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

Jim Daniels

Preventing and Managing a Crisis

B y 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 with 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

I.   What is a crisis communications plan?

II.   Why is a crisis communications plan needed?

III.   Preventing crises

IV.   Preparing for potential controversy

V.   Developing a rapid response procedure

VI.   Implementing your crisis communications plan

VII.   Managing unexpected trial closures

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 defuse or minimize the potential crisis quickly, efficiently, and compassionately

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.

> **TIP**
>
> **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.**

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) members 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).

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.

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.

Jim Daniels

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 defusing 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

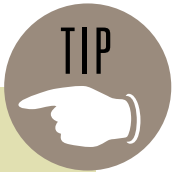The crisis communications team is responsible for anticipating and defusing controversies. This includes:

- 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

TIP

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.

TIP
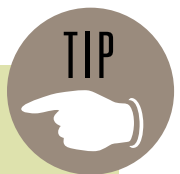
Tips for trial spokespersons

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. These include 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 a 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).

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 roles 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 above 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. (Click here to download a template.) 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.

Always communicate with compassion and empathy.

YouthNet/FHI

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 defusing 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.