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

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

I. **The purpose of this handbook**

II. **Challenges posed by clinical trials**

III. **Origins of the handbook**

IV. **How this handbook is organized**

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.

I 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. Another resource that may be useful to community liaison and outreach staff is the Stakeholder Engagement Toolkit for HIV Prevention Trials, which is a guide to engaging a wide range of key stakeholders, including community members, in every stage of a clinical trial.

TIP

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

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 the tasks of 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," now coordinated by AVAC 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; 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 (now FHI 360), 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.

Chapters 2 to 6 detail the steps typically involved in the implementation of a clinical trial. They take 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

Chapters 7 to 9 focus 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.
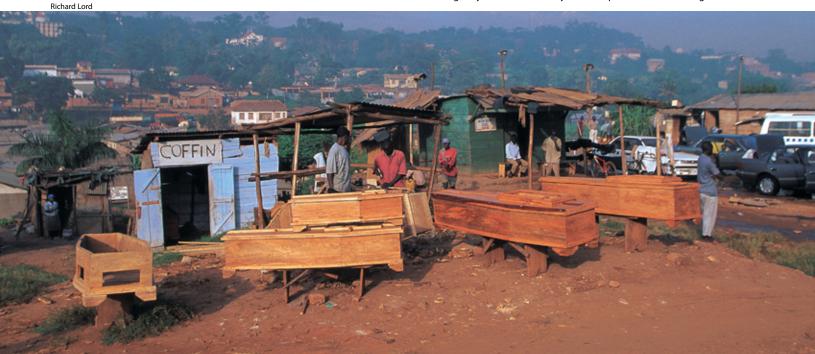
Templates and tools. Sample templates, worksheets, and checklists are included in the appendices and are referenced in the relevant chapters. These resources, including blank copies of the templates, are available for users to download.

Video. Short video clips illustrating topics covered in the handbook accompany each chapter. They feature interviews with trial staff, communications experts, advocates, and others involved in clinical research.

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. To submit materials, email: commshandbook@avac.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 communications procedures	Chapter 2
Site initiation training ● Good Clinical Practices ● Ethics orientation ● Protocol requirements, etc	**Develop strategic communications 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.