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

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.

Elizabeth T. Robinson/FHI

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

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 the network. A full copy of the network's questionnaire is available in Appendix 2.1 and can be downloaded as a template..

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 2.1.

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 2.2 for an example or download the template for this tool). 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 communications 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 a research network reserve at least 10 percent of its 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. (To download a blank template of this budget worksheet, click here.) A basic program would be appropriate for a small trial 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 (see Box 2.5 or download the template). 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.

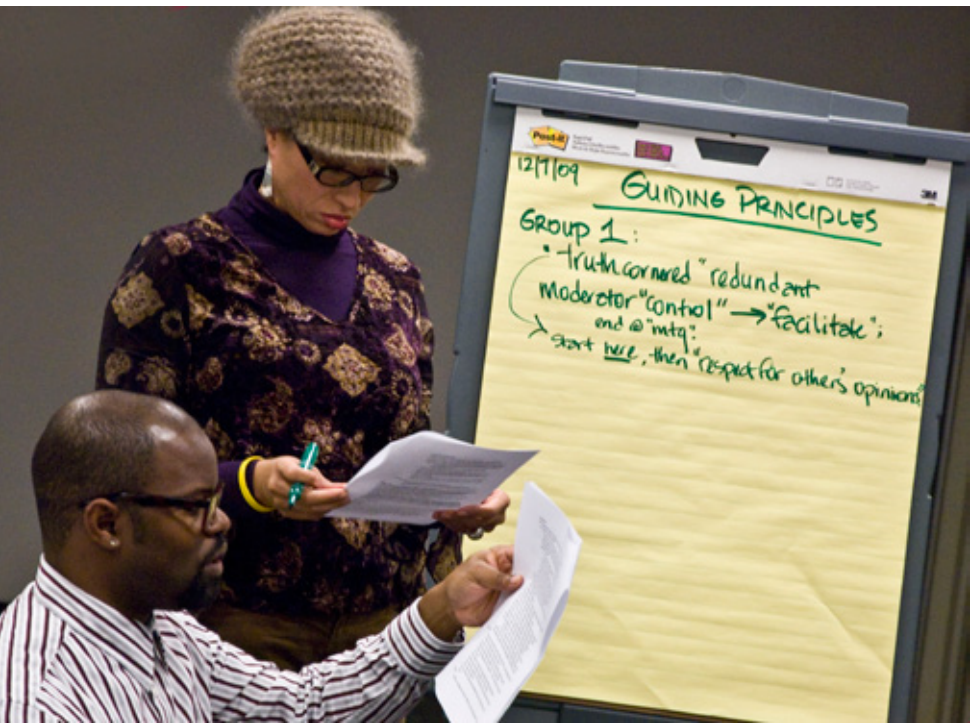
Communication teams should include staff who work closely with the community, in addition to individuals with scientific and communications expertise. In this photo, FEM-PrEP trial staff gather in Nairobi.

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, they read their answers 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 spokespersons 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.