

Stakeholder Engagement Toolkit

for HIV Prevention Trials

by Kathleen M. MacQueen, Sarah V. Harlan,
Katie West Slevin, Stacey Hannah,
Emily Bass and Jill Moffett



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This work is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID). The contents are the responsibility of FHI 360 and do not necessarily reflect the views of USAID or the United States Government. Financial assistance was provided by USAID under the terms of Cooperative Agreement GH0-A-00-09-00016-00, the Preventive Technologies Agreement.

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Acknowledgments

The **Stakeholder Engagement Toolkit** was developed through the efforts and experiences of many people. The generous input and support from the toolkit's potential users and other stakeholders resulted in high levels of international cooperation. The toolkit has benefited from the willingness of researchers, stakeholder-engagement specialists and others to describe the challenges they have encountered while attempting to engage their stakeholders — and the ways they overcame these challenges. Key insights were also gained from visits to HIV prevention research sites in Africa.

We are grateful to the following individuals who enriched the toolkit with their knowledge of stakeholder engagement:

Matthew Alexander, Ifakara Health Institute, Tanzania

Chibuikwe Amaechi, New HIV Vaccine and Microbicide Advocacy Society, Nigeria

Deborah Baron, formerly with the Microbicides Media and Communications Initiative

Modesta Chileshe, Centre for Infectious Disease Research in Zambia

Manju Chatani, AVAC: Global Advocacy for HIV Prevention (AVAC), New York City, United States

Somer Cooper, FHI 360

Jennifer Deese, FHI 360

Michael Dejene, Dr. Michael Dejene Public Health Consultancy Services, Ethiopia

Nancy DeSousa, formerly with FHI 360

Samukeliso Dube, Global Campaign for Microbicides, South Africa

Natalie T. Eley, FHI 360

Paul Feldblum, FHI 360

Barbara Friedland, Population Council, United States

Janet Frohlich, Centre for the AIDS Programme of Research in South Africa (CAPRISA)

Mitzy Gafos, Microbicides Development Programme (MDP) 301, Africa Centre for Health and Population Studies, South Africa

Vera Halpern, FHI 360

Pauline Irungu, Global Campaign for Microbicides, Kenya

David H. Jolly, North Carolina Central University, Durham, North Carolina, United States

Altaye Kidane, FHI 360/Ethiopia	Patrick Ndase, Microbicides Trial Network and Partners in Prevention trial, Kampala, Uganda
Charles Kilel, Walter Reed Project–Kenya,	
Kenya Medical Research Institute	Bahati Prince Ngongo, IAVI, United States
Andrew Lambert, formerly with International Partnership for Microbicides (IPM), South Africa	Busi Nkala, Perinatal HIV Research Unit (PHRU), South Africa
Christine Lasway, FHI 360	Smanga Ntshele, Aurum Institute for Health Research, South Africa
Shelley Lees, formerly with MDP, Africa Centre, South Africa	Margaret Onah, New HIV Vaccine and Microbicide Advocacy Society, Nigeria
Peggy Madikoe, IPM, South Africa	Victoria Geogian Oyier, International Centre for Reproductive Health, Kenya
Martha Masaki, Kilimanjaro Reproductive Health Project, Tanzania	Joel Odondi, Kenya Medical Research Institute (KEMRI) and University of California, San Francisco (UCSF) Infectious Disease Research Training Program, KEMRI Kisumu Site, Kenya
Doreen Medupe, Manguang University of the Free State Community Capacity Program, South Africa	Kago Phofuetsile, Centers for Disease Control and Prevention (CDC)–Botswana (Heterosexual Trial–TDF2), Botswana
Alex Menezes, International AIDS Vaccine Initiative (IAVI), United States	Malebo Ratlhagana, Setshaba Research Centre, South Africa
Nkosinathi Mhlongo, MDP, Africa Centre, South Africa	
Lori Miller, AVAC, United States	Randy C. Rogers, Durham County Health Department, Durham, North Carolina, United States
Sally Mtenga, Ifakara Health Institute, Tanzania	Charles Shagi, African Medical and Research Foundation (formerly at MDP), Tanzania
Peter Michira, Partners in Prevention, Kenya	Francesca Stuer, FHI 360/Ethiopia
Vuyelwa Mtimkulu, formerly with Setshaba Research Centre, South Africa	
Kennedy Mundia, MDP, Zambia	Lut Van Damme, FHI 360
Richard Mutemwa, MDP, United Kingdom	Mama Aaron Wandoa, Tanzania
Misiwe Mzimela, MDP, Africa Centre, South Africa	Rhonda White, FHI 360
Shekha Nasser, Ifakara Health Institute, Tanzania	Merywen Wigley, FHI 360
	Martha Zewdie, Armauer Hansen Research Institute, Ethiopia

We are deeply indebted to the following people for their substantive contributions to the development of the toolkit:

Tom Milroy, Durham, NC, United States

Catherine Hart, FHI 360

Stella Kirkendale, FHI 360

Dominick Shattuck, FHI 360

Elizabeth T. Robinson, Futures Group, United States

We also wish to acknowledge the following organizations:

Community Involvement Community of Practice

Global Campaign for Microbicides

HIV Prevention Trials Network

Microbicide Trials Network

We are grateful to the following individuals at FHI 360 who reviewed the contents of the toolkit:

Paul Feldblum

Stella Kirkendale

Amanda Troxler

Lut Van Damme

Elizabeth Mosley, FHI 360, provided valuable administrative assistance and helped to write the glossary.

Barbara Scott, Raleigh, North Carolina, United States, copyedited the toolkit.

Michael Szpir, FHI 360, edited various drafts of this toolkit.

Finally, we wish to thank the United States Agency for International Development (USAID), which provided funding for this work.

Kathleen M. MacQueen, FHI 360

Sarah V. Harlan, formerly of FHI 360

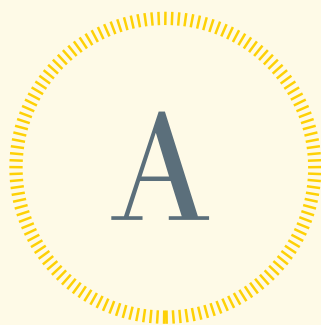
Katie West Slevin, Consultant

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July 2012



About This Toolkit

Introduction

A stakeholder is a critical ally in any HIV prevention research endeavor. By definition, a stakeholder is someone at the local, national or international level who can affect or be affected by the research — potentially a large group of people who are deeply interested in the results of your trial. A stakeholder's perception of the research is important not only for the success of your trial, but also for the support of future research. The premature closure of several important HIV prevention trials in the past decade highlights the need to actively engage stakeholders in a timely and respectful manner. Working with a wide range of stakeholders throughout all stages of a research project has many benefits, including the development of mutual trust, lasting partnerships, capacity building and research results that are well understood by those who stand to benefit.

Purpose of the toolkit

It is generally recognized that researchers in a clinical trial need to engage a broad range of stakeholders when they conduct an HIV prevention trial. Little systematic guidance has been provided, however, on how to engage stakeholders in an effective and efficient way. We designed this toolkit to fill that gap.

Effective stakeholder engagement is built on trusting relationships. Developing someone's trust takes time, and trust grows as one demonstrates appropriate and reliable behavior. Do you do what you say you will do? How do you handle mistakes and misunderstandings? Are you open and honest? Do you consider the concerns of others when you make a decision? There are no short cuts to building trust. But a systematic process can prevent a haphazard approach and save time.

We designed this toolkit to help your research team plan for stakeholder engagement through every stage of your research. It should help you document your plans, your accomplishments and the approaches that did or did not work in a setting. The toolkit will make it easier for research teams in different settings to compare their approaches and to identify the best practices that work across settings.

The toolkit can be a helpful guide for us because, although we have been doing many of the things that are in the toolkit, we know that we have not been systematic about it...This toolkit provides stakeholders with an opportunity to improve a research idea before the research starts.

— Country director of an international nongovernmental organization in Ethiopia

Objectives

- Provide step-by-step guidance to help HIV researchers and their staffs engage a broad spectrum of stakeholders in an efficient and transparent manner.
- Provide tools to help research staff document their plans and experiences as they implement a stakeholder engagement strategy and systematically identify activities that work in their research settings.
- Make it easier for research teams in different settings to compare their methods and to identify best practices that work across different settings.

Users

The toolkit has been developed for use by these individuals:

- **Research leadership** (principal investigators, local investigators and trial coordinators)
- **Staff members who will lead stakeholder engagement activities** in a research trial
- **Other staff members with responsibilities that support stakeholder engagement** — this can include community liaison officers (CLOs), community outreach specialists, support staff and others
- **Other audiences** — including funding agencies, leaders of research organizations and regulatory agencies — who find this toolkit useful

Related activities and publications

We designed this toolkit from a broad perspective to ensure that efforts to engage a local community are integrated into a comprehensive strategy that recognizes and addresses the need for transparency and trust at every level — local, national and international.

The toolkit was developed to complement the following publications:

- *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials.*¹ Available from: www.avac.org/gpp
- *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results.*² Available from: <http://communications4clintrials.org/>

¹ Joint United Nations Programme on HIV/AIDS (UNAIDS). Good participatory practice: guidelines for biomedical HIV prevention trials [Internet]. 2nd ed. Geneva: UNAIDS; 2011 [cited 2012 April]. Available from: www.avac.org/gpp

² Robinson ET, Baron D, Heise L, Moffett J, Harlan SV. Communications handbook for clinical trials [Internet]. Research Triangle Park (NC): FHI 360 and Microbicides Media and Communications Initiative (MMCI); 2010 [Cited 2012 April]. Available from: <http://communications4clintrials.org/>

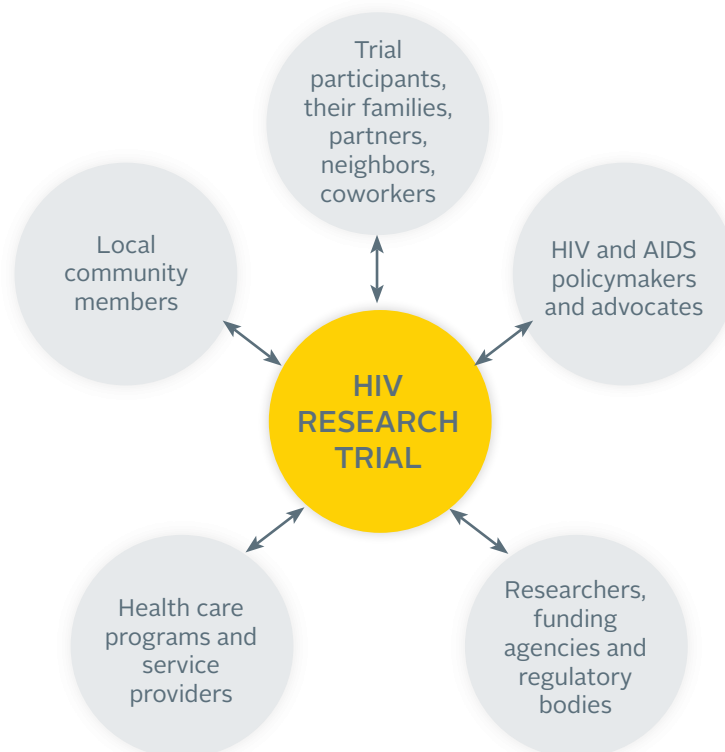
This toolkit also builds on and complements materials and lessons learned from the Global Campaign for Microbicides Community of Practice and the HIV Prevention Trials Network (HPTN) Core Community Program.

Who are the stakeholders?

A stakeholder is someone who can affect or be affected by the actions associated with a trial. Five broad groups of stakeholders are mentioned in this toolkit. A person may be a member of more than one stakeholder group. For example, people living with HIV or AIDS are key stakeholders who may be advocates for HIV prevention, members of the local community or both.

Stakeholder engagement includes, but is not limited to, community engagement. It is important to understand that these activities are not the same. Stakeholder engagement needs to be a team effort because different types of stakeholders may be most effectively engaged by staff in different roles, such as lead investigators, clinicians, health educators and regulatory staff. The team may be led by an experienced full-time CLO, but the work of engaging stakeholders needs to cut across the many roles of a research team.

FIGURE 1 *Five groups of stakeholders should be engaged during a clinical HIV prevention trial.*



Stakeholder engagement is the creation of relationships with internal and external individuals and groups — at the local, national and international levels — to ensure cooperation and alignment of interests among parties. This process draws from the principles of good participatory practice:

1. Respect
2. Mutual understanding
3. Scientific and ethical integrity
4. Transparency
5. Accountability
6. Community autonomy

It is also important to recognize power imbalances and to respect cultural sensitivities. Step Two of this toolkit will address these ideas — and the principles listed above — in detail.

Challenges addressed by the toolkit

This toolkit will help research teams address the special challenges of HIV prevention research, an endeavor that involves several sensitivities. To assess the effectiveness of an intervention, clinical trials must recruit large numbers of healthy, HIV-negative individuals as trial participants. The principles of research ethics stipulate that safety and effectiveness trials should take place in a population that needs the intervention under study and that the population is likely to have access to and use the intervention should it prove to be effective. HIV prevention trials are located where HIV is most prevalent; often this means trials take place among people and in communities that are vulnerable in several aspects, including social, economic and political dimensions. The design and conduct of biomedical HIV prevention trials must recognize these vulnerabilities and develop practices that do not inadvertently aggravate or reinforce these drivers of health disparity.

This toolkit also considers the introduction of communication technologies and biomedical advances that are changing the global landscape of scientific research. Research in HIV prevention is expanding and offering more evidence of potential tools — such as oral pre-exposure prophylaxis (PrEP), microbicides and vaccines — that could be available soon. The

thoughtful and sincere engagement of stakeholders will also help with the eventual rollout and delivery of effective HIV prevention tools as they are identified.

How to use this toolkit

This toolkit can be used in the following ways:

- Research teams that are planning to implement their first HIV-related clinical trial at a single site may wish to use the toolkit in a simple, stepwise fashion.
- A research team that has some experience implementing an HIV-related clinical trial and is planning a new trial can use the toolkit as a step-by-step reference during various stages of the trial.
- The toolkit can be used to evaluate the current status of stakeholder engagement and then adjust the team's actions as needed.
- A research team that is collaborating with teams at other sites may wish to implement a common protocol for stakeholder engagement. In such instances, the toolkit could serve as a template for trial-wide guidance. This toolkit may also be used to supplement whatever guidance is provided by larger trial networks, filling in gaps as needed on a site-by-site basis.

Research is helpful but sometimes it ends and goes into a dark cupboard without any feedback to the community — and so the community gets reluctant to be involved the next time.

— Chairman of a community advisory board in Tanzania

Seven steps to stakeholder engagement

This toolkit consists of seven steps (see Figure 2). Each step outlines a series of tasks to perform to successfully complete the step. The tasks describe a course of action, the expected result and an explanation that will help you to understand and accomplish the task. In some instances, a series of tools (see *Appendix: Tools*) are also provided to help you complete the tasks in each step. Each step also contains one or more case studies that describe real-world examples that illustrate the step's importance.

As with any multistep process, you may be tempted to disregard a step. Doing so, however, may introduce mistakes and increase your burden later in the process. It may also undermine whatever successes you have already achieved. We encourage you, whenever possible, to implement each step. You may, however, need to modify the order of the steps or conduct parts of the steps in parallel as your circumstances dictate.

FIGURE 2



Figure 2. This toolkit outlines the stakeholder engagement process in a series of seven steps. Stakeholder engagement is a continuous process — it develops relationships and builds capacity that prepares all parties for future research projects.

Stakeholder engagement and the other components of an HIV research trial

Good-quality engagement of stakeholders must take place during every stage of the research life cycle: from the conceptualization stage, through trial implementation and onward into discussions of findings and the next steps after a trial closes.

The following timeline shows how the seven steps of stakeholder engagement relate to other critical activities in a clinical trial. Note that you will need to begin planning for all seven steps before your trial recruits its first participant.

Although this timeline and the toolkit describe a successive series of steps, these processes are not *necessarily* sequential. Some steps may need to be conducted in a different order, or even in parallel. The application of these steps will vary by location and with the type of trial you are conducting. You may also find that some steps require a greater effort with certain stakeholders, especially those who are unfamiliar with the research process. The steps can be adapted according to your needs.

The timeline for a trial will vary according to several factors:

- The size of the trial
- The nature and extent of the capacity building needed in (a) the communities where the trial will take place and (b) among the organizations participating in the trial, including those that provide services or programs to the trial's participants
- Each community's experience with and response to previous HIV prevention trials
- The research literacy of the stakeholders

HIV prevention trials demand substantial and prolonged engagement with the community and national stakeholders prior to the initiation of a trial.

— Research Rashomon: Lessons from the Cameroon pre-exposure prophylaxis trial site

FIGURE 3 *Timeline*

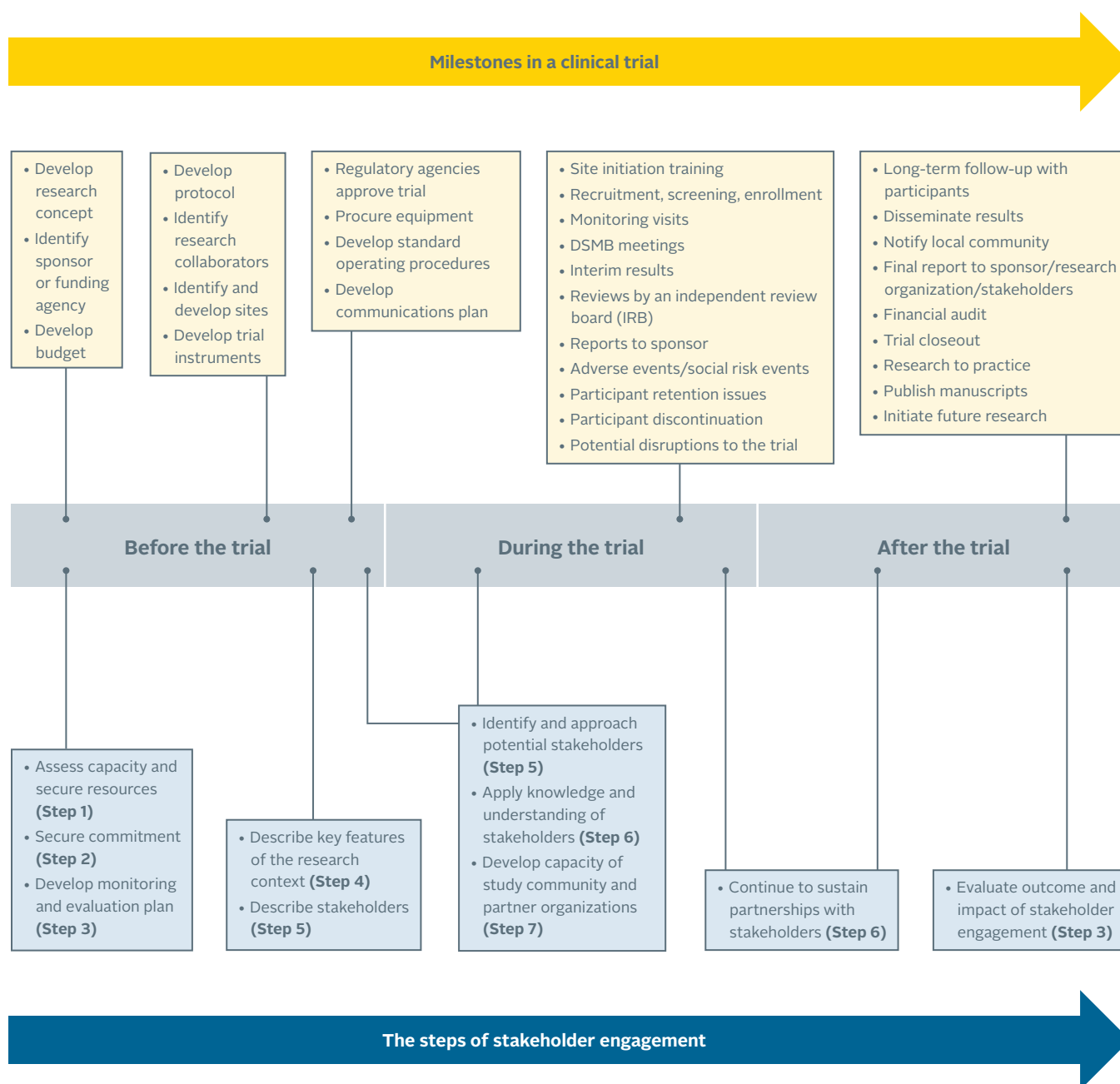


Figure 3. Stakeholder engagement should begin in tandem with planning for a clinical trial. Ideally, each step of the stakeholder engagement process should be initiated before the clinical trial begins to recruit participants.

Benefits of effective stakeholder engagement

- Provides insights from stakeholders about potential social harms and other trial disruptions
- Increases stakeholder support for the trial
- Improves the capacity of community members and partner organizations to successfully fulfill key roles and responsibilities in the trial
- Enhances the mutual accountability of stakeholders
- Increases the likelihood that stakeholders will play a positive role in the dissemination of research findings
- Improves the way that the potential applicability of a research discovery is communicated
- Establishes a foundation for rollout and uptake of a successful intervention
- Increases the likelihood of engaging stakeholders for future research projects



Plan and Budget for Stakeholder Engagement

Introduction

Before you go through the steps of stakeholder engagement, you need to start *here*. Planning ahead will ensure that you determine your “baseline” — one you can use to measure your progress later — and that you have the necessary resources and the appropriate personnel to engage stakeholders and sustain the relationships you develop.

The tools in this step provide a systematic way to evaluate your team's current capacity and to identify any gaps. Establishing your baseline will help you determine which steps in this toolkit may be the most important for your team. In this way, Step One provides direction to your team as you implement the stakeholder engagement process.

Once you have established your baseline, make sure that a budget is in place for stakeholder engagement. Without adequate funds, you may not be able to continue current engagement activities, much less fill in the gaps you identified at your baseline. Even the most constrained budget should provide some money for stakeholder engagement. This step provides sample budget tools for the most basic stakeholder engagement activities and also offers ideas if you have the benefit of a larger budget.

It is essential to have a realistic understanding of the resources you will have available for stakeholder engagement. As you build relationships, it is important not to overpromise or to suggest that you can provide support beyond your means.

Once your budget is determined, you will assemble your stakeholder engagement team and ensure that everyone has the training they need to move forward. In this step, you will find sample job descriptions, suggestions for training exercises and other resources to help you build a solid team with the capacity to identify and engage stakeholders.



Goals of Step One

- Identify — and provide direction to — the other steps of stakeholder engagement that will be most useful to your trial team.
- Develop a baseline: Take inventory of your organization's resources, knowledge and skills; identify your weaknesses and strengths.
- Determine your budget for stakeholder engagement and create your plan.
- Develop your staff's capacity to engage stakeholders; hire new staff members and provide training if appropriate.

Why you need to plan and budget for stakeholder engagement

A systematic approach in this step will make it easier for your team to:

- Know what is expected of them.
- Be aware of their strengths and weaknesses with regard to stakeholder engagement.
- Measure and assess the trial's future stakeholder engagement activities.
- Budget for stakeholder engagement, and account for the use of resources.
- Monitor progress.
- Maintain — and resist compromising — stakeholder engagement activities.
- Develop an organizational structure that supports stakeholder engagement.
- Ensure you are prepared to meet commitments.

Task list

1 Establish your team's baseline.

Action: Take a systematic inventory of your current capacities and practices.

Result: This process will make the trial's team — and eventually, the trial's stakeholders — realize that stakeholder engagement can be a regular, organized process with clearly definable results. Also, establishing your baseline will help to identify the other steps in the toolkit that may be most important for your team. For example, you may discover that your team's strength is describing the broad context but that you completely lack a system for keeping track of the team's interaction with stakeholders.

Explanation: Complete an *Organizational Self-Assessment* (the baseline assessment; see Tool 1A). You will answer questions about your staff's experience working with stakeholders, including processes, knowledge and current relationships. Keep this assessment handy, as it will show you where you need to build capacity. It will also guide you as you go through the other steps in this toolkit. Furthermore, you will come back to this assessment from time to time to evaluate the stakeholder engagement process. Your team can assess its performance (a) over time and (b) between locations and studies. All of your future work in stakeholder engagement — the remaining steps in this toolkit — will be compared to this baseline.

2 Determine what you still need, and identify opportunities.

Action: Looking at your baseline assessment, identify your weaknesses. Then, with your staff, think of upcoming opportunities that could help you address these weak areas.

Result: Determining your team's strengths and weaknesses and thinking strategically about upcoming opportunities will help you develop your plan for stakeholder engagement (see Task 3). This exercise will also help you to identify the skill set you will need when the time comes to hire a new person for your team.

Explanation: Identify weaknesses, write them down and brainstorm about ways to address them (see *Tool 1B: Gaps and Opportunities*). If you find, for example, that you have a system in place but you lack the staff members required for the work, you will know that you need

to build your team. You can then determine whether an upcoming conference, event or other occasion could help you address your team's needs. This is an important intermediate step between your baseline assessment and a plan for stakeholder engagement. Doing this task well will ensure that your team creates realistic goals and objectives, and that your plan incorporates the team's strengths and addresses any gaps. This will also help you identify and take advantage of opportunities — this will be important, especially if your trial has a limited budget (see the next task on budgeting).

3 Develop a budget for stakeholder engagement.

Action: Create a budget for stakeholder engagement. Make sure to include funds for key activities, staff, training and other items that are in line with your trial's budget.

Result: When you have a budget dedicated to stakeholder engagement, you bring about greater accountability for the use of resources. Furthermore, the trial is less likely to compromise stakeholder engagement activities if the activities are part of the plan and the budget from the beginning.

Explanation: Developing a budget ensures that stakeholder engagement activities are built into the trial's plan. The budget will probably need to be submitted early — even before you have hired additional staff or developed your strategic plan. Try not to rush this process; make sure you allow enough time to consider the sorts of activities you would like to pursue. Be sure to talk to the principal investigator of the trial, members of the research network (if applicable) and others about the funding that may be available to your team.

Even a tight budget should have some funds to support basic levels of engagement. It may be a major challenge to find funding that will allow for in-depth stakeholder involvement. Where funding is tight, you may need to streamline capacity building, the production of educational materials and the translation of these materials to local languages. Further, operational costs of community advisory boards (CABs) and similar structures — as well as advocacy and

When funders make the budgets, they usually put the bulk of the funding into the implementation phase, whereas stakeholder engagement needs to take place during the conceptualization phase.

— Community liaison officer for HIV prevention research projects in Tanzania



Tips

Ensuring that you have some funds for stakeholder engagement may mean being ready to defend your team's activities: Be prepared to negotiate for an adequate budget to ensure the identification, engagement and capacity building of your stakeholders. Even a small amount of extra money can make a huge difference for your trial.

research literacy initiatives not related to specific trials — are often considered “extra” activities even though they are key to a trial's success.

If funding is not simply tight but inadequate to meet basic stakeholder engagement needs, document the deficiencies so that funders, sponsors and trial investigators are aware of the limitations.

Once you have a better understanding of the funds available to your team, you should complete a budget tool. *Tool 1C:*

Budget for stakeholder engagement provides a template for a basic budget (the minimum package), which may be appropriate for a small trial or one with limited funding. This template provides the major line items you should include in your stakeholder engagement activities. *The tool also* offers suggestions for what to include if your trial has more funding available for stakeholder engagement. Once you have a budget in place, you will be able to determine the kind of activities you can plan for during your strategic planning phase (see Task 4).

You may want to develop a list of “needs” versus “wants.” Make sure that everything essential for stakeholder engagement — your “needs” — makes it into the budget. Then, if you have extra funding, you can add items from your list of “wants.”

Here is an example of such a list:

NEEDS	WANTS
Brochures	Videos
Translations	T-shirts
Printing	Capacity-building workshops
Meeting support (including transport, airtime for mobile phones, venue for meeting)	Roadshows
Staff training	Public address system (for events)
Training for community advisory group	Training and recruitment of community peer educators
Dedicated staff member	
Computer	

Thinking creatively: stakeholder engagement on a tight budget

If your trial has a very limited budget, you can still engage stakeholders. But you may need to think a bit more creatively.

A one-on-one meeting with a key stakeholder is often the most effective way to establish and sustain a relationship, and it usually requires minimal staff time and transportation costs. If you would like to reach more stakeholders at a single event but you do not have the budget for multiple large-scale meetings, your team can make use of existing community events. For example, with little more than staff time and a few promotional items, your team could participate at local events that commemorate World AIDS Day, International Women's Day and other occasions.

As a way to keep their own costs down, some research teams help to organize community events and ask community businesses for support. For example, the Microbicides Development Programme's (MDP) South Africa study team held a football tournament as part of their stakeholder engagement efforts for the MDP 301 trial. A local sports shop donated football uniforms for the winning team with the name of the study team's organization printed on the jersey. This was an effective way to engage stakeholders at the local level, and it did not require a large budget.

By participating in such events, you can get to know and educate your stakeholders (through materials or one-on-one conversations). Perhaps most important, your study will be known as part of the community, which can go a long way toward establishing and maintaining relationships with stakeholders.

4 Assemble your team.

Action: Establish who will be primarily responsible for stakeholder engagement for your trial or site, and then determine who will be on the stakeholder engagement team.

Result: Having a group of staff members working together on stakeholder engagement will ensure accountability, provide a range of expertise and knowledge and provide a backstop to the lead staff member on the team.

Explanation: It is important to have a clear leader — who will work closely with the principal investigator — who has a background in stakeholder engagement, community mobilization, public relations or communications. This may be a new staff member or a current one. If it is a new member, be sure to develop a proper job description with the skills needed to undertake the task of stakeholder engagement (see Task 6).

If your trial is part of a global or national research network, it may be important to include someone from the research network on this team. This may be especially important when it comes to working with global- or national-level stakeholders. You may also want to include some support staff or information technology staff on your team because you may need help setting up meetings, developing presentations, printing materials, creating a website, maintaining email lists and so on.

Often, the staff member who takes the lead for stakeholder engagement is the trial's community educator or CLO. It is preferable to have this staff member dedicated to stakeholder engagement on a full-time basis. This can be challenging because these individuals tend to have skills that make it tempting to pull them into other areas of the trial — such as recruitment, communications or other tasks — particularly if the trial is underfunded or understaffed.

In addition to dedicating a staff member to lead stakeholder engagement, it is vital to have a team working on stakeholder engagement to ensure that these activities are not pushed aside because of other pressing concerns. Having a team also ensures that stakeholder activities are not dropped when the leader is out of the office for travel, vacation, illness, family emergencies or other reasons.

Team members may have other responsibilities, but they should meet regularly. Meeting agendas should include updates on action items from previous meetings. The team's leader should work closely with other research team members, attend core leadership meetings, review trial materials and be aware of any changes in research implementation.

A team approach makes it easier to engage all stakeholders — including those beyond the local community — because you are tapping into the networks of staff members with diverse professional and personal relationships.

It is crucial to have a core group of people who have stakeholder engagement as an explicit part of their job responsibilities to ensure that the work will get done. Although you will probably make use of most members of the research team at some point, keep the core group to a manageable size — three or four people should be adequate for most studies.

5 Develop a plan for stakeholder engagement.

Action: Set goals and objectives for your trial's stakeholder engagement activities. Then develop your plan, which can be organized in a grid format that lists the stakeholder groups. You will also need to develop a work plan, an action plan and a timeline.

Result: A well thought out plan will ensure the involvement and buy-in of a broad cross section of stakeholders, and can ultimately lead to the success of not only your current trial but future trials as well.

Explanation: If you are developing a stakeholder engagement plan for the first time, creating your goals, objectives and action plans takes time. Remember that this work will pay off in the long run. Be patient. Don't rush the front end of this process. Also, remember that planning does not preclude doing some of the basic work. Stakeholder engagement activities and opportunities will occur concurrently with the planning process. Establishing the team's vision for stakeholder engagement early is critical so that this vision can guide individual actions. With that said, don't let planning become an obstacle to doing the work of stakeholder engagement!

If stakeholder engagement is to be a critical part of a research project, the commitment has to be very evident among the top levels of project management.

— Senior strategic planner for a research organization in Tanzania

Plan for stakeholder engagement

Goals and objectives

Develop your goals first. They will provide direction to your objectives, work plan, timeline and other planning materials. Goals are broad statements of what your team wants to accomplish, and goals focus on ends rather than means. Think of the large scale impact that your team is aiming for, but be realistic. You can have more than one goal, but try not to have more than a few — all should be achievable.

Here is an example of a well-written **goal** for a microbicide trial:

- Increase awareness of HIV/AIDS, clinical trials and microbicides.

Your objectives are steps that your team plans to take to achieve your goal(s). To develop your objectives, identify obstacles that can be overcome by engaging stakeholders.

Here is an example of **objectives** to support your goal:

- To assess the knowledge of stakeholders — at the local, national and global level — on clinical research, HIV prevention and microbicides
- To address any identified gaps through outreach and education efforts

Action plan and activity prioritization

Now that you have outlined your goals and objectives, you can plan specific activities (sometimes called “strategies”). See *Tool 1D* for a simple “action plan” matrix that itemizes the person(s) responsible, materials, indicators and outcomes.

Examples of **activities** to support your goal and objectives:

- Develop a needs assessment tool.
- Conduct a needs assessment at the local, national and global level.
- Analyze findings from the needs assessment,
- Share your findings with the stakeholder groups (among which they were conducted).

Once you have determined your activities (or strategies), you should prioritize the activities based on their importance and urgency (see *Tool 1E* for a template that will help your team think through this process).

Matrix of stakeholders

Next, your team should develop your matrix of stakeholders (see *Tool 1F*). Note that this matrix is different from a contact list of stakeholders (which you will develop later in *Step*

Five). The matrix is used for planning purposes, and it will focus on your overall strategy for engaging the five broad groups of stakeholders.

This matrix will guide the rest of your team's planning process. In developing this matrix, you will discuss the potential role of the stakeholders, the strategy for engaging them (such as face-to-face meetings and community events), the desired outcome (such as support from local leaders or global advocates), a follow-up strategy to ensure continued engagement and the timing of engagement. Some of these items may need to be left blank until you complete some of the later steps in this toolkit. For example, you probably have not identified all of your stakeholders this early, so you will need to wait until you complete *Step Five* to complete this grid. But you can at least set up your matrix and begin establishing the overarching strategy for stakeholder engagement in your trial.

Work plan

Now that you have completed your goals, objectives and action plan and prioritized your activities, you can create a written work plan. For a work plan template, refer to *Tool 1G*.

Exactly what is included in your trial (or site) work plan may be dictated by your research network or funder. Most work plans, however, have some combination of the following: basic information about the trial or site (including the name of the principal investigator); goals, objectives and planned activities; and a basic assessment of the trial community (including any current issues that the team should be aware of). A section may also be included about the involvement of a community advisory board (CAB) or community advisory group (CAG); these will be discussed in more detail in *Step Six*.

Timeline

After your work plan is complete, construct a timeline (see *Tool 1H*). A timeline can help your team ensure the completion of key stakeholder engagement activities, and it will help ensure that your work plan is realistic. First determine the month you will begin your activities; then plan your work for the upcoming year (and longer, if you choose).

Ideally, you will assemble your entire stakeholder engagement team to draft your timeline. You may want to write each activity on a note card. Then as a team, you can put the cards in order on a table (or taped to the wall) before deciding on the final timeline.

Some activities will need to be repeated more than once, and others may not yet have a place on the timeline. By the end of your exercise, though, you should have all of the cards in order and you will be ready to assign months (or years) to each activity. This is a good time to make sure that someone on your team is responsible for each activity.



Case Study

The importance of documentation

Based on: Kirkendale S, Omullo P, Agot K, Odhiambo J, Ratthagana MJ, Malamatso R, Ahmed K, Van Damme L, Corneli A. Documenting community involvement in FEM-PrEP. IAS 2011 Conference, Rome, Italy. Poster MOPE392. Geneva: International Aids Society; 2011.

FEM-PrEP was a Phase III randomized, placebo-controlled, clinical trial designed to assess the safety and effectiveness of a daily oral dose of an antiretroviral drug (ARV) called Truvada for HIV prevention among women. HIV-negative women between the ages of 18 and 35 who were at high risk of HIV exposure volunteered to take part in FEM-PrEP at four sites in Kenya, South Africa and Tanzania.

At the Bondo, Kenya site, the community involvement activities included general community education in the chief's *barazas* (public meetings), in churches, with men's and women's groups and in meetings with key stakeholders, either individually or in groups. The community team also attended community meetings that were not organized by the study staff but to which they were invited to address the people gathered.

Stakeholder engagement activities were planned monthly, and *ad hoc* meetings were also conducted when needed. Meetings were coordinated by a community liaison officer and assisted by field staff members who took minutes, noting issues raised, questions asked and responses given. The notes were expanded at the end of each meeting.

During community outreach the team learned that some participants may not have informed their partners about their participation in the study. Male community members also expressed concern about not being informed about their partners' participation. For example, one male partner reported, "If I find my wife taking these pills without my knowledge, I will throw them away." A lack of support from a partner could impair a participant's ability to adhere to the study product or attend the study visits. In response, the team increased outreach efforts to meet with men and to address their concerns.

Stakeholder engagement at the Bondo site included these activities:

- More than 600 general community education meetings during the preparedness phase, during trial implementation and after trial closure
- Establishment of a community advisory board that held quarterly and ad hoc meetings to obtain community feedback
- More than 70 meetings to involve males (targeting men only)
- More than 36 well-attended stakeholder meetings in the local districts

The documentation and constant, timely and respectful feedback processes at the sites and communities contributed to the broad-based support of FEM-PrEP and an overall decrease in rumors and controversy. Many men who had misconceptions about the study were satisfied after they took advantage of opportunities for discussions and explanations of the research.

6 Develop job descriptions.

Action: Determine main job responsibilities and write position descriptions for staff members working on stakeholder engagement activities.

Result: With detailed job descriptions for new positions, your team will attract the right candidates. And you will ensure that you hire people with skills that can boost your stakeholder engagement activities. Writing job descriptions for staff members will make sure that staff members know what is expected of them and makes it more likely that they will be accountable for their various tasks. Having job descriptions in writing that are approved by the principal investigator and the rest of the trial's leadership will also ensure that the organizational structure of your trial team is supportive of stakeholder engagement and that a system is in place to continue this work, even in the case of staff turnover.

Explanation: You will need to write job descriptions for each person with direct responsibility for stakeholder engagement tasks — whether it is a current staff member or a new recruit (see Tool 1I for sample job descriptions).

How do you find the right staff members to implement stakeholder engagement? What should the skill set of a potential staff member look like? These are questions your team needs to address before developing job descriptions for each team member who will work on stakeholder engagement (including filled and open positions).

Make sure that your team has one or more people with the following skills:

- **Language proficiency:** It will be important for one or more people on your team to speak the main language(s) of the key trial stakeholders, including community members, global advocates and others. The ability to read, write and speak in the major international language of the region or research network — such as English, French or Spanish — as well as being fluent in local language(s) is crucial.
- **Public relations:** The staff selected will spend much of their time interacting with stakeholders who are important to your trial's success, so it is important that they have some previous experience in public relations. They can obtain on-the-job training (see the section on capacity building) to complement their experience, but it is important that they feel comfortable speaking in public and that they present themselves well. Remember that they will be ambassadors for your trial.
- **Communications:** One or more people should have the ability to write materials, plan and facilitate meetings and develop messages to share with the stakeholders. You may

wish to ask for writing samples from the potential candidates. You might ask them to give a presentation because the ability to communicate well in a group setting will be important.

- **Organization and project management:** Stakeholder engagement will involve many moving parts, including planning and implementing activities, keeping track of stakeholders at multiple levels, monitoring and evaluating the process and working with stakeholders to develop capacity. To keep track of your team's progress and your stakeholders, your team leader will need to be organized and should have experience managing collaborative projects.
- **Partnership building:** Someone who can build partnerships with stakeholders at all levels — from local to global — will be an asset to your team. Familiarity with the major stakeholders in the country or region — and the local community and customs — in which the team will be working is also important.
- **Technical knowledge:** Although all staff will have on-the-job training about the trial's protocol and any issues specific to the trial, it will serve the trial well to have stakeholder-engagement staff members with some technical knowledge of research, particularly HIV prevention research.
- **Teamwork:** Everyone must be a strong team player with the ability to function smoothly as a key member of the research team.
- **Consulting skills:** A broad range of consulting skills for those coordinating stakeholder engagement processes is essential. The following article on "Choosing a Consulting Role"¹ gives practical and realistic guidance for people in this role who need to decide on the most appropriate role(s) for them to fulfill:
<http://www.questia.com/library/1G1-8167764/choosing-a-consulting-role>

7 Ensure capacity building among the staff.

Action: Ensure that your staff members have the proper training and resources to undertake stakeholder engagement activities.

Result: Your stakeholder engagement staff will spend their time interacting with people who are crucial to the trial's success. As ambassadors for your trial — at the community, regional, national, and global levels — it is important that your staff have proper training and accurate information to adequately speak for the trial to stakeholder groups.

¹ Champion DP, Kiel DH, McLendon, JA. Choosing a consulting role [Internet]. Training & Development Journal; 1990 Feb 1 [cited 2012 April]. Alexandria (VA): ASTD. Available from: <http://www.accessmylibrary.com/article-1G1-8167764/choosing-consulting-role.html>

Explanation: All staff members who are involved in stakeholder engagement should be trained in the following areas:

- **Ethics:** Training in research ethics will be required for all staff members who will work on your research trial. The specifics will likely be dictated by your research network or sponsor, but there are a number of resources that can be used either as core training or to supplement required training. For example, FHI 360 offers an online training course in research ethics and a research ethics curriculum specifically for community representatives, which is well suited for face-to-face group training. (Please see the Additional Resources section at the end of this toolkit for a link to this course.)
- **Communications and public relations:** Your team should ensure that someone with appropriate expertise in communications and media skills provides training to each person working on stakeholder engagement. Even if your stakeholder-engagement staff members are not official spokespersons for the trial to the media, you should ensure that they have the proper training and that they are aware of any standard operating procedures related to communications and the media. You may want to collaborate with your trial's communications team for this training — or have the training provided by your communications staff (if possible). For more on training staff members in public relations and communications — including techniques staff members can use to practice delivering key messages about the trial — refer to Chapter 2 of the *Communications Handbook for Clinical Trials*. (Please see *Additional Resources* at the end of this toolkit for a link to this resource.)
- **Trial protocol:** Make sure that stakeholder engagement staff members understand the basics of HIV prevention research and that they are familiar with the trial protocol. The most efficient way to do this is to include stakeholder engagement staff in the basic protocol trainings offered to other members of the research team. This will ensure that everyone is hearing the same messages and benefiting from any discussions that occur during the training. You may need to arrange for HIV prevention research literacy training for stakeholder engagement staff prior to the protocol training if they do not have sufficient on-the-ground experience with such clinical research. As ambassadors of the trial to the larger community — and to stakeholders at the national and global levels — engagement staff should be prepared to answer questions about the trial and to speak accurately about research methods.



Checklist: Step One

Use this checklist to make sure that you accomplished all the tasks required in Step One.

- ☐ Establish your team's baseline for stakeholder engagement.
- ☐ Identify gaps and opportunities.
- ☐ Develop your budget.
- ☐ Create an overall plan for stakeholder engagement.
- ☐ Assemble your team, ensuring necessary capacity and organizational structure.



Secure Commitments to Guiding Principles

Introduction

In Step One, you established baseline information. At this point, you should know your research team's capacity for stakeholder engagement, your ongoing efforts toward stakeholder engagement, your goals and objectives for stakeholder engagement and any gaps in your plan.

The primary goal during Step Two is to tackle some of the initial gaps in your team's commitment to the guiding principles of stakeholder engagement. If members of the research team are not familiar with or do not value stakeholder engagement activities, you may need to sensitize them and gain this commitment before you begin your outreach efforts.

Two guidance documents highlight the principles of ethical trial conduct: the UNAIDS/AVAC *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*¹ and the UNAIDS/WHO *Ethical Considerations in Biomedical HIV Prevention Trials*.² They serve as useful references about the importance of adequately addressing the concerns of participants and external stakeholders. The guiding principles of good participatory practices (GPPs) reflect a set of values that call for positive, collaborative and mutually beneficial relationships between trial funders, sponsors, implementers and all other stakeholders, including trial participants.

Your team should follow these guiding principles of GPP:

1. **Respect.** Research requires fundamental respect for the human rights and the confidentiality of trial participants, including respect for local cultural values. Respect for and among stakeholders also protects and empowers key decision-making groups and other authorities.
2. **Mutual understanding.** Involving stakeholders in research means that external stakeholders should develop an understanding of the given trial and the larger research agenda *and* researchers should develop an understanding of the surrounding environment.

¹ Joint United Nations Programme on HIV/AIDS (UNAIDS). Good participatory practice: guidelines for biomedical HIV prevention trials [Internet]. 2nd ed. Geneva: UNAIDS; 2011 [cited 2012 April]. Available from: www.avac.org/gpp

² Joint United Nations Programme on HIV/AIDS (UNAIDS). Ethical considerations in biomedical HIV prevention trials: UNAIDS/WHO guidance document [Internet]. Geneva: UNAIDS; 2007; additional guidance point added 2012 [cited 2012 April]. Available from: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf

3. **Scientific and ethical integrity.** Maintaining the highest standards requires (1) adherence to scientific processes to make sure trials achieve valid results and (2) consideration of the social and ethical issues that may be linked to a trial and (3) adherence to universal ethical principles of respect for persons, beneficence and justice.
4. **Transparency.** External stakeholders need to receive honest and understandable information about a trial, and they should understand their roles in the trial. Stakeholder feedback should be legitimately addressed, and stakeholders should know the extent to which their input will influence trial-related decisions. This dialogue with the stakeholders should be open and frequent.
5. **Accountability.** Trial funders, sponsors and implementers are responsible to external stakeholders for conducting sound research and using participatory practices. This includes ensuring adequate funding for optimal engagement efforts. Community stakeholders are accountable for providing representative input from key groups.
6. **Community autonomy.** A wide range of stakeholders may be engaged in a trial, and at times different stakeholder groups may have differing opinions about the conduct of a trial. All interests, opinions and concerns should be considered. In cases where different perspectives exist, the research team and key stakeholders who are fully informed should identify legitimate concerns and the best way to proceed.



Goals of Step Two

- Develop a plan of action for securing commitment to stakeholder engagement.
- Familiarize the research team with the guiding principles and the practical implications of engaging stakeholders in clinical trials.
- Establish consensus among the team that stakeholder engagement is critical to their trials.
- Secure written commitment to stakeholder engagement from key members of the research team.

Why you need to secure commitments to guiding principles

A systematic approach to securing commitments will enable your team to:

- Establish a common understanding of the meaning and value of stakeholder engagement.
- Gain consensus on a strategy for stakeholder engagement action, including key objectives and outcomes of activities.
- Consider equitable budgeting issues, and plan accordingly.
- Develop more effective engagement plans.

Task list

1 Become familiar with information and tools.

Action: Review the principles and the references discussed in the introduction to Step Two.

Result: You will have increased your capacity to explain the guiding principles of stakeholder engagement and the implications of following them — or not — on the ethical conduct of clinical trials, and you will have familiarized yourself with methods for conducting sensitization with groups or individuals.

Explanation: Several key resources outline the principles of stakeholder engagement. The primary resource is the GPP guidelines document developed by AVAC: Global Advocacy for HIV Prevention and UNAIDS. This guidelines document contains useful background information on the significance of stakeholder engagement in research, as well as principles and standards for good practice. The GPP guidelines and other resources described below provide background for your sensitization activities.

A number of tools have been developed by AVAC to complement the GPP guidelines. These tools are meant to help research teams (and others, if relevant) to implement the GPP guidelines at various levels. One tool is a GPP training curriculum that provides interactive exercises to teach various audiences about basic concepts of stakeholder engagement. The curriculum will be especially useful for Step Two. Review this resource thoroughly, and consider activities you might use to sensitize members of your research team to stakeholder engagement principles. The GPP guidelines and implementation tools are listed in the *Additional Resources* section and available at www.avac.org/gpp.

2 Make an action plan for securing commitment to guiding principles.

Action: Identify targeted individuals or groups that need to be committed to the principles of stakeholder engagement, and develop sensitization approaches.

Result: You will have an action plan outlining all details for gaining commitment to stakeholder engagement principles.

Explanation: Consider your research team's understanding of stakeholder engagement principles. Do certain members have more appreciation for the principles than others? Could all members benefit from training or orientation about the principles? Which members of your team should provide written commitment to the principles? Are these team members key individuals, such as the heads of departments or teams? Would it be beneficial to gain written commitment from all team members? In Step One of this toolkit, you identified individuals or teams from your research center that may not have engagement capacity and understanding or appreciation of stakeholder engagement principles; these individuals may need special consideration when putting your plan together.

Use the action planning guide (*Tool 2A*), to outline specific objectives for orienting these individuals to the principles, and consider appropriate sensitization approaches for each.

Again, note that the GPP training curriculum provides an array of training activities about stakeholder engagement concepts that you may find useful. We recommend using participatory approaches, such as those provided in the GPP training curriculum. Other approaches may include a brief presentation or discussion of stakeholder engagement principles, informal focus group discussions and question-and-answer sessions.

3 Implement your action plan for securing commitment to guiding principles.

Action: Conduct sensitization activities.

Result: You will have reports from your sensitization activities that will describe the participants' commitment level and any other issues that you may need to address.

Explanation: Once you have developed your action plan, make sure that it is reviewed and approved by relevant members of the research team, which may include principal investigators or other clinic coordinators, program directors, country directors and other management staff members. You may wish to conduct a meeting with these individuals to review the action plan, to answer questions and discuss the timing of activities, and to gain buy-in.

Conduct sensitization activities with targeted audiences and individuals according to your action plan. Ensure that background materials and references have been distributed before the activities. Be sure to capture participant perspectives and other key data from the activities. You might write a simple report for each activity or use a standard note-taking template for each activity, which could then be compiled into one comprehensive report for all sensitization activities. File this report with the written commitment documents.

4 Secure commitment from your research team.

Action: Gain written commitment from key individuals on your research team.

Result: Key members of your research team will have pledged commitment to the guiding principles and potentially to specific actions for engaging stakeholders.

Explanation: Complete *Tool 2B* with the individuals who signed a written commitment to the guiding principles. You might choose to gain a written commitment during your sensitization activities. You can decide on this approach during your action planning process.



Case Study

A “more full” understanding of stakeholder engagement

Perspectives from Simon Sigirenda, Uganda Virus Research Institute–International AIDS Vaccine Initiative (UVRI-LAVI)

Our research program has an extensive history of reaching out to the surrounding community and to stakeholders at broader national and global levels. Currently we are working in Ugandan fishing communities, where we’ve seen that this marginalized population has high rates of HIV, a lack of basic health care infrastructure and services and many challenges in their daily lives that make HIV prevention a lesser priority. To ensure that these communities are involved in HIV prevention research efforts, it is essential to gain their trust and to engage them in dialogue. The first step in this process is to identify the key gatekeepers and opinion leaders, which can vary according to the particular dynamics of the community.

Everyone on our team understands the need to engage with the community throughout the research process — before, during and after. Our management team and our trial sponsors strongly support stakeholder engagement, and these activities are given priority and required support.

Our team recently went through an orientation and self-evaluation of the *Good Participatory Practices*. It was interesting that some of our team members said during this training that they weren’t aware that such guidelines existed and, in learning more about *GPP*, they came to a better appreciation of stakeholder engagement principles. All of our team members have been involved in engagement activities. But when they learned about the *GPP* principles, they expressed an interest in knowing whether our research center was meeting *GPP* standards. Some key members — even some of our lead investigators — agreed that having a more full understanding of stakeholder engagement principles and the *GPP* guidelines caused them to be more committed to these types of activities. Since we have strong support from our surrounding community, and from national and international stakeholders, we don’t always think about what might happen if we didn’t adhere to these principles. Participatory approaches are an integral part of how we conduct our trials, but the *GPP* guidelines serve as an important reminder that stakeholder engagement can never be an afterthought.

Simon Sigirenda is the community liaison officer and a social scientist at UVRI-LAVI.



Checklist: Step Two

Use this checklist to make sure that you accomplished all the tasks required in Step Two.

- ☐ Develop an action plan for securing commitment to stakeholder engagement that can be agreed on by all implementers.
- ☐ Orient all members of the research team to the guiding principles of stakeholder engagement; obtain oral commitment to guiding principles as necessary.
- ☐ Disseminate resources and other supportive materials as appropriate to members of the research team.
- ☐ Obtain written commitment to principles by key members of the research team.



*Design a Monitoring
and Evaluation System*

Introduction

In Step Two, your team (and others relevant to your work) made a commitment to the principles of stakeholder engagement. Once you have a plan and the commitment, the real work begins!

Your efforts should be based on the answer to this question: What do we want to accomplish by engaging stakeholders? In Step One, your team thought about concrete objectives for your work with the stakeholders in light of your trial and the broader research agenda. Now that you have defined the goals of stakeholder engagement, you can establish a framework for determining whether your efforts are effective and worth the time and resources involved.

Monitoring and evaluation (M&E) of stakeholder engagement activities can be especially challenging. The successful engagement of a stakeholder may be neither concrete nor definable. And it may be a result of various initiatives or activities — some of which may not even be linked to stakeholder engagement efforts. For instance, success is sometimes defined as “support for the conduct of a given trial,” but support may be indicated by a *lack* of negative media coverage or the *absence* of civil society controversy. The quick enrollment of participants in a trial may be a result of effective community engagement and a broad understanding of the trial in the community — which are stakeholder engagement efforts — but it also may be a result of efficient recruitment practices by the clinical team. Developing a meaningful M&E mechanism can help resolve some of these challenges.

Your overarching goals and the resulting objectives should have formed the basis of the stakeholder engagement plan (including a work plan and action plan) developed in Step One. The activities included in your plan should reflect a set of key objectives and should be linked to short-term and long-term goals. Your team will need to think about all of these factors — goals, objectives and activities — and define measurable indicators of progress at given times. Indicators may be qualitative or quantitative, and they may be focused on process or impact, depending on the goals you have identified. (See Task 3 in this section for an explanation of process indicators and impact indicators.) You will also need to consider whether your M&E mechanism will be participatory or not.

A number of resources are available for M&E activities about advocacy and HIV. You should use these tools as you develop an M&E mechanism for your stakeholder engagement program. Full references are included in the *Additional Resources* section at the end of the toolkit. Two of these resources have provided much of the background for the approach used in *Step Three*:

- *Measuring Up: HIV-Related Advocacy Evaluation Training Pack*.¹ This training pack consists of two guides that provide definitions and explanations of M&E related concepts, plus modules for training secondary audiences.
- *A Guide to Participatory Monitoring of Behavior Change Communications for HIV/AIDS: Getting the Community and Program Staff Involved in Assessing and Improving Programs*. This guide outlines processes for conducting participatory M&E.²



Goals of Step Three

- Define a set of indicators based on your long-term and short-term goals for stakeholder engagement activities.
- Agree on your team's M&E approach; if it is participatory, identify the stakeholders to be involved.
- Implement the M&E process as agreed by all relevant team members.

¹ Davies N, Brotherton L. Measuring up: a guide for learners [Internet]. International HIV/AIDS Alliance and the International Council of Aids Service Organizations (ICASO). Brighton, UK: International HIV/AIDS Alliance, Secretariat; 2010 July [cited 2012 April]. Available from: <http://www.aidsalliance.org/includes/Publication/Measuring-up-a-guide-for-learners.pdf>

² Gill K, Emah E, Fua I. A guide to participatory monitoring of behavior change communication for HIV/AIDS: getting the community and program staff involved in assessing and improving programs [Internet]. Seattle: PATH Publications; 2005 [cited 2012 April]. Available from: <http://www.path.org/publications/detail.php?i=1138>

Why you need to design a monitoring and evaluation system

A systematic approach to designing a monitoring and evaluation system enables your team to:

- Define the desired impact of the research team's stakeholder engagement activities on the clinical trial agenda.
- Justify the need and budget for these stakeholder engagement activities.
- Increase the rigor of stakeholder engagement programs, including the potential need to change your strategy and action planning.
- Establish your accountability with the stakeholders.

Task list

1 Establish a stakeholder engagement M&E working group.

Action: Identify appropriate people at your research center who can establish an M&E system, and determine who will be committed to continuously monitoring the team's stakeholder engagement activities.

Result: You will have an established team of people responsible for monitoring and evaluating the stakeholder engagement program.

Explanation: The stakeholder engagement program should be monitored and evaluated by a variety of research staff members. Data collected in *Step One* and *Step Two* will help you identify appropriate individuals to work on an M&E mechanism. The group should consist of a cross section of staff members, including those responsible for stakeholder engagement and finance, plus operational and clinical activities. The group should not be too large (ideally around five people and no more than 10), but it should be big enough to include the suggested cross section of staff. Members should be willing to meet at least once

every quarter and devote additional work time to writing, reviewing and other necessary responsibilities. One member should be designated as the leader for the M&E activity.

2 Develop an M&E framework.

Action: The M&E working group should discuss and agree on the best way to implement an M&E process.

Result: You will have an established M&E framework and a timeline for collecting indicator data.

Explanation: There are various approaches to M&E. The most straightforward approach is to conduct all M&E internally. Your team will develop indicators, decide on the appropriate team members to regularly collect data, establish a timeline and collect and store indicator data on a regular basis. Several resources discuss the basic process of M&E for HIV programs and advocacy-related work. As noted above, one excellent resource is *Measuring Up: HIV-Related Advocacy Evaluation Training Pack*.³

Another popular approach is known as *participatory* program evaluation. This approach involves external stakeholders who monitor and evaluate your activities, rather than merely relying solely on internal M&E. A number of resources discuss participatory M&E, and these are listed in the *Additional Resources* section. Your M&E working group should review these resources and consider whether it might be necessary or beneficial to use participatory methods. For example, a participatory approach might be beneficial in situations where trust has been compromised with one or more stakeholders (by your research team or others).

The following steps outline a generic process for developing an M&E framework:

- **Determine who will receive evaluation data.** Who wants this information? Trial sponsors or networks? Funders? The community or other stakeholders? How do you ensure the information will be useful for internal program monitoring purposes? Will any of the information be confidential, i.e., for internal use only? If yes, consider the potential consequences if such information were to go public.

³ International HIV/AIDS Alliance and the International Council of Aids Service Organizations (ICASO). *Measuring up: HIV-related advocacy evaluation training pack* [Internet]. Brighton, UK: International HIV/AIDS Alliance (Secretariat); 2010 July [cited 2012 April]. Available from: <http://www.aidsalliance.org/publicationsdetails.aspx?id=477>

- **Map your stakeholder engagement work.** In most cases, this would be your stakeholder engagement work plan or other plan.
- **Prioritize what to evaluate.** According to your stakeholder engagement plan, is it necessary to evaluate every activity? Should you group activities that might be appropriately evaluated together or evaluate progress according to larger objectives or goals?
- **Select indicators.** This step will be the core of your M&E mechanism and is described in detail below.
- **Decide on an approach to measurement.** Various monitoring approaches are commonly practiced; these are discussed below and in the *Additional Resources*.
- **Identify data collection methods.** This includes identifying the frequency of collecting indicator data, who is responsible for data collection and how the data and source documentation will be stored.

Remember that this is a recursive process that can be modified. For instance, you may choose to evaluate a different set of activities after you select the indicators and determine your data collection methods. Factors may change throughout the collection of indicator data.

3 Select indicators.

Action: Based on your established framework, your M&E working group will develop a set of indicators of success for your stakeholder engagement program.

Result: You will have established sets of process-related indicators and impact-related indicators for the short-term and the long-term. These indicators reflect your progress toward the goals and objectives of your stakeholder engagement program.

Explanation: Use the stakeholder engagement plan developed in *Step One* as the basis for selecting the indicators. For each goal, objective and activity, ask this question: How do we know whether we have achieved success? The answer will help you identify an indicator of success or progress. If your plan is in a matrix format, you may create an extra column for indicator information.

Stakeholder engagement generally focuses on program activities and advocacy, so you may need to develop an array of different indicators. You will probably conduct two types of monitoring, oriented toward process and impact.

Process indicators tend to reflect progress within a short time-frame or show outputs or outcomes that together will build into a greater goal or impact. They may be quantitative,

such as recording the number of stakeholder meetings conducted, the number of outreach events or the number of contacts made. Process indicators may also be qualitative, where narrative information is given about the quality of operations or activities, such as the documentation of feedback — good or bad — received from stakeholders.

Impact indicators are broader than process indicators and often reflect a desired end result of stakeholder engagement activities. These may be short-term or long-term indicators. For instance, a short-term impact indicator may assess the number of stakeholders who have provided feedback on the trial or the number of times that the research center has effectively responded to media inquiries. A long-term impact indicator may reveal that the local civil society has a positive perception of the trial or that national policymakers are committed to the future rollout of the intervention being tested.

Figure 4 depicts the logical relationship between different links in the chain of events in a stakeholder engagement program.

FIGURE 4 *A stakeholder engagement program follows a logical chain of events.*



In the logic chain of stakeholder engagement programs, resources and inputs are processed into outputs through activities. The activities produce outcomes — such as knowledge and behavior change — which eventually create an impact — perhaps changes in the conduct of a trial or the larger research agenda.

Inputs	Activities	Output Indicators	Outcome Indicators	Impacts
Efforts of community liaison officer and other responsible staff	Monthly meetings of the community advisory board (CAB)	CAB meeting reports, including outstanding needs and next steps	Community members who are well informed about the research	Efficient and ethical trial recruitment and retention
Efforts of principal investigator	Annual briefings on research to policymakers and other national decision-makers	Robust plan for issues management	Policymakers who support the research	Decreased time from research results to policy access
Designated budget	Development of an issues-management plan for the research		Positive relationships with key stakeholders Influential champions at local and national levels	Mitigation of controversy at local, national, international levels

(Adapted from: Davies N, Brotherton L. Measuring up: A guide for learners. International HIV/AIDS Alliance and the International Council of Aids Service Organizations (ICASO). Brighton, UK: International HIV/AIDS Alliance; 2010 July.)

For each of the goals, objectives and activities in your stakeholder engagement plan, consider process and impact indicators. You may want to make separate columns in your plan to record both types of indicators. It may not be necessary to develop both indicators for every element of your plan, but your group should at least consider the possibilities for each element (see *Tool 3A*).

Once your group has defined indicators, assess the list and prioritize those that will best reflect the progress in your stakeholder engagement program. You may need to eliminate repetitive indicators or arrange activities together that have similar indicators. Select the final list of indicators after you've taken these steps.

For each indicator you have selected, determine when it should be measured. For stakeholder engagement activities, the quarterly measurement of indicators is usually sufficient. In some cases twice a year will suffice. However, there may be some instances — such as during the conduct of a large-scale trial — where your team may want to measure indicators more frequently. Indicate the frequency of measurement somewhere on your M&E framework or other document you are using for M&E information.

4 Implement your M&E process.

Action: Conduct regular reviews to evaluate your progress according to your indicators.

Result: In time, you will have a well-documented collection of indicator data reflecting the progress of your stakeholder engagement program.

Explanation: Your last task in this list is to implement the M&E process. The process should be clear based on your identified indicators and other key aspects of your M&E framework.

The process should be led by one or two staff members who are primarily responsible for the stakeholder engagement program. They should ensure that all data are collected at the determined time points. If data are needed from other staff or stakeholders, these individuals will be responsible for collecting data in a timely manner. If your team is conducting a participatory evaluation, please refer to the Program for Appropriate Technology in Health (PATH) *Guide to Participatory Monitoring of Behavior Change Communication for HIV/AIDS* for details on implementation. If necessary, you may decide to convene the M&E working group to review the data and the collection methods each time data are collected.



Case Study

Perspectives from a trial sponsor and advocate

Alex Menezes, International AIDS Vaccine Initiative (IAVI)

Indicators for community and advocacy-focused work can be hard to define due to the fluid nature of what “community support” means in each context. But there are a few ways to deal with this. It’s important to find a systematic way to measure the stakeholder engagement work as one would measure other elements of the research process.

At the outset of a trial, or other relevant time point in the research life cycle, it’s important to agree as a team on what you hope to accomplish through stakeholder engagement efforts. Based on these predefined goals, one can define indicators that break down the steps necessary to reach the team’s objectives. In addition to process indicators, such as the number of people reached with messages about the research program, one can also try to capture how efficiently the research team is able to respond to changes in the environment or to community needs. This can be measured by the time it takes to respond to media enquiries or by the team’s ability to effectively address concerns raised in the community.

It’s also important to think beyond the life cycle of a given trial. Often, stakeholder engagement in a trial or in the trial’s process can lead to an impact that may occur only *after* a trial is completed. Consider, for example, the response of local stakeholders to the results of an HIV prevention trial. Ultimately, a well-briefed set of stakeholders will have an accurate understanding of the purpose and outcomes of a research program before it is completed, so that the results can inform policy. In some cases, however, policymakers or community leaders may be suspicious and unaccepting of trial results; they may resist engaging in conversations about implementation, even in a context of demonstrated benefits. The ease and swiftness of these discussions, as well as the level of support from policymakers, are clear indicators of the impact of engaging such stakeholders during the research process.

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All aspects of the implementation should be adapted to increase effectiveness according to the needs of the key staff members and the M&E working group.

Remember that the M&E process is not linear. When data are collected, re-evaluate your selected indicators, your method and frequency of data collection and other aspects of your approach.

Most importantly, use your M&E data to improve the effectiveness of your stakeholder engagement process.



Checklist: Step Three

Use this checklist to make sure that you accomplished all the tasks required in Step Three.

- ☐ An M&E working group has been established and all members have made a commitment to the group.
- ☐ An M&E framework has been developed by the working group; all relevant members of the research team agree to the framework.
- ☐ Meaningful indicators have been established.
- ☐ Time points for data collection are clearly established.



*Describe Key Features of
the Research Context*

Introduction

In Step Three, you established a framework for monitoring and evaluating your stakeholder engagement efforts. In Step Four, you will identify key features of the context — local, national, regional and international — in which your trial will take place.

International HIV prevention trials are often conducted by researchers and research organizations that are outside the country where the research occurs. As a result, researchers may have a limited understanding of the various factors that might have a profound effect on the trial. An understanding of these factors will help researchers to:

- Become familiar with critical, nonlocal features that can have a bearing on how the research is conceptualized, planned, conducted, and disseminated.
- Efficiently overcome barriers — and build on enabling factors — that are specific to a context, such as a history with previous trials, access to research outcomes, and any issues related to the political, cultural and economic climate.
- Engage the stakeholders as partners in the research endeavor.

The challenge to be addressed by this chapter is multifaceted: to identify, describe and constructively address the multiple factors — at various levels — that may affect your trial.



Goals of Step Four

- Partner with stakeholders to create a multilayered description of the local, regional, national and international contexts for the trial.
- Identify questions, current issues and historical precedents that may affect how your trial is perceived at the local level — as well as strategies for how to address them.
- Incorporate national, regional and international issues into plans for the trial's conduct.
- Develop an appreciation for the complexity of the research process and the importance of relationships — between people, between competing priorities and among social groups, organizations and institutions.

Why you need to describe key features of the research context

A systematic approach in Step Four will lead to the following benefits and outcomes:

- You will be able to more readily identify local, national, regional and international stakeholders whose views and engagement — whether supportive, critical or both — will affect your trial.
- You will better understand the relationships and networks that link stakeholders — from the local to the international — and help to build such relationships where they are lacking.
- The research concept — its relevance and potential acceptability — will be more easily communicated and explored with national, regional and international stakeholders.
- You will learn how the project's local context relates to the national and regional context; this knowledge can guide and support the conduct of formative research, the identification of potential research sites and the identification of staffing needs.
- You will be able to develop a research project that is well adapted to the broad context.

Task list

1 Describe the local context for the trial

Action: Develop a multilayered description of the boundaries — social, political, economic, transportation, religious and others — in the community where you will be conducting the trial.

Result: Your research project will be better understood and accepted because it was developed with an understanding of the local context.

Explanation: Research happens in the context of many factors that can profoundly influence the outcome of a trial — and those factors may not always be apparent to a trial team. Many trials have used community-based mapping to develop a literal and figurative map for the trial's location. This process can be done in collaboration with community members, and the process itself may build trust and facilitate relationships. The maps can be used to select research sites, identify priorities for formative research and guide other decisions during the trial.

Be sure to ask these basic questions of your key informants: What do you consider to be the boundaries of this community in geographical, social and cultural terms? Where does the community start and end? Who are the “insiders,” and who are the “outsiders”? Also investigate the social and cultural history of the location. How are the people in this community perceived by people in other parts of the country? How do they perceive themselves? How and where is power consolidated within the community? Who are the recognized leaders? Who makes decisions in less formally recognized ways? How is the community tied to the country as a whole in terms of its relationship to political power? Is it a region affiliated with the ruling party or with the opposition? Is it perceived to be the beneficiary of many public health services, or is it neglected?

Table 4.1 summarizes some of the important characteristics to consider when describing stakeholder communities. It also offers examples of how these characteristics vary relative to some different types of communities that researchers often work with.

FIGURE 4.1 Characteristics of types of communities in biomedical research.

Examples are aboriginal, Kahnawake; geographic/political, Jackson, MI, and Iceland; religious, Amish; disease, HIV; ethnic/racial, Ashkenazim; occupational, nurses; and virtual, email discussion group (adapted from Weijer C, Emanuel EJ. Protecting communities in biomedical research. *Science* 2000;289, 5482:1142-1144). Used by permission.

Community characteristic	Type of community						
	Aboriginal	Geographical/Political	Religious	Disease	Ethnic/Racial	Occupational	Virtual
Common culture and traditions, cannon of knowledge, and shared history	++	+	++	+/-	+	++	+
Comprehensiveness of culture	++	+/-	++	-	+	+/-	-
Health-related common culture	++	+	++	++	+	+/-	-
Legitimate political authority	++	++	+/-	-	-	+/-	-
Representative group/individuals	++	++	++	+	+	+/-	+/-
Mechanism for priority setting in health care	+	+	+/-	+	+/-	+/-	-
Geographic localization	+	++	+/-	+/-	+/-	-	-
Common economy/shared resources	++	++	+/-	+/-	+/-	-	-
Communication network	++	+	+	+/-	+/-	+	++
Self-identification as community	++	++	++	+/-	+	+/-	+

++ The community nearly always or always possesses the characteristic. +The community often possesses the characteristic. +/- The community occasionally or rarely possesses the characteristic. - The community rarely or never possesses the characteristic.

2 Describe the broad context in which the trial will take place.

Action: Survey and analyze the social, political and historical factors that are relevant to your trial at the local, national, regional and international levels.

Result: You will have compiled information that can help you identify and anticipate challenges, and guide messaging, stakeholder outreach and other critical decisions.

Explanation: Clinical trials do not take place in isolation. A trial's success can be altered by any number of factors, including a region's history, economy, politics, culture and its approach to providing services in the communities where you will be working. International perceptions of the trial from groups outside of the country or region can also have a profound effect on the trial's outcome.

For example, early trials of PrEP for HIV prevention came under intense international scrutiny in 2004. Concerns from local groups were amplified by critiques from international groups,

and these actions eventually halted PrEP trials in Cambodia and Cameroon. Subsequently, in the Pre-exposure Prophylaxis Initiative (iPrEx) trial of men who have sex with men and transgender women, the trial team worked with local advocates from the gay community to understand their needs, which included safe, respectful counseling and health services, the availability of condoms and lubricants, and spaces for community gathering. The result was an approach that implemented the trial in partnership with local nongovernmental organizations (NGOs). The research team also sought the support of global advocacy groups. In Thailand, stakeholders who were engaged in discussions about the proposed RV144 AIDS vaccine trial voiced their frustrations with prior internationally sponsored research that had not resulted in benefits



Tips

Identify a civil society partner who is interested in convening stakeholder dialogues about the broad context. Offer to present and participate, but support the civil society group in taking the lead in convening, identifying participants and following up. This ensures that your research project is situated in the broad context of relevance to some of your key allies. It provides an opportunity for you to listen and engage without placing your trial at the center of the discussion. These meetings often work as a series of updates, not one-off conversations.

to the participating community. Understanding past sources of disappointment and distrust guided the trial team's decisions about the roles of the various international and national partners. In South Africa, the Centre for the AIDS Programme of Research in South Africa (CAPRISA) tenofovir gel trial (CAPRISA 004) took place in a rural community where the research team had been previously approached by the local chief to help him find solutions to a high prevalence of HIV among his people.

Different questions should be posed to different stakeholder groups. For example, some groups — district or provincial health authorities and political, religious and civil society leaders — can help you identify the existing services and the services you may need locally. Have other research projects taken place in a similar context? Policymakers at national and regional levels can share their views on how your research relates to their current challenges and priorities. What are their concerns or questions about the proposed project? Are they interested in — or are they wary of — the implementation of an effective intervention? Members of civil society groups can be queried about what did or did not work when the research team tried to engage the local stakeholders. Were the stakeholder engagement strategies, such as the dissemination of results, effective? What strengths and weaknesses do these informants identify in health services at the national and local level? How do they think the research will fit (or not fit) into the bigger picture?

Other questions to consider include these:

- Historically, are any related trials viewed as successful (or problematic) with respect to their conduct, the dissemination of results and eventual access to the intervention?
- What are the strengths and weaknesses of existing prevention or treatment services that are related to the intervention you will be evaluating?
- Are there national, regional or international mobilization efforts that are relevant to your research? For example, are there campaigns about funding, access or implementation of proven strategies?
- What is the human rights landscape (including legislation criminalizing HIV transmission, sex work and homosexuality) in the country and the region?
- Have international groups raised issues about similar studies? Are there local groups that have strong ties to international groups with specific views or agendas?
- Have the results of a similar trial triggered actions in a different country? Were those situations successfully resolved? If so, by whom?



Case Study

National stakeholder engagement on PrEP research in Uganda

Patrick Ndase, Microbicides Trial Network (MTN) and Partners in Prevention trial, Kampala, Uganda

In Uganda, national stakeholder engagement of PrEP research has been a key activity. In 2009, the Partners in Prevention trial participated in a capacity-building session for civil society and a meeting for a broad group of stakeholders that was initiated by AVAC and other in-country partners. Those meetings have been followed by smaller briefings with Uganda's Ministry of Health AIDS Control Program, the National Drug Authority and other stakeholders not directly involved in the trial but crucial to the broader context. A meeting for high-level stakeholders occurred in 2010, and now we are planning a briefing to help put recent research results in context. At each of these meetings, we presented information and learned about questions from implementers. We also took note of specific action items such as follow-up briefings or provision of additional materials that we could accomplish immediately.

In the context of a clinical trial that is being conducted for the benefit of public health, we do not want to get into a situation where trial stakeholders begin to discuss the intervention only after the result was released. The goal of our broad engagement strategy is promoting a wider acceptance of, first, the intervention and then the science of the intervention. We want to help would-be implementers think through some of the operational challenges that may come with the intervention should it be proven to work. One goal is to hasten the implementation process. The recent experience with [long delays in the implementation of] male circumcision for HIV prevention in Uganda highlights why broad engagement is crucial far in advance of a clinical trial finding.

Patrick Ndase is the Africa regional physician for MTN and Partners in Prevention.

3 Get to know the national and regional stakeholders.

Action: Initiate and develop relationships with stakeholders at national, regional and international levels.

Result: You will cultivate a group of allies at various levels who understand the goals of your research and can help guide decision-making and strategy.

Explanation: Step 5 and Step 6 focus on identifying and engaging with stakeholders who are directly involved in the trial's conduct. It is also critical to engage with stakeholders who are part of the broad context — including international, regional and local activists and advocates; program implementers and policymakers; and representatives of normative agencies such as WHO and UNAIDS. A perception among any of these individuals that they were not informed or engaged with the research process early on may result in conflicts once the trial is underway or after the results are disseminated. By the same token, these stakeholders can serve as allies, information sources and champions, providing insights on how to explain your project to different audiences. In this step, consider allies who are already working on related issues and who might be interested in attending discussion forums about your research project. Consider having an outside partner from civil society and nonresearch institutions not only attend but convene the conversations — with the representatives of the trial team attending as one of many participants. Wherever possible, be part of the conversation rather than the subject of discussion.

4 Identify global issues and engage international audiences and allies.

Action: Gather information about the global context from international conferences, email forums, trials-network meetings and from knowledgeable individuals.

Result: You will acquire an understanding of the issues, the individuals and the organizations at an international level that can facilitate routine communications. This will help you to develop appropriate messages for unexpected issues



Tips

Use international conferences as an opportunity to engage with stakeholders working at international, national and regional levels. Consider joint sponsorship — with other research partners and other stakeholder partners — of round-table discussions or satellite events to facilitate updates and discussions of news and challenges.



Case Study

Broad stakeholder engagement as a part of the planning for trial success

Manju Chatani, AVAC, New York City

In January 2011, AVAC partnered with the Microbicide Trials Network (MTN), Southern African AIDS Trust and the Treatment Action Campaign in Johannesburg, South Africa, to organize a consultation with civil society. The “Next Steps for ARV-based Prevention” consultation focused on follow-up research that might take place after the VOICE trial (Vaginal and Oral Interventions to Control the Epidemic). VOICE is evaluating different ARV regimens for HIV prevention: daily oral tenofovir (TDF), daily TDF and emtricitabine (FTC), and daily 1 percent tenofovir gel. Such preparations were important in light of the rapidly emerging results from various HIV prevention trials with ARVs, including the CAPRISA 004 microbicide trial, the iPrEx trial, the Partners PrEP trial, the TDF2 trial and the FEM-PRÉP trial.

Part of the civil society consultation was allocated to discussions of MTN 018, or CHOICE, a planned follow-on trial that would be initiated if one or more of the strategies being evaluated in the VOICE trial were found to be safe and effective. The 40 advocates from eastern and southern Africa discussed the proposed design of the MTN 018 trial as well as the regulatory process for approving the gel should it show effectiveness in VOICE. Following this community consultation, the MTN 018 protocol development team met and incorporated feedback from the consultation into its deliberations. Engaging civil society while the trial protocol is in development is an example of good participatory practice guidelines in action.

VOICE used the same gel candidate (1 percent tenofovir) as the CAPRISA 004 trial, but with a different dosing strategy. The 1 percent tenofovir gel arm of the VOICE trial was stopped in 2011 due to futility, but other trials continue to evaluate 1 percent tenofovir gel.

Manju Chatani is a senior program manager with AVAC.

associated with trial closure, data and safety monitoring board (DSMB) recommendations and other events.

Explanation: In the past few years, trials have flourished or faltered on the basis of feedback from individuals and organizations that were well outside the community or country where the trial occurred. Rapid global communication means that no trial takes place in a vacuum. International discussions on trial-related ethics, evolving standards of care and prevention, funding and research priorities can have a direct bearing on the outcome of your trial.

Here are some strategies for engaging with knowledgeable individuals and learning about the international context:

- Provide staff time and resources for structured engagement with open-forum email lists and information sources on relevant topics. For example, one might consider the African Microbicide Advocacy Group, the International Rectal Microbicides Alliance and webinars hosted by the AVAC Advocates' Network and by others.
- Provide staff time for participation in multistakeholder communications — such as the Microbicides Media and Communications Initiative (MMCI) and the PrEP Communications Working Group — and other initiatives where information can be shared at a global level.
- Invite members of civil society and other stakeholders to open sessions of your trial's team meetings; encourage them to present information and engage in discussions and to report back to constituencies afterwards.
- Have quarterly or twice-yearly meetings where the stakeholder engagement team and the science leadership share information on meetings, conferences and workshops at the national, regional and global levels of stakeholder engagement.

5 Review the implications of your information-gathering and relationship-building activities.

Action: Conduct a formal discussion of your broad contextual analysis and community mapping with the trial team to ensure that members of the trial team are aware of the findings, and that your plans are modified accordingly.

Result: The design and conduct of your research project will be relevant and acceptable to stakeholders at national, regional and international levels.

Explanation: It may seem obvious that information gleaned from the engagement of stakeholders should be used to adjust the proposed research project, but this does not always take place. This can cause difficulties if stakeholders are asked to provide advice or opinions and then do not perceive that their thoughts have been considered. Hold one or more meetings to discuss and document the stakeholders' ideas, your proposed responses and potential alterations to your trial. Always follow up with stakeholders. Thank them for their input, tell them how you are acting on their advice, and offer to keep them informed.

6 Develop a system for ongoing engagement with national and international stakeholders.

Action: Create two-way channels of communication with stakeholders at national, regional and international levels.

Result: You will create an up-to-date contextual analysis of factors affecting your trial and a basis for building trust and solving problems with stakeholders who are not directly engaged in the trial or its advisory system (see *Step Six: Engage Stakeholders and Sustain Relationships*).

Explanation: One of the best strategies for ensuring that your trial team is aligned with and cognizant of the broad context is to have a system for sharing and receiving regular updates. A formal strategy, such as a newsletter or portion of the trial website oriented to international audiences, can help. Just as important are individual relationships between site staff members (who are designated to communicate about the trial) and key stakeholders in the international arena. Establish trust by sharing concerns, questions and information about the trial as well as explaining how concerns will be acted upon. There is no single approach to establishing these relationships — the keys are mutual respect and a willingness to listen to and work with partners who have expertise outside of the research arena.



Checklist: Step Four

Use this checklist to make sure that you accomplished all the tasks required in Step Four.

- ☐ Develop and initiate processes for describing local, national, regional and international contexts.
- ☐ Identify key partners who will help you convene discussions on topics relevant to the broader context of your project.
- ☐ Identify some of the key national issues or processes that may have an impact on your research — for example, related technologies (female condoms, ARV therapy and postexposure prophylaxis), financing issues (President's Emergency Plan for AIDS Relief, Global Fund to Fight AIDS, Tuberculosis and Malaria [GFATM]), and other research projects.
- ☐ Develop a series of stakeholder forums, small meetings or one-on-one interviews to gather information on these issues, upcoming developments or changes that might take place over the project's life span.
- ☐ Discuss the findings from your analysis of the broad context, develop plans for responding to concerns and ensure that all of your stakeholders understand the actions that have (or have not) been taken to address their concerns.
- ☐ Use international forums, the open-forum email lists, or the networks (or groups) you are working with to identify key questions, priorities, precedents or relevant topics on an international scale. Consider different ways to generate feedback on the proposed research — a global teleconference call, a forum at an international meeting or a fact sheet for an international audience.
- ☐ Develop key messages, contingency plans and communications strategies to address international issues.
- ☐ Revisit your “maps” of the local, national and international issues over the course of the trial. The maps are fluid and may change with time. Be alert to changing priorities, questions and potentially controversial issues that may arise. Update your strategies accordingly.



*Identify and
Describe Stakeholders*

Introduction

As you outline the broad context of your trial, you have probably begun to identify potential stakeholders and to collect relevant information about them. This step will help you create a comprehensive list of individuals and organizations that have a stake in your project, compile background details about them and organize these data in a useful way. Taking the time to identify and compose descriptive profiles of key stakeholders will provide an invaluable resource to you throughout the project.

Many nonprofit organizations and research teams tend to collect this information informally. They often rely on a single, well-connected individual to develop relationships with partners. This informal style makes the institution vulnerable should that person leave the organization or not be available at a critical moment. It could also limit the diversity of the stakeholders that might be identified. You can avoid that pitfall by acting as a team. Act as a group when you identify whom to contact, document the results of contacts, and have mechanisms to share successes, challenges and lessons learned.

Learning what you can about your stakeholders will also help you to develop relationships with them. Begin this work early, and continue it throughout the project. Taking the time to identify and describe stakeholders will also provide an important foundation when translating findings into intervention programs.¹

¹ MacQueen KM, Cates WC. The multiple layers of prevention research. *Am J Prev Med* 2005;28(5):491–495.



Goals of Step Five

- Compile a thorough list of key local, regional, national and global stakeholders.
- Collect relevant data about these individuals and organizations using information-collection sheets.
- Create a system for organizing this information.
- Contact stakeholders.
- Secure the active involvement of a core group of stakeholders.
- Maintain a stakeholder database, and update the profiles throughout the life of the project.

Why you need to identify and describe stakeholders

A systematic approach in Step Five will make it much easier for your team to:

- Identify the organizations and individuals who are relevant to your project.
- Decide who to contact and how to contact them.
- Create a database that will be useful for this project and for future research.
- Obtain suggestions for other stakeholders whose involvement may be critical to the success of your research.
- Use stakeholder information throughout the project to conduct meaningful preliminary research in the community, explain trial goals and make accurate statements about the generalizability of your trial's conclusions.

Task list

1 Host an in-house brainstorming session.

Action: Get the team together and make a list of everyone that you can think of who might be interested in, benefit from, apprehensive about or alienated by your project.

Result: You will have a great starting point for identifying stakeholders for your project without having to do any external research.

Explanation: The first step in identifying stakeholders is using the resources that are right in front of you. People who are part of your trial team may already have good connections to or knowledge of individuals and organizations that have a stake in your project. By using those connections as a starting point, you'll be well on your way to developing a comprehensive list. Be mindful, however, that your team may have a limited scope. For example, your team may know many researchers but no advocates, or many health service providers but no one in the target population. It's important to realize that this is just a first step toward developing an inclusive list of stakeholders. Use the Stakeholder Identification Sheet (*Tool 5A*) to help you organize this initial list.

2 Develop stakeholder descriptions.

Action: Now that you have a list of stakeholders, collect some information about them.

Result: You will have an annotated list that includes contact information, background details, and selection criteria to make it easier for you to prioritize whom to contact, when and why.

Explanation: Although the first part of this step is relatively informal, making sure that you systematically decide whom to contact can help you to control the process. Be sure to collect contact information, including email addresses and phone numbers. It is also helpful to collect background information such as press releases, white papers and statements released by the organizations. Make notes about potential referrals that you may receive

from these individuals or organization.² *Tool 5B: Stakeholder data collection sheet* and *Tool 5C: Identification of stakeholder roles* can be modified to suit the needs of your project, and they will help you collect this information in a systematic way.

General guidelines for identifying stakeholders

- Identify the individuals and organizations that will be directly or indirectly affected by the research.
- Identify the individuals or organizations that will support the research. Determine what they might contribute to the research and what they might gain from it.
- Identify individuals or organizations that will oppose the research. Determine why they are opposing it and how you might address their resistance to the research.
- Determine the best way to leverage insights or address objections and concerns.
- Itemize your objectives for engaging each stakeholder on your list.

Adapted from: Stop TB Task Force, World Health Organization (WHO). Engaging stakeholders for retooling TB control [Internet]. Geneva: WHO;2008 [cited 2012 April]. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

3 Refine your list.

Action: Based on the information you gathered in Task 2 above, reduce your list of stakeholders to a more manageable size, making sure that all the relevant groups are represented.

Result: You will have a targeted list of people to contact as partners for your project.

² Schmeer K. Guidelines for conducting a stakeholder analysis. Bethesda, MD: Partnerships for Health Reform, Abt Associates Inc.; 1999 Nov.

Possible secondary sources of information

- Newspapers
- Institutional reports and publications
- Speeches
- Political platforms
- Annual reports (staff size and number of offices)
- Websites and Internet searches
- Expenditure data
- Other studies and opinion polls

Adapted from: Schmeer K. Guidelines for conducting a stakeholder analysis. Bethesda (MD): Partnerships for Health Reform, Abt Associates Inc.; 1999 Nov.

Explanation: It is a good idea to start with an exhaustive list of every person and organization that might have a stake in your project. But this list will not be useful unless it has been carefully edited to suit your purposes. Do you have adequate representation of the relevant groups? Advocates? People living with HIV or AIDS? Is your list culturally diverse? Do you have representatives from the target population? If not, how will you make sure they are included? You will need to answer these questions before you take the next step.

Your team should prioritize the list of potential stakeholders to include only those individuals or organizations that have a direct interest in the trial and could impact its implementation.³ Use *Tool 5A: Stakeholder identification tool* to organize this information.

4 Create an electronic database.

Action: Create a shared database where you can store contact information and other relevant details about the stakeholders.

³ World Bank Group, Public Sector Governance Group. Stakeholder analysis [Internet]. Washington: The World Bank; 2001 [cited 2011 May 5]. Available from: <http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm>

Result: By keeping all this information in a single location that the team can access, you will make communications and follow-up more efficient. This database should also make it easier for your team to contact stakeholders for future studies and initiatives.

Explanation: Develop a system that works for your team. For example, some of these data may need to be confidential, particularly if you are including participants or people who are HIV positive. But it is also important that members of the team can access contact information when they need to. Determine who will manage the database, and come up with a protocol for how to access it. Update the database regularly when contact information changes, if a person or organization drops out or if a new stakeholder comes on board.

Note how often organizations wish to be involved, and include some notes about past interactions.

For an in-depth discussion on how to work with the media, please refer to the *Communications Handbook for Clinical Trials*.⁴

Start as early as possible! There's a constant tension between the community and scientists coming up with a research idea. What we often hear from the community is, "Yes, we can help if you bring a study to us midway through the development process, but it would have been more helpful if we could have given our input from the beginning."

– Sam Griffith, Operations Manager, HPTN o61

⁴ Robinson ET, Baron D, Heise L, Moffett J, Harlan SV. Communications handbook for clinical trials [Internet]. Research Triangle Park (NC): FHI 360 and Microbicides Media and Communications Initiative (MMCI); 2010 [Cited 2012 April]. Available from: <http://communications4clintrials.org/>

5 Approach the individuals and organizations on your list.

Action: Call or email the people on your list and invite them to participate in the project.

Result: You will have a preliminary idea of who will participate in your process.

Explanation: Identify the best person on your team to approach each stakeholder. Might it be someone who knows them? Should you get an introduction from a mutual acquaintance? If the person is busy, would it be best to approach them by email or by telephone? Would a letter be better? What is your plan for following up if the individual does not respond to initial overtures? And how will you extend the invitation? Once you ask them to participate, make sure they feel that they are part of the process. For example, you may invite them to join the CAB or attend an open house to find out more about the project. Use *Tool 5D* to plan and track initial contact with new stakeholders.

6 Conduct interviews and record notes.

Action: Once you have made the initial contact with stakeholders, schedule a short interview with them.

Result: Taking the time to gather in-depth information will help you develop a more accurate description of the people you have identified.

Identifying stakeholders is something you do throughout your project; maintain relationships and get new relationships, pulling in new stakeholders as you realize that they should be involved. It's something that you have to keep in mind, throughout the project.

– David Jolly, N.C. Central University



Case Study

Building relationships in LinCS 2 Durham

Randy C. Rogers, M.S., Durham County Health Department and LinCS 2 Durham HIV Prevention Project, Durham, North Carolina

For the Lincs2 Durham study, the research team created a list of people to contact. Given my role in the community, I began to identify folks who were active in HIV work: folks from AIDS service organizations, the Durham Housing Authority and college students. We also identified stakeholders through word of mouth, and we had them refer us to others. It was important to connect with people we already had an established relationship with, who lived in Durham and who were cognizant of research in general. These people could then spread the word and raise awareness about the study.

Initially we invited members of the community to open houses in different areas of the city. We invited people who had different roles — faith-community leaders, those who lived in housing development communities, clinicians and providers who worked with individuals with HIV.

I collected their contact information and age, and tracked their stakeholder role, as I perceived it. If they became involved more intimately, we had them identify their role — for example, grassroots, research enterprise, program or target population. I continue to manage the database in terms of updating the information, and I'm the only one who can edit. We have a Wiki website, and the database is on there so that staff can access it whenever they need to. If there are referrals for potential stakeholders, usually they will be fed through me.

Part of being successful in identifying stakeholders is talking with a community member who is influential and asking him or her about the best way to connect in a way that's respectful, genuine and shows that you want this to be a partnership and cooperative effort. That's the baseline. If you don't know folks directly who can be of assistance, be able to ask, "Whom do I need to talk to? What is the most respectful and appropriate way to approach the community?" Building relationships can be labor intensive, but the most important thing is establishing relationships that are built on trust. It will take some time.

Randy C. Rogers is a health education specialist with the Durham County Health Department and serves as the collaborative council coordinator for the LinCS 2 Durham study.

Explanation: The interviewers should follow the protocol established by the group, with one person as the lead interviewer. Four major attributes are important for describing stakeholders: their position on the issue, the level of influence they hold, the level of interest they have in the trial and the group or coalition to which they belong or can reasonably be associated with.⁵ Review any background literature about the group or coalition before you start to collect the data. Do your homework and show up prepared.

If your team is fairly knowledgeable about one of the groups or individuals on the list, you may not need to interview them. Your goal is to make sure you know enough details to adequately engage each stakeholder.

7 Get referrals.

Action: When you contact stakeholders, be sure to ask them to recommend other potential stakeholders, even if they decline to participate.

Result: You will have a richer pool of stakeholders. And you may get recommendations of stakeholders that you might have overlooked. Some names will come up repeatedly, which will help you understand who the “prime movers” are.

Explanation: Aside from gathering a more comprehensive list of stakeholders, taking the time to ask for recommendations shows that you are sincere about building partnerships and drawing on the expertise of everyone you contact.

8 Classify stakeholders according to type.

Action: Using the information gleaned from your experience, the interviews and the background information, classify each stakeholder according to broad groups. Record their views of your trial.

Result: You will have an easy-to-use index of the stakeholder groups (and their interest in the trial) that you can use for focus groups, communications, media and other situations where you might need stakeholder feedback.

⁵ World Bank Group, Public Sector Governance Group. Stakeholder analysis [Internet]. Washington: The World Bank; 2001 [cited 2011 May 5]. Available from: <http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm>



Case Study

Getting the target population to the table

David H. Jolly, Ph.D., N.C. Central University, Durham, North Carolina

With the LinCS 2 Durham project, I don't think there was anything magical or formal about identifying stakeholders. It was a matter of pulling various people together and brainstorming; it's a known community. We drew on personal contacts, and that gave us a great list of people who work on HIV in Durham. Our target population consists of 18- to 30-year-old black adults in Durham, and we wanted to make sure the target population was represented well in our collaborative council. But we've been much less successful in getting our target population to the table.

One thing that made it difficult is that our collaborative council has regular two-hour meetings. We meet monthly, which involves a higher level of commitment than is usually asked of a community advisory board. This structure works for older people and professionals who are used to meetings with an agenda. That is not a model that appeals to young people. We have had young people come to a meeting or two, and then they just disappear. And we have not had much success with our social networking attempts through our website, Facebook or Twitter.

So we have devised another model. It's called the "target advisory board." It does not involve the level of commitment required by the collaborative council. It involves a series of meetings in which we discuss the project and get feedback from young black adults. But there is no expectation that they need to come to more than one meeting. The agenda is structured so that we can gather information or ideas about an issue or problem in a single meeting. It is led by research team members who are themselves 18- to 30-year-old black adults.

With any of these projects, it is going to be easy to identify policymakers, service providers and others. But just because you come up with a good list of these folks, don't feel too smug. It is critical to get key community people, and that can be a labor-intensive process — you need to identify those people, engage them, gain their trust and get their commitment. That takes a long time. If you are not from that community, it's going to take a lot longer. Identify some bridge people, and work with them.

Associate Professor David Jolly chairs the Department of Public Health Education at N.C. Central University.

Pitfalls to avoid

- Inviting only stakeholders who agree with a proposed plan
- Selecting only stakeholders from the organizations that are directly involved in the trial
- Omitting certain groups of stakeholders
- Inviting stakeholders to a preliminary briefing but not including them in decision making, problem solving or trial design
- Including stakeholders who may not be able to contribute or make decisions because they do not have that power in the community or the organization
- Creating expectations about the project at the beginning, but doing little or no follow-up about the results of the initiative

Adapted from: Stop TB Task Force, World Health Organization (WHO). Engaging stakeholders for retooling TB control [Internet]. Geneva: WHO Press; 2008 [cited 2012 April]. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

Explanation: Different kinds of stakeholders will have different concerns relative to the research and are likely to require different engagement strategies. Five broad groups of stakeholders need to be included in your efforts. By categorizing your list of stakeholders into these five groups, you can quickly see major gaps. These are the five major stakeholder groups:

- Trial participants and their families, partners, neighbors and co-workers
- Local community members
- Health care programs and service providers
- Researchers, funding agencies and regulatory bodies
- HIV and AIDS policymakers and advocates

You may also wish to create descriptive subcategories to further document stakeholders encompassed in these broad groups. For example, under local community members, you might have people living with HIV or AIDS, faith leaders, nonprofit workers and brothel owners; under health care programs and service providers, you might have private physicians and family planning clinics; under HIV and AIDS policymakers and advocates, you might have

ministry-level officials and civil society organizations. You should use the level of detail that is most helpful for your trial and context.

Having gathered information about the stakeholders, their interests and their capacity to oppose or support the trial, the research team can decide how to best integrate the stakeholders' concerns into the research.⁶

Other tips:

- Organize your list of stakeholders according to their relative power (influence), so that you can better understand their potential effect on the trial.
- Consider using a matrix to organize and classify the information. Such a matrix can provide an at-a-glance grouping of the stakeholders into those that have something to gain or lose from the trial and whether they can significantly affect the process.⁷
- Use *Tool 5C: Identification of stakeholder roles* to organize this information.

9 Secure active involvement from the partners.

Action: Invite stakeholders to an event or a meeting where you can outline the ways they can be involved.

Result: The stakeholders will be actively involved and can make a commitment to the project.

Explanation: Once you have made the contacts, you are ready to secure their active involvement. Will you invite them to participate in a CAB? Will they volunteer at a community outreach project? Will they provide constructive comments on your research? How often will you meet with them? What time and energy commitment do you require? You may want to offer the stakeholders a variety of options on how they might participate — they will have various levels of desire, ability and time to dedicate to your trial. Having different options provides assurance that the stakeholders will be involved in different ways at a variety of levels. Keep track of this information.

⁶ World Bank Group, Public Sector Governance Group [Internet]. Stakeholder analysis [updated 2001; cited 2011 May 5]. Available from: <http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm>

⁷ World Bank Group, Public Sector Governance Group [Internet]. Stakeholder analysis [updated 2001; cited 2011 May 5]. Available from: <http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm>

10 Update the database regularly.

Action: Add to or edit the database as needed throughout the project.

Result: You will have a list that your team will use for many different aspects of your project, and possibly for future research as well.

Explanation: The stakeholder information list is a living document that must be current to be useful. Although some of the information must be kept confidential, you should try to make the database or selected parts of it accessible to those who need it. One idea is to create a secure internet space, where people can access and edit the background information. Be careful to manage access in a way that ensures accuracy and maintains confidentiality!



Checklist: Step Five

Use this checklist to make sure that you accomplished all the tasks required in Step Five.

- ☐ List all key stakeholders.
- ☐ Collect information about individuals and organizations .
- ☐ Enter information into an electronic database.
- ☐ Create expanded profiles.
- ☐ Clearly define stakeholder groups.
- ☐ Secure active involvement.
- ☐ Update database throughout the project.



Engage Stakeholders and Sustain Relationships

Introduction

Now that you have identified your potential stakeholders — as well as their priorities, concerns and skills — you are ready to begin building relationships. There are a number of creative approaches to stakeholder engagement, and we encourage you to approach it as a continuous learning process — modifying and adding new strategies to your expanding engagement toolbox. Step Six provides some basic strategies and tools to help you begin to develop those relationships and sustain them throughout the research process.

Forming, strengthening and maintaining good relationships between researchers, the community and other relevant stakeholders is essential to ensuring genuine stakeholder participation and engagement. In your work you will encounter different groups of stakeholders, and their level of involvement will vary. Some will be part of formal advisory structures that meet on a regular basis; others you will request meetings with to sustain relationships and provide updates. Still others — like the host community — will be more loosely defined, and you will need to engage them in a more public way. In all of your engagement activities — regardless of which stakeholders you are targeting — strive to be inclusive and responsive to local needs, and strive to provide opportunities for stakeholders to genuinely influence decisions around the research.

Remember, it is just as important to know when to engage your stakeholders as it is to know who to engage and how to engage them. Community preparedness and stakeholder engagement related to research requires a long-term investment and, ideally, should not be linked to any one trial. Instead, sites should engage stakeholders in an ongoing and sustained manner, throughout the research cycle, forming supportive relationships that extend beyond individual studies.



Goals of Step Six

- Build lasting partnerships and alliances with a range of stakeholders.
- Provide mechanisms by which stakeholders can offer input into the research process.
- Disseminate correct and accurate information about HIV and AIDS, the scientific process and your specific trial.
- Educate and update stakeholders and the community about your trial and its progress.
- Network with staff members at other HIV prevention research studies.
- Document and continue to build your toolbox for stakeholder engagement.

Why you need to engage stakeholders and sustain relationships

A systematic approach in this step will make it much easier for your team to:

- Ensure that correct and accurate information about your trial is reaching your stakeholders and the community.
- Combat misperceptions and rumors about HIV and research in the community.
- Establish trust, transparency and two-way communication with the host community and other stakeholders.
- Improve your stakeholder engagement approaches and implement better practices.

Task list

1 Build partnerships and alliances.

Action: Make contact with various stakeholders, set-up meetings and invite them to planned trial events.

Result: You will develop relationships with a diverse range of relevant stakeholders and begin to establish the necessary buy-in for the successful conduct of your trial.

Explanation: The first step in building partnerships is to make contact. Using the information you collected about potential stakeholders in Step Five, begin reaching out to various stakeholder groups, requesting meetings and inviting them to trial launch events. Building partnerships and alliances ensures that stakeholders have a vested interest in the research and secures them as important allies. It is essential to establish these partnerships early on — ideally before a trial begins — to ensure community and stakeholder participation throughout all stages of the research process.



Tips

Organize “motivator meetings” to inform local and government officials and other stakeholders about the trial’s objectives, potential benefits for trial participants and elements of HIV prevention research. Hold separate meetings for different categories of stakeholders.

Provide opportunities for stakeholders and participants to ask questions, provide testimonies and raise concerns. Document and use these responses to improve strategies for effective stakeholder engagement.

Adapted from: Shagi C. Standard operating procedure: Guidelines for community mobilization. Microbicide Development Programme; 2008.

Think about the networks that already exist in your community. Introduce yourself and your trial. By tapping into existing networks, you capitalize on previously mobilized groups of credible operators that can help to disseminate information, establish trust and introduce you to other potential stakeholders. Similarly, establishing relationships with, and gaining the support of, local government and community leaders that others look to for guidance will help to establish your credibility with a wider range of stakeholders and ensure you have the necessary buy-in for your trial.

Be sure to ask stakeholders how and how often they would like to be contacted, and include that information on *Tool 6A: Stakeholder contact sheet*. You can also use the contact sheet to keep track of how and how often you contact each stakeholder or stakeholder group. Check the sheet often to make sure you keep up regular contact with your stakeholders and track your progress.

2 Establish local stakeholder advisory mechanisms.

Action: Establish one or more formal advisory mechanisms for your trial site or research project. For local community representatives to provide a contribution to the research methods and design, you may need to invest in some capacity-building activities. This will be covered in *Step Seven: Developing Local Stakeholder Capacity*. Include stakeholders in your decisions on how to establish advisory groups. Develop guidelines for the group's purpose, scope and structure.

Result: You will have an active and engaged group of local stakeholders who can contribute to your trial and facilitate two-way communications with the surrounding communities.

Explanation: Local stakeholder engagement occurs formally and informally. One strategy for formal engagement is to establish one or more advisory mechanisms or groups. In many cases, this has taken the form of a CAB. Although CABs have their merits, a CAB — as it is traditionally conceived — might not be the best strategy for every setting.

Research sites have used a variety of models for advisory mechanisms. Some sites follow the traditional CAB model where a diverse range of stakeholders are recruited or elected to serve on the board. Others have established participant advisory groups made up exclusively of current and former trial participants. Still others have separated stakeholder groups — establishing one group for community leaders, NGOs, community-based organizations (CBOs), service providers and other stakeholders and a separate group for trial participants — or they have chosen to adapt and implement alternative models, like those that rely on

Community advisory boards

Community advisory boards (CABs) — a concept originally advanced by AIDS treatment activists in North America and Europe — are advisory bodies composed primarily of non-scientists whose members advise on research protocols and help to educate communities about the research taking place. In time, however, communities, advocates, and researchers alike began to argue that, although CABs play an important role in research, they suffer from limitations and should not be the only method used to engage and solicit input from stakeholders. As a result, research sites began to implement more diverse and multifaceted approaches to stakeholder engagement in addition to the CABs and other advisory mechanisms.

Adapted from: West Slevin K, Ukpong M, Heise L. Community engagement in HIV prevention trials: evolution of the field and opportunities for growth. Aids2031 background paper. Seattle: PATH Publications; 2008 Nov.

well-networked peer educators. Some research studies inherit CABs or advisory boards from their host institution — sometimes with a dedicated CAB member to represent their trial. Work with stakeholders and other members of the research team to develop one or more stakeholder advisory structures that meet your needs and circumstances. You may decide that a single comprehensive group is adequate. Or you may decide that a single group cannot sufficiently represent the needs of your multiple stakeholders and will choose to establish two or more advisory groups to serve stakeholders' different needs.¹

Regardless of the type of local advisory mechanisms you establish, each mechanism should serve similar aims:²

- To serve as community voices, representing local community perspectives
- To act as a bridge between researchers and local communities
- To help make the language of research materials and messages culturally relevant and comprehensible

¹ Gottemoeller M & Hantman J. Mobilization for community involvement in microbicide trials: A report from a dialogue in Southern Africa. Washington: Global Campaign for Microbicides; 2004.

² Gottemoeller M & Hantman J. Mobilization for community involvement in microbicide trials: A report from a dialogue in Southern Africa. Washington: Global Campaign for Microbicides; 2004.

Some examples of local stakeholder advisory mechanisms

Institutional CAB	The Perinatal HIV Research Unit in South Africa is a research organization with established institutional CABs. The unit has three CABs: one that advises prevention trials, one that advises treatment trials and one that supports adolescent research. CAB members are elected, and each of the CABs has developed its own constitution to guide its governance and decision-making.
Trial-specific CAB	Some studies, when they start, do not have an established institutional CAB at their disposal. In that case, CABs can be established to advise on the specific research project at hand. CAB members are typically recruited or elected to serve, on a voluntary basis, for agreed-upon terms.
Multiple advisory groups	CAPRISA in South Africa established a number of what they refer to as community research support groups (CRSGs). CRSG members are drawn from NGOs and local health facilities, as well as previous and current trial participants, all of whom can nominate new members to join the group.
	The site for the MDP 301 microbicide trial in Tanzania set up two separate advisory groups — the Stakeholder Advisory Committee (SAC) and the Community Advisory Group (CAG). The CAG is composed exclusively of trial participants. Each elected CAG member represents a geographical area where the members hold monthly meetings with participants who work or live in the area. Quarterly CAG meetings are held to discuss issues in each geographical ward. The SAC includes a wide variety of stakeholders, including medical officers, local nongovernmental organizations (NGOs), community-based organizations (CBOs), faith-based organizations (FBOs), town council members and the media. Four elected CAG members also sit on the SAC.
	The TDF2 trial staff at the CDC HIV Prevention and Research Clinic in Botswana formed a participant advisory group and a community advisory group, and partnered with local youth and HIV/AIDS organizations to solicit stakeholder input.

- To provide input about certain aspects of the trial — notably informed consent and the compensation or benefits that trial participants and the local communities receive
- To serve as a vehicle through which local communities can learn about and provide input to the trial as it moves forward

The type of model you employ is not as important as how it is developed. Regardless of the model, the advisory mechanism(s) should be developed as one part of a broader stakeholder engagement strategy and should not represent the full extent of stakeholder and community engagement for the trial. People become much more invested in processes that they help to create. You should work with local stakeholders to determine the type of advisory group or groups that are needed, how members will be chosen, and the aims and functions of the group(s).

Invite local stakeholders to a workshop to discuss the establishment of advisory mechanisms. Inform the stakeholders about the various models that have been used in other settings and some of the typical roles and responsibilities of advisory groups. Ask participants if they know of other models or have experience serving on advisory groups. Facilitate agreement on some aims of the group or groups and how members should be selected. (See *Tool 7F: Facilitating Agreement*).

Once the group or groups are established, you will want to have additional discussions about roles, responsibilities and expectations with the advisory group and work together to establish guidelines for the group's purpose, scope and structure (see *Tool 6B: Establishing advisory group guidelines*).

In addition to formal advisory groups, consider implementing other advisory and feedback strategies such as these:

- Having meetings or support groups for the trial participants to give them the opportunity to share their experiences, air their concerns and provide feedback about the trial.³
- Providing a comment box in the trial's clinics to elicit feedback from trial participants and staff.
- If you have a trial website, include a mechanism where people can submit feedback or ask for additional information.

³ UZ-UCSF Collaborative Research Programme. Guidelines for retention of study participants. Unpublished. Zimbabwe: UC-UCSF Collaborative Research Programme;2006.



Case Study

Establishing advisory mechanisms in Mwanza

Charles Shagi, African Medical and Research Foundation, Mwanza, Tanzania

In Mwanza we took a slightly different approach from the traditional CAB model. We thought that in order to get the feedback we needed from participants, we needed to create a forum where they could interact with each other, without other stakeholders present.

First, we conducted a mapping. For our study we were targeting women who worked in recreational facilities (bars, restaurants, hotels, brothels) and women who prepared and sold food and traditional liquor in pombe shops (makeshifts) — the women we refer to as mamalishes. So we mapped where these facilities and women were and organized the area into wards. From there, participants elected a representative — one per ward — to sit on the CAG. Each CAG member would hold a monthly ward meeting to discuss difficulties affecting their participation, problems at the clinics, problems in the community, or any other concerns or suggestions. We held trainings with the CAG members and the ward secretaries (one per ward) to build their counseling and documenting skills so they were better equipped to facilitate the meetings and document what was discussed. Community staff from the site would also be on hand to answer questions or clarify points. The CAG would then meet for a full day every quarter to discuss issues across wards and hear from various members of the research team. It was with the CAG that our team developed our engagement strategy and decided that we needed to reach out to a wider group of stakeholders.

So, in addition to the CAG, we also organized a stakeholder advisory committee (SAC) that included service providers from the hospital and clinics, people from the media and FBOs and community leaders. We put together a kind of job description to explain what was being asked of SAC members and approached different organizations for representatives. We also decided we needed to have CAG representation on the SAC and held elections for four CAG members to also serve on the stakeholder's group.

We used a number of participatory methods to engage the CAG and to build their capacity, which progressively increased their confidence. The participatory aspect of the methods enabled the solutions to come from the participants and give voice to those most affected by research decisions — the women themselves. It engaged them as partners in the research, peer educators and ambassadors for the trial. Now that the trial has ended, SAC members have helped to place some former CAG members as peer health educators with local NGOs and CBOs around Mwanza.

Charles Shagi is a program officer at the African Medical and Research Foundation and formerly served as community liaison officer with MDP 301.

3 Set expectations

Action: Engage local stakeholders early to establish expectations.

Result: You will establish clear and agreed-upon expectations between local stakeholders and the research institution.

Explanation: Setting expectations early is one of the keys to building sustainable partnerships. It's not only important to set expectations about what the research will and will not accomplish but also about the level of influence various stakeholders can expect to have. Understanding the potential influence and translating that to a goal for stakeholder participation is a critical component of conducting effective stakeholder engagement and establishing trust.

This is particularly important for local stakeholder advisory groups. It is important to clearly communicate that advisory group members are not members of the research team. The research institution does not employ them nor will they be paid a salary. Instead, their participation is voluntary and their role is advisory. They are not empowered to make decisions about the research, though their advice and recommendations should always carry weight with the research team.

Community perceptions about the advisory group(s) are also important. Even if advisory group members are clear about their role, local communities can wrongly think that members are receiving favors or are being employed by the research site. Sometimes this can be complicated if some advisory group members are able to attend meetings as part of their jobs — for example, if they are community health workers tasked with outreach and engagement.

Engage advisory group members in activities to discuss and set agreed-upon expectations. For other types of stakeholders, be clear in your



Tips

Stakeholders can have many roles, and it is important that the research team and the stakeholder have a shared understanding of the reasons she or he has been asked to participate in an advisory group.

One stakeholder we know has a good strategy. At meetings where he might have multiple roles, he asks at the beginning which “hat” he is being asked to wear. By doing so, he ensures that everyone understands his role.



Defining stakeholder roles for a community collaboration

Kate MacQueen, FHI 360, Durham, North Carolina

When we wrote the proposal that generated the funding for LinCS 2 Durham, we identified five types of stakeholders as our starting point for outreach and building collaboration: (1) advocacy and policy, (2) community or civil society, (3) the research enterprise, (4) HIV prevention consumers and (5) operations and program development. We met with interested stakeholders to determine the most effective way of working together. These discussions shaped our current “collaborative council.”

Early on we collectively revisited the original stakeholder classification outlined in the research proposal and developed definitions to reflect the diversity of perspectives and roles that the collaborative council sought to include. We use these definitions to track membership in the collaborative council. This strategy helps us identify our strengths in each category so we can ensure that the voices of all stakeholders are represented.

Stakeholder classifications	Stakeholder definitions developed by LinCS 2 Durham collaborators
Advocacy and policy (AP)	AP stakeholders play a remarkable role in generating funding and setting the guidelines and standards for HIV prevention research at the local, state and national levels, based on the needs and perspectives of the other stakeholder groups (GR, RE, PS and TP).
Grassroots (GR)	GR stakeholders are persons who represent the pulse of the community in terms of identifying strengths and challenges of their community and articulating insight and relevant information about why strengths and challenges exist.
Research enterprise (CRE or LRES)	The term “enterprise” doesn’t necessarily mean “corporate” or “business” and must include principal investigators (PIs) and those paid by research entities. Community research enterprise (CRE) stakeholders may include people employed by research institutions and persons who self-select as moving research forward. All staff members of LinCS 2 Durham should identify as LRES.
Programmatic stakeholders (PS)	PS are persons connected to local infrastructures, agencies or programs who serve the population being affected or researched. Programmatic stakeholders may very well connect with persons involved in advocacy and policy, grassroots and the target population to assist in defining their objectives.
Target Population (TP)	TP would be Black men and women between the ages of 18–30 in the Durham community. This group is disproportionately impacted by HIV/AIDS and depending on environmental context and behaviors may be at a higher risk of becoming infected by HIV than other groups.

Kate MacQueen is a senior social scientist with FHI 360 and serves as principal investigator for the LinCS 2 Durham study.

communication. Explain what you are asking from them and what will happen with the feedback they give you. Discuss expectations about what the research project will accomplish and what it will not. Discuss with them their expectations for involvement and updates.

Also, be sure to communicate the role of your established advisory groups with other stakeholders and the community so that people are clear about the group's role. The advisory group can be introduced to other stakeholders as a resource and a link between the research team and the wider community.

4 Be visible in local communities.

Action: Organize local community events, community dramas and town hall meetings or open forums to educate and engage local communities (see *Tool 6C: Organizing an event*).

Result: Local communities will become informed, knowledgeable, engaged and supportive.

Explanation: Connecting with local communities will expand your network and is a good way to gain exposure and support. Being visible in communities fosters a sense of transparency and trust. It signals to community members that you have nothing to hide. Arrange for opportunities to engage in open discussions with participants, their partners and the communities from which they come.

There are several ways to stay visible in local communities. Community events and dramas held in well-attended areas can help to educate members about your trial and HIV prevention research, and help to combat rumors and misperceptions before they start. Open forums and town hall meetings allow for a two-way dialogue — with researchers learning about community perceptions, needs and concerns, and communities hearing from researchers about the need for research and the specifics of the trial being conducted.

Some research sites have also found the following strategies useful:⁴

- Maintain relationships with civil society groups during and after the preparedness phase.
- Hold community education forums and meetings at the trial site or at well-known community sites such as schools or places of worship.

⁴ Robinson ET, Baron D, Heise L, Moffett J, Harlan SV. Communications handbook for clinical trials [Internet]. Research Triangle Park (NC): FHI 360 and Microbicides Media and Communications Initiative (MMCI); 2010 [Cited 2012 April]. Available from: <http://communications4clintrials.org/>

- Participate in local events, celebrations, community health forums and events hosted by other NGOs and CBOs. These events are opportunities for you to communicate with the local public, not only about your trial, but also about health issues more generally.
- Work with the trial staff, advisory groups and other partners to draft drama scripts or poetry slams on relevant topics such as myths and rumors, HIV and AIDS, how research works and participant retention. Once completed, seek out spaces to perform the dramas or poems in order to educate participants, their immediate families and the local communities.⁵

Be sure to document any activities you undertake (see *Tool 6D, Field report*). When deciding which kinds of events to organize, use *Tool 6E: Deciding on a strategy* to think through some of the advantages and limitations of each strategy. See additional tools to help you with agenda planning (*Tool 6F*), brainstorming (*Tool 6G*) and engaging communities with theatre (*Tool 6H*).

5 Use local media

Action: Use local media — including radio and local press — to communicate your messages broadly.

Result: You will inform stakeholders and create opportunities to establish transparency about the conduct of your trial.

Explanation: There are many reasons to positively engage with the media. The media can influence public opinion as well as opinions of funders, policymakers, regulatory bodies and potential participants.⁶ Proactively educating and informing the media about your trial, the need for HIV prevention research and how research is conducted can help to prevent miscommunication and misperceptions about your trial. Some research sites have invited local media to sit on their advisory group(s), involving them as partners in the research endeavor.

⁵ UZ-UCSF Collaborative Research Programme. Guidelines for retention of study participants. Unpublished. Zimbabwe: UZ-UCSF Collaborative Research Programme; 2006.

⁶ Robinson ET, Baron D, Heise L, Moffett J, Harlan SV. Communications handbook for clinical trials [Internet]. Research Triangle Park (NC): FHI 360 and Microbicides Media and Communications Initiative (MMCI); 2010 [Cited 2012 April]. Available from: <http://communications4clintrials.org/>



Case Study

Using football to engage men in Mtubatuba

Mitzy Gafos

Effective HIV prevention requires the support of both women and men. Studies enrolling women have found that participants' partners can often present barriers to study participation, retention and product adherence. Engaging men in HIV prevention research — particularly in microbicide trials — has been an ongoing challenge for the field.

As a way to get young men talking about HIV and the need for microbicides, our site decided to host a football tournament — with eight teams playing 14 games in one day. For the prize, we worked with a local sports shop to donate football kits (uniforms) for the winning team with MDP printed on them. Between games, our staff gave talks and facilitated question-and-answer sessions about HIV, the need for microbicides and the MDP study. We also performed songs about microbicides that our staff and participants had written to entertain and educate the audience and teams. At the end of the day a football team called “Disco” won the tournament and the MDP football kit. The members of the winning team subsequently participated in an educational workshop to learn about HIV, microbicides and why we were conducting the MDP study.

Afterward, every time the “MDP” team played football — which was every week — somebody would ask them what MDP was and the team would tell him or her, engaging in a discussion. It was a fabulous way of getting young men to talk about some of these issues. The experience also encouraged them to help educate others and to build community support.

Mitzy Gafos served as a co-principal investigator for the Microbicides Development Programme (MDP) 301, Africa Centre for Health and Population Studies, South Africa.



Case Study

Using radio in Kisumu

Joel Odondi, Partners PrEP Study, KEMRI, Kisumu, Kenya

Radio can be an excellent tool for engaging stakeholders and potential study participants — particularly those you may not have the opportunity to engage in other ways.

For two years, we held a one-hour radio show every Saturday. We were always careful not to lecture on a topic but to pose questions to the listeners, encouraging them to call in and talk to one another. That way the community works to elevate one another, learning together. We asked questions such as, How can we promote disclosure? Why should people participate in research? And then I would fill in the blank spaces and correct misinformation, helping to build the learning. When participants come to the site to get tested and screened for our studies, we always ask them how they heard about the site. Most of them answer that they heard about us through the radio. Our people listen to the radio. They may go to the farm, but they have a radio next to them.

With limited resources and staff, it can be difficult to find ways to reach large numbers of stakeholders. It can be equally difficult to find creative and entertaining ways of engaging them. Radio provides a way to do both and to help start community conversations about HIV and HIV prevention research.

Joel Odondi is the outreach and retention manager for the Partners PrEP Study.

Beyond avoiding potential misinformation and conflict, local media can be a channel for distributing information. Communicating with people through credible sources they trust is essential to building and sustaining support for the research project. Use local media outlets to advertise community events and forums and to educate stakeholders about your research trial, HIV and AIDS and the need for HIV prevention research. Work with your site's communications staff or principal investigator to make sure the media has accurate and up-to-date information. Consider holding a radio talk show where listeners can call in to ask questions about the trial.

For an in-depth discussion on how to work with the media please refer to our companion publication, the Communications Handbook for Clinical Trials.

6 Draft and disseminate educational and informational materials

Action: Draft educational and information materials.

Result: You will create groups of informed, knowledgeable and supportive participants, participant support systems and other stakeholders.

Explanation: Informative materials, drafted in easy-to-understand language, are an important component of stakeholder engagement. Materials could include question and answer documents, a backgrounder (such as a summary of the “who, what, when, where, and why” of the trial),⁷ a song or video, or a simple brochure that communicates the main points of the research project.

Develop these materials with the help of the research team and your advisory group(s) to ensure that the concepts and the language used are accurate and culturally and contextually appropriate. Research has shown that materials are more acceptable and effective when written in local languages and when pictures and illustrations include relevant objects that are easily recognizable in the local situation.⁸

⁷ Robinson ET, Baron D, Heise L, Moffett J, Harlan SV. Communications handbook for clinical trials [Internet]. Research Triangle Park (NC): FHI 360 and Microbicides Media and Communications Initiative (MMCI); 2010 [Cited 2012 April].

Available from: <http://communications4clintrials.org/>

⁸ Zimmerman M, Larivee C, Quiroga R, Gopinath CY, Ringheim K, Wood S, Wilson A, Daunas P, Bruce L, Sedlak P. Developing materials on HIV/AIDS/STIs for low-literate audiences: A guide [Internet]. Seattle: PATH Publications; 2002 [cited 2012 April]. Available from: <http://www.path.org/publications/detail.php?i=688>

Use the materials widely, giving them to:

- Attendees at community events to encourage further education about HIV, scientific research and your trial.
- Health care and service providers to help educate them about the trial, help solicit their buy-in and encourage them to discuss the trial with their patients.
- Policymakers, advocates and other local research organizations to proactively answer questions they may have about the trial.
- Trial participants and partners to help answer their questions and assist with the disclosure of trial participation.

Detailed information on how to communicate science clearly, craft messages, and develop materials can be found in the *Communications Handbook for Clinical Trials*.

General guidelines for materials production

Before drafting new materials, think about whether or not materials already exist that could be easily adapted for your target audiences. If so, work with other members of the research team and your advisory group(s) to translate them into the local language, ensure that pictures and illustrations are relevant to your setting, and to make any other necessary changes.

Text

1. Choose a type style and size that is easy to read.
2. Use uppercase and lowercase letters and regular type.
3. Test the reading level.
4. Review repeatedly. (Review drafts with the research team first, to ensure technical accuracy, before reviewing them with advisory groups or other stakeholders).

Illustrations

1. Use appropriate colors (colors can have different meanings in different communities or cultures).
2. Use locally familiar images (i.e., activities, clothing, buildings) and symbols (i.e., crosses, arrows, symbols that represent time).
3. Use realistic and simple illustrations.
4. Use a positive approach.

Design and Layout

1. Present one message per picture or illustration.
2. Limit the number of concepts and pages per material.
3. Make the material interactive whenever possible (i.e., include simple question and answer sections).
4. Leave plenty of white space.

Adapted from: Zimmerman M, Larivee C, Quiroga R, Gopinath CY, Ringheim K, Wood S, Wilson A, Daunas P, Bruce L, Sedlak P. Developing materials on HIV/AIDS/STIs for low-literate audiences: A guide [Internet]. Seattle: PATH Publications; 2002 [cited 2012 April]. Available from: <http://www.path.org/publications/detail.php?i=688>



Case Study

Break it down, don't dumb it down

Natalie T. Eley, FHI 360, Durham, North Carolina

The LinCS 2 Durham study — Linking Communities and Scientists to Durham HIV Prevention — brings community members and scientists together in an attempt to identify research interventions that might prevent or reduce HIV in the Black community in Durham, North Carolina. A crucial part of the study is the “collaborative council,” which consists of community members and research staff members.

The council provides support to the LinCS 2 Durham research study by influencing the study’s activities. For example, the council offers feedback and actively participates in various study activities. The collaborative council’s involvement in the study helps to ensure the integrity of the study’s community-based participatory research method.

On a number of occasions, the collaborative council has provided comments on our communication materials and presentations at council meetings. A recurring theme stands out in their feedback: Do not oversimplify information with the assumption that target audiences will not be able to understand the words or the concepts.

It is important to respect the intelligence of your audience, while recognizing that they may not be familiar with your ideas or your methods. So we introduce new terms and definitions, but not in an obtrusive way, and we are sensitive to approaches that may be insulting to the audience. Our motto became “break it down, don’t dumb it down.”

We have since applied this motto in all of our meetings, presentations and materials, regardless of the target audience. We have strived to convey the objectives and the activities of our study in a way that is informative, attractive and well received by various audiences.

Natalie T. Eley is a research associate at FHI 360 and serves as project coordinator for the LinCS 2 Durham study.



Case Study

Engaging through song

Mitzy Gafos

One creative way we found for engaging the community and communicating about the study was to use songs. The idea for the songs initially came out of a staff training session where somebody's example of how they would explain microbicides to their family was by using a song. So what we began to do at very regular sessions was to identify a topic or key message that we wanted to communicate. A group of staff and participants would then volunteer to develop a song. They would go away and work on it and then come back in and sing it to the team. The songs were usually to the tune of church songs so they were familiar to people. A dance would often go along with the song. Then, we'd work as a team to refine the song and ensure that the messages were coming across clearly. Once the song was finished, the team would learn it and record it onto CDs so that we could play them in the clinic waiting rooms. Eventually, we developed a CD with a number of songs, a short introduction about the study and a role play of a question-and-answer session that helped to reinforce the messages in the songs.

During the same time, we discovered that there were rumors spreading in the community that study participants were going into town to have sex because they were being seen getting in and out of taxis with their boxes of gel. We began working with the local taxi association to educate the drivers and try to halt the rumors. Toward the end, the drivers agreed to play our CD in their taxis. The CDs were so widely played in the community that it got to the point that our team would walk in to do a talk or a workshop somewhere, begin a song and find that half the audience would join in. The songs helped to get our messages out to the community and also to build a sense of familiarity with the trial and trial staff members.

Mitzy Gafos served as co-principal investigator for MDP 301, Africa Centre, South Africa.

7 Provide regular education and updates.

Action: Use a variety of methods — including local media, town hall meetings, community events, individual stakeholder meetings and targeted educational materials — to communicate with stakeholders. Be proactive in your communication.

- Organize community events.
- Use local media.
- Conduct question-and-answer sessions and open forums.
- Organize participant and partner events.
- Organize stakeholder update meetings.

Result: You will have a group of informed stakeholders and the necessary political buy-in and support for conducting HIV prevention research in the community.

Explanation: Communication is essential to maintain stakeholder engagement; however, effective communication takes time and effort. Communication is a two-way process that involves the exchange, transfer and understanding of information. Clear and proactive communication is critical to ensuring collaboration, partnership, transparency and accountability. Confusing communication can undermine your credibility within the community. Think carefully about what you want to communicate and the best methods to use. Remember to always build feedback loops into your communication processes so you can better judge whether or not you are getting your messages across to your intended audience or if you need to change your strategy. Communicate early and often; don't wait for a crisis to emerge.

Know your stakeholders, and show interest in their work and circumstances. One time we were going up to the municipality, and we found out that there had been a death of a counselor. So it was very important that we find that sort of thing out before[hand] . . . so we could start our presentation by giving our condolences in an appropriate way.

– Mitzy Gafos, former co-principal investigator, MDP 301, Africa Centre, South Africa

Community events, question-and-answer sessions, open forums and local media provide opportunities to educate and update stakeholders on a large scale. Participant and partner events can be combined with community events or organized separately to celebrate their special contributions. Stakeholder update meetings can be held one-on-one or with groups of stakeholders. Establishing partnerships and sharing your trial's progress with local and government structures through regular updates will be vital to the ongoing success of your trial. Ask these stakeholders how and how often they would like to receive updates. Do they prefer regularly scheduled in-person meetings, formal presentations to their staff or written updates? Whom do they wish to receive the updates from? What language should be used for the updates? Regardless of the format, be sure you consider the expectations you originally discussed with your stakeholders. Are you updating them as frequently as you promised? Do your original expectations need to be revisited (due to membership or staff changes or other circumstances)? Keep track of how often you are updating stakeholders and any outcomes or agreements from your meetings with them (see *Tool 6A: Stakeholder contact sheet*).

Also, think about who the best spokesperson will be for your audience. The spokesperson will likely change depending on which group or groups of stakeholders you are engaging. If you're having a meeting with government officials or high-level community leaders, the principal investigator might be the trial's best spokesperson. If you are hosting a radio call-in show about a health topic, someone from the clinic staff might be best suited. One study found that for conducting outreach to men employed at a local sugar mill, the study's Zulu male doctor was best suited because he spoke the language, could speak to health concerns and was respected by the audience.⁹

The same strategies used for providing regular updates and education can also be excellent capacity-building opportunities. We will discuss this in more detail in the next chapter, *Step Seven: Developing Stakeholder Capacity*.

8 Monitor and respond to community voices and stakeholder views.

Action: Monitor community perceptions of research and your research project. Respond immediately, and in a transparent manner, to any rumors.

⁹ Gafos M. Personal communication; 2011, April, 7.

Result: You will combat misinformation about your trial and research generally, creating a supportive environment and an informed community.

Explanation: The need to combat myths about HIV prevention trials and overcoming suspicions on the part of potential trial participants and the community is among the most significant challenges faced by researchers.¹⁰ Providing regular communication and building research literacy among stakeholders should help to combat rumors and establish trust. In addition, advisory groups and other stakeholders can alert researchers about rumors in the community. And, when armed with the correct information, these stakeholders can also help to combat rumors. Community events, dramas, educational materials and other initiatives can help to combat myths and rumors before and after they start. Rumors left unattended, however, can have disastrous consequences for trial enrolment and support for research. Consider incorporating all or some of these approaches into your stakeholder engagement plan:

- Invite community leaders, advisory group members and other important stakeholders to tour the trial site to learn firsthand about trial procedures.
- Be visible in the community and transparent and honest in your communication.
- Update stakeholders regularly.
- Use dramas with your advisory groups to explore common myths and rumors and how to address them (see *Tool 6H: Engaging communities with theatre*).
- Invest in capacity-building activities (see *Step Seven: Developing Stakeholder Capacity*) to help educate stakeholders about research, research procedures and participant protections.

9 Maintain clearly written records.

Action: Maintain clearly written records of stakeholder engagement and discussions, agreements and unresolved issues.

Result: You will establish accountability for stakeholders and researchers and create a clear account of your engagement efforts and next steps.

Explanation: To help organize and keep track of your engagement activities, it's important to keep clearly written records. Note which individuals and groups you have organized

¹⁰ International Council of AIDS Service Organizations (ICASO). Community involvement in HIV vaccine research: Making it work. Toronto: ICASO; 2006.



Case Study

Combating myths and rumors in Mwanza

Charles Shagi, African Medical and Research Foundation, Mwanza, Tanzania

Myths and misperceptions — if gone unchecked — can wreak havoc on a study, resulting in the loss of stakeholder support and mistrust by the participants. Throughout the study, we were careful to collect information on myths and rumors through in-depth interviews and focus-group discussions and discussed them regularly with community stakeholders. Our CAG members documented any issues that were coming up in the community, and we worked with them and our stakeholders' advisory committee to incorporate discussions of common myths and rumors into informed consent materials and into community mobilization activities.

But the collection of blood was of particular concern to the community — with many believing that the blood was collected and either sold or stolen for the purposes of witchcraft. In response, we invited a group of community stakeholders to visit the study lab to see how we collected and disposed of blood. For them to come and see firsthand where the blood was being taken and what happened with the blood — how we put it under the microscope and examined it, and how we were protecting confidentiality using only study numbers and not participant names — was crucial. For them, instead of just explaining concepts that might be difficult to grasp, showing them helped them understand it. Once they understood it, then they could speak to it — and they did.

During our study, some trials were closed in West Africa and the media contacted one of our participant CAG members without our consultation. But the CAG member had been to the study and seen our study procedures. Because of that, she was able to speak confidently saying, “We know what we’re doing; there’s no problem here.” Listening to our stakeholders and engaging them in a way that was meaningful to them helped put an end to community misperceptions and resulted in broad understanding and support for our trial.

Charles Shagi is a program officer at the African Medical and Research Foundation and formerly served as community liaison officer with MDP 301.

meetings with, and follow up on scheduled meetings. Keep track of how and how often you interact with various stakeholders, any agreements you make, any unresolved issues and any concerns or suggestions you discuss. Keeping consistent written records will also give you documentation to refer back to and will help you to stay organized and keep any promises you might have made to the stakeholders.

Use these tools to maintain records of your engagement activities: *Tool 6A: Stakeholder contact sheet* and *Tool 6D: Field log*. Also refer back to *Step Three: Design a Monitoring and Evaluation System* for more suggestions and tools on how to track your progress.

10 Continue to expand your partnerships.

Action: Continue to reach out to new stakeholder groups, and allow currently engaged stakeholders to take on new roles. Understand that some stakeholders may rotate off. Remember to celebrate successes and stakeholder contributions.

Result: You will sustain stakeholder relationships and encourage continued energy and motivation for engaging with the research institution.

Explanation: The best ways to keep individuals and organizations motivated is to involve them, acknowledge their contributions and encourage new people and organizations to become involved. People do not participate if their contributions are not valued and recognized, or if their participation is perceived as not being meaningful. Don't ask for the involvement and help of community members if you are not willing to give them a role or address their interests and needs.¹¹

At the same time, avoid relying on the same small group of individuals and organizations. Involving new individuals and organizations is an important way to maintain motivation. It is equally important to create the opportunity for individuals or organizations to change their roles, allowing them to renew their commitment.¹²

Stakeholder engagement is a balancing act. You want to make sure that stakeholders feel that their participation is valued, while not exhausting their level of commitment. Invite

¹¹ Frank F, Smith A. The community development handbook: A tool to build community capacity. Hull (Quebec): Human Resources Development Canada; 1999.

¹² Frank F, Smith A. The community development handbook: A tool to build community capacity. Hull (Quebec): Human Resources Development Canada; 1999.

stakeholders to only those events and meetings that will be most beneficial to them. Prepare for the meetings to ensure the time is used wisely and that stakeholders leave feeling they have contributed to and benefited from the experience.¹³

11 Learn from others.

Action: Network with staff at other research sites, NGOs, CBOs and other groups engaged in stakeholder engagement.

Result: You will build a continuously expanding inventory of lessons learned, better practices and various strategies for engaging stakeholders.

Explanation: This toolkit and the resources it lists will provide many practical tools and techniques on how to identify, engage, sustain relationships with and build the capacity of a diverse range of stakeholders. However, we encourage you to engage NGOs, CBOs and research staff at other sites — within and outside of your own network — to learn about other techniques and strategies and help to build a community of engagement experts. Networking with colleagues who are also involved in stakeholder engagement can provide some of the best opportunities for learning.

Remember to document the strategies and tools you use for engagement so you can easily share them with others. When written down, these tools can be used as evidence of your growing expertise and can be quickly adapted to use in various contexts. Use the sample template provided (see *Tool 71: Template for documenting your own tools*) to start documenting your engagement strategies and building your engagement toolbox.

¹³ Shagi C. Personal communication; 2011 April 5.



Checklist: Step Six

Use this checklist to make sure that you accomplished all the tasks required in Step Six.

- ☐ Make contact with various stakeholders from the list you compiled in Step Five. Set up meetings and invite the stakeholders to planned study events.
- ☐ Establish one or more advisory mechanisms for your study site or research project.
- ☐ Use activities with your advisory group(s) to set expectations and agree on a collective purpose, scope and rules for how you will operate.
- ☐ For other stakeholder groups, engage them early on in research activities to establish expectations.
- ☐ Organize community events, community dramas, town hall meetings and open forums to educate and engage the wider community.
- ☐ Use local media to communicate your messages broadly.
- ☐ Draft educational and information materials. Engage the research team, stakeholders and your advisory group(s) to help draft and review these materials.
- ☐ Use a variety of methods — including local media, town hall meetings, community events, individual stakeholder meetings and targeted educational materials — to communicate with stakeholders.
- ☐ Communicate early and often; don't wait for a crisis to emerge.
- ☐ Monitor community perceptions of research and your specific research project.
- ☐ Respond immediately, and in a transparent manner, to any rumors that are circulating.
- ☐ Maintain clearly written records of stakeholder engagement, as well as discussions, agreements and unresolved issues.
- ☐ Continue to reach out to new stakeholder groups.
- ☐ Allow previously engaged stakeholders to take on new roles.
- ☐ Celebrate successes and stakeholder contributions.
- ☐ Network with staff at other research sites, NGOs, CBOs and other groups engaged in stakeholder engagement.
- ☐ Continue to expand your inventory of lessons learned, best practices and various strategies for engaging stakeholders.
- ☐ Document the tools you use.



*Develop
Stakeholder Capacity*

Introduction

Now that you have established important stakeholder relationships and formed advisory mechanisms, you are ready to launch one of the most important activities of stakeholder engagement — capacity building. In this toolkit, “capacity building” refers to developing the skills and attitudes necessary to sustain your relationships with the stakeholders.¹

Capacity building can increase knowledge and awareness, encourage collaborative action and help to sustain long-term commitment. In the context of a research trial, it can also promote trial recruitment and retention, build support, avoid potential controversy, benefit participants and the community, and lay the groundwork for the eventual introduction of a trial product (should it prove to be effective). Community leaders and other stakeholders who are knowledgeable about HIV prevention research can encourage greater community involvement and help to lay the foundation for future research programs.²

Research literacy (for stakeholders) and community literacy (for researchers) are the foundations for engagement, and they are essential to the success of any research endeavor. As such, they constitute the core stakeholder capacities to be developed. However, facilitating this kind of capacity building requires skill and effort. Step Seven provides a straightforward approach to capacity building with a list of activities that you can undertake. Implementing Step Seven will help to ensure that your stakeholders are fully educated about HIV prevention, clinical trials, the role of the community in research, the ways to raise awareness and educate a community about a trial, and how the community can participate in advisory mechanisms. It will also help to ensure that you and your research colleagues are fully educated on stakeholder priorities, strengths and needs.

¹ Russell N, Gryboski K, Miller Vostrejs M, Nash-Mercado A. Igniting change! Capacity building tools for safe motherhood alliances. Baltimore: JHPIEGO; 2004.

² International Council of AIDS Service Organizations (ICASO). Community involvement in HIV vaccine research: making it work. Toronto: ICASO; 2006.



Goals of Step Seven

- Identify the capacity-building needs of your stakeholders.
- Design, plan and facilitate capacity-building activities for a diverse range of stakeholders.
- Incorporate capacity-building activities into your engagement activities.
- Assess what the stakeholders have learned.

Why you need to develop stakeholder capacity

A systematic approach to capacity building will make it much easier for your team to:

- Guarantee that all stakeholders are operating from a common base of knowledge.
- Provide stakeholders with the knowledge and skills to appropriately and effectively engage with the research and each other.
- Ensure that stakeholders are providing correct and accurate information to their communities or constituencies.
- Combat misperceptions that stakeholders may have about HIV, scientific research or research participants to avoid controversy over your trial.
- Foster a sense of collective ownership and investment in the research enterprise.
- Strengthen local capacity to ensure sustainable improvements in the community.
- Strengthen the capacity of national and global stakeholders to understand how the research fits into the broader context of HIV prevention and public health.

Task list

1 Assess the capacity and knowledge gaps of your stakeholders.

Action: Take an inventory of the current capacities and knowledge gaps of your stakeholders.

Result: You will have developed a baseline (which identifies existing capacities and which will help to measure future learning) and a needs assessment (which identifies the skills and knowledge that are lacking among your stakeholders).

- a. Conduct a needs assessment and determine which capacity-building activities are needed (see *Tools 7A* and *7B*).

Explanation: All stakeholders have skills they can contribute. The challenge is to organize and support individuals, organizations and interest groups so that they can make a contribution. You must understand their current capacity, however, before you can provide support. There are several ways to identify the knowledge and skills of your stakeholders.

First, assess their current capacities. Second, identify gaps in their knowledge and skills. And third, decide which capacity-building activities will best meet your collective needs. Use *Tool 7A* to help you take an inventory and conduct a needs assessment. For the third step, solicit input from staff members and stakeholders. Hold brainstorming sessions (see *Tool 6G: Brainstorming*) with your team, advisory group(s), participants and other partners.

Engaging staff and stakeholders in the planning, development and execution of capacity-building activities is capacity building itself, and it's a great way to include stakeholders as partners in the research endeavor. What's more, the various stakeholder groups are best positioned to identify the topics of interest and the activities that are the most appropriate and compelling.

In the tasks that follow, we will discuss potential activities for filling the gaps for each stakeholder group and possible strategies to support individuals while they learn to apply new skills and knowledge.

2 Plan capacity-building activities for community advisory groups.

Action: Develop, plan and facilitate CAG trainings, workshops and other capacity-building activities.

Result: You will have a group of informed, knowledgeable and engaged advisory group members.

Explanation: Community advisory groups are critically important to the success of HIV prevention research, yet these groups often include stakeholders who have limited knowledge about such studies. Education for advisory group members facilitates their ability to (1) collect and make available information that can be used to address rumors and misconceptions, (2) provide input on trial protocols and procedures, (3) craft messages and educational materials and (4) facilitate wider community education about the importance of trial participation and completion.³ Capacity building also helps to build and maintain trust between researchers, stakeholders and the community. Regular meetings and discussions about research concepts and relevant issues — explained in plain language — can help advisory group members better understand the specifics of individual trials as well as build research literacy.



Tips

Develop messages in easy-to-understand language and deliver them using interactive methods.

For helpful ideas, see the tools in the Appendix to this Toolkit and Chapter 8 in the *Communications Handbook for Clinical Trials*.

Consider incorporating these activities into your engagement plan:

- Conduct interactive workshops and trainings on topics such as HIV and AIDS, research literacy, research ethics, gender awareness and your research project.
- Use interactive and participatory learning methods in your trainings and workshops.
- Include advisory group members when you craft messages and develop educational and informational materials (see Step Six: Engage stakeholders and sustain relationships).
- Hold brainstorming sessions and engage advisory group members when you plan, develop and carry out capacity-building activities for other stakeholder groups.

³ HIV Prevention Trials Network. Community involvement in international research: Lessons learned from the HIV Prevention Trials Network. Research Triangle Park (NC): Family Health International; 2006.

3 Plan capacity-building activities for trial participants, their families and their partners.

Action: Develop and organize capacity-building activities and disseminate accurate and appropriate information to participants, their families and their partners. Use planned events for participants and their partners or clinic wait times as opportunities for capacity building.

Result: You will have a group of informed, knowledgeable and supportive participants, partners and participant-support systems. You will increase their knowledge of the trial, the key messages and the importance of HIV prevention research.

Explanation: Capacity building for participants starts with ensuring that accurate and appropriate information is disseminated during the mobilization and recruitment process so that participants fully understand their volunteer role. Information dissemination and education should continue throughout the trial, addressing any concerns or misunderstandings that may arise.

To facilitate research participation, it may also be important that participants' partners and families are well informed about the trial and the research enterprise. This is often addressed on a community level (see Task 4). Some trials have found it helpful to hold special events for participants and their partners or to invite partners and family members to visit the trial clinics to speak to counselors and to ask questions.

To facilitate and give voice to women, participatory methodologies were used by borrowing and adapting methods such as participatory rural appraisal and participatory learning and action. Through these methods, women were facilitated to discuss and actively take part in decision making on issues related to their participation in the trial.

– Charles Shagi, program officer, African Medical and Research Foundation, Mwanza, Tanzania

These are optional activities, but they can be important for generating social support for the participants over the months or years of their participation in the trial. Whenever events or clinic visits are offered to partners and family members, the research team needs to be sensitive to equity issues, especially gender equity. The confidentiality of the participants must be maintained; always let the participant decide whether and what personal information is to be shared with partners and family members.

Consider incorporating these activities into your engagement plan:

- Organize events especially for participants, or for participants and their partners, to educate, disseminate information, reinforce key messages, maintain contact, celebrate their participation and build partner support.
- Incorporate creative and interactive methods in your events (such as songs, skits, dances; see *Tool 6C: Organizing an event*).
- Include participants in planning, developing and carrying out participant events and capacity-building activities.
- Create spaces for participants to share their experiences.
- Encourage two-way communication, and solicit input from participants on trial procedures, their needs and concern, and their feedback on capacity-building and engagement activities. Consider providing comment boxes in the trial clinics or holding focus-group discussions.
- Invite partners — directly or through the participants — to attend trial clinics for counseling, HIV testing, sexually transmitted infection (STI) screening or treatment, or to simply ask questions.
- Give health talks or use informational materials in the clinic waiting rooms. Some sites have played videos or songs they produced about their trial or about HIV prevention research as entertainment for participants during long clinic waits.
- Incorporate capacity-building activities into clinic visits. Have clinic staff, particularly counselors, reinforce key messages and discuss rumors and misconceptions during regular trial visits.



Case Study

Organizing participant events in Mtubatuba

Mitzy Gafos

We knew it was going to be a challenge to get the participants to return at the completion of the trial to be unblinded and to receive the results, so the team decided to organize and promote three successive annual events for participants and their partners. The details of the first event — including the date and location — were advertised before the first women started to exit the trial. Details of the subsequent events were promoted a year in advance. This way we were able to achieve great turnout for the events by former and current trial participants and their partners.

The first event was held just after the first set of women had finished their follow-up; our goal was to retain the women beyond the end of the trial to make sure we could give them the results. We told the women about the duration of the trial and encouraged them to keep in contact with us. We also talked about the importance of completing their participation in the trial, about coming for their regular trial visits and about not sharing their gels. We asked participants and staff to come together and develop skits to explain the key messages. One group of participants performed a song and dance, and a male partner of one participant gave a testimonial about condom use.

The second event was designed to prepare participants and their partners for the results of both the HPTN 035 trial and the MDP 301 trial the following year. We developed skits to explain the history of HIV and HIV prevention research to emphasize that research takes a long time and that even disappointing results contribute to our knowledge. The skits also explained the potential outcomes of the trial — effective, not effective and signs of harm.

Then we asked participants to vote for the scenario they thought was most likely. This helped us to get a sense of how well we had managed expectations about the potential impact of the trial: Did the participants assume the trial product would prove to be effective, or did they understand that other outcomes were possible? Participants and members of the trial team worked together to develop the skits, songs and color-coded visuals we used to give updates on the trial and deliver our key messages.

The third and final event was successful in attracting well over half of all the women who had joined the trial in the previous three years. We explained the trial results to them as soon as the results were available; women were also unblinded at that time.

The events were challenging to organize but helped us to maintain close contact with former participants and helped to enhance the participants' understanding of the research process. Our interactions with the women took place over several months (as we planned the event), not just on the day of the event. Within the team, we held brainstorming sessions and discussed what we wanted to accomplish and how we might do it. We got input from the CAB and the participant-stakeholders group — an informal group of women from each of our three trial clinics that would ask other participants whether they would like to help. Staff and participants volunteered for the different bits of work that needed to be done.

My advice to others is to involve the participants as soon as possible — they were the real drivers of the event — and to make sure that the entire team has the opportunity to get involved. Make sure that participants get a space to share their experiences and opinions during the events and that their confidentiality is respected. Finally, make sure the event has lasting value. For example, after the events were over, we held workshops and focus-group discussions to solicit feedback and to check participants' comprehension of the key messages that had been promoted; this allowed us to document the value of this type of engagement and capacity building.

Mitzy Gafos served as a co-principal investigator for MDP 301, Africa Centre, South Africa.

4 Plan capacity-building activities for the local community.

Action: Develop and organize capacity-building activities, and disseminate accurate and appropriate information to the wider community. Include capacity-building elements into your planned community events, and use the local media.

Result: You will have an informed, knowledgeable, engaged and supportive local community.

Explanation: Capacity building for the wider community goes beyond trial-specific information and should include activities aimed at continued education and awareness about basic knowledge of HIV and AIDS, reducing stigma and discrimination, the importance of research, how research is conducted and why this trial is being held in their community. Consider linking activities to other topics and events that are important to the community (such as public health awareness days or holidays). Being visible in the community helps to support transparency, builds trust and engages the community at-large as vested stakeholders in the research project. Community capacity-building activities can be used to engage men (including partners of trial participants), especially in studies that enroll women and men who have sex with men.

Consider incorporating these activities into your engagement plan:

- Organize community events to educate, disseminate information and dispel myths and rumors.
- Incorporate creative and interactive methods in your events (such as songs, dramas, dances). See *Tool 6C: Organizing an event*.
- Use local media (such as newspapers, radio stations) to disseminate information. Consider hosting a regular interactive radio show to engage the community in a more direct way.
- Link activities with other opportunities to engage the community. What events are already being planned in the community? Are there days or weeks that are of interest to community members (World AIDS Day, National or International Women's Day, other health awareness days or weeks)? Are there activities that are of interest to the community and have the potential to draw a crowd (such as football tournaments, competitions)?
- Partner with other health research groups in the local community to offer joint events and activities.
- Offer to co-sponsor events that reach out to your key stakeholders in the local community. This could include donating funds to support needs, such as the purchase

of event T-shirts, printing of flyers or rental of a sound system. Or you could also offer in-kind support, such as help in setting up and breaking down seating at the event venue, leafleting and agenda planning.

- Hold community roadshows, town hall meetings or other community forums.
- Incorporate dramas, theatre, poetry slams, song and even fashion as a way to educate people in an interactive and entertaining way.
- Consider holding informational talks at the premises of large employers in your area.
- Engage small (and large) community groups. Invite churches and women's groups — including income generating groups, traditional healer associations and so on.

5 Plan capacity-building activities for other stakeholder groups, including policymakers, advocates, traditional leaders, and program and service providers.

Action: Develop, plan and facilitate “update” meetings and educational workshops for policymakers, advocates, traditional leaders and providers of local programs and services. Use update meetings as opportunities for capacity building with stakeholders

Result: You will achieve the political buy-in and support needed for conducting HIV prevention research in the community.

Explanation: Capacity building for policymakers, advocacy groups and other leadership structures will likely involve wider community activities (see Task 4) and updates and educational workshops given by the research staff to various NGOs, government agencies and other stakeholder groups. In your initial contact with stakeholders, be sure to come to an agreement on how often they would like to be updated and what, if any, capacity-building trainings and workshops they might be interested in (see *Step Six: Engage Stakeholders and Sustain Relationships*, Task 1). Consider inviting representatives from these groups to any stakeholder trainings and workshops you organize. Also consider inviting stakeholders to research staff trainings that may be of value to them professionally; for example, AIDS 101, research ethics, Good Clinical Practice, and methodological overviews. Even if you can only accommodate one or two key stakeholders, such training opportunities may be significant for the persons involved and they may become trial ambassadors as well.

Capacity building for providers of programs and services will likely take place during wider community activities (see Task 4), update sessions and workshops planned by the research staff for local stakeholders or during advisory group activities. Support from local providers



Case Study

Engaging stakeholders through capacity building

Joel Odondi, Partners PrEP Trial, KEMRI, Kisumu, Kenya

For the success of a trial, it is crucial to identify and engage the community gatekeepers so that you can build their capacity. They can be very helpful if they are brought on as partners, and they can be very destructive if they feel they have been left out or if you fail to help them see the benefits of the research.

At the Partners PrEP site in Kisumu, we made a point of engaging religious leaders. We invited all of the bishops and religious leaders and presented them with information about HIV and the benefits of research. We told them that in order to combat HIV, we needed to work together with them. Some of them were hesitant. Others were looking for financial incentives for letting us talk to their congregations. But we were able to bring the leaders together and explain to them that we wanted to work together to teach people about HIV so that they take precautions. And we did it in a way that respected the leaders' authority and beliefs. Now we go to churches and give information or help to build the capacity of the pastor so he or she can deliver the messages.

You need to know your stakeholders and how to approach them. By reaching out to community leaders with large social networks, we were able to widely communicate our messages, simultaneously building support for research, combating misperceptions and stimulating interest in the trial. By engaging religious leaders we have also been able to bring the issue of HIV into the churches — helping to combat HIV and stigma on a broader level.

Joel Odondi is the outreach and retention manager for the Partners PrEP Trial.

of programs and services will also ease referrals to local services from the trial, and help to integrate local care and care from the trial staff members. Include providers of programs and services in advisory groups, and encourage them to participate in community events and other stakeholder activities. Remember that engaging with the trial is a small part of the work they do; talk to the staff about ways to simplify their workload in the trial (such as changes to the referral slips or procedures and encouraging participants to visit referral centers on certain days).



Tips

See *Partnering for Care In HIV Prevention Trials: A How-To Manual* in Additional Resources for practical help on building effective referral processes with providers, including a series of how-to steps and checklists.

Consider incorporating these activities into your engagement plan:

- Conduct interactive workshops and trainings on topics such as HIV and AIDS, research literacy, research ethics, gender awareness and your research project.
- Use interactive and participatory learning methods in your trainings and workshops.
- Incorporate capacity-building activities into your regular stakeholder update meetings.
- Invite representatives from these groups to stakeholder trainings and workshops and to sit on advisory groups.
- Inform these stakeholder groups about any community-wide events that you may plan.

6 Plan capacity-building activities for the research staff.

Action: Develop, plan and facilitate staff trainings on stakeholder literacy and the importance of stakeholder engagement. Provide opportunities for staff to get involved in engagement activities.

Result: You will have an engaged, transparent research staff that understands the importance of stakeholder engagement. You will begin to build the capacity of staff members by engaging stakeholders.

Explanation: The research staff is a critical group of stakeholders that you should not overlook. Staff members will have varying amounts of knowledge and experience of HIV, scientific research, stakeholder engagement, stakeholder perspectives and ways to engage the stakeholders. Just as building stakeholders' capacity around HIV and AIDS and research literacy is critically important to the research endeavor, so too is the importance of building

stakeholder and community knowledge and capacity among the research staff — from drivers and participant trackers to the principal investigator. This idea of “joint literacy” — in which researchers are trained to work with communities and their realities, and communities are trained on research concepts — strengthens all aspects of the trial.⁴

It is also important to help the research staff move away from viewing community and stakeholder engagement as simply recruitment and retention activities to a more nuanced understanding of the critical importance of engagement for the success of the research, the development of appropriate trial procedures and messages, and the eventual introduction of and access to trial products — if and when they are proven effective.

Consider incorporating these activities into your engagement plan:

- Conduct interactive workshops and trainings for staff members on community literacy.
- Use interactive and participatory learning methods in your trainings and workshops.
- Plan a research staff capacity-building event where stakeholders are invited to provide overviews of the work they do, the resources they have available and areas where they are seeking assistance.
- Identify opportunities where research staff members can engage in volunteer work with stakeholder organizations; organize transportation to facilitate their participation.
- Include staff members in planning, developing and carrying out engagement events and capacity-building activities.

7 Assess capacity.

Action: After each capacity-building activity, assess learning and collect feedback to ensure that your activity has met its aims. This will also help you — and the wider field — to build evidence on the importance and benefits of stakeholder engagement and to better integrate research and stakeholder engagement.

Result: You will have practical information on which capacity-building methods are successful and which need to be amended, as well as information about the gaps that still exist. You will create strong links between stakeholder engagement and research and build a body of evidence on the importance of stakeholder engagement.

⁴ Joint United Nations Programme on HIV/AIDS (UNAIDS). Creating effective partnerships for HIV prevention trials: Report of a UNAIDS Consultation, Geneva 20–21 June 2005. AIDS. 2002;20:W1–W11.

We worked with a group of participants and...did a training session with them [on violence against women]...and then we gave them a camera and encouraged them to develop pictorial flip charts that they then used to go out and give talks in their own communities about challenging violence against women. We did it with women and with men. And you know, it was under the umbrella of microbicides, but it was a side issue. But it was about women, it was linked to HIV, and it was linked to the need for microbicides. And that sort of capacity building for me was probably the greatest thing that we could leave behind us.

– Mitzy Gafos, former co-principal investigator, MDP 301, Africa Centre, South Africa

Explanation: After conducting capacity-building activities, you can use various strategies and methods to assess what your stakeholders (including research staff members) have learned, how effectively you are communicating your messages and what gaps — if any — remain.

There are many ways to assess and evaluate what participants have learned and what gaps may still exist, including these possibilities:

- **Individual Assessment:** Give participants a pretest before the training begins. At the end of the training, give participants the test again, or a modified version of the test, and compare the answers and see where the gaps in understanding remain. You will need to develop these tests based on the content you plan to cover in your training.
- **Small Group Assessment:** After the training, conduct focus group discussions with a sampling of participants to assess their learning and solicit feedback on the training content and methods.
- **Large Group Assessment:** After the training, use assessment tools (such as *Tool 7H: Agree/disagree*) to evaluate participants' learning, correct misinformation and reinforce the training content.

For a more detailed discussion on M&E techniques, refer to *Step Three: Design a Monitoring and Evaluation System*.



Checklist: Step Seven

Use this checklist to make sure that you accomplished all the tasks required in Step Seven.

- ☐ Take an inventory of current capacities — the skills and knowledge that already exist among your stakeholders — and gaps.
- ☐ Based on your inventory, determine which capacity-building activities you need to organize.
- ☐ Plan capacity-building activities for advisory groups. Develop, plan and facilitate advisory group trainings and workshops.
- ☐ Develop messages in easy-to-understand language, and deliver them using interactive methods.
- ☐ Plan capacity-building activities for and disseminate accurate and appropriate information to trial participants and their families, and partners.
- ☐ Use events for participants and partners as opportunities for capacity building.
- ☐ Create spaces for participants to share their experiences.
- ☐ Encourage two-way communication and solicit input from participants on trial procedures, their needs and concerns, and their feedback on capacity-building and engagement activities.
- ☐ Incorporate capacity-building activities into clinic visits. Have clinic staff members reinforce key messages and discuss rumors and misconceptions during regular trial visits. Give health talks or use informational materials (such as printed materials, videos, songs.) in the clinic waiting rooms.
- ☐ Plan capacity-building activities for the local community, and disseminate accurate and appropriate information to them.
- ☐ Include capacity-building elements into your planned community events.
- ☐ Use local media.
- ☐ Plan capacity-building activities for other stakeholder groups, including policymakers, advocates, traditional leaders, and program and service providers. Develop, plan and facilitate update meetings and educational workshops, and use update meetings as opportunities for capacity building.
- ☐ Plan capacity-building activities for the research staff. Develop, plan and facilitate staff trainings on the importance of stakeholder engagement.
- ☐ Provide opportunities for the staff to get involved in engagement activities.
- ☐ After each capacity-building activity, assess learning to ensure your activity met its aims and to build a body of evidence on the importance and benefits of stakeholder engagement.
- ☐ Include participants, staff and advisory group members in planning, developing and carrying out capacity-building activities and events.



Appendix

Tools: Step One

Tool 1A: Organizational self-assessment

Tool 1B: Gaps and opportunities

Tool 1C: Budget for stakeholder engagement

Tool 1D: Action plan

Tool 1E: Activity prioritization grid

Tool 1F: Matrix of stakeholders

Tool 1G: Work plan

Tool 1H: Timeline

Tool 1I: Sample job descriptions

Tool 1A: Organizational self-assessment

This tool will help you assess the strength and consistency of the organization's commitment to stakeholder engagement.

You may wish to answer this questionnaire with several staff members; pooling your knowledge may increase the tool's validity. You could ask individuals who have differing perspectives on your organization — trial staff members, leaders of partner organizations and funders — to complete this with your trial in mind.

Tool 1A: Organizational self-assessment (baseline assessment)

Name of Organization: _____

Please answer yes or no to the following questions and provide additional details where relevant.

1. Does anyone on your staff have experience with stakeholder engagement?

Yes _____ No _____

If yes, please describe:

2. Does your team have a process for doing stakeholder engagement?

Yes _____ No _____

If yes, please describe or note where this process is documented:

3. Does your trial team follow a set of guiding principles for engaging with stakeholders in a research trial?

Yes _____ No _____

If yes, please describe or note where these principles are documented:

4. Has your trial team conducted an environmental scan, done formative research or otherwise identified and documented key features of the country, regional and local context (as appropriate) where the research is taking place?

Yes_____ No_____

If yes, please describe:

5. Does your trial team have the budget, staff and other resources necessary to support stakeholder engagement through the entire life cycle of the proposed research project — and even beyond that time frame?

Yes_____ No_____

If yes, please describe:

If no, please indicate which resources are lacking:

6. Has your trial team already identified stakeholders (in a systematic way) in the following stakeholder groups:

- | | | |
|--|----------|---------|
| a. Trial participants and their families and partners? | Yes_____ | No_____ |
| b. The local community? | Yes_____ | No_____ |
| c. Policymakers and advocates? | Yes_____ | No_____ |
| d. Other researchers, funders and sponsors? | Yes_____ | No_____ |
| e. Program and service providers? | Yes_____ | No_____ |

7. How would you rate your site's knowledge of the following groups?

- a. Trial participants and their families and partners

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- b. The local community

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- c. Policymakers and advocates

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- d. Other researchers, funders and sponsors

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- e. Program and service providers

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

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

- a. Trial participants and their families and partners

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- b. The local community

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- c. Policymakers and advocates

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- d. Other researchers, funders and sponsors

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

- e. Program and service providers

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

9. Has your team ever undertaken a stakeholder analysis before?

Yes_____ No_____

If yes, please describe or note where this analysis is documented:

10. Do you have descriptive profiles of any stakeholders? Or has your organization ever created profiles for another trial?

Yes_____ No_____

If yes, please describe or note where these descriptive profiles are documented:

11. Does your organization monitor and evaluate the effectiveness and efficiency of stakeholder engagement?

Yes_____ No_____

If yes, please describe or note where the M&E activities are documented:

12. Do you begin stakeholder engagement during the conceptualization phase of a trial?

Yes_____ No_____

If yes, do you modify the engagement process during any other part of the trial (e.g., during the dissemination of the trial's results)?

Yes_____ No_____

If yes, please describe:

Tool 1B: Gaps and opportunities

This tool will help you pull information from your baseline assessment (Tool 1A) and determine how to address your team's weaknesses. You should complete this tool immediately after you conduct the baseline assessment, with the same group of people.

Gaps	Opportunities

Example — Completed Tool 1B: Gaps and opportunities

Gaps	Opportunities
We have identified stakeholders, but we have limited relationships, especially policymakers and other researchers.	Upcoming conference in Nairobi will offer our team the chance to develop relationships with other key researchers in the country — we will plan to attend. We will also hire a staff member who has experience working with the Ministry of Health — this should give us the chance to improve our relationships with policymakers.
Our team engages with stakeholders early on in the trial (the conceptualization phase), and sometimes during results dissemination, but does not keep engaging throughout the trial.	We will plan (and budget for) events to continually engage with stakeholders during the course of the trial. We will also work with our communications staff to develop materials for various audiences.
No one on the team has experience with M&E of stakeholder engagement.	Write M&E experience into new job description.

Tool 1C: Budget for stakeholder engagement

This template includes suggested line items for your stakeholder engagement budget. You can refer to your list of “needs” versus “wants,” and select some of the items in your “wants” list for your expanded budget if you have the benefit of a larger budget. If you are conducting a large trial — or simply have more funds for stakeholder engagement — we have included suggestions for some “extra” activities — “wants” — to help enhance your team’s portfolio. (Note the items that have been added to this budget are shown in **green text**.) When planning for staff time, be sure to consider all stages of the stakeholder engagement process, including work planning, ongoing engagement and capacity development.

Tool 1C: Budget for stakeholder engagement.

Black text indicates suggested basic items; green text indicates suggested extra activities.

Name of project:			
Protocol number:			
Date completed:			
Is this a revised version of an earlier budget? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Budget categories			
Exchange rate: [funder currency] = [local currency]			
Salaries (title and effort)			
Director of stakeholder engagement (___ % for ___ months)			
Community educator/liaison (___ % for ___ months)			
Administrative support (___% for ___ months)			
Site PI (___% for ___ months)			
Other staff (___% for ___ months)			
Subtotal salaries \$			
Staff training			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Training materials/duplication/printing/binders/etc.			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal training \$			

Promotional items			
Materials development (brochures, leaflets, thank-you cards, other items)			
Translation			
Printing costs			
T-shirts, condoms, bags, etc.			
Subtotal promotional items \$			
Stakeholder engagement meetings			
Room rental			
Trainer/facilitator			
LCD projector; video camera rental, tapes			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal meetings \$			
Stakeholder engagement roadshows			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal roadshows \$			
Stakeholder engagement workshops			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal workshops \$			
Operational costs			
Telephone (including minutes for mobile phones), Internet, fax, courier			
PA system (for events)			
Local travel to meet with stakeholders (gas, mileage)			
Postage			
Computer, printer, back-up drive, thumb drives, Internet access			
Digital recorders, cameras, video			
Subtotal operational \$			
Overhead \$			
TOTAL \$			

Tool 1D: Action plan

This tool should be completed after your team has developed its goals and objectives. Use this form to outline the activities that you will complete in support of your goals and objectives. You should complete a separate matrix for each objective, and you can outline persons responsible, materials needed, indicators and measurable outcomes (for M&E purposes). This tool was adapted from an activity grid created by the Microbicide Trial Network's VOICE trial.

Tool 1D: Action plan

Date completed:

Objective:

Activity	Responsible Persons	Materials	Indicators	Measurable Outcomes
1.1				
1.2				
1.3				

Example — Completed Tool 1D: Action plan

Date completed: 12 June 2011

Objective 1: To assess the knowledge of community volunteers and community members on clinical research, microbicides and PrEP through a needs assessment exercise.

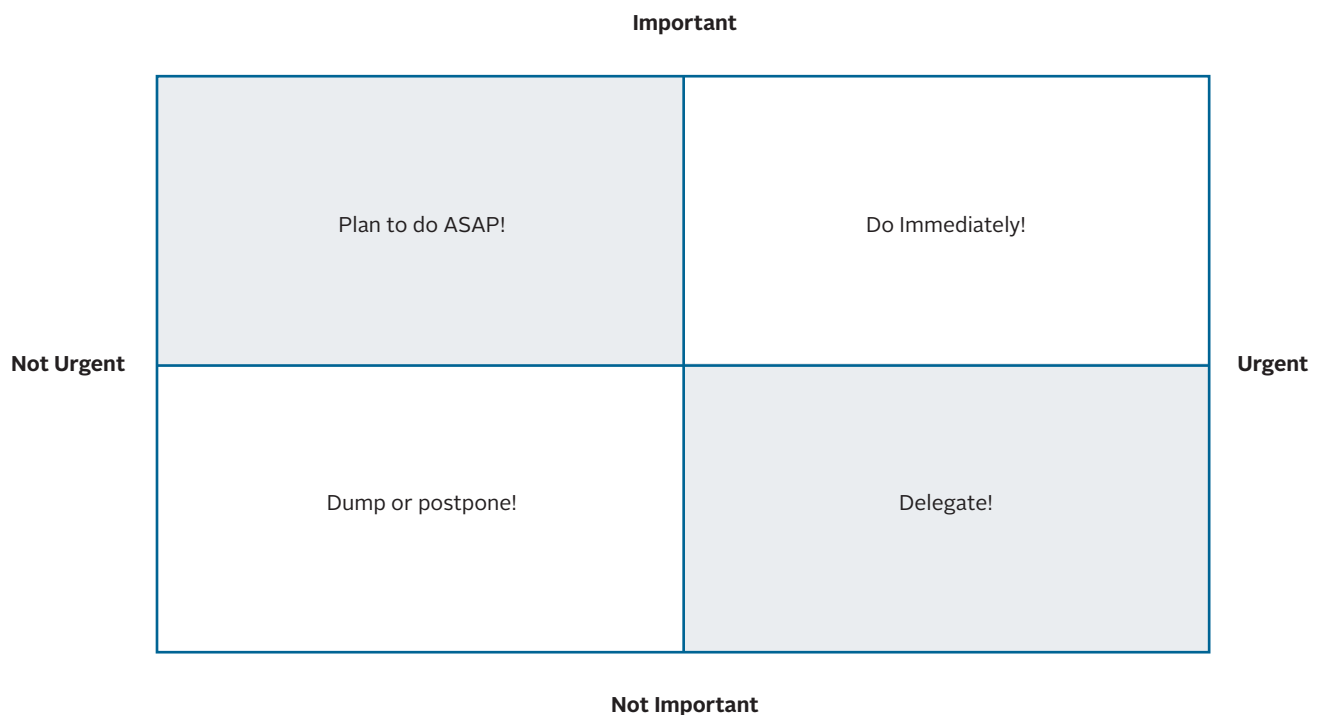
Activity	Responsible Persons	Materials	Indicators	Measurable Outcomes
1.1 Develop assessment tools	Community educator	Personnel Paper Pens	Tools developed	Various types of tools developed according to the target audiences.
1.2 Conduct needs assessment for CAB and Outreach Workers	Community education team	Personnel Paper Pens Hire of venue Transport refund Snacks/drinks Questionnaires Flip charts	Needs assessment conducted for all the CAB and outreach workers	Assessment conducted and knowledge gaps identified among CAB members and Outreach Workers.
1.3 Conduct needs assessment for stakeholders and general community members using questionnaires and small group discussions	Community education team with CAB members	Personnel Paper Pens Hire of venue Transport refund Snacks/drinks Questionnaires Flip charts Water for interviewers	Needs assessment conducted for all the stakeholders and randomly selected general community members in targeted communities	Assessment conducted and knowledge gaps identified among stakeholders and randomly selected general community members in targeted communities.

Tool 1E: Activity prioritization grid

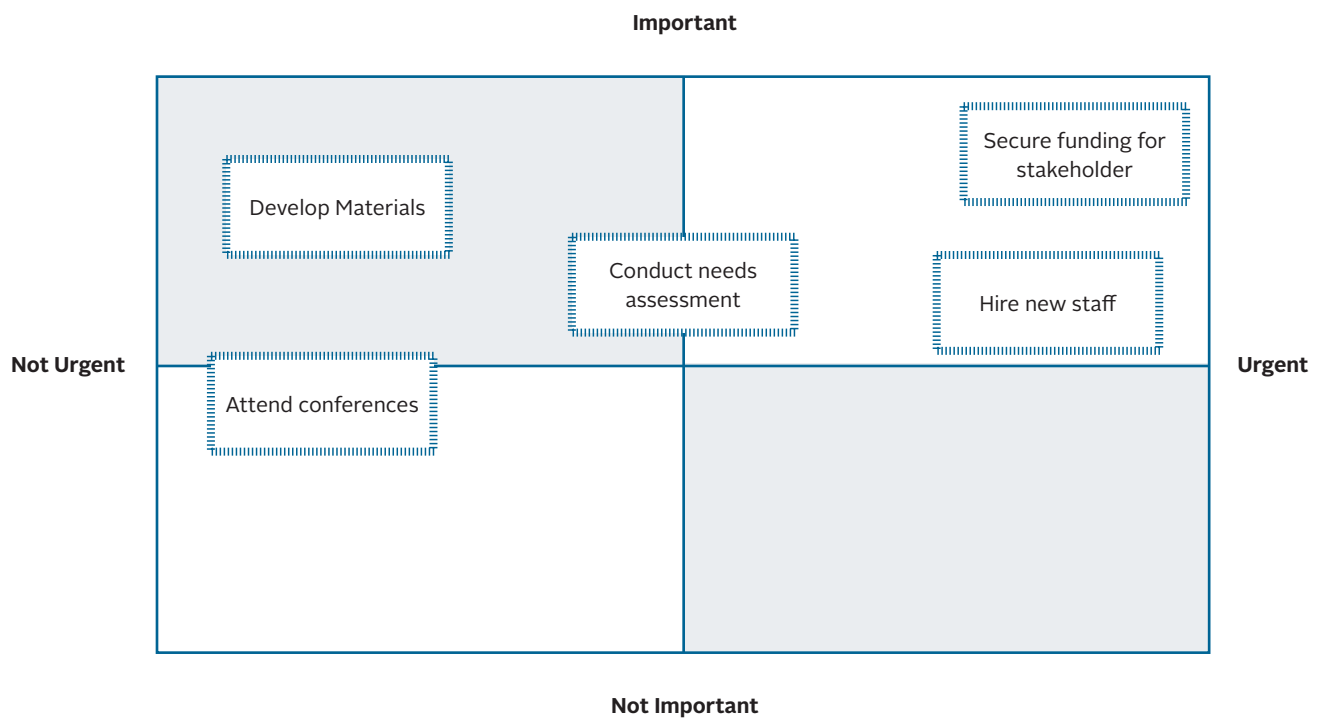
Once you have outlined your team's activities, you can use this simple grid to prioritize activities. For each task, decide how important and urgent it is. Tasks that are important and urgent will be placed in the upper right quadrant. These tasks should be completed first. Tasks that are less important, but still urgent, can be placed in the bottom right quadrant. These tasks should be completed second. Tasks that are important but not urgent should be placed in the upper left quadrant and should be completed third. Tasks that are neither urgent nor important should be placed in the bottom left quadrant. These tasks can be completed as time and resources allow.

As a team, write each activity on your grid in the appropriate spot. When you are finished, your team should have a clear idea of the order in which to complete each activity. This can feed into your timeline (see *Tool 1H: Timeline*).

Tool 1E: Activity prioritization grid



Example — Completed Tool 1E: Activity prioritization grid



Tool 1F: Matrix of stakeholders

The following tool can be used to plan your stakeholder strategy. This matrix is crucial to the rest of your planning process. Some items may need to be left blank until you complete some of the other steps in this toolkit, but you should set up your matrix and begin establishing the overarching strategy for stakeholder engagement in your trial. Adapted with permission from this resource: MEASURE Evaluation, USAID. Stakeholder engagement: An assessment and implementation tool for identifying stakeholders in a data collection initiative and engaging them as contributors and beneficiaries. Data demand and information use, part 2: Strategies and tools [Internet]. Available from: <http://www.cpc.unc.edu/measure>.

Tool 1F: Matrix of stakeholders — for overall plan

Date completed: _____

Stakeholder (organization, group or individual)	Potential role in the trial	Engagement strategy	Desired outcome	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Trial participants, their families, partners, neighbors, co-workers					
Local community members					
Health care programs and service providers					
Researchers, funding agencies and regulatory bodies					
HIV and AIDS policymakers and advocates					

Example — Completed Tool 1F: Matrix of stakeholders for overall plan

Date completed: 15 June 2011

Stakeholder (organization, group or individual)	Potential role in the trial	Engagement strategy	Desired outcome	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Trial participants, their families, partners, neighbors, co-workers					
	Ambassadors to community	Meetings, initial appointments (with participants and partners)	Represent accurate information about the trial to other community members	Regular meetings, appointments, brochures, other materials	Periodic engagement — from conceptualization until after results dissemination
Local community members					
		Meetings, presence at community events	Participate in trial planning, represent the study accurately to other stakeholders	Continue to participate in community events and hold regular CAB meetings (as well as larger meetings)	
Health care programs and service providers					
Researchers, funding agencies and regulatory bodies					
Researchers in other HIV prevention trials	Scientific partners	Conference calls, contact at scientific meetings and conferences	Support for current study, partnership in future trials	Monthly calls, regular emails and e-newsletters	Begin at trial launch, continue through dissemination and beyond
The X Foundation	Funder	Conference calls	Support during the study, support for future trials	Monthly check-in calls, regular emails	Early engagement and regular contact
HIV and AIDS policymakers and advocates					
Treatment Action Coalition (TAC)	Advocate for trial	Contact at meetings and conferences	Support for trials, advocacy for HIV prevention research	Semi-annual calls, regular emails and e-newsletters	

Tool 1G: Work plan

Use this template to create your team's work plan. What you include may be partially dictated by your research network or sponsor. However, you should make sure to include some background and basic details about the trial, along with information about your goals, objectives and activities. The previous tools you have completed (1A–1F) can be used to fill out your team's work plan. This work plan has been adapted with permission of the Microbicide Trials Network.

Tool 1G: Work plan

Stakeholder engagement work plan

Clinical research site: _____

[Relevant research network information]: _____

Staff member completing the work plan: _____

Community advisory board (CAB) chair/representative signature:

_____ Date signed: _____

Principal investigator (PI) or investigator of record (IoR) signature:

_____ Date signed: _____

Date submitted: _____

I. Stakeholder assessment

- a. Please provide the names and contact information (office and mobile numbers, and email addresses) for your site's stakeholder and/or community engagement staff.
- b. Describe any challenges that your site expects to experience with current or upcoming trials. Describe how your staff (and the CAB, if appropriate) plans to respond to these challenges.

- c. Have there been changes in the population of your community during the past year that might affect the site's education, awareness and sensitization efforts? If so, please describe.
- d. Describe any events happening in your community that might adversely affect participant accrual, retention, adherence or community ownership of current or upcoming studies.
- e. Are there new messages or information about upcoming trials that the site needs to consider in planning its education, awareness and sensitization efforts?

II. Stakeholder involvement

- a. New scientific information about HIV, HIV prevention strategies and microbicides (*or PrEP or other HIV prevention methods being studied*)
 - i. How will the stakeholders be kept up-to-date on new scientific information, HIV prevention strategies, and microbicides (or PrEP or other HIV prevention methods being studied)?
 - ii. Is there any stakeholder training planned for the upcoming year? If yes, please describe.
 - iii. Describe the structure of your CAB.
 - iv. In reaching out to the larger community, which groups does your team work with?
 - v. Are there groups that you have not previously been successful in reaching? How do you plan to reach out to these groups in the coming year?
- b. New stakeholder information about HIV, HIV prevention strategies and relevant research
 - i. How will the stakeholders keep the research team informed about new activities, programs, collaborations, etc.?
 - ii. Do research team members sit on key boards or otherwise participate in community groups so that they can learn from the stakeholders?

III. Goals/objectives/activities

a. Goal 1

i. Objective

- 1. Activity 1*
- 2. Activity 2
- 3. Activity 3
- 4. Activity 4

ii. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

b. Goal 2

i. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

ii. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

**For each activity, you may wish to provide the following details: responsible person(s), materials needed, indicators, measurable outcomes and estimated cost. This information can be obtained from your action plans (see Tool 1D) and your budget (see Tool 1C).*

Example: Completed Tool 1G: Work plan

(This is a fictitious example.)

Stakeholder Engagement Work Plan

Clinical Research Site: Lusaka, Zambia

Trial: Protocol 003

Staff member completing the work plan: Mary Demke

Community advisory board (CAB) chair/representative signature:

Pastor Nixon Mundia, CAB Chair

Principal investigator (PI) or investigator of record (IoR) signature: Dr. Francis Pilusa

Date submitted: 29 August 2010

I. Stakeholder assessment

- a. Please provide the names and contact information (office and mobile numbers, and email addresses) for your site's stakeholder and/or community engagement staff. Sena Chiti, community educator, (234) 123-456-789, sena@domain.org; Geradine Beta, recruitment nurse, (234) 987-654-321, geradine@domain.org
- b. Describe any challenges that your site expects to experience that are related to current or upcoming studies. Describe how your staff (and the CAB, if appropriate) plans to respond to these challenges. There were rumors in the last trial about the transmission of HIV to trial participants through blood draws. We did extensive education, but still expect some problems, so we will plan community education via community events, drama presentations and brochures.
- c. Have there been changes in the population in your community during the past year that might affect the site's education, awareness and sensitization efforts? If so, please describe. No
- d. Describe any events happening in your community that might adversely affect participant accrual, retention, and adherence, or community ownership of current or upcoming studies. We will have a new president soon and should keep this in mind when planning our engagement efforts.
- e. Are there new messages or information about upcoming trials that the site needs to consider in planning its education, awareness, and sensitization efforts? There are other gel trials going on at the same time, and we should consider this when developing messages in order to avoid confusion or conflation of the various trials.

II. Stakeholder involvement

- a. New scientific information about HIV, HIV prevention strategies, and microbicides (*or PrEP or other HIV prevention methods being studied*)
 - i. How will the stakeholders be kept up-to-date on new scientific information, HIV prevention strategies, and microbicides (*or PrEP or other HIV prevention methods being studied*)? Regular meetings and emails
 - ii. Is there any stakeholder training planned for the upcoming year? If yes, please describe. The CAB will have ethics training, as well as training on the transmission of HIV.
 - iii. Describe the structure of your CAB. We have 20 members, representing the diversity of trial participants.
 - iv. In reaching out to the larger community, what groups does your team work with? Churches, AIDS advocacy groups, district clinic staff, traditional healers, VCT clinics, schools
 - v. Are there groups that you have not reached successfully? How do you plan to reach out to these groups in the coming year? We had difficulty reaching larger (global) advocacy organizations, but we plan to attend conferences and participate regularly in open-forum email lists, conference calls, etc.

III. Goals/objectives/activities

- a. **Goal 1:** Increase awareness of HIV and AIDS, clinical research trials, PrEP and microbicides.
 - i. **Objective 1:** Assess the awareness of stakeholders about HIV and AIDS, clinical research trials, PrEP, and microbicides.
 - 1. Activity 1: Develop assessment tools.
 - 2. Activity 2: Conduct needs assessment among CAB members and other stakeholders.
 - 3. Activity 3: Analyze findings of the needs assessment.
 - 4. Activity 4: Share the findings with stakeholders.
 - ii. **Objective 2:** Fill the identified gaps from the needs assessment.
 - 1. Activity 1: Develop messages to be used with each stakeholder group.
 - 2. Activity 2: Print messages on brochures and fliers.
 - 3. Activity 3: Develop email newsletters with messages.
 - 4. Activity 4: Hold community meetings where messages are delivered and discussed.

- b. Goal 2:** Develop and strengthen relationships with stakeholders, especially global advocates.
- i. Objective 1:** Identify key stakeholders — especially global advocacy organizations — and deliver messages about HIV prevention research and our trial.
1. Activity 1: Identify stakeholder groups and obtain contact info.
 2. Activity 2: Arrange meetings or trainings for the identified groups.
 3. Activity 3: Provide ongoing trial updates to these groups.
- ii. Objective 2:** Partner with other trials to engage advocacy groups and other key global audiences.
1. Activity 1: Participate in regional and global HIV meetings.
 2. Activity 2: Participate in related conference calls.
 3. Activity 3: Participate in community events where global nongovernmental organizations may have a presence.
 4. Activity 4: Monitor global media and open-forum email lists.

Tool 1H: Timeline

This timeline should be filled out after your work plan is complete. You can fill out just the first year of the trial, or you can begin a multiyear timeline and fill it out as you go. You can use different colors to designate audience, person responsible or level of importance and urgency.

Tool 1H: Timeline

Date completed:

[Activity]					[Activity]			[Activity]			
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	[Activity]			[Activity]					[Activity]		

Example — Completed Tool 1H: Timeline

Date completed: 11 August 2011

Staff			Conduct needs assessment						Fill gaps identified in needs		
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Ethics training with stakeholders		First CAB meeting							Regional conference	

Tool 1I: Sample job descriptions

Position title:

Director of stakeholder engagement

Position summary:

The director of stakeholder engagement is responsible for directing and managing the stakeholder engagement function in clinical studies that are conducted by *(insert name of research institution or name of large trial)*.

Accountability:

The director of stakeholder engagement is jointly accountable to (a) the director of research programs *(or similar title)* and (b) the principal Investigator(s) in specific research studies. The position holder will be a member of the executive management team and trial management teams.

Key roles and responsibilities:

1. Assures that assessments of the nature, extent, and quality of relationships with the following groups of stakeholders are undertaken: (a) trial participants and their partners, (b) local communities, (c) research colleagues and other staff members of the research enterprise, (d) policymakers and advocates and (e) service providers or program implementers
2. Identifies and explains enabling factors and barriers that are affecting the stakeholder engagement process — and makes recommendations for strengthening the enabling factors and removing the barriers.
3. Oversees the development, implementation and evaluation of strategies for (a) developing new relationships and (b) enhancing relationships with stakeholder groups during each phase of research — conceptualization and protocol development, clinical trial implementation and dissemination of research findings.
4. Develops and oversees the budgets for the stakeholder engagement component of research trials.
5. Develops, maintains and contributes to a database of “promising practices” in stakeholder engagement.
6. Identifies and develops opportunities for the testing of promising practices — and the subsequent identification and description of “best practices in stakeholder engagement.”
7. Develops strategies for ensuring that best practices in stakeholder engagement are (a) identified and (b) become institutionalized.
8. Collaborates closely with the communications manager.

9. Provides training and guidance on all aspects of stakeholder engagement.
10. Remains abreast of the current literature on stakeholder engagement — and assesses its applicability in HIV prevention research.
11. Participates in an online “community of the practice of stakeholder engagement” and maintains contact with colleagues working in this area.
12. Maintains an inventory of resources that are relevant to HIV prevention research (including audio-visual resources).
13. Supervises the stakeholder engagement specialist(s) and administrative staff.
14. Routinely reports to the executive board (*for those employed by institutions*) or the trial management team (*for those employed on a research project*).

Skills and experience required:

- management
- leadership
- community assessment
- community organization
- organizational development
- facilitation
- partnership building
- communications (verbal, written and audiovisual)
- public health

Position Title:

Stakeholder engagement specialist

Position Summary:

The stakeholder engagement specialist is responsible for building, supporting and sustaining positive and productive relationships with the stakeholders in research trials conducted by (*insert name of research institution*).

Accountability:

The stakeholder engagement specialist is accountable to the director of stakeholder engagement.

Key roles and responsibilities:

1. Assesses the nature, extent and quality of relationships with at least two of the following stakeholder groups: (a) trial participants and their partners, (b) local communities, (c) research colleagues and other staff members of the research enterprise, (d) policymakers and (e) service providers or program implementers
2. Identifies and explains enabling factors and barriers that are affecting the stakeholder engagement process — and makes recommendations for strengthening the enabling factors and removing the barriers.
3. Develops, implements and evaluates strategies for (a) developing new relationships and (b) enhancing existing relationships for at least two of the above stakeholder groups during each phase of the prevention science research continuum (PSRC) — conceptualization stage, clinical trial stage and application stage.
4. Develops, maintains and contributes to a database of “promising practices” in stakeholder engagement.
5. Identifies and develops opportunities for the testing of promising practices — and the subsequent identification and description of “best practices in stakeholder engagement.”
6. Develops strategies for ensuring that best practices in stakeholder engagement are (a) identified and (b) become institutionalized.
7. Collaborates closely with the communications manager.
8. Provides training and guidance on all aspects of stakeholder engagement.
9. Remains abreast of the current literature on stakeholder engagement — and assesses its applicability for HIV prevention research.
10. Participates in an online community of practice for stakeholder engagement and maintains contact with colleagues who are also working in this area.
11. Maintains an inventory of resources that are relevant to stakeholder engagement in HIV prevention research (including audiovisual resources).
12. Routinely reports to the director of stakeholder engagement.

Skills and experience required:

- community assessment
- community organization
- organizational development
- facilitation
- partnership building
- leadership
- communications (verbal, written and audiovisual)
- management
- public health



Appendix

Tools: Step Two

Tool 2A: Action planning guide for securing commitment to stakeholder engagement

Tool 2B: Stakeholder engagement commitment sheet

Tool 2A. Action planning guide for securing commitment to stakeholder engagement

Use this tool to develop your action plan to acquire commitment from your team for stakeholder engagement. Use the outcomes of the baseline assessments in Step One to guide you.

Tool 2A. Action planning guide for securing commitment to stakeholder engagement

Name of organization: _____

Please answer the following questions based on the baseline assessment conducted in Step One and on your understanding of the research team members.

1. Which research team members need to be sensitized to stakeholder engagement principles? List the names of individuals, teams, departments or other groups.
2. What type of sensitization activity would be most appropriate for each individual listed? Choose from the activity tools referenced and other approaches suggested in item two of the Task list.
3. Do you require a written commitment from this individual?
4. Are there any other relevant details about sensitizing this group or individual?

Use the following chart to capture the details above. Insert as many rows as necessary.

Name, Team, Department or other	Type of activity — Training, Focus-Group Discussion, Interview or other	Written Commitment Required?	Additional Detail

Using the information captured above, consider the best way to implement sensitization activities. Consider the following factors:

- Are dynamics such that all members of the team could attend a training or sensitization session together?
- Do certain individuals require more information or convincing than others?
- Would it be an advantage or disadvantage to conduct a sensitization activity combining groups or individuals with varying degrees of knowledge, power and acceptance of principles?
- Would certain individuals or groups respond better to focus group discussions or individual interviews?
- From which members of the team do you require written commitment? Could these individuals be consulted as a group?
- Do you require any further external resources to support the need for stakeholder engagement? This might include testimonials from research teams with strong stakeholder engagement programs.
- Do members of your team know the principles well enough to conduct sensitization activities, or should external facilitators be obtained?

Example — Completed Tool 2A: Action planning guide for securing commitment to stakeholder engagement

Name of Organization: Best Practices Research Center

Please answer the following questions based on the baseline assessment conducted in Step One and on your understanding of the research team members.

1. Which research team members need to be sensitized to stakeholder engagement principles? List the names of individuals, teams, departments or other groups.
Sarah Dogood, principal investigator
Peter Headstrong, director of finance and administrator
Community outreach team, 3 people
Lab team, 6 people
Recruiters, 4 people
2. What type of sensitization activity would be most appropriate for each individual listed? Choose from the activity tools referenced and other approaches suggested in item two of the Task list.
Group training, one-on-one discussions
3. Do you require a written commitment from this individual? *Only from principal investigator and director of finance and administration*
4. Are there any other relevant details about sensitizing this group or individual? *Many members of the lab team and the recruiters do not think that stakeholder engagement is part of their responsibility list.*

Use the following chart to capture the details above. Insert as many rows as necessary.

Name, Team, Department or other	Type of activity – Training, Focus-Group Discussion, Interview or other	Written Commitment Required?	Additional Detail
Lab team	Half-day training workshop for orientation to stakeholder engagement principles. Exercises to be taken from <i>GPP Training Manual</i> , available at www.avac.org	No	May combine this with training for community outreach team and recruiters
Principal investigator	One-on-one discussion about principles and purpose of gaining commitment to stakeholder engagement principles	Yes	Will also invite her to participate in trainings for other staff
Director of finance and administration	One-on-one discussion about principles, purpose of gaining commitment to stakeholder engagement principles, need for designated budget	Yes	Will discuss possibility of including finance and administrative staff in the training workshops

Using the information captured above, consider the best way to implement sensitization activities. Consider the following factors:

- Are dynamics such that all members of the team could attend a training/sensitization session together?
Some may be combined; this will depend on initial discussions with principal investigator and director of finance/administration.
- Do certain individuals require more information or convincing than others?
Principal investigator will need to understand why her commitment is critical to stakeholder engagement at the research center and commitment of the other staff.

- Would it be an advantage or disadvantage to conduct a sensitization activity combining groups or individuals with varying degrees of knowledge, power and acceptance of principles? *Will be an advantage to combine groups and get as many staff involved in training activities as possible; need to discuss with principal investigator for perspectives and approval.*
- Would certain individuals or groups respond better to focus group discussions or individual interviews? *Will conduct individual discussions with PI and director of finance/administration.*
- From which members of the team do you require written commitment? Could these individuals be consulted as a group? *Principal investigator and director of finance and administration; will try to consult with them together depending on availability.*
- Do you require any further external resources to support the need for stakeholder engagement? This might include testimonials from research teams with strong stakeholder engagement programs. *Will share a peer-reviewed publication about the importance of stakeholder engagement with the principal investigator, and with other staff during trainings.*
- Do members of your team know the principles well enough to conduct sensitization activities, or should external facilitators be obtained? *Will consult with contacts at FHI 360 and AVAC to develop training workshops and to get remote technical support for conducting exercises.*

Tool 2B. Stakeholder engagement commitment sheet

This tool should be given to individuals who need to provide a written commitment to the principles of stakeholder engagement, according to your action plan for securing commitment to stakeholder engagement.

Tool 2B: Stakeholder engagement commitment sheet

Name of organization: _____

Date: _____

Instructions

If you are completing this tool, you have participated in a session (training, meeting, interview, etc.) on the principles of stakeholder engagement.

Please read the statement below, review a draft of the stakeholder engagement work plan (or its equivalent) for your research team, and sign below to affirm your commitment to the principles and concepts discussed during the session.

Statement:

I, _____, hereby declare my commitment to follow stakeholder engagement principles at the above named organization. I have reviewed or attended a session to reinforce my understanding of these principles. I have reviewed any existing or proposed work plan for stakeholder engagement activities, and I have provided feedback.

List any specific stakeholder engagement activities you will ensure are conducted:

List any outstanding concerns or ideas about stakeholder engagement:

Signatory _____

Example — Completed Tool 2B: Stakeholder engagement commitment sheet

Name of organization: Best Practices Research Center

Date: 1 August 2011

Instructions

If you are completing this tool, you have participated in a session (training, meeting, interview, etc.) on the principles of stakeholder engagement.

Please read the statement below, review a draft of the stakeholder engagement work plan (or its equivalent) for your research team, and sign below to affirm your commitment to the principles and concepts discussed during the session.

Statement:

I, *Sarah Dogood*, hereby declare my commitment to follow stakeholder engagement principles at the above named organization. I have reviewed or attended a session to reinforce my understanding of these principles. I have reviewed any existing or proposed work plan for stakeholder engagement activities, and I have provided feedback.

List any specific stakeholder engagement activities you will ensure are conducted:

- *Regular meetings of the community advisory group*
- *Individual discussion with primary decision makers in the surrounding community to brief them about the upcoming trial*
- *High-level briefings with parliamentarians and other key contacts at national level*

List any outstanding concerns or ideas about stakeholder engagement:

- *Need to ensure there is a comprehensive stakeholder engagement plan for the research center.*
- *Consider developing a mechanism for monitoring effectiveness of community advisory group members and assessing membership on a regular basis, such as yearly.*

Signatory *Sarah Dogood*



Appendix

Tools: Step Three

Tool 3A: Indicator examples

Tool 3A: Indicator examples

This tool may be used by the M&E working group to help develop indicators for the stakeholder engagement program.

Tool 3A: Indicator examples

This tool may be referenced or used as a guide when developing your indicators. It contains examples of indicators for community and stakeholder engagement at different levels in the clinical trials process. Please note that you are not restricted to the examples given when developing your team's indicators.

Level	Process Indicators	Impact Indicators
Local/ community	<ul style="list-style-type: none">• Number of CAB meetings conducted• Percentage of CAB members attending meetings• Number of community outreach events• Number of potential trial volunteers referred from partner health institutions or other partnering organizations	<ul style="list-style-type: none">• Number and description of misconceptions in the surrounding community about research• Speed of trial recruitment• Number of local stakeholders declaring support for trial conduct• Description of feedback provided by stakeholders on a trial protocol• Successful referral of research participants and linkage to care and services
National	<ul style="list-style-type: none">• Number of national consultations conducted• Number of country-specific policies or related documents written or revised concerning research or rollout of intervention• Description of supportive media reporting	<ul style="list-style-type: none">• Level of funding committed by national governments• Qualitative description of statements made concerning research by national stakeholders• Commitment of policymakers and other thought leaders to future rollout of interventions
Global	<ul style="list-style-type: none">• Number of peer-reviewed publications on the value of stakeholder engagement• Number of presentations, international conferences and other forums on stakeholder engagement work	<ul style="list-style-type: none">• Level of funding by major international donors• Description of stakeholder input into the design of global, multisite, large-scale trials



Appendix Tools: Step Five

(No tools are included for Step Four)

Tool 5A: Stakeholder identification sheet

Tool 5B: Stakeholder data collection sheet

Tool 5C: Identification of stakeholder roles

Tool 5D: Stakeholder contact record

Tool 5A: Stakeholder identification sheet

Use this tool at your brainstorming session. Review and adjust each of the headings and subheadings in *Column A* to suit the country or regional context in which the trial will take place. If necessary, rephrase the headings in *Column A* so that they are compatible with the national and regional contexts. Categorize each of the listed stakeholders according to one of the main headings in *Column A* and one of the subgroups in *Column B*. For institutions, list a point person if possible. You do not need to fill in all of the subgroup cells in *Column B*; rather, use them as a guide to help you think about the possible stakeholders. Add new subgroups where appropriate for your context.

Tool 5A: Stakeholder identification sheet

(A) Stakeholder Groups	(B) Stakeholder Subgroups	(C) Stakeholder's Name (Institutions/ Individuals)	(D) Institution Point Person
1. Trial participants, their families, partners, neighbors and co-workers	<i>Trial participants target population</i>		
	<i>Immediate families of trial participants.</i>		
	<i>Partners of trial participants</i>		
2. Local community members	<i>Formal community leaders</i>		
	<i>Informal community leaders</i>		
	<i>Community advisory boards</i>		
	<i>Local community health partnerships</i>		
	<i>Businesses</i>		
	<i>Religious institutions (churches, mosques, synagogues, etc.)</i>		
	<i>Schools</i>		
	<i>Other educational institutions</i>		
	<i>Youth representatives</i>		
	<i>Local political leaders</i>		

(A) Stakeholder Groups	(B) Stakeholder Subgroups	(C) Stakeholder's Name (Institutions/ Individuals)	(D) Institution Point Person
2. Local community members (continued)	<i>Community theater</i>		
	<i>Other local media (e.g., local singers and poets)</i>		
	<i>People living with HIV or AIDS</i>		
	<i>Racial and ethnic representatives</i>		
	<i>Gender representatives (e.g., women, GLBT)</i>		
3. Researchers, funding agencies and regulatory bodies	<i>Leadership of national research institutions</i>		
	<i>Leadership of international research institutions</i>		
	<i>Principal funders</i>		
	<i>Other sources of funds/ resources</i>		
	<i>Principal investigators</i>		
	<i>Co-investigators</i>		
	<i>Other scientific staff</i>		
	<i>Trial managers</i>		
	<i>Behavioral and social scientists</i>		
	<i>Ethicists</i>		
	<i>Stakeholder engagement specialists</i>		
	<i>Site identification and development</i>		
	<i>Trainers</i>		
	<i>Instructional design specialists</i>		
	<i>In-house communications specialists</i>		
	<i>In-country investigators</i>		
	<i>Internal publications staff</i>		
	<i>Scientific spokespersons (often big names in the field)</i>		
	<i>Other international research organizations</i>		
	<i>The broad scientific community</i>		

(A) Stakeholder Groups	(B) Stakeholder Subgroups	(C) Stakeholder's Name (Institutions/ Individuals)	(D) Institution Point Person
4. HIV and AIDS policymakers and advocates	<i>National advocacy groups</i>		
	<i>Party leadership</i>		
	<i>International advocacy groups</i>		
	<i>Civil society organizations</i>		
	<i>Regulatory agencies (national)</i>		
	<i>Regulatory agencies (bilateral, multinational)</i>		
5. Health care programs and service providers	Senior technical staff (regional/national)		
	Health facility staff		
	Community health workers		
	Traditional birth attendants		
	Community-based distributors		
	Physicians		
	Health educators		
	Nurses and clinical officers		
	Other clinic staff		
	Outreach workers		
	Program directors		

Completed by: _____

Date: _____

Updated by: _____

Date: _____

Tool 5B: Stakeholder data collection sheet

Use this sheet to collect information about the stakeholders that you wish to approach.
Modify the sheet to suit your purposes.

Name:

Position(s)/Role(s):

Organization(s):

Community/neighborhood:

Contact information:

Stakeholder category:

Other relevant information about this stakeholder:

Interests of this stakeholder in (a) HIV and AIDS prevention research and (b) the specific research project that is being discussed:

- 1.
- 2.
- 3.

Interests of researchers in relation to this stakeholder:

- 1.
- 2.
- 3.

History of working relationships with this stakeholder:

- 1.
- 2.
- 3.

Ideas and strategies for clarifying and strengthening our working relationships with this stakeholder:

- 1.
- 2.
- 3.

Ways in which this stakeholder can potentially be a “champion” of HIV and AIDS prevention research:

- 1.
- 2.
- 3.

Additional information about this stakeholder:

Entered by: _____

Date: _____

Updated by: _____

Date: _____

Example — Completed Tool 5B: Stakeholder data collection sheet

Name: *Mr. Big Tibbs*

Position(s)/Role(s): *Bar owner*

Organization(s): *Tibbs' Big Bar*

Community/Neighborhood: *Marwani district*

Contact information: *btibbs@mybar.com*

Stakeholder category: *local community member*

Other relevant information about this stakeholder: *none*

Interests of this stakeholder in (a) HIV/AIDS prevention research in general and (b) the specific research project that is being discussed:

1. *Serves community that is at high risk for HIV*
2. *Project is about preventing HIV in commercial sex workers, and many CSWs find clients at Mr. Tibbs' bar.*
3. *Interests of researchers in relation to this stakeholder:*
4. *Good place to recruit participants*
5. *Important to build a relationship with the bar owner so that he will be an ally in the project*

History of working relationships with this stakeholder:

1. *No history of working with him, but we have worked with other business owners in the area*
2. *Ideas and strategies for clarifying and strengthening our working relationships with this stakeholder:*
3. *Make sure to get permission from Mr. Tibbs before recruiting participants on his property*
4. *Invite him to participate in a stakeholders meeting; ask him for his ideas about how to prevent HIV among these clients*
5. *Be careful not to stigmatize the business or alienate him by disrespecting his business*

Ways in which this stakeholder can potentially be a “champion” of HIV/AIDS prevention research:

1. *By speaking favorably about the project to his customers*
2. *By reassuring clients that he is not watching them*

Additional information about this stakeholder: *none*

Entered by: *Ms. Research Assistant*

Date: *06/29/2011*

Updated by:

Date:

Tool 5C: Identification of stakeholder roles

Use this sheet to identify and prioritize which potential stakeholders can fill needed roles for your trial. Could they be part of the CAB? Will you invite them to review your materials? Are they information gatekeepers who should receive newsletters and announcements about community events? Once again, modify this sheet to personalize it for your trial. It is important to complete this step before you convene a meeting with your stakeholders.

Tool 5C: Identification of stakeholder roles

(A) Activity area	(B) Description of roles needed	(C) Suggested stakeholders to fill roles	(D) Preliminary actions required	(E) By whom?	(F) By when?	(G) Status
Consultation						
Deliberation						
Advocating						
Facilitation						
Community outreach						
Community organizing						

(A) Activity area	(B) Description of roles needed	(C) Suggested stakeholders to fill roles	(D) Preliminary actions required	(E) By whom?	(F) By when?	(G) Status
Championing the trial						
Disseminating information						
Providing resources						
Oversight and monitoring						
Evaluating						
Training						
Observing and reflecting						
Translating and interpreting						

Completed by: _____ Date: _____

Updated by: _____ Date: _____

Updated by: _____ Date: _____

Updated by: _____ Date: _____

Tool 5D: Stakeholder contact record

Use this sheet to plan and track initial contact with new stakeholders. You can use this form as a task assignment sheet for research team members, filling out the contact information for each person or organization that you would like that team member to contact. Once again, modify this sheet to personalize it for your trial.

Tool 5D: Stakeholder contact record

Purpose of contact:				
Person making contact:				
Name of organization & contact person	Email	Phone number	Comments	Contacted (date/ notes/follow-up needed?)

Example — Completed Tool 5D: Stakeholder contact record

Purpose of contact: <i>To introduce our research organization to these stakeholders and let them know about our proposed work on HIV prevention trials.</i>				
Person making contact: <i>Sam Staffman</i>				
Name of organization & contact person	Email	Phone number	Comments	Contacted (date/ notes/follow-up needed?)
County Health Dept., Ms. Carla Smith, VCT Coordinator	csmith@state.gov	O: 999-999-9999 C: 999-888-8888	Could be helpful source for recruitment strategy. Our screening data could be of interest to her office.	09/06/2011: emailed to introduce study; call scheduled for the 10th at 9:30am
AIDS Volunteers, Mr. Ben Brown, Health Educ.	Bbrown@group.org	O: 999-111-1111 C: 999-111-2222	Long-time treatment advocate	09/06/2011: called him at 2:15pm; scheduled to meet on the 7th. 09/07/2011: Met at his office. He is concerned about ensuring good referral for care for positive screens. Wants more info on referral plan.



Appendix

Tools: Step Six

Tool 6A: Stakeholder contact sheet

Tool 6B: Establishing advisory group guidelines

Tool 6C: Organizing an event

Tool 6D: Field report

Tool 6E: Deciding on a strategy

Tool 6F: Agenda planning

Tool 6G: Brainstorming

Tool 6H: Engaging communities with theatre

Tool 6A: Stakeholder contact sheet

Use this sheet to keep record of your various stakeholders, how and how often you are updating them, key agreements and expectations and any stakeholder requests. Keep the sheet up-to-date, and check it regularly to track your progress. It is best if this sheet is kept electronically so that you can easily insert additional rows as you need them. Also, remember to periodically check in with your stakeholders about your initial agreements and expectations. Do they need to be revisited (due to membership or staff changes or other circumstances)?

Tool 6A: Stakeholder contact sheet

Stakeholder organization, group or individual	Agreements & expectations				Stakeholder updates/engagement activities				Stakeholder requests		
	Frequency of updates	Who will do the updates	Special interests/requests	Location and language of updates	Date	What	Where	Who	Request	Date request made	Date request filled

Example — Completed Tool 6A: Stakeholder contact sheet

Stakeholder organization, group or individual	Agreements & expectations				Stakeholder updates/engagement activities				Stakeholder requests		
	Frequency of updates	Who will do the updates	Special interests/ requests	Location and language of updates	Date	What	Where	Who	Request	Date request made	Date request filled
Municipality	Every six months	PI	Concerns about reduction in condom use	Municipality headquarters (English)	15/10/10	Update meeting	Municipal HQ	PI & CLO			
					11/04/11	Update meeting	Municipal HQ	PI			
Traditional leadership	Every six months	PI and community liaison officer (CLO)	General update	Tribal leadership (Zulu)	05/11/10	Update meeting	Tribal lands	PI & CLO			
					24/01/11	Roadshow	Tribal lands	Community team, PI			
					10/03/11	Update meeting	Tribal lands	PI & CLO			
Hlabisa provincial hospital	Monthly	Medical officer (MO) and CLO	HIV and STI prevalence rates	Hospital (Zulu)	03/01/11	Update meeting	Hospital	MO & CLO	IEC materials for clinics	03/01/11	07/01/11
					07/02/11	Update meeting	Hospital	MO & CLO			
					17/02/11	Training for hospital staff	Research center	Community team, one member of each clinic team			
					07/03/11	Update meeting	Hospital	MO & CLO			
					04/04/11	Update meeting	Hospital	MO & CLO			

Tool 6B: Establishing advisory group guidelines

When establishing advisory groups — be it a formal CAB, a more loosely defined stakeholder advisory group or a participant's group, you will need to consider the purpose and scope of the group(s) and how the group will function. What are you asking the group to do? Why does this group need to be formed? How will they communicate and work with one another? This tool provides a series of questions to consider when thinking about the purpose, scope and structure of your advisory groups. Once you have answered some of the basic questions about what the advisory group will do, who will serve and how members will be selected, work with the group to develop working guidelines. For an example of complete guidelines, see the HIV Prevention Trials Network's *Community Advisory Boards (CABs) Guidelines*, listed in *Additional Resources*.

Tool 6B: Establishing advisory groups

Purpose and scope

- What are the aims of the group(s)?
- Who is the advisory group representing? Are they involved in choosing their representatives? What contact will advisory group members have with those they represent?
- Will they assist with the development, planning or implementation of stakeholder engagement and community education?
- Will they advise on study procedures?
- Will they advise on reimbursement policies for study participants?
- Will they review and give input on study protocols or on informed consent materials?
- What groups or views need to be represented? Consider government leadership, traditional leadership, study participants, local service providers, advocates, local NGOs, CBOs, FBOs, traditional healers, media representatives and others.
- What power imbalances, if any, exist? Would it be beneficial to separate or combine groups where power imbalances exist?
- Do any groups have opposing viewpoints that need to be considered with regard to establishing separate or combined groups?

Structure and function

How will members be chosen?

- Will you solicit names and invite people within the community to participate as community advisors for the site? If so, who will choose the members?
- Will you identify CAB members through stakeholder meetings and other activities? If so, who will choose the members?

- Will you hold an election for membership? If so, who gets to vote?
- How long will members serve, and what is expected from members?

How will the group(s) function?

- Will they develop their own constitution or terms of reference?
- Will there be group leadership such as a chairperson, secretary or other leaders?
If so, how will those positions be appointed or elected? What will the terms be?
- How will the group reach agreement: What decision-making processes will the group use?

How will the group communicate?

- How often will meetings be held? Where will they be held? How long will they last?
- Will the group use other means of communication — short-message service, email, newsletter, etc.?

What will be expected of the group and its members?

- What is the minimum requirement for a member to be considered active?
- What happens if a member is inactive? Will they be given a warning or dismissed from the advisory group? Will their organization be asked to name a replacement?

What can the group expect from the research institution?

- Will members be reimbursed for transport (to and from meetings and trainings)? Will they be reimbursed for their time?
- Which member of the research staff will regularly interact with the group?
- What are the benefits of participation?
- How often will the group receive updates on the study from the research staff?

What capacity exists among the members, and what are the group's capacity-building needs?

- What trainings does the group require to fulfill its purpose and function? Who will facilitate those trainings?
- What other trainings does the group require or show an interest in?

Tool 6C: Organizing an event

Whether you are organizing a community roadshow, a stakeholder meeting or training, an informational workshop or a participant event, you will need to keep a few things in mind. Use this checklist to help you plan and prepare for each aspect of your event. Adapt the checklist to better fit your setting and circumstances.

Tool 6C: Organizing an event — A checklist

The basics

- ☐ Determine the aims and objectives for the event, and decide what type of event you will hold.
- ☐ Discuss the event with and obtain any necessary permission from leadership, such as the site's principal investigator, traditional leadership, government officials and so on.
- ☐ Identify the target(s) of the event. Whom will you invite? Will the event be tailored to study participants and their partners, the advisory group, policymakers, a diverse range of stakeholders, the community at-large or a mixed group?
- ☐ Decide on a date and time for the event (this will likely need to be done in consultation with the study team and possibly other stakeholders).
- ☐ Determine the location of the event. Consider the need for special equipment, the cost, whether the location is easily accessible and so on. Will transportation have to be provided?
- ☐ Determine limitations: budget, staff time, resources.

Roles, responsibilities and agenda planning

- ☐ Assign one person to be ultimately responsible for planning and organizing the event. This includes following up with other staff members and volunteers about specific duties and responsibilities they have been assigned (this person could be you or someone else on your team).
- ☐ Ask for volunteers. Include others in the development and organization of the event. Including staff, study participants, advisory group members and other partners will help to build their capacity, ensure the event is appropriate for your audience(s) and generate enthusiasm for the event.
- ☐ Hold a brainstorming session or sessions with various stakeholder groups (staff, study participants, advisory groups) to discuss the event's objectives. What are you trying to accomplish? Consider different ways of achieving your aim: What should the event include? Don't come to the group with a set agenda; instead, ask them for their suggestions and discuss the possibilities with them.

- ☐ Task volunteers or groups of volunteers with specific assignments and responsibilities — solicit donations from local shops and restaurants to be used as prizes, develop a skit, a song, a talk or a presentation on a particular topic.
- ☐ Discuss the next steps, and set due dates for when tasks should be completed. Remember to budget time for reviews (of skits, presentations and materials) and be realistic about your timeline!
- ☐ Ensure volunteers are clear about their responsibilities and all due dates and next steps.
- ☐ Develop an agenda for the event (see Tool 6F: Agenda Planning), and decide who will lead, facilitate and participate in various discussions, activities and presentations.
- ☐ Continue to check in with your volunteers and others who are leading or participating in the event to make sure they are prepared. Ask them about any equipment or materials needed for their portion of the event.

Budget

- ☐ Establish a budget for the event.
- ☐ Be creative: Are there local businesses you can ask for donations (for food, refreshments, or prizes)? Are there venues you can use for free or a reduced cost (from partners or other stakeholders, local churches, outdoor spaces or other facilities)?

Invitations and advertising

- ☐ Create a list of whom to invite to the event. Will it be a list of individuals or organizations (for a training or workshop), or will it be groups of people you need to target (for a community event, roadshow or similar event)?
- ☐ Are there groups or individuals that are important to invite for political reasons — government officials, community or traditional leaders, church leaders, representative from other nearby research sites?
- ☐ Decide how to advertise or invite individuals to the event:
 - personalized invitation letters
 - flyers or posters (to be used in the community, in study clinics or other health centers)
 - radio announcements
 - email invitations
 - personal phone calls
 - T-shirts for staff members and volunteers that advertise the event
 - announcements at other events
- ☐ Consider whether “too much” advertising could create problems. Can you accommodate everyone who might want to come? If not, how will you deal with this?
- ☐ Once the date, time and location have been confirmed, send invitations or create advertising materials. If necessary, you can send a “save-the-date” message to individuals before the time and location have been set to alert them that an event is being planned.

- ❑ Ask people to respond to your invitations so you can get an accurate estimate of how many people to expect; however, don't expect the count to be accurate. Consider cultural norms for each stakeholder group when managing responses and planning attendance.
- ❑ Follow up (by email, telephone or in person, as appropriate) with invitees who have not responded to your invitation.

Logistics

- ❑ Make a list of any equipment and materials needed — data projector and screen; sound system; information, education and communication (IEC) materials or other print-outs; prizes; materials needed for activities or games and so on.
- ❑ Decide if you will serve food or refreshments, and determine how much you will need. Will you need plates, napkins, serving utensils, cups, or will they be provided? Be culturally sensitive regarding food choices, vendors and other choices.
- ❑ Determine any transportation needs. Will participants need to be reimbursed for transportation? If you will reimburse the participants, decide in advance how you will handle reimbursements so it does not detract from your event. Let people know if and how this will be done.
- ❑ Task someone on staff to be at the event to answer questions, help resolve any problems that arise and handle participant concerns.
- ❑ Confirm, confirm, confirm: Confirm all details with the location, any vendors (food, refreshments, equipment, transport), and staff members and volunteer that will be helping with the event.

Follow up (after the event)

- ❑ Be sure that you or someone on the staff is tasked with sending thank-you notes to invited participants and to follow up with any materials or answers that were promised during the event.
- ❑ Evaluate the success of your event. Decide beforehand how you will solicit feedback from participants — focus group discussions after the event, written or interactive evaluations during the event, comment boxes or other means.

Tool 6D: Field report

To track your progress and document any agreements, issues, or concerns among your stakeholders, it is important to maintain clearly written records of your engagement process. This will also help you begin to document the tools and strategies you have put into practice and the success of those strategies (see also *Tool 7: Template for Documenting Your Own Tools*). Use this field report template to keep a record of all your engagement activities.

Tool 6D: Field report

Adapted from: Shagi C. A template for field reports. Microbicides Development Programme, Africa Centre.

Title:

Date:

Documented by:

Description of activity:

Objective(s):

Accomplishments/agreements:

Staff present:

Key lessons learned/issues/concerns:

Next steps/recommendations:

List of participants:

Example — Completed Tool 6D: Field report

Title: April 2011 update meeting: Baragwanath hospital

Date: 11/04/2011

Documented by: Katie West-Slevin

Description of Activity: Regularly scheduled update meeting with Baragwanath Hospital leadership and staff. The meeting lasted for approximately one hour and was attended by six hospital personnel. The CLO presented the hospital staff with the monthly update, including current prevalence rates of HIV and STIs, before discussing any concerns or issues the hospital staff might have.

Location: Baragwanath Hospital

Staff Present: Pauline Mphoto, CLO and Katie West-Slevin, community educator

Objective(s): To provide hospital staff with the latest monthly update, including HIV and STI rates, per original stakeholder agreement.

Accomplishments/Agreements: Update was successfully given. The hospital director and CLO agreed that the study will provide a joint training for hospital and study counselors and nurses on the study aims, the importance of research and referral procedures between the hospital and the study (date, time, and location to be confirmed).

Key Lessons Learned/Issues/Concerns:

It was difficult for everyone to see the prevalence figure and charts. Next time, bring handouts of relevant figures and charts for all participants.

The study is adding to the burden of patient flow at the hospital. Staff at both institutions need to be well trained in the referral procedures that have been set-up.

Not all hospital staff are well informed about the study, and there is some concern among the staff.

Next Steps/Recommendations:

The study will provide a joint training for hospital and study counselors and nurses on the study aims, the importance of research and referral procedures between the hospital and the study (date, time and location to be confirmed).

List of Participants:

Gugu Ngakane	Mavis Mohapi
Pinky Motsepe	Promise Nkasa
Tebogo Kekana	Gavin Adrian

Tool 6E: Deciding on a strategy

You can plan your stakeholder engagement activities in several ways. Whether planning with your team or engaging stakeholders in action planning, it can be helpful to consider a variety of methods, their potential strengths and their limitations before deciding which will best serve your purposes.

Tool 6E: Deciding on a strategy/activity

Goal/ Purpose	Strategy	Strengths	Limitations

Example — Completed Tool 6E: Deciding on a strategy/activity

Goal/ Purpose	Strategy	Strengths	Limitations
Addressing myths and misperceptions about research	Role Play	<ul style="list-style-type: none"> • Good for practicing real-life situations • Good for stimulating active audience participation 	<ul style="list-style-type: none"> • Usually used in small groups (more restricted audience)
	Radio	<ul style="list-style-type: none"> • Reaches a wide audience • Appropriate for both literate and low-literate • Messages can be repeated many times 	<ul style="list-style-type: none"> • Can be expensive • Requires preparation (scripts, etc.)
	Community Drama/Theater	<ul style="list-style-type: none"> • Can be performed anywhere and used multiple times • Interactive (can encourage audience participation) • No reliance on technology (low cost) • Ability to improvise allows performers to react to audience responses 	<ul style="list-style-type: none"> • Difficult to ensure that the target audience will be present when the play is performed

Tool 6F: Agenda planning

Facilitation experts recommend that you should spend twice the length of any meeting on planning and preparing for that meeting. That means, for a two-hour meeting, you will typically need to spend four hours preparing to make the meeting as effective as possible. Tool 6F provides a template for planning your meetings and workshop agendas. First, define the purpose of the meeting (why you're having it) and your desired outcomes (what you hope to get out of it). In the far right column, list the topics you wish to cover. Then, from left to right, note the activities and methods you will use to cover the topic (how), who will facilitate that part of the meeting (be sure to also list other roles such as note-taker/recorder), how long it will take (be realistic) and finally, the desired outcome that the agenda item corresponds to. Each activity/topic for the meeting should directly relate to a desired outcome. If it doesn't relate to a desired outcome, it should not be included on the agenda. When preparing an agenda for the meeting's participants, you can delete the "How" and "Desired Outcome" columns from the template, but leave the columns on the facilitator's agenda.

Tool 6F: Agenda planning

Purpose: [State the purpose of the meeting]

Desired Outcome: By the end of this [meeting/workshop/training] we will have:

- [Desired outcome]
- [Desired outcome]

Agenda				
What	How	Who	Time	Corresponding desired outcome
Set-up: <ul style="list-style-type: none"> • Roles • Desired outcomes • Agenda • Ground rules • Agreement on how decisions will be made 				Not applicable
[Activity/topic]				
[Activity/topic]				
Next steps/evaluation				

Example — Completed Tool 6F: Agenda planning

Purpose: To get to know each other, agree on the purpose of and the structure of the group, and establish a sense of ownership among group members.

Desired outcome: By the end of this [meeting/workshop/training] we will have:

- A shared understanding of different stakeholder engagement strategies employed by the HIV prevention field
- A shared understanding of values, vision and mission and why they are needed
- Key elements of a vision of success for the group

Agenda				
What	How	Who	Time	Corresponding desired outcome
Set-up: Welcome Introductions Ground rules Desired outcomes Agenda	Charts / Ice breaker Clarity	Katie	9:00–9:30 (30 min)	Not applicable
How community departments are structured	Each organization was asked to do an exercise before coming to the meeting to share with the group. Groups will then write this out on poster paper and hang on the walls around the room. Participants will do a gallery walk to read all the “reports,” and then we will discuss. Write/visually represent: <ul style="list-style-type: none"> • Two sentences describing how your community department is structured (what mechanisms do you use: CAB, etc.). • Two things that make your site unique in terms of your community approach. • One challenge that you currently face. • Create a visual representation of your site/community department/community work 	Sarah	9:30–10:30 Write/draw (15 min) Gallery walk (20 min) Discussion (25 min)	A shared understanding of different stakeholder engagement strategies employed by the HIV prevention field
Values, mission, and vision planning	Presentation: What are values, mission and vision, why are they important, how are they different? Q's for Clarification	Emily	10:30–11:00 (30 min)	A shared understanding of values, vision and mission and why they are needed

Agenda				
What	How	Who	Time	Corresponding desired outcome
Vision	Small groups What would success look like? (5 years from now the Mail & Guardian has written their feature article about our group and our success. What does the headline read? What image is used?) Report back Facilitate agreement Clarity	Stacey to introduce Michael to facilitate agreement	11:00–12:00 Small groups (20 min) Report back (20 min, ~3 min per group) Facilitate agreement (20 min)	Key elements of a vision of success for the group
Lunch			12:00–1:00 (One hour)	
Logistics: How the group will function and work	Introduction (So we've talked about what our purpose is. How should we then organize ourselves to achieve our purpose? How will we communicate with each other: calls, email forum, meetings? How often should we meet? Do we need to have particular roles to accomplish our mission (who, what)? Small groups Report back Facilitating agreement Clarity	Jill	1:00–2:15 Introduction (5 min) Small groups (20 min) Report back (20 min) Facilitate agreement (30 min)	A draft plan for how the group will operate
Closing	Plus/delta (On a flip chart write two columns: one with a plus (+) and one with a delta (Δ) to signify change. Ask participants, "What did you like; what can we improve?" List responses on the sheet. Use this sheet to improve the next meeting or, if a multiday meeting, to review the agenda and improve for day 2.)	Katie	2:15–2:30 (15 min)	

Tool 6G: Brainstorming

Adapted from: Centre for Development Innovation (CID). Participatory planning monitoring & evaluation: Managing and learning for impact in rural development. The Netherlands:CID;2012.

Objective: Quickly gain ideas from a group.

Materials Needed: Flip charts, markers

Approximate Time: 10 to 20 minutes

How to Use It:

1. Ask participants to think of as many ideas as they can about the topic in question.
2. Ask participants to share their ideas (this can be done by participants raising their hands or by having the facilitator call on each participant).
3. Write participants' ideas down on a flip chart so everyone can see them.

Facilitator Tips: When making long lists on flip charts, use two different colored markers, alternating colors in the list (e.g., blue, red, blue, red, and so on). This makes it easier to distinguish ideas from one another and makes the list easier to read.

Tool 6H: Engaging communities with theatre

Adapted from: International HIV/AIDS Alliance. Tools together now! 100 participatory tools to mobilize communities for HIV/AIDS and the Global Campaign for Microbicides. Prevention Research Literacy training curriculum. Brighton, UK: International HIV/AIDS Alliance;2006.

Objective: Using community drama or theatre is a creative way to explore sensitive issues and to get your messages across in a nonthreatening and engaging way. Dramas can be developed and performed by trial staff members to engage and educate communities about your trial, prevention research, HIV and AIDS or other health topics. Dramas can also be used as capacity-building tools during stakeholder workshops and trainings.

Materials Needed: Written scenarios, stopwatch (to keep time)

Approximate Time: 2 to 2.5 hours (depending on group size)

For dramas developed and performed by staff members, the preparation and practice time may be longer and the performance time may be shorter (approximately 10 to 30 minutes).

How to Use It:

1. Divide actors (or participants) into three or four groups, depending on the number of participants.
2. Describe three or four different scenarios or characters (see example below for “Exploring Common Research Myths and Rumors”). Give each group a description of one of the scenarios, and ask them to develop a short drama (five to 10 minutes). For the “Exploring Common Research Myths and Rumors” example, ask participants to act out the myth or rumor and then ask them how they might respond to it. Each group will have 45 minutes to one hour to develop their drama.
3. Ask each group to perform their drama (five to 10 minutes). Use a stopwatch to keep track of time.
4. Once all groups have performed their dramas, encourage the participants to discuss what the dramas revealed. What were the challenges? Are there any key messages that the dramas did not touch on?

Facilitator Tips: There are many ways to use community drama as a tool — be creative!

Community Drama Example: Exploring Common Research Myths and Rumors

Reprinted from Prevention Research Literacy Training Curriculum, Global Campaign for Microbicides. (Used with permission from the Global Campaign for Microbicides.)

Myth/Rumor	Facilitator Notes: Key Points/Possible Responses for Discussion
<p>Myth 1: on trial product:</p> <p>"The trial products contain HIV and will infect the participants."</p>	<ul style="list-style-type: none"> • HIV prevention products under research are made to reduce sexual transmission of HIV and in some cases other sexually transmitted infections (STIs). • The trial products [pills/gels] do not contain HIV. They are being tested in clinical trials to see if they can help protect men and women from HIV infection. • Participants in HIV prevention clinical trials receive risk reduction counseling and are provided with high quality condoms and educated on their use. They are also treated for STIs. However, despite these risk reduction measures by the clinical trial staff, some participants will become exposed to HIV. Not because of the trial but simply because, as we know, not everyone is able to use a condom at every sex act.
<p>Myth 2: on determining the efficacy of a product:</p> <p>"For researchers to find out if the gel works, they are deliberately exposing participants to HIV."</p>	<ul style="list-style-type: none"> • To establish whether a product works, researchers randomly divide the participants into two groups at the beginning of the trial. One group gets the product with the active drug, while the other group gets a placebo or comparator (a similar product but without the active drug). HIV infections are monitored throughout the trial process. And at the end of the trial, the researchers compare the number of infections in the active drug group and the placebo group to determine if the product works or not. • Participants in the active group and the placebo group get condoms, are instructed on how to use them and get risk reduction counseling. Because of the intensive counseling and use of condoms, rates of HIV among trial participants are lower than they are in the surrounding community. Yet despite these measures, and because trials have to take place in areas where high rates of HIV occur, some participants in both groups will become HIV positive during the trial. Not because of the trial but simply because, as we know, not everyone is able to use a condom at every sex act.

Community Drama Example: Exploring Common Research Myths and Rumors

Reprinted from *Prevention Research Literacy Training Curriculum, Global Campaign for Microbicides.*
(Used with permission from the Global Campaign for Microbicides.)

Myth/Rumor	Facilitator Notes: Key Points/Possible Responses for Discussion
<p>Myth 3: on funding by big drug companies:</p> <p>“Big pharmaceutical companies are conducting research among poor uninformed African communities exposing them to huge health risks and exploiting them.”</p>	<ul style="list-style-type: none"> • HIV prevention products such as microbicides and PrEP are what are referred to as “classic public health goods” because they would most benefit communities highly affected by HIV. As such, governmental institutions and private philanthropic foundations, not pharmaceutical companies, mostly fund HIV prevention research. • A series of ethical principles guide how HIV prevention research is conducted. Under these principles, there have to be benefits to the participants for volunteering to take part in a clinical trial. Participants typically receive a range of services that can include the provision of contraceptives, contraceptive counseling, risk reduction counseling, provision of condoms, screening and treatment for a range of STIs, and in some cases cervical screening and Pap smears. Because of these prevention and care services, HIV rates among trial participants tend to be lower than those of the surrounding communities.
<p>Myth 4: on the promotion of promiscuity:</p> <p>“Researchers are encouraging (or paying) women to have more frequent sex with different partners.”</p>	<ul style="list-style-type: none"> • Researchers promote risk-reduction measures to trial participants through comprehensive risk-reduction counseling, partner reduction, safer sex and provision of high-quality condoms as well as treatment of STIs. • While trials sometimes use the term “sexually active women,” this means that the women have sex and are not celibate. It does not mean that women have multiple partners or increase frequency of sex. • Despite risk-reduction measures, not everyone can or chooses to use a condom at every sex act. This is why a wider range of prevention options is needed in the first place.
<p>Myth #5: on satanic rituals and witch craft:</p> <p>“Blood drawn from participants is used for Satanic rituals or sold for witchcraft purposes.”</p>	<ul style="list-style-type: none"> • Blood samples are used to test for HIV and sometimes other STIs. Because it is important to monitor the HIV status of each participant regularly, blood samples are taken at regular visits so that each participant can be monitored and, at the end of the trial, the researchers can be able to see how many people got infected. Beyond the trial results, it is also important to monitor participants’ HIV status so that if they do become HIV+, researchers can help them to access care, treatment and support services as soon as possible and so that a woman, if she chooses, can inform her partner so that he can also get tested.



Appendix

Tools: Step Seven

Tool 7A: Capacity-building needs assessment

Tool 7B: Assessment of capacity-building needs for use with individuals

Tool 7C: Building capacity with participant role play

Tool 7D: Action planning for communities and participants

Tool 7E: Setting group norms and guidelines

Tool 7F: Facilitating agreement

Tool 7G: Developing a shared vision

Tool 7H: Agree/disagree

Tool 7I: Template for documenting your own tools

Tool 7A: Capacity-building needs assessment

There are several ways to conduct a needs assessment and gap analysis. The aim is to collect information from your target audience (in this case stakeholders and research staff members) about their current capacity and gaps in their relevant knowledge and skills. This will help you to design workshops and trainings, and identify topics for groups. To gather this information, you can use individual interviews, focus-group discussions, workshops, or surveys and questionnaires. This tool provides a basic questionnaire that can be adapted for your circumstances. You can also use the tool to help develop questions for focus-group discussions, interviews and workshops.

Tool 7A: Assessment of capacity-building needs for groups and organizations

Use this tool to begin a discussion with stakeholders, partners and the research team about capacity and potential capacity-building needs. Ask organizations or stakeholder groups how they would score themselves in each category. (Adapted from: Communities Responding to the HIV/AIDS Epidemic (CORE) Initiative. CBO/FBO capacity analysis: A tool for assessing and building capacities for high quality responses to HIV/AIDS. Washington, DC: CORE Initiative; 2005.)

Organization/group: _____

Date: _____

Assessment by: _____

Question		Capacity-building score			
		1	2	3	4
HIV and AIDS knowledge	What do stakeholders, partners, and the research team understand about HIV and AIDS?	A few people know basic facts about HIV such as methods of transmission, prevention, care and support.	People know the basic level of knowledge needed to perform their duties.	HIV and AIDS issues are well understood (such as causes of vulnerability, effects of stigma, availability of treatment), but members get no (or limited) regular training.	HIV and AIDS issues are well understood; people are trained for the work they do and often provide training and support to others.
Research knowledge and ethics	What do stakeholders, partners, and the research team understand about the basics of research?	No understanding	People have a basic understanding of research concepts, but many misperceptions or gaps in understanding still exist.	People have a firm understanding of research concepts, including participant protections, data safety monitoring, and the ethics review process, but they do not get regular training on the subject.	People have expert knowledge of research concepts and receive regular research literacy training.
HIV prevention research	What do stakeholders, partners, and the research team understand about the HIV prevention research specifically?	No understanding	People have a basic understanding of HIV prevention research but many misperceptions or gaps in understanding still exist.	People have a firm understanding of HIV prevention research and are knowledgeable about how HIV prevention research is conducted and the importance of HIV prevention research but do not get regular training on the subject.	People have expert knowledge of HIV prevention research and receive regular research literacy training.

Question		Capacity-building score			
		1	2	3	4
Your trial [insert name of trial]	What do stakeholders, partners, and the research team understand about your trial [insert name of trial]?	No understanding	People have a basic understanding of what question the trial is designed to answer.	The trial is well understood and people are familiar with basic trial procedures, but few (or none) have received training on the trial.	The trial is well understood and most have been trained on the trial purpose and procedures.
Stakeholder engagement (For use with research staff)	What do staff members understand about the importance and aim of stakeholder engagement and capacity building?	No understanding	The staff has a basic understanding of the need for stakeholder engagement as they relate to trial recruitment and retention.	Staff members have an understanding of international guidance on stakeholder engagement and good participatory practice, but few (or none) have received training,	The staff has a nuanced understanding of the importance of stakeholder engagement and capacity building — beyond the meeting of trial targets — for the success of the trial and benefit of the community.
Gender and HIV and AIDS	What do stakeholders, partners, and the research team understand about the relationship between gender and HIV and AIDS?	No understanding	People know that gender inequality and gender norms influence HIV risk but do not know what to do about it.	The organization has taken steps to integrate a gender perspective into its research activities and programs.	The organization always analyzes how gender is affecting vulnerability to HIV and access to services within the community, and responds with appropriate strategies.
Score Note the number of 1's, 2's, 3's and 4's					
Other capacity-building needs: Are there other topics that could benefit the stakeholders, partners and the research team that are not listed above (e.g., training on couples counseling, gender-based violence and similar topics)?					
Needs assessment: Based on the responses, what gaps exist and what steps are needed to build capacity and fill those gaps?					

Tool 7B: Assessment of capacity-building needs for use with individuals

Using this tool, have individuals evaluate their own understanding of certain topics and identify areas where they may need or want additional training. *(Adapted from: CORE Initiative. CBO/FBO capacity analysis: A tool for assessing and building capacities for high quality responses to HIV/AIDS. Washington, DC: CORE Initiative;2005.)*

Name: _____

Organization/affiliation: _____

Date: _____

Please rate your level of knowledge and expertise on the following topic areas:

Question	Capacity-building score			
	1 This topic is new for me, I have no or little knowledge of this	2 Basic: I have some training on this topic	3 Intermediate: I have some experience applying knowledge on this topic	4 Expert: I can mentor or train others on this topic
HIV and AIDS Including how HIV works, causes of vulnerability, effects of stigma and the availability of prevention and treatment.				
Clinical research and research ethics Including an understanding of basic research concepts, such as participant protections, data safety monitoring and the ethics review process.				
HIV prevention research Including how HIV prevention research is conducted and the importance of HIV prevention research.				

Question	Capacity-building score			
	1 This topic is new for me, I have no or little knowledge of this	2 Basic: I have some training on this topic	3 Intermediate: I have some experience applying knowledge on this topic	4 Expert: I can mentor or train others on this topic
[Insert trial name] Including why the trial is being conducted and basic trial procedures.				
Stakeholder engagement Including international guidance on good participatory practice and the importance of stakeholder engagement and capacity building — beyond the meeting of trial targets for enrollment and retention.				
Gender and HIV and AIDS Including how gender affects vulnerability to HIV and violence and access to services within the community. And, I am familiar with strategies for addressing the effects of gender.				

1. Have you ever received training on HIV and AIDS?

Yes _____ No _____

If yes, please describe:

2. Have you ever received general training on clinical research and how research is conducted?

Yes _____ No _____

If yes, please describe:

3. Have you ever received training on HIV prevention research?

Yes _____ No _____

If yes, please describe:

4. Have you ever received training on research ethics?

Yes _____ No _____

If yes, please describe:

5. Have you ever received training on good participatory practice or stakeholder/ community perspectives and engagement?

Yes _____ No _____

If yes, please describe:

6. Have you ever received training on gender and HIV and AIDS, gender sensitivity training, or training on gender-based violence (sometimes referred to as violence against women)?

Yes _____ No _____

If yes, please describe:

7. Would you like to receive training on any of the topics listed above?

Yes _____ No _____

If yes, please explain:

8. Would you like to receive training on any topics that are not listed above, such as couples counseling, gender-based violence or other issues?

Yes _____ No _____

If yes, please explain:

9. Do you have experience training others on any of the topics listed above?

Yes _____ No _____

If yes, please explain:

10. Is there anything else you would like to share with us?

Tool 7C: Building capacity with participant role play

Adapted from: International HIV/AIDS Alliance and the Global Campaign for Microbicides. Tools together now! 100 participatory tools to mobilize communities for HIV/AIDS. Prevention Research Literacy training curriculum. Brighton, UK: International HIV/AIDS Alliance; 2006.

Objective: Role play as a capacity-building tool helps participants to act out and practice potential real-life scenarios, so they can confidently discuss what they've learned with others.

Materials needed: Prepared list of scenarios, or flip chart and markers to brainstorm a list of scenarios with the group, stopwatch (to keep time)

Approximate time: 30 minutes to one hour

How to use it:

1. Before the training or workshop, create a list of scenarios that might be helpful for participants to role play. You can also ask participants to brainstorm a list of scenarios they would like to practice through role play.
2. Ask for volunteers to act out the role play (giving them 15 minutes to prepare).
3. Ask the volunteers to act out the role play for the group. Encourage the other participants to watch and listen carefully, and to write down any questions that might occur to them.
4. Discuss the role plays with the larger group. Ask them what they learned.

Facilitator tips:

- Role plays are not just about what people say, but what they do. Pay attention to the body language of the volunteers and the audience.
- It can be useful to “pause” a role play at an interesting point and have a discussion. You can then restart the story afterwards. Audiences can also suggest different actions or endings at this point.
- It can be useful to have a series of role plays with slight variations on a single situation. For example, in alternative role plays, the key characters might be women rather than men, the players may have positive rather than negative attitudes, or they may be counselors rather than trial participants.

Tool 7D: Action planning for communities and participants

Adapted from: International HIV/AIDS Alliance and the Global Campaign for Microbicides. Tools together now! 100

Participatory tools to mobilize communities for HIV/AIDS. Prevention Research Literacy training curriculum. Brighton, UK: International HIV/AIDS Alliance; 2006.

Objective: Action planning is a participatory method to help communities and groups of individuals collectively plan activities and to help participants break down large activities or tasks into smaller, more manageable ones.

Materials needed: Flip chart or paper, markers or pens

Approximate time: One to two hours (depending on the complexity of the activity and the number of participants)

How to use it:

1. Draw an action-planning matrix (see below).
2. Introduce the activity under discussion (event, town hall meeting or other activity), or ask participants to think about the group's objectives and needs to identify an activity for planning.
3. Ask participants to think about potential activities that will achieve the activity or goal. Write these in the far left column of the action planning matrix.
4. For each activity identified, ask participants who should carry it out. Should they do it alone? With others? Or are other people or organizations better positioned to carry out the activity? Write the names of each person or organization in the appropriate column.
5. Ask participants when each activity should be completed. Should it be completed immediately? Soon —within a few weeks or months? Or later — in a few months? Ask them to write the date in the appropriate column.
6. Ask participants to consider the resources that will be required to carry out each activity successfully. These could be physical (for example, condoms, transport, venue) or financial resources. Write these resources in the last column.
7. With the aid of the participants, identify the people who will take the lead for each activity to make sure it is done. Write the names of these people next to each activity.
8. Ask participants to look at the action plan as a whole. Does it make sense? Is anything missing? Is it realistic?

Facilitator tips: Remember, if a stakeholder is not present when their roles and responsibilities are being discussed, they must be fully consulted before plans are finalized!

Action-planning matrix

Activity	Who?			When?			Required Resources
	On our own	With others	Others only	Now	Soon	Later	
Activity 1							
Activity 2							
Activity 3							

Tool 7E: Setting Group Norms and Guidelines

Adapted from: The Examining Community-Institutional Partnerships for Prevention Research Group. Developing and sustaining community-based participatory research partnerships: A skills-building curriculum [Internet]. Seattle, WA: University of Washington; 2006. Available from: www.cbprcurriculum.info

Objective: Agree on ground rules and group norms for workshops, focus groups, trainings and other events and meetings.

Materials needed: Paper, flip chart, markers or pens

Approximate time: 30 to 45 minutes

How to use it:

1. Ask participants to take five to 10 minutes to complete the following task individually: Think about groups in which you've had positive experiences, and write down three to five things that contributed to that positive experience. If you haven't had any positive experiences working in a group, think about groups you've been a part of that were not effective. Identify three to five factors that could have made it a more effective group. Write them down.
2. Ask participants to share their responses with the larger group and record them on a flip chart.
3. Ask the group if any factors are listed that they do not agree with and discuss.
4. Ask for agreement on the collective list of guidelines.

Facilitator tips: When writing out a list on a flip chart, alternate the colors of the items.

Tool 7F: Facilitating agreement

Adapted from: Interaction Institute for Social Change (IISC). Facilitative Leadership®: Tapping the power of participation. Training Curriculum. Boston, MA: IISC; 2012.

Objective: Conduct productive discussions that end with proposals or agreements.

Materials needed: Flip chart, markers or pens

Approximate time: One to two hours (depending on the complexity of the discussion)

How to use it: Every discussion can be broken down into three stages: the open stage (where ideas are generated), the narrow stage (where you start to narrow your focus) and the close (where you reconcile differences and come to agreement).

Open stage

1. Open the discussion. To open a discussion, use one of the following strategies:
 - Make a proposal: To start the discussion, provide a suggestion for the group to consider;
 - List: Work together to generate a short list of ideas for the group to consider; or
 - Brainstorm: Ask the group to brainstorm, coming up with a longer list of ideas. Allow the group to produce as many ideas as possible — you will narrow the list later. This is a great way to generate many ideas in a short amount of time.
2. Clarify: Make sure each participant understands the meaning of all the ideas listed (from the proposal, list or brainstorm you generated in step 1). Example: *“Take a few minutes to review the list of ideas. Which ones need to be clarified?”*

Narrow stage

1. Combine duplicates: From the list you generated in the opening, ask participants to consolidate similar ideas. Example: *“Are there any ideas listed that are the same or similar that we can combine to simplify our list?”*
2. Prioritize/rank: Use the following ranking tool to identify the ideas that are the most important to the group. Count the ideas on your list after you have combined any duplicates. Divide that number by three. That is the number of votes each group member has. For instance, if there are 18 ideas, you would divide 18 by three ($18 \div 3 = 6$), so each person gets six votes. In this instance, you would ask participants to vote for the six ideas they like best. You can invite participants to put a hash mark next to the ideas they like on the flip chart. Or you can read off each idea, asking for a show of hands, and recording the

number of votes next to the idea. With a different-color marker, circle those ideas with high vote counts.

3. Advocate: Before eliminating the ideas that received a low number of votes, ask the participants whether anyone wants to convince the group to keep any of the low-ranking ideas. Allow a few minutes for the participants to discuss any of the low-ranking ideas advocated by another member.

Close stage

1. Negative poll: The use of a negative poll can help to eliminate low-ranking ideas so you can quickly agree on the high-ranking alternatives. Ask participants, “*Is there anyone **not** willing to take [insert low-ranking idea here] off the list?*” Continue until you have a manageable number of ideas, ideally those with the highest ranking.
2. Build up and eliminate: If there is disagreement about removing ideas from the list, see if you can adjust the idea to make it work for the group. For example, “*What could we add to [option A] to make it work for you?*” Or, “*Is there any way you could combine what you like about [option A and option B] to come to an agreement?*”
3. Both/and: It may not be possible to come to single solution that works for an entire group. Avoid win or lose solutions. Is it possible to consider more than one idea as your final solution or agreement? For example, you could propose, “*Do we need to choose between these final two decisions? Could we try both?*”

Facilitator tips: Be sure to read through each step and practice the tool to get familiar with it before using the tool with a group.

Tool 7G: Developing a shared vision

Adapted from: Russell N, Gryboski K, Vostrejs MM, Nash-Mercado A. Igniting change! Capacity-building tools for safe motherhood alliances. Baltimore, MD: JHPIEGO; 2004.

Objective: Stakeholders often have different reasons for engaging in HIV prevention research or joining a stakeholder advisory group. By taking the time to develop a shared vision, participants can find common ground and build a sense of collective ownership and commitment. Discussing a group's shared vision can also offer the opportunity to discuss and help manage expectations about what the research project can and cannot achieve.

Materials needed: Newspaper headline(s)

Approximate time: Two or more hours

How to use it:

1. Cut out the main headline from the front page of your local newspaper. Tape the headline on the wall or insert the headline into a PowerPoint presentation so that participants can see it.
2. Discuss the headline with participants. How does it make them feel? What is their first reaction?
3. Explain what a shared vision is and why it's important: "A shared vision is the long-term goal we will set for ourselves and will strive to achieve."
4. Divide into at least three small groups, and have each group look three to five years into the future (or to the end of the trial). Have each group write the headline and the first few lines or paragraph of the trial's story for one of the following outcomes, ensuring that at least one group addresses each outcome:
 - a. The trial demonstrates that the intervention is safe and effective for preventing HIV.
 - b. The trial is unable to demonstrate that the intervention protects against HIV.
 - c. The trial is stopped early because the intervention has harmful side effects.
5. Have each group present their headlines and paragraph to the larger group.
6. Using the headlines as a starting point, discuss, agree upon and document a shared long-term vision.

Facilitator tips: Remember — success does not necessarily mean that the trial product was successful. Take this time to discuss different visions of success. If the product is not shown to prevent HIV, could the trial still be considered a success? Discuss with the group.

Adapted from: Interaction Institute for Social Change (IISC). Facilitative Leadership®: Tapping the power of participation. Training Curriculum. Boston, MA: IISC; 2012.

Definition	
Values	Beliefs or judgments about what is worthy, important or desirable that are reflected in individual and organizational behavior.
Mission	A task, purpose or calling of an individual team or organization.
Vision	An image of the mission accomplished, the ideal future.

Tool 7H: Agree/disagree

Objective: Assess participants learning (after a training) or perceptions and knowledge (before a workshop or training).

Materials needed: Prepared list of true and false statements about the content of the workshop or training content; hang “agree” and “disagree” signs on opposite sides of the room (optional).

Approximate time: 30 minutes to one hour (depending on time allowed for discussion)

How to use it:

1. Develop a list of true and false statements from the material in your workshop or training.
2. Ask participants to stand in the middle of the room.
3. Assign one side of the room as “agree” and the opposite side of the room as “disagree.” The middle of the room corresponds to “I am unsure.”
4. Read the questions aloud one at time, asking participants to stand in the area of the room that reflects their response (agree, disagree or unsure).
5. Ask participants to explain why they chose the side of the room they did to encourage discussion. If used at the end of a training workshop, this can also help to correct misinformation and reinforce key messages and information.

Tool 7I: Template for documenting your own tools

Title

Adapted from: [Is the tool an original idea or did you adapt it from another source?]

Objective: [What does the tool accomplish? Why would someone use it?]

Materials needed: [What materials are needed to complete the tool or activity? Is there anything that needs to be prepared ahead of time?]

Approximate time: [From your experience, how much time is required for the tool or activity? Estimate the number of minutes or hours. It is important to be realistic about the amount of time a tool takes so that facilitators can plan accordingly.]

How to use it:

[Write out how to perform the activity or tool in a stepwise fashion. Use as many steps as you need. Be very clear, and make sure that you don't skip any steps. Someone unfamiliar with the tool should be able to successfully use the tool simply by reading your instructions.]

Facilitator tips: [Do you have any tips or reminders for the facilitator?]



Additional Resources

Additional Resources

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Acronyms and Abbreviations

ARV:	antiretroviral
AVAC:	Global Advocacy for HIV Prevention
CAPRISA:	Centre for the AIDS Programme of Research in South Africa
CHOICE:	Committed to Having Options for Interventions to Control the Epidemic (MTN-018)
CAB/CAG:	community advisory board/community advisory group
CBO:	community-based organization
CLO:	community liaison officer
CORE:	Communities Responding to the HIV/AIDS Epidemic
CRSG:	community research support group
DSMB:	data and safety monitoring board
FBO:	faith-based organization
FHI 360:	formerly FHI, Family Health International
FTC:	emtricitabine (an antiretroviral drug)
GFATM:	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPP:	good participatory practice
HPTN:	HIV Prevention Trials Network
IAVI:	International AIDS Vaccine Initiative
IEC:	information, education and communication
IoR:	investigator of record
iPrEx:	Pre-exposure Prophylaxis Initiative
MDP:	Microbicides Development Programme
MO:	medical officer
M&E:	monitoring and evaluation
MMCI:	Microbicides Media and Communications Initiative
MTN:	Microbicides Trial Network
NGOs:	nongovernmental organizations
PATH:	Program for Appropriate Technology in Health
PI:	principal investigator
PrEP:	pre-exposure prophylaxis
SAC:	stakeholder advisory committee
STIs:	sexually transmitted infections
TB:	tuberculosis
TDF:	tenofovir disoproxil fumarate (an antiretroviral drug)
TDF/FTC:	tenofovir disoproxil fumarate/emtricitabine
UNAIDS:	Joint United Nations Programme on HIV/AIDS
USAID:	United States Agency for International Development
VOICE:	Vaginal and Oral Interventions to Control the Epidemic (MTN-003)
WHO:	World Health Organization

Glossary

Capacity building: development of the skills and attitudes necessary to sustain the relationship between researchers and a community or other stakeholders. Capacity building can increase knowledge and awareness, sustain long-term and collaborative commitment, promote trial recruitment and retention, build support and avoid potential controversy, and lay the groundwork for the eventual introduction of trial products should they prove to be effective.¹

Community advisory board or group: a body composed primarily of nonscientists whose members advise researchers on research protocols and help to educate communities about the research taking place in the community. Because of their limitations, community advisory boards should not be the only method used to engage and solicit input from stakeholders.² Community engagement: a continuous process that involves the creation of relationships with parties at the local level to ensure cooperation and alignment of interests among parties — such as researchers and those potentially affected by a research trial — across the life of a project. It is a type of stakeholder engagement.

Impact indicator: a measurable statement that describes what a successful outcome looks like for a course of action. Impact indicators should be based on the objectives of the project.

Mapping: a process of surveying and analyzing social, political and historical factors at national, regional and international levels with relevance to a community. The resulting documentation can be used to select research sites, identify priorities for formative research and guide other decisions.

Matrix of stakeholders: a tool for planning a stakeholder engagement strategy that lists the following domains of each stakeholder: the potential role of the stakeholder, the strategy for engaging them, the desired outcome, a follow-up strategy to ensure continued engagement and the timing of engagement.³

Messaging: in communications strategy, the content of the information conveyed to the stakeholders.

Participatory program evaluation: a method that involves providers, partners, beneficiaries and other stakeholders in the various steps of program evaluation: planning and design;

gathering and analyzing data; identifying the findings, conclusions and recommendations of an evaluation; disseminating results; and preparing an action plan to improve the program.⁴

Postexposure prophylaxis (PEP): the administration of anti-HIV drugs within 72 hours of a high-risk exposure — including unprotected sex, needle sharing or occupational needle-stick injury — to prevent an HIV infection from developing.⁵

Pre-exposure prophylaxis (PrEP): an HIV prevention strategy that involves the use of antiretroviral medications to reduce the risk of HIV infection among HIV-negative people at risk for HIV.⁶

Process indicator: a measure of whether planned activities are being carried out and how they are being carried out.

Research network: a network of investigators who collaborate on the development and conduct of clinical trials. In HIV prevention research, these networks develop and test the safety and efficacy of interventions — typically products that are administered orally or topically — that are designed to prevent the transmission of HIV. For example, various networks — the HIV Prevention Trials Network (HPTN), the Microbicides Trials Network (MTN), the HIV Vaccine Trials Network (HVTN), the International Partnership for Microbicides (IPM) and the International AIDS Vaccine Initiative (IAVI) — assemble teams of international investigators along with partners in the community and industry to conduct HIV prevention trials throughout the globe.

Stakeholder advisory mechanisms: strategies that facilitate dialogue between researchers and stakeholders and that allow stakeholders to provide input into the research methods, design and implementation of a trial. Examples of stakeholder advisory mechanisms include community advisory boards, community research support groups, stakeholder advisory committees, participant advisory groups and community advisory groups.⁷

Stakeholder engagement: an inclusive and continuous process that involves the creation of relationships with internal and external parties at the local, national and international levels to ensure cooperation and alignment of interests among parties — such as researchers and those potentially affected by a research trial — across the life of a project.⁸

Stakeholders: parties at the local, national and international level who can affect or be affected by the actions associated with a research trial. In the context of this toolkit, stakeholders are grouped into five categories: (1) trial participants, their families, partners,

neighbors and co-workers; (2) HIV and AIDS policymakers and advocates; (3) researchers, funding agencies and regulatory bodies; (4) health care programs and service providers; and (5) local community members.⁹ Within these categories, other important stakeholder groups can and often should be identified. For example, people living with HIV or AIDS are a key group of the local community and potentially of advocates as well.

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