immediately of the media interest, the topic, and any necessary action.

5.3.5. Send an e-mail copying the PI to inform him or her of this contact with the media.

5.3.6. If the media contact needs to be responded to, the PI or designee should return the call within 24 hours and in time for the reporter to meet his or her deadline.

5.3.7. If the media person is persistent about asking you for information, ensure that you give the correct information and do not answer more than what is asked. Get all contact information; ask if this is going to be published, and where and when. Write down everything you say to the reporter media for the records and inform the PI as soon as possible.

5.4. Media Training and Responsibilities

5.4.1. People responsible for the above-mentioned procedures need to be adequately trained and frequently updated in media relations and communications. The training will be prepared in advance with the trial sponsor.

5.4.2. It is the responsibility of the CEO who is conducting community education or community meetings to know who is in the audience and whether the media is represented at the community meetings or education sessions.

5.4.3. It is also the responsibility of the CEO who conducted the community meeting or education session to notify the PC or PI about any media personnel who were present, to record what was said, and to assist in follow-up, including finding out when the information will be published or broadcast and obtaining copies of published articles.

5.4.4. Before publication or broadcast, the PI or designee should contact the reporter to offer assistance and any clarification that might be necessary and to reinforce key messages. Also, the PI or spokesperson should follow up by e-mail to clarify in writing any information that the reporter appeared to have difficulty understanding, or to emphasize an important point that may have been missed. The PI or spokesperson should also offer to review a reporter's draft story for technical accuracy to ensure that factual information is disseminated.

5.4.5. It is the responsibility of the PI and PC to inform the sponsor about the above-mentioned activities.

5.4.6. It is also staff's responsibility to update the FAQs used for community education.

6. Acknowledgment Of Reading And Comprehension Of A Document

SOP Title: Media Communication For X Trial

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Sample Letter to the Editor in Response to a Negative News Article

News Article

MPs warn on Depo Provera family planning method

Women should be encouraged to use other methods of family planning than Depo Provera, due to its terrible side-effects, MPs have said.

Sharing their experiences, the female legislators said the method causes delay in conception and excessive bleeding during menstruation.

The women also said they had their menstrual cycle altered after using the contraceptive.

One women MP said she failed to conceive for seven years, a matter that brought conflict in her home. "After my first-born, I decided to use Depo Provera. I had planned to have the next baby after three years. But it took me seven years to conceive again. My husband was very angry and wondered whether I had only one egg," she said.

She narrated that a woman in her constituency used it and failed to conceive. "When she did after eight years, she developed pressure. Unfortunately, she died."

Excerpted from New Vision (Kampala, Uganda).

Response By Scientist

Contraception for women who want to get pregnant–later

Dear Editor,

Millions of women in countries all over the world use Depo-Provera—or DMPA—as a way to prevent pregnancy. Injectable contraceptives are one of the most popular forms of birth control, and have been available for more than 20 years. Recent news reports have put the spotlight on injectables. Women want to know is Depo-Provera safe? And if they use Depo-Provera, will they still be able to get pregnant when ready to have children?

The scientific research says yes, on both counts. Some women who have experienced problems getting pregnant after they stop getting the shots assume that their infertility was caused by DMPA. This is not the case: the scientific evidence proves that DMPA does not cause infertility. Often, problems getting pregnant are the result of infertility caused by sexually transmitted infections. Infertility is often perceived as only a woman's problem. But in about half of the cases, men are either the single cause of or contribute to the couple's infertility.

The Ministry of Health supports DMPA as a recommended form of family planning and is helping with a project to make it available to women who are interested. This is an important public health initiative, as many women in rural areas have limited access to clinical services. When used with condoms—which reduce the risk of getting a sexually transmitted infection—injectable contraceptives can help prevent infertility and improve the chances that women will become pregnant when they choose to do so.

Sincerely,

Author Data Form for Writing a Press Release

Use this form for internal purposes to assist in preparing a press release.

Name and degrees: Affiliation: Address: E-mail: Telephone: Fax:	
Name of publication:	Expected publication date:
1. What are the three most important findings of your research in relationship to their significance in the field?	
1)	
2)	
3)	
2. Explain the topic in lay-person's language. (How would you explain it to your neighbor?)	
3. Please indicate if your research affects (check all that apply):	
_____ Health care providers	_____ Changes in clinical practice
_____ Health program managers/policymakers	_____ Health policy/government
_____ Other research organizations	_____ Further research and grants
_____ Regular individuals going to their doctor	_____ Public health programs and practice
_____ Other: If other, please specify	
4. Do you have any media contacts that would be interested in your article? If so, please list them here.	
5. Should a journalist require more information from which to write an article, do you wish to be interviewed? (Y/N)	
6. If yes, how would you like to be contacted: _____ Telephone: _____ Best time: _____	
_____ E-mail: _____	
7. Does a research partner institution have a press office? (Y/N) If yes, please provide a contact:	

Adapted from Beyond Scientific Publications

Press Release Template

[insert organization's or study's logo]

For Immediate Release

Contact:

Author's Name, Title

School/Department

Address

Telephone

Fax

E-mail

One-Line Attention-Getting Title

(City, STATE) Date of Distribution–This is a sample press release. Every release should begin with a short (25 words or less), one-line paragraph that hooks the reader's interest.

The purpose of a press release is to provide newsworthy information to the media. "Newsworthy" means that the information is **(1)** timely (has some immediate impact on readers); **(2)** novel (the first, the best, etc.); **(3)** consequential (a development that will have significant impact on readers); **(4)** dramatic (reveals something quirky or colorful about the human condition or character); **(5)** prominent (relates to a public figure or organization); or **(6)** proximate (affects people living in an area). Contrary to popular belief, newspapers and television stations are not sitting around with empty space to fill, nor do they feel a moral responsibility to write about PSU.

The press release should be a concise (no more than two double-spaced pages), factual, informative, and straightforward piece of writing that describes what you want the public to know. The most important and indispensable information (who, what, when, where, etc.) is located at the beginning of the story; the most expendable information is at the end. Make every paragraph, sentence, and word count.

Text in all press releases should be typed in the font Tahoma, size 10. If you don't have Tahoma, use Palatino, Helvetica, or Times Roman.

If you are unable to fit your information in the preferred one-page format, end page one with:

(more)

Add the following heading at the top of page two:

Page 2—Key Words from Title

Otherwise, end the body of the press release with the following symbol:

###

If you are announcing an event, be sure to include accurate information about the time, date, location (including street address and room number), and cost. Proofread, proofread, and proofread. Most media require at least 2 to 3 weeks lead time to publish your event.

If you use a quote, and it is recommended that you do, give it its own paragraph so that the reporter can easily pick it out.

At the end, add "boilerplate" text about your research institution. For example: The Center for Interdisciplinary Research on AIDS (CIRA) was established in 1997 and is currently New England's only National Institute of Mental Health (NIMH)-funded AIDS research center. CIRA brings together scientists from 20 different disciplines and two institutions, including Yale University in New Haven, CT and The Institute for Community Research in Hartford, CT.

Research institution name here

Physical/mailing address here

Telephone number here

Fax number here

# #

Adapted with permission. This work was supported, in part, by Yale University's Center for Interdisciplinary Research on AIDS (CIRA), through grants from the National Institute of Mental Health to Paul Cleary, Ph.D. (No. P30 MH 62294).

Sample press release

For Immediate Release

January 25, 2005

Contact: Kim Best, Science Editor

919.544.7040

Oral Contraceptives and Weight Gain

Updated research review still finds no evidence that oral contraceptives cause weight gain

Research Triangle Park, NC—Many women stop using oral contraceptives early or never start using them because of concerns about gaining weight. But an updated review of studies examining the relationship between hormonal contraceptive use and weight change continues to find no evidence that contraceptive pills increase weight.

This review, published in the latest issue of the Cochrane Library, includes two additional studies beyond those originally reviewed by researchers at Family Health International (FHI) and published in 2003 in the Cochrane Library. In total, 44 hormonal contraceptive trials containing information about study participants' weight changes—the majority of which addressed oral contraceptive use—have now been examined.

One strength of the review, which was an exhaustive search of the scientific literature on this topic, was that it was limited to randomized controlled trials, the "gold standard" of trial designs for reducing the potential for bias.

Three of the trials compared weight changes in women taking oral contraceptives versus weight changes in women taking placebos. None of the three showed an association between oral contraceptives and weight gain. The remaining trials that considered oral contraceptive use compared weight changes between women taking different oral contraceptive regimens. While some women gained weight and some lost weight over time, overall differences between groups were minimal. The largest difference in weight change between groups was less than five pounds.

"In comparing different combination contraceptives, you would expect differences between groups if the estrogen or progestin in the pills or the type of pill was causing weight gain," says FHI researcher and review coauthor Laureen Lopez. "But we did not see any major differences between groups taking different types of pills," she says.

Combined oral contraceptives are the most common form of contraception in the United States and are used by more than 100 million women worldwide. If taken correctly and consistently, they are more than 99 percent effective at preventing pregnancy. Under typical use, they are less effective.

Studying the association between oral contraceptives and weight gain has been difficult for multiple reasons, including the facts that many different oral contraceptive regimens exist and some women gain weight over time regardless of whether they use contraception. "It is very reassuring news," says coauthor Dr. David Grimes of FHI. "A widely held myth suggests that oral contraceptives cause weight gain, but the answer as best we can tell is they do not," he says.

The Cochrane Library is an electronic database of the Cochrane Collaboration, an international organization committed to helping people make informed health care decisions by preparing, maintaining, and promoting systematic reviews of the effects of health care interventions. Family Health International contributes to the Cochrane Collaboration by producing reviews of randomized clinical trials of contraceptive methods. For more information on the Cochrane Collaboration, see http://www.cochrane.org/. To learn more about Family Health International, see http://www.fhi.org/.

Source

Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight (Cochrane Review). In: The Cochrane Library, Issue 1. Chichester, UK: John Wiley & Sons, Ltd., 2006.

Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention and care. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems.

Selected Additional Resources

Disseminating Research

Explaining Research: How to Reach Key Audiences to Advance Your Work
Dennis Meredith. 2010. Oxford University Press, New York.

Explaining Research is a comprehensive communications guidebook for scientists, engineers, and physicians. It explains how to use Web sites, blogs, videos, webinars, lectures, news releases, and lay-level articles to reach key audiences.

Communicating Public Health Information Effectively: A Guide for Practitioners
David E. Nelson, Ross C. Brownson, Patrick L. Remington, Claudia Parvanta. 2002. American Public Health Association, Washington, DC.

This U.S.-oriented 230-page guide explains what is involved in translating public health data into messages for different audiences, persuasive health communication approaches, risk communication planning, and more.

Developing an Effective Dissemination Plan
National Center for the Dissemination of Disability Research. 2001. Austin, TX. Available from: http://www.researchutilization.org/matrix/resources/dedp/index.html#ten.

This online guide is easy to read and provides checklists for basic elements of a plan. It walks readers through steps needed to conceptualize a dissemination plan that ensures dissemination efforts will promote the use of new knowledge in programs and policies.

Smart Chart 3.0: An Interactive Tool to Help Nonprofits Make Smart Communications Choices
Spitfire Strategies. 2010. Washington, DC.

The Interactive Smart Chart is a planning tool that helps nonprofits develop high-impact communications strategies. It explains how to use "message boxes" to develop messages that will resonate with your audiences and overcome existing misconceptions. It is available at no cost after online registration from: http://www.smartchart.org/about.php.

Issues Management and Crisis Communication

Strategic Issues Management: Organizations and Public Policy Challenges
Robert L. Heath. 1997. Sage Publications, Inc., Thousand Oaks, CA.

This 410-page text reviews theory and evidence on issues management. It focuses on four key challenges: strategic planning, constant issue surveillance, organizational responsibility, and public discussion of ideas and issues. Chapters on crisis communication and risk communication are particularly pertinent to health research.

Best Practices in Crisis Communication: Evolution of Practice through Research
Robert L. Heath. 2006. Journal of Applied Communication Research. 34(3):245–8.

This article provides a concise summary of best practice in crisis communication. It is available for purchase online from: http://www.informaworld.com/smpp/title~content=g748001667~db=all.

A Case Study of Crisis Communication at Mercyhurst College
Melissa Hancock, Anthony Peyronel, Jennifer Allen. Date unavailable. Edinboro University, Department of Communication and Media Studies, Edinboro, PA.

Mercyhurst College, located in Erie, PA, was faced with a crisis after a six-page story in the Erie Times-News accused then president, Dr. William P. Garvey, of physically and sexually abusing boys from the 1960s through the 1980s. This article analyzes efforts to respond to the accusation, applying Heath's best practices in crisis communication. It is available free for download from: http://66.102.9.132/search?q=cache:W0fj5fgI-Q4J:departments.edinboro.edu/ commmedia/custom/commmedia/documents/ Best%2520Practices%2520in%2520Crisis%2520Communication.doc+crisis+communication+
heath&cd=37&hl=en&ct=clnk.

The Peter M. Sandman Risk Communication Web site
Peter M. Sandman, 2010. Princeton, NJ.

This Web site includes useful tips and guidance about managing health and environmental crises. It includes numerous case studies of past communications challenges and useful articles, such as "Managing Justified Outrage: Outrage Management When Your Opponents Are Substantively Right." See: http://www.psandman.com.

Crisis Communication for the Social Media Age
Aliza Sherman. 2009. WebWorkerDaily.com.

Tips on how to anticipate and respond to media flares in cyberspace, the blogosphere, and other social media are provided in this short online article, available for download from: http://webworkerdaily.com/2009/06/01/crisis-communications-for-the-social-media-age/.

Useful Case Studies of the Communications Challenges of Trials

South Africa's Experience of the Closure of the Cellulose Sulphate Microbicide Trial
Gita Ramjee, Roshini Govinden, Neetha S. Morar, Anthony Mbewu. 2007. PLoS Policy Forum. 4(7):e235, 1167–73.

This article is available online from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1950203.

Research Rashomon: Lessons from the Cameroon Pre-Exposure Prophylaxis Trial
Elizabeth McGrory, Andrea Irvin, Lori Heise. 2009. Global Campaign for Microbicides, Washington, DC.

Available for download from: http://www.global-campaign.org/clientfiles/Cameroon.pdf.

Preventing Prevention Trial Failures: A Case Study and Lessons for the Future from the 2004 Cambodia Tenofovir Trial
Anna Forbes, Sanushka Mudalier. 2009. Global Campaign for Microbicides, Washington, DC.

Available for download from: http://www.global-campaign.org/clientfiles/Cambodia.pdf.

Dealing with the Media

A Media Handbook for HIV Vaccine Trials for Africa
Yinka Adeyemi. 2001. Joint United Nations Programme on HIV/AIDS (UNAIDS), Geneva.

This handbook is designed to help equip scientists, communications staff, and others who work on HIV vaccine trials to deal effectively with the media. It describes how to write a press release, plan a press conference, and handle "nightmare" scenarios. Available for free download from: http://portal.unesco.org/ci/en/files/25327/11891582741A_Media_Handbook_for_HIV_Vaccine_Trials_for_Africa.pdf/A%2BMedia%2BHandbook%2Bfor%2BHIV%2BVaccine%2BTrials%2Bfor%2BAfrica.pdf.

Handling the Media: A Toolkit
Karen Hurt. 2004. CIVICUS: World Alliance for Citizen Participation, Johannesburg.

This toolkit is especially useful for those who provide interviews to news media, and offers practical guidelines and detailed checklists to help you prepare for interviews with newspaper, radio, or television journalists; issue press statements; or write press releases. It is available free online from: http://www.civicus.org/new/media/Handling%20the%20Media.pdf.

Spin Works! A Media Guidebook for Communicating Values and Shaping Opinion
Robert Bray. 2000. The Spin Project, Independent Media Institute, San Francisco, CA.

The book uses easy-to-understand language and provides concrete examples of media plans, press releases, and other communications materials. It also offers case studies of social justice organizations and step-by-step guidelines for creating and sticking to a strategic communications plan. Information on a newer edition—Spin Works! A Media Guide for the Rest of Us—is available from: http://www.spinproject.org/article.php?id=172.

100+ Resources to Boost Your Social Media Savvy in 2009: Top Tips and Advice from the Experts.
Robin Broitman. 2009. Interactive Insights Group, Reston, VA.

This Web site compiles easy-to-read articles on social media, such as "50 Ways to Use Social Media, by Objective," "Blogging for Beginners," and tips for using Twitter, Podcasts, wikis, and other electronic communications. 100+ Resources is available online from: http://www.interactiveinsightsgroup.com/blog1/100-resources-to-boost-your-social-media-savvy-top-tips-advice-from-the-experts/.

Resources for Communicating Science Clearly

News and Numbers: A Guide to Reporting Statistical Claims and Controversies in Health and Other Fields.
Victor Cohn, Lewis Cope. 2001. Iowa State University Press, Ames, IA.

Written by two former science writers for the *Washington Post* and the *Minneapolis-St. Paul Star Tribune*, this book helps the reader answer three key questions about all scientific studies, polls, and other statistical claims: What can I believe? What does it mean? How can I explain it to others? It is a useful resource for helping trial staff communicate clearly about scientific concepts.

Developing Materials on HIV/AIDS/STIs for Low-Literate Audiences: A Guide
Program for Appropriate Technology in Health (PATH), Family Health International (FHI). 2002. Washington, DC.

This manual offers guidelines for developing materials for illiterate and low-literate groups. Among other topics, it includes chapters on how to conduct "audience" research to assess and understand community members' needs and concerns and on using data from focus group discussions to develop messages and communicate them pictorially in a clear, sequential manner. The manual is available free for download from: http://www.path.org/publications/details.php?i=688.

Communicating Science News: A Guide for Public Information Officers, Scientists and Physicians
National Association of Science Writers (NASW). 2006. Berkeley, CA.

This short online guide contains useful information, especially about interacting with international media at scientific conferences. It can be accessed on NASW's Web site at: http://www.nasw.org/resource/pios/csn/index.htm.

Resources for Advocacy

Advocacy Tools and Guidelines: Promoting Policy Change
Sophia Sprechmann, Emily Pelton. 2001. CARE, Atlanta GA.

This document is an easy-to-use manual on how to plan and implement advocacy strategies including developing compelling messages, delivering messages strategically, building constituencies, and other useful strategies. It is available for download from: http://www.care.org/getinvolved/advocacy/tools/english_00.pdf.

Engaging Advocates from Concept to Results: Summary Report of the Advocates' Consultation on HIV Prevention Trials: Carraguard and VOICE Studies.
Microbicide Trials Network, Population Council. 2007. Johannesburg.

Available online from: http://www.popcouncil.org/pdfs/MIC_AdvoConsultationOct2007.pdf.

Community Engagement in HIV Prevention Trials: Evolution of the Field and Opportunities for Growth
Katie West Slevin, Mornike Ukpong, Lori Heise. 2008. aids2031, Science and Technology Working Group, New York.

Available online from: http://www.aids2031.org/pdfs/aids2031%20preconf%20reading%20-%20community%20engagement%20_west_.pdf.

Translating Research into Practice

Going Beyond Research: A Key Issues Paper Raising Discussion Points Related to Dissemination, Utilization and Impact of Reproductive and Sexual Health Research
Ian Askew, Zoe Matthews, Rachel Partridge. 2002. University of Southhampton, Southampton, UK.

Written for individuals responsible for health service programs and policy, researchers, and research and program funders, this paper provides pointers for effective communication of research findings and approaches to promoting their use in policies and programs. It is available from: http://www.popcouncil.net/pdfs/frontiers/reports/Going_beyond_research.pdf.

Communication of Research: Guidance Notes for Research Programme Consortia
Communications Team, Central Research Department, UK Department of International Development (DFID), The Communication and Information Management Resource Centre (CIMRC). 2005. DFID, London.

This resource focuses on how to develop a communication and advocacy strategy to encourage the translation of research findings into policy and practice reforms. It includes links to many other useful documents. Available for free download from: http://www.dfid.gov.uk/Documents/publications/communication-research.pdf.

Making a Differences to Policies and Programs: A Guide for Researchers
Robert W. Porter, Suzanne Prysor-Jones. 1997. Support for Analysis and Research in Africa (SARA) Project. Academy for Educational Development, Washington, DC.

Developed in collaboration with the Joint Health Systems Research Programme, the Essential National Health Research (ENHR) Africa Secretariat, and the Council on Health Research for Development (COHRED), this booklet includes a summary of key steps in communicating research results using a three-way process linking researchers, decision makers, and communities. It is available free online from: http://sara.aed.org/publications/cross_cutting/policy_programs/html/eng_intro.htm.

IHE Report: Effective Dissemination of Findings from Research
Institute of Health Economics (IHE). 2008. Alberta, Canada.

This 80-page report analyzes approaches to knowledge translation, and knowledge transfer and exchange, with a focus on health research. It identifies evidence-based strategies and offers case studies. The report can be downloaded from: http://www.ihe.ca/documents/Dissemination_0.pdf.

Evaluating the Impact of Communication Efforts

Monitoring and Indicators for Communication for Development: Technical Note
Ministry of Foreign Affairs of Denmark. 2007. Technical Advisory Service, Danish International Development Agency (DANIDA), Copenhagen.

Full text of this publication, which contains indicators of use to groups interested in evaluating the impact of research dissemination, can be downloaded from: http://www.danidadevforum.um.dk/NR/rdonlyres/EC4B438C-071E-4971-B1B9-A0F9A0C235D6/0/Monitoringandindatorsofcommuniaton.pdf.

Guide to Monitoring and Evaluating Health Information Products and Services
Tara M. Sullivan, Molly Strachan, Barbara K. Timmons. 2007. Center for Communication Programs, Johns Hopkins Bloomberg School of Public Health, Washington, DC; Constella Futures, Cambridge, MA; Management Sciences for Health, Boston, MA.

This guide is available from: http://www.infoforhealth.org/hipnet/MEGuide/MEGUIDE2007.pdf.

Web sites with Easy-to-Understand Information on Prevention Research

AIDSMAP/NAM
http://www.aidsmap.com

AVAC: Global Advocacy for AIDS Prevention
http://www.avac.org

Clearinghouse on Male Circumcision for HIV Prevention
www.malecircumcision.org

Family Health International
www.fhi.org

Global Campaign for Microbicides (GCM)
http://www.global-campaign.org

Joint United Nations Programme on HIV/AIDS (UNAIDS)
www.unaids.org

SciDev Net (Science and Development Network)
http://www.scidev.net/en/health

Acronyms

ACSA: Asociación Civil Selva Amazonica
AMAG: African Microbicide Advocacy Group
AVAC: Global Advocacy for HIV Prevention
ART: Antiretroviral therapy
BMJ: The British Medical Journal
BST: British Summer Time
CAB/CAG: Community Advisory Board/Community Advisory Group
CAPRISA: Centre for the AIDS Programme of Research in South Africa
CDC: U.S. Centers for Disease Control and Prevention
CEO: Community Educating Officer
CIDRZ: The Centre for Infectious Disease Research in Zambia
CIRA: Center for Interdisciplinary Research on AIDS
CLO: Community Liaison Officer
CROI: Conference on Retroviral and Opportunistic Infections
CS: Cellulose sulfate
DAIDS: Division of AIDS
DFID: U.K. Department of International Development
DMC: Data Monitoring Committee
DSMB: Data and Safety Monitoring Board
DST: Daylight Savings Time
FAQ: Frequently Asked Questions
FHI: Family Health International
GCM: Global Campaign for Microbicides
GCP: Good Clinical Practice
GHS: Global Health Strategies
GLBT: Gay, Lesbian, Bisexual, and Transgender
GOI: Government of India
GTZ: Gesellschaft für Technische Zusammenarbeit (German cooperation agency)
HPTN: HIV Prevention Trials Network
HSV: Herpes simplex virus
HVTN: HIV Vaccine Trials Network
IAVI: International AIDS Vaccine Initiative
ICRH: International Centre for Reproductive Health
IDMC: Independent Data Monitoring Committee
IPM: International Partnership for Microbicides
IRB: Institutional Review Board

IRIN: Integrated Regional Information Networks
LSHTM: London School of Hygiene and Tropical Medicine
MDP: Microbicides Development Programme
MEDUNSA: Medical University of South Africa
MHRP: U.S. Military HIV Research Program
MMCI: Microbicides Media and Communications Initiative
MOH: Ministry of Health
MOPH: [Thai] Ministry of Public Health
MRC: Medical Research Council
MSM: Men who have sex with men
MTN: Microbicide Trials Network
MU-JHU: Makerere University-Johns Hopkins University
NARI: National AIDS Research Institute
NEJM: New England Journal of Medicine
NHVMAS: New HIV Vaccine and Microbicide Advocacy Society
NGO: Nongovernmental organization
NIAID: National Institute of Allergy and Infectious Diseases
PATH: Program for Appropriate Technology in Health
PC: Project Coordinator
PHRU: Perinatal HIV Research Unit
PI: Principal Investigator
PIP: Partners in Prevention
PLWHA: Person living with HIV/AIDS
PR: Public relations
PrEP: Pre-exposure prophylaxis
Q&A: Question(s) and Answer(s)
REC: Research Ethics Committee
RHRU: Reproductive Health & HIV Research Unit
SAAVI: South African AIDS Vaccine Initiative
SEC: Securities and Exchange Commission
SIV: Simian immunodeficiency virus
SOP: Standard operating procedure
STI: Sexually transmitted infection
VCT: Voluntary counseling and testing
UNAIDS: The Joint United Nations Programme on HIV/AIDS
USAID: U.S. Agency for International Development
UW/ICRC: University of Washington/International Clinical Research Center
UZ-UCSF: University of Zimbabwe-University of California San Francisco
VOICE: Vaginal and Oral Interventions to Control the Epidemic
WHO: World Health Organization

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Communications Handbook for Clinical Trials

Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results provides practical guidance to clinical trial staff and research partners on how to anticipate and respond to the special communications challenges posed by the conduct of clinical research.

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—Prof. Linda-Gail Bekker, Desmond Tutu HIV Foundation, University of Cape Town, South Africa

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—Dr. Timothy M. Farley, Department of Reproductive Health and Research, World Health Organization, Geneva

"In an era where research into tangible health-related interventions is a global effort, this handbook represents a thoughtful, well-organized approach to developing communication strategies that address today's challenges."

—Dr. Patrick Ndase, Microbicide Trials Network and International Clinical Research Center, University of Washington, Kampala, Uganda

Preface written by ARCHBISHOP EMERITUS DESMOND M. TUTU, who is a tireless champion in the fight against AIDS and tuberculosis, and serves as patron of the Desmond Tutu HIV Foundation and the Desmond Tutu HIV Centre at the University of Cape Town's Institute of Infectious Disease and Molecular Medicine.