Unit 13

Conducting Research

Cover photo: A PIH lab staff member examines a blood sample in Neno, Malawi

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Overview

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> *"Creating a research platform that is ethical and has a postive impact on the lives of the poor is an enormous task."*
>
> – Paul Farmer, Co-founder, Partners In Health

INTRODUCTION

Your program can use research to develop evidence-based interventions, tools, or strategies to improve the health of patients. Conducting good research can be a complex endeavor in a resource-poor setting, particularly when your primary goal is service provision. Your research team, which may be the local clinical staff, should include some members who have formal training in health-related research methods. Although you may not have dedicated funding and technological resources initially, these will likely be required if you do plan to do research that is more extensive or involved than a pilot study. If you do not have adequate resources or staff with the appropriate research training, you should collaborate with academic and medical institutions for guidance, mentorship, or to help access resources needed to conduct research properly and ethically.

Rigorous research is a key component of PIH's programs. By drawing on our affiliations with academic and medical institutions, we conduct research to answer questions about how disease affects communities, how the distribution of wealth and power shapes the distribution and outcome of infectious disease, and how health care is related to human rights. Research findings also demonstrate the effectiveness of our programs to potential donors and can be used to advocate for policy change at the national and international level.

Program managers and front-line clinical staff will inevitably be involved in the research in a number of ways. It is important to think through carefully how they will be included in the planning process and throughout implementation. Incorporating research at an early

stage of program planning and in collaboration with the community will help to define research priorities, the scope of the research, and logistical requirements. The extent and type of research you conduct will depend on a variety of factors, many of which will be outlined in this unit, along with tips for overcoming common challenges.

1. WHAT IS RESEARCH?

Research is the systematic search for knowledge. It can be used to develop interventions, tools, or strategies to enhance a program's effectiveness. A wide array of activities falls under the category of research: performing a review of literature; identifying optimal treatment strategies for the disease, population, or geographic location of concern; conducting a baseline community survey; doing a pilot study; and participating in a clinical trial. These activities are explained in more detail below.

1.1 *Literature review*

Clinicians often use literature reviews as guides for helping to make clinical decisions. If there are published strategies that your team thinks that it can pursue at the site, then developing programs based on this evidence may improve outcomes. Researchers and other front-line staff can also use review articles to inform their own research questions. A review of the medical and public health literature on a given area of interest, such as uptake of HIV testing, can provide up-to-date information on best practices. A systematic review is more than just an extensive literature review, but rather a process that defines inclusion and exclusion criteria, as well as your research strategy. This process also involves statistical methods to summarize data across studies. There are a number of papers that discuss how to carry out a systematic literature review; however, it is advisable to seek out someone with research experience who can offer advice on the best way to proceed.

TIP: *If insufficient information is provided in the published material, you may want to contact the corresponding author of the publication to obtain additional detail necessary for implementation, such as on outreach strategy, health education curricula, and so on.*

1.2 *Quantitative and qualitative methods*

Research can involve quantitative or qualitative methods, or both. For research pertaining to improving access or quality of services, a combined use of quantitative and qualitative methods may be useful. Quantitative data are generated using structured questionnaires or laboratory results, with closed-ended limited response options (for example, a laboratory test result might be positive, negative, or unknown). Qualitative methods rely on open-ended questions, allowing study participants to elaborate on issues they find to be relevant to the content; these can include key informant interviews and/or focus group discussions, among other methods.

An example of a combined use of these methods would be a study to evaluate a specific drug regimen, such as simplifying combination therapy for HIV. Quantitative methods can allow for assessment of clinical outcomes, such as CD4 count, or body mass index, in response to the new therapy versus the standard of care therapy. In addition, through quantitative methods you can assess adherence through a number of methods, such as a pill count on a monthly basis. Qualitative methods can complement these findings and shed light on mechanisms for limited adherence that could not be obtained through pill counts or structured questions. Published studies are currently relying on combined qualitative and quantitative methods more frequently than has been done in the past.

2. WHY DO RESEARCH?

If published strategies do not appear to match your current needs in the field, you may want to build upon existing research to develop novel strategies and then evaluate them. Community surveys and pilot studies can often provide preliminary evidence for health programs or strategies that may need to be pursued in your catchment area, such as assessing uptake of prevention of mother-to-child transmission (PMTCT) of HIV services in the community and piloting strategies to improve uptake. A nonprofit operating in a resource-poor setting might also conduct research to: identify possible patterns of unmet need, generate an evidence base for medical and public health interventions, strengthen advocacy, or secure future funding through documentation of successes. These are elaborated on below.

If your site is observing an increase in occurrence of disease, such as childhood malnutrition, a community survey of your catchment area may help you to identify specific regions that are at high risk. In addition, some acute cases, such as children with severe acute malnutrition who require hospitalization, can be identified and brought into the health center or hospital. The survey results may also point to aspects of your program that need improvement or to the need for more preventive measures to reduce the overall burden of disease. Improved health outcomes also rely on practices that are evidence based.

Figure 1: Using insecticide-treated bednets is a low-cost measure for preventing the spread of malaria in Rwanda

If a challenge that you face is not adequately addressed in the peer-reviewed medical and public health literature, particularly for your geographic target area, consider conducting research to identify an effective strategy to increase uptake. An example would be testing strategies for increasing uptake of insecticide-treated bednets to prevent malaria.

Using data to demonstrate the burden of disease in vulnerable groups can enhance advocacy efforts and potentially increase public and private funding to reduce this burden. For example, PIH's research on the results of directly observed therapy for multidrug-resistant tuberculosis (MDR TB) in Russia and Peru helped overturn assumptions and policies that had denied treatment to patients in poor countries. The data demonstrated

that "untreatable" patients are in fact treatable when treatment addresses all aspects of the disease—supplying housing, employment, food, and moral support, in addition to high quality care—and that such a program works.[1] The conventional standard of care endorsed by the World Health Organization (WHO) was overturned. The treatment program is now a replicable standard worldwide, recommended by WHO for even the poorest of countries.

Performing research to evaluate your site's performance may also increase your capacity to obtain future funding. PIH has used research results that show better outcomes among patients who receive antiretroviral therapy (ART) for HIV infection to secure funding from bilateral and multilateral donor organizations. (For more information on applying for grants from bilateral and multilaterals, see *Unit 9: Creating a development strategy.*)

TIP: *Whatever your reasons are for conducting research, be clear about why the research is being done and how your target population and your front-line health care providers can benefit from it.*

3. YOUR ORGANIZATION'S ROLE IN RESEARCH

Your organization's role in research will vary depending on its size, mission, and goals, as well as its available resources. Keep in mind that research can be very broadly defined and that there are many ways that an organization can participate in research activities. For example, you may be asked to help write a research grant, to refer patients to a study being conducted by another organization, or to conduct your own study. Your organization may take on additional roles not described here, or you may find that the scope of the work will evolve over time. Here are some key questions that can help to identify resources and define the scope of your responsibilities:

If your own organization will be implementing the research, ask:

- Why and how will your organization conduct the research?
- Does your organization have adequate human and financial resources for carrying out the work?
- Is external funding available to conduct the research?
- Who within your organization will participate?
- What, if any, external partners will be collaborating on the project?
- What are the roles of staff and partners in carrying out the project?
- What is the estimated time commitment for carrying out specific responsibilities?
- What is the time frame for carrying out the work?
- What is needed in terms of infrastructure (lab equipment, supplies, transportation)?

[1] Mitnick, C. et al. (2003). Community-based therapy for multidrug-resistant tuberculosis in Lima, Peru. *New England Journal of Medicine,* 348(2):119–28.

If you will be planning or developing the research, ask:

- Is your organization developing key research questions?
- Is your organization assisting in developing the methodology and tools to be used?
- Is your organization developing indicators to be tracked? (See *Unit 12: Using monitoring and evaluation for action.*)

If your organization will be identifying local consultants to do the research, ask:

- What local groups or other entities operating in-country have the relevant expertise?
- Does the consultant have a track record of competence?
- Does the consultant have the appropriate cultural sensitivities for undertaking the research?

If you plan to facilitate the relationship between research institutions and communities, ask:

- How can your organization introduce researchers to the communities in which you operate? Who are key contacts within the community?
- How can your organization ensure that the researchers have credibility in the eyes of the community?
- How can your organization facilitate research meetings, focus groups, and administration of questionnaires or field surveys?

If you intend to disseminate findings, ask:

- How can your organization facilitate dissemination of findings in a way that is most useful to key stakeholders?
- What stakeholders should be included in the dissemination plan?
- How will your organization give credibility to the findings?

If your organization will be offering expertise, ask:

- Which staff members from your organization can offer expertise for the organization conducting the research?
- On what criteria are research staff chosen?
- How will the organization conducting the research ensure that your staff will maintain confidentiality?

If your organization will be serving in an advisory capacity, ask:

- What types of research might be particularly sensitive for a given community?
- With whom will you consult about potential research projects?
- Will you need to modify any suggested research activities to avoid making people in the community feel uncomfortable, ashamed, or embarrassed?
- How will your organization convey this information to the organization conducting the research?

4. WHO IS INVOLVED?

If your organization is conducting research, it is important to involve relevant groups at different stages of the study to ensure that all stakeholders can benefit from research findings. Your staff, people in the community (including patients if your study is in a clinical setting), collaborators, and the government of your host country will have different experiences with research and will want to know what you are looking into and why. These groups will want to know what their respective roles will be in the research, the knowledge they will contribute, the expectations for their participation, and how results will be used. Communicating the goals of your research to all those involved from the beginning is therefore of critical importance.

4.1 *Your staff*

For your research to have a chance of being successful and sustainable, local clinicians need to see the potential benefits of the research—that is, improved care and better health outcomes. Accordingly, it is important that the local clinical team provides essential input and information to set the research agenda, because it is the clinical team that witnesses firsthand the health problems that patients face.

Figure 2: PIH lab staff in Neno, Malawi

Figure 3: A training session for Zanmi Lasante's psychologists and social workers

When local staff have ownership of the research it also helps to build local capacity. Conducting research is an opportunity for both local clinicians and other program staff to receive on-the-job education and training in research methods and public health. Participating in research can also help local staff understand and visualize how they would organize and conduct their own study in the future.

Communicate to staff at all levels the purpose of the research, what it hopes to accomplish, and how staff will participate in it. Research activities should be well integrated into the staff's daily work. Consider carefully whether this is feasible. If not, hiring additional staff to conduct the research will be needed to ensure the quality of data collected and to prevent staff burnout. At the conclusion of a research project, elicit feedback from study personnel on their experiences with the project so that your organization can continually improve upon the research.

PIH NOTE

The dedicated psychosocial team at Zanmi Lasante (ZL), PIH's sister organization in Haiti, performed a study in collaboration with researchers at Harvard Medical School (HMS) to assess the feasibility of a psychosocial support group program with HIV-affected families in central Haiti. The main steps for performing the research study included the following:

1. *Recruit study personnel. What are the tasks involved? How many staff are required? What types of skills and qualifications are needed? What positions can be filled by local people?*
   Example: *ZL hired social work assistants to support the current social worker staff so that the team would not be overburdened. A research coordinator as well as a data manager were recruited and trained along with data entry staff. All new recruits were Haitian.*
2. *Train and retrain staff. Systematic training and capacity building of staff in research methods and implementation is vital for ensuring that research ethics are upheld and high quality data collection and service provision occur.*
   Example: *ZL's training sessions offered opportunities for social workers to share their experience with each other and strengthen the intervention.*
3. *Develop a study protocol, timeline, and structured questionnaires. What tools are available in the relevant literature? How can they be adapted to suit our needs? Do they require translation into the local language?*
   Example: *The study protocol was available in French; however, all questionnaires for the study were translated into Haitian Creole.*
4. *Address quality. Are study personnel following the protocol? Are there opportunities for study personnel to provide feedback on quality issues? Are translations accurate?*
   Example: *The psychosocial team met with HMS researchers on a regular basis to brainstorm solutions to any obstacles encountered in research implementation. HMS researchers were directly involved with data quality and worked closely with the data manager and the research coordinator in central Haiti to ensure completion of the study according to the timeline and study protocol.*
5. *Collect complementary data. Can qualitative, open-ended interviews and focus groups provide additional data that are not collected through structured questionnaires?*
   Example: *Involvement of the patients through qualitative methods allowed the team to understand how the intervention was most useful, and what needed improvement.*
6. *Analyze the data. What statistical methods will best address the study's specific aims? How can the results inform your programming moving forward?*
   Example: *The ZL psychosocial team and HMS researchers collectively analyzed the data. The final results demonstrated that the psychosocial support group intervention with HIV-affected families in Haiti was feasible and preliminary findings suggested improvements in psychosocial health outcomes, such as reduced depression, improved functioning, increased social support, and reduced HIV-related stigma.*
7. *Present the data. Who needs this information and how will it be presented? What are the appropriate channels for disseminating the data?*
   Example: *Both Haitian and HMS researchers presented the findings of the study at international conferences. Based on these findings, PIH expanded this program to other sites in the catchment area.*

4.2 *External collaborators*

Participation of external organizations, such as universities or other institutions, is common when an NGO does not have the capacity to conduct research on its own. You may find that establishing a partnership with the local university, if there is one in your host country, facilitates your study through added capacity to carry out the research. A university partner can offer skills in research methods and resources in the form of laboratories, computers, or administrative oversight. The advantage of working with these institutions is that they will likely be aware of in-country laws pertaining to research and local cultural norms and practices, and they may be able to offer advice on how to involve other collaborators and people in the community.

If an investigator from another country wishes to lead the research at your site, it is important to weigh the potential benefits and drawbacks of this kind of partnership. For the research to be relevant and sustainable, an investigator should have an acute sense of the needs of the program, speak the local language, and be knowledgeable about cultural norms; such a background would suggest that the investigator has spent considerable time in your host country and is very familiar with how things work there.

Figure 4: A medical resident from the U.S. during her rotation at Zanmi Lasante in Haiti

4.3 *The community*

Although the clinical team should be central in formulating the research questions—the questions that you hope the study will answer—the community plays an important role in all stages of the research. Including community input when developing the goals and priorities of your research is also necessary.

Figure 5: PIH's community health educators reach out to local leaders to help spread the word about preventing cholera transmission in rural Haiti

Holding focus groups in your target population(s) is one way to include community input. Focus groups provide a forum for probing for information on open-ended questions. They are often used to assess cultural and personal preference factors that influence health behaviors, such as the adoption of family planning methods. Focus groups are one of several methods of obtaining qualitative data, which are useful for designing more effective communication campaigns, giving voice to the poor or vulnerable populations, and providing better services to target groups.

The opinions of community leaders, such as village chiefs, and members of local committees, such as associations for people living with HIV/AIDS (PLWHA), is important because these people often have an acute sense of the main constraints and challenges affecting the health of their community. These constraints and challenges can often provide a good starting point for forming your research questions.

Consider creating a community advisory board (CAB). CAB members are generally volunteers from the community who have an interest in the research being conducted at the site. They meet periodically throughout the study to discuss community issues and questions related to the research. For example, CAB members can tell you whether people from the same community have been asked to participate in research in the past. If they have, you can then find out what the purpose of the research was and what local people's perceptions and experiences were with research projects.

Community members who have experience with researchers coming to their homes and asking questions may feel quite different about your research than those who are unfamiliar with the concept of a research study, depending on whether their past experiences were positive, negative, or neutral. Some people may be very willing to participate, while others may be skeptical, particularly if previous foreign investigators made promises that they did not keep. Additionally, if your research topic requires asking community members sensitive questions, such as those pertaining to sexual behavior and practices, gender norms, class, or ethnic conflict, a CAB can provide insight into whether this research should be done in the first place. Alternatively, the community advisory board can advise on how to approach your research aims in a way that is nonthreatening to the community. This knowledge can help you decide what to investigate, how you can involve the community throughout the life of the study—not just the initial stages—and how you will communicate your intentions to different local stakeholders. If you create a CAB, someone from your organization should be designated to help coordinate the activities of the group.

4.4 *The public sector*

Consult with the ministry of health (MOH) and other local government bodies about your intention to conduct research. Having the support of the government lends credibility to your organization and could encourage the use of your research findings to inform government health policy or treatment protocols. (See *Unit 14: Maximizing impact through advocacy.*) If you are working in a government-run facility, such as a district hospital, close collaboration with the MOH is imperative if you wish to conduct research. In this case, hospital administrative and clinical leadership will need to be part of any discussions about research plans from the

Figure 6: Community members, patients, and government officials show their support to fight TB in Peru
Photo: Socios En Salud

start. Remember that some governments might look upon foreigners conducting research in their country with skepticism. If you are open about your plans from the beginning, you are more likely to have the MOH's ear when you disseminate your research findings.

5. DEVELOPING A RESEARCH PLAN AND IMPLEMENTING YOUR STUDY

The principal investigator (PI), who is usually someone with a medical degree or academic doctorate, is responsible for the overall scientific oversight and management of a study, encompassing the intellectual, ethical, technical, administrative, and fiscal elements of a project. Although the PI of the study typically takes the lead in developing the research plan, a program manager can use this plan to apply for funding, assist in defining staff roles in the research, hire research personnel, communicate and help to implement the plan, and make sure that people adhere to timelines and fulfill their responsibilities.

Putting your research plan in writing will help you think through some important components of the plan and help you address potential challenges to conducting research in a resource-poor setting. For example, you may face conflicting priorities—either with external institutions or within your own program—or have to contend with limited physical infrastructure, including insufficient access to electricity, computing resources, Internet access, space/laboratory facilities, and transportation to remote areas. Lack of experience and limited capacity of local staff to assume additional responsibilities, including oversight and management of the research and data quality control at all stages, may also hamper your progress.

5.1 *Research goals and objectives*

If your organization is taking on its own research project, you will need to prioritize what to research based on the needs of your patients. Before you apply for funding, you should have a clear idea of your research goals and objectives.

Research goals state the desired outcomes or general intentions of the research, which "paint the picture" of your research proposal. Goals should be written in a way that states *what* you want to accomplish, not *how* you plan to accomplish it. They focus on desired project outcomes over the *long term* rather than the short term. An example of a research goal would be: *"To examine whether condom distribution by community health workers increases safe sex activity over the next five years."*

Research objectives, or your specific aims, are more narrowly defined. They should clearly state specific content that relates directly to the research goals. Make sure that the objectives can be addressed through systematic analysis of qualitative data or statistical analysis of quantitative data. An example of a research objective/specific aim might be: *"To examine the effect of condom distribution by community health workers on consistent condom use in the past three months."*

Research objectives should be SMART (specific, measurable, attainable, relevant, and time-bound).[2]

Specific	Objectives should be precisely described and emphasize how stated research goals will be accomplished.
Measurable	Objectives should be measured objectively and comparable across groups and projects, thus allowing changes to be compared and aggregated.
Attainable	Objectives should be achievable by the project.
Relevant	Objectives should be relevant to the project in question and make accurate use of concepts. They should be achievable within a reasonable time and at a reasonable cost.
Time-bound	Objectives should describe by when a certain change is expected.

Figure 7: SMART research objectives

Accomplishing research objectives can take a long time and can require considerable resources. For this reason, most health-related research is carried out in stages, and usually depends on seeking and obtaining external funding (discussed further below). Prioritizing your research objectives will help maximize your time and effort. Consider which aspects of your research you can accomplish in the short term, and which can be addressed in the long term.

As you develop your research objectives, you may find it useful to organize your progression in terms of three stages:

1. "Grab the low-hanging fruit." In other words, start with what is within reach, by describing and reporting on the experiences or outcomes that your organization is, to some extent, already recording.
2. Identify your organization's most important or novel practices, with impacts that are relatively easy to measure. This helps you identify how to build effective research on existing strengths.
3. Develop and refine designs for future, more complex studies. This stage may ultimately provide a more scientifically rigorous assessment of your organization's interventions than the earlier stages, but such progress often depends on the outcome of pilot or feasibility studies.

5.2 *Funding*

Nearly all research activities require dedicated funding. Preliminary studies can sometimes be carried out without a grant if they are small and you have a team of individuals willing to carry out the research tasks in addition to their existing responsibilities. However, most studies beyond the pilot phase require dedicated funding. In all likelihood, you

[2] Family Health International. (2001). Introduction. In *Strategies for an expanded and comprehensive response to a national HIV/AIDS epidemic.* Arlington, VA: Family Health International. SMART objectives are also discussed in this Guide (with examples) in *Section 1.3.2* of *Unit 12: Using monitoring and evaluation for action.*

will need to pursue public or private grants to support your research activities. Do not make the common mistake of focusing all your efforts on one "ideal" funder. To improve your chances of winning a grant, diversify the types of funders to which you apply. Even the most experienced proposal writers receive many more rejection letters than they do grants. The range of print and electronic resources available to grant seekers is extensive. Governments, private foundations, public charities, and even individuals solicit requests for grant proposals for health interventions. (See *Unit 9: Creating a development strategy* and *Unit 10: Working with partners.*) A list of research funding websites can be found in *Resources* at the end of this unit.

5.3 *Supervision*

Your plan should list the individual or individuals who will be responsible for overseeing the research, along with a statement or list of their specific responsibilities. The PI may delegate certain tasks, but he or she retains ultimate responsibility and accountability for the research. In addition, a study should have a dedicated project manager who supervises the staff interviewers, data entry clerks, laboratory technicians, and other study personnel as needed.

The project manager works with the staff and PI to ensure that data are collected in a timely manner and are of high quality. (See *Unit 12: Using monitoring and evaluation for action* for additional information on improving data quality.) If resources are available, a dedicated data manager is hired to review completed questionnaires, examine data after they have been entered into the study database, and run preliminary analyses to assess the quality of the data. The PI and other investigators should work closely with the project manager and data manager to analyze the data and provide constructive feedback to staff. It is ideal if the PI is permanently based at the site, but if he or she is not, then it is imperative that the local project management staff have the authority and responsibility to ensure the timeliness and quality of the work.

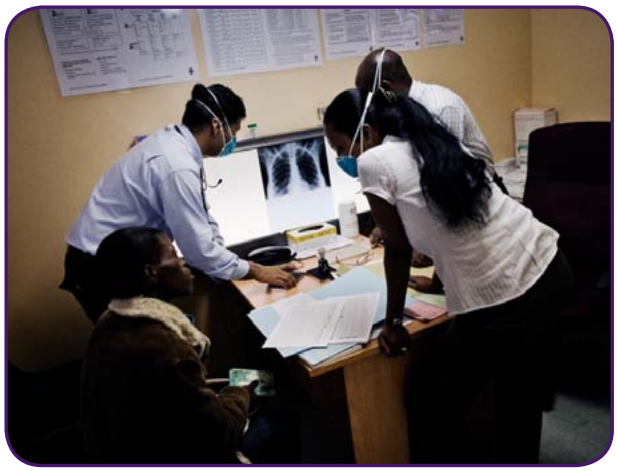

Figure 8: A PIH researcher looks at a chest x-ray at an outpatient clinic in Lesotho
Photo: Pep Bonet

Training front-line staff to do interviews and data clerks to perform some of their own quality assurance provides an opportunity for greater ownership of these tasks and more engagement in the overall research process. Open communication is essential, and staff should feel it is also part of their role to provide feedback to study management and investigators when there are challenges or problems, such as when the workload or insufficient time may prohibit them from giving the research the high quality attention and precision it requires in how they carry out their daily work.

5.4 *Research staff*

Determine which types of study personnel will be required to accomplish the research. Much time, effort, and money could potentially be wasted if there are not enough people to carry out the work, or not enough people who have the necessary skill set. For example, certain study personnel should have experience in developing or implementing survey tools and have skills in data analysis and research methodology. In addition to the project and data managers, you may require the following types of study personnel:

- Clinical staff
- Community health workers
- Data collection staff
- Data entry clerks/data editors
- Epidemiologists
- Information Technology (IT) personnel
- Laboratory technicians
- Programmers
- Statisticians

Figure 9: The XDR TB research team at Socios En Salud in Peru
Photo: Socios En Salud

TIP: *Someone trained in public health or statistical methods (at a master's level or higher) can help ensure that the study you plan to carry out will properly address what you want to investigate. This person can help guide you in the appropriate research methodology, implementation, and analysis for your study.*

If you do not have the capacity within your organization and it proves impossible to hire or find personnel with the right skills or experience, consider carefully whether you should take on the research as originally planned. Even if you succeed in obtaining project funding, it is not advisable to do research without a good study design, appropriately skilled staff, or the necessary resources, and such efforts (even with funding) are unlikely to lead to useful results.

5.5 *Equipment and supplies*

Decide what equipment and supplies are needed to carry out the research. It can be very difficult to source certain equipment and supplies locally. While importing tools and supplies may be costly, doing so may be your only option if you cannot find them in country. (See *Unit 4: Managing a procurement system,* for more information.) Find out whether another local organization has materials, vehicles, or office space that you could borrow or rent for a reduced fee. For the items below, consider availability, initial cost, cost of maintenance and repairs, required infrastructure, transport, and installation:

- Laboratory equipment, diagnostic kits, and reagents
- Medicines and medical supplies
- Photocopying and printing supplies (such as toner and paper) for printing forms related to data collection and program evaluation
- Computers, printers, software
- Internet technology (see *Unit 3: Building site infrastructure* for more details)
- Office and storage space
- Vehicles

Figure 10: Lab technicians examine patient samples at the Tomsk Oblast TB Dispensary in Russia

5.6 *Managing data*

Your research plan should outline how you will manage the research data in a way that is useful for the designated purpose of the information collected and that will ensure protection of your study participants. Training of staff is essential for promoting high quality data and managing data well. Training should occur at the outset of your study, and retraining of study staff should be conducted periodically (at least annually). In addition, hold an initial meeting with staff to discuss your plans about how and at what stage of the research they will be involved with the data and how data quality will be maintained throughout the study. A designated data manager can work directly with staff to ensure timely collection of data that are high quality. Hiring a qualified, local person to manage data on site typically allows for the generation of higher quality data, rather than hiring someone to manage data remotely. (For additional information on data management, see *Unit 12: Using monitoring and evaluation for action*.)

You should outline in your data management plan the resources, infrastructure, and staff needed for the following:

- Study protocol development
- Training
- Form development
- Database design
- Data collection
- Data entry
- Data storage and security
- Data quality assurance

TIP: *Developing the study protocol collaboratively with the staff will prevent duplication or inefficiency in data collection, and give staff ownership of the general flow of the data—what is collected, how, by whom, and when.*

5.7 *Translation*

When considering your data sources, decide whether forms and questionnaires require translation into the local language(s). Developing a form that is available in one or more local languages can be a complicated and time-consuming process, so you should allow ample time for this step before the study begins. "Back-translation" is one strategy that can be used to highlight potential areas of confusion during form development. This is the process of retranslating a text back into its original language to filter out errors and omissions. Pilot testing eight to ten forms in each language before the study begins is another strategy for avoiding translation problems caused by cultural or other misunderstandings.

Figure 11: A patient's house with a corrugated metal roof in Rwanda

If you cannot find a translator in your host country, you may have to broaden your search to identify a good and reliable translator who can work remotely. While there is a significant market for professional translators in developed countries, keep in mind that translation services are generally quite expensive, particularly for rare languages or dialects.

PIH NOTE

A questionnaire that PIH used in Rwanda asked community members what material their roof was made from. "Sheeting" was listed as a possible answer. American investigators interpreted "sheeting" to mean corrugated aluminum, whereas some of the Rwandan data collectors translated it in Kinyarwanda as a plastic covering, such as a tarp. If used to design a health intervention based on the questionnaire, the responses to this question would result in very different activities. Metal sheeting would be considered adequate covering, and plastic sheeting would suggest that the respondent required a better roof. Researchers might also conclude that households with roofs made of aluminum sheeting would have a higher socioeconomic status than households with roofs made of plastic sheeting. Unfortunately, data collected for this question were unusable because of the translation problem. If we had back-translated and pilot tested the questionnaires first, we would have saved the study staff's time and resources.

6. RESEARCH ETHICS

Human research ethics rest on principles of respect, beneficence, and justice. All regulations or guidelines governing research ethics are based on these principles, which transcend all geographic, cultural, economic, legal, and political boundaries. Balancing the conflicting interests of patient confidentiality and providing access to sufficiently detailed information for research can be challenging, and this inherent tension raises concerns about safeguarding the rights of study participants. The concept of written informed consent of study participants is central to maintaining the highest ethical standards. Before the study begins, potential participants must be given required information about the study, including the potential risks and benefits, to help them make an informed decision about participating. Obtaining informed consent also ensures that people are participating in the study of their own free will.

6.1 *The Institutional review board (IRB)*

If your research involves human participants, you will need the approval of an institutional review board (IRB) or ethics committee *before* you begin any research activities. These bodies exist to ensure that investigators conducting research with human participants conform to the highest ethical standards. Contacting the IRB for guidance on requirements for approval before you begin planning your research can help you expedite the approval process. Applications to the IRB often require fees, so be sure to account for this in your budget. The IRB can advise on whether the proposed study requires explicit consent from study participants or if a waiver of consent will suffice (see below for more detail on the meaning and purpose of consent). Be prepared to explain to the IRB what principles or techniques will be used to ensure data security, either by limiting access to data or by modifying or structuring data so that they cannot be linked to the identity of individual study participants.

Figure 12: A Ministry of Health technician completes a white blood cell count at a lab in Neno, Malawi

You will need to seek the approval of an IRB or ethics committee if your study involves direct observations on individual people or sometimes on tissue specimens from them. Even analyzing aggregated patient data (current or historical) raises concerns about confidentiality and institutional liability, so review and approval is necessary. As a general rule, you should seek the guidance of an IRB if your data collection is 1) systematic; for example, if the research involves identifying people with certain histories or medical characteristics and, after giving informed consent, these individuals answer questionnaires that solicit specific kinds of information about experience, exposure, or family history; 2) potentially traceable to an individual; for example, if you are studying data or stored tissue specimens that can lead to the identification of a study participant; and 3) if there is any potential that it might become public information; for example, if you

will/plan to present a poster at a conference or publish a manuscript in a peer-reviewed journal.

Some IRBs are located at the national level, such as at your host country's Institute of Health or equivalent body. A major university in your host country may also have an IRB or ethics committee that you can consult. Sometimes private institutions, such as hospitals, have an IRB. A list of international research ethics committees and IRBs can be found in *Resources* at the end of this unit.

Your funding source(s) often influence or determine which IRBs or ethics committees will oversee your research. For example, if an investigator is awarded a grant from the United States National Institutes of Health (NIH) for a study being conducted at your project site abroad, the terms of the award will probably stipulate that you obtain IRB approval from several entities, including IRBs at the hospital, university, or other affiliated institution(s) where the research funding is allocated and an in-country equivalent at the national level (if one exists).

PIH NOTE

Before Haiti had a ministry-level IRB, Zanmi Lasante formed one on its own, following U.S. government standards. Doctors, anthropologists, a bioethicist, a psychologist/priest, researchers, and public health specialists have served on the ethics committee of the site in Haiti for several years. The impetus to create an official IRB recognized by the U.S. government (called a Federalwide Assurance) came when PIH was granted funding for a National Institutes of Health (NIH) study that would take place at the Haiti site. The process for forming such an IRB involves completing a form, available on the Office for Human Research Protections website, to request approval as an IRB. Because we had taken care to create an IRB and follow its recommendations, the NIH, as well as the international community, had assurance that our published research had been held to standards consistent with U.S. regulations.

6.2 *Human subjects training*

Any study personnel directly interacting with human subjects and their identifiable specimens or data must complete human subjects training before the study begins. Staff who conduct interviews with participants must be trained in informed consent. Training interviewers on obtaining informed consent can help avoid misunderstandings by participants about the study or about potentially serious consequences of participation. For information on research ethics training in different languages online, see *Resources* at the end of this unit.

PIH NOTE

Zanmi Lasante has held training sessions for doctors and nurses specifically on research study design and ethics. We adapted human subjects training modules from a U.S.-based university's website to meet the needs of our Haitian colleagues; our adaptation included translating the contents into French and Creole. The training emphasized informed consent, the history of biomedical ethics, the principles behind research ethics, and designing research studies to protect study participants. A separate training session was then held for data clerks and focused on the ethics of data entry, particularly confidentiality.

7. SHARING RESULTS

Once your research is complete, it is the responsibility of the PI and the organization hosting the research to disseminate results through the appropriate channels to the right groups in the appropriate order. Some important questions to ask when planning to share your results include:

Figure 13: Socios En Salud provides information to the university community on ways to prevent the spread of TB at the "2011 Healthy Universities Campaign" in Lima
Photo: Socios En Salud

- **What:** What is the impact you hope to make through disseminating your findings?
- **Who:** Who is responsible for the execution of the dissemination plan to the appropriate parties? Which populations will be affected by the study results?
- **When:** When do different stakeholders receive study results?
- **How:** Through which avenues will you reach these populations to make them aware of these results?

Should the study close prematurely because of unexpected events, appropriate stakeholders will have to be notified, even though you will lack any results to share. Failing to disseminate your results to key stakeholders can have major negative ramifications. If you do not inform donors of your results (whether successful or not), for example, your funders may believe the money was spent elsewhere, and they will not renew the funding. Likewise, study participants will be less likely to participate in the next study if they do not understand the justification for the first one. Disseminating your results well allows community members to see the value of your research. This, in turn, increases community support for and trust in your organization. When results—even preliminary ones—are shared with MOH, the ministry is more likely to collaborate with your organization to improve the health of its people.

7.1 *Publishing your findings*

Publishing your findings, if they are valid, is the best way to disseminate them to the broader research community. Publication of the latest scientific and medical research in a form that will carry the most weight with research and funding communities is usually limited to competitive academic peer-reviewed journals in the relevant specialty, such as medicine, public health, anthropology, or health policy. Most of the journals that have the greatest influence on their field are available online through their publisher's website or through large information clearinghouses. Some of these journals are listed in *Resources* at the end of this unit. Online access may be restricted to subscribers, but most medical schools and research universities purchase a license that allows them to offer free online access to their faculty and staff. If staff members at your organization have academic affiliations, they may have free access to these scientific and medical journals that would otherwise require a license, subscription, or fee. (See *Section 7.3, Open access journals*, in this unit.)

TIP: *Supporting local investigators in submitting first authorship of research articles helps to advance their academic careers and build local capacity. When local staff are given documented credit for making a major contribution to the work and taking a lead in the writing, they are more likely to receive research funding in the future, as well as participate in academic conferences and meetings.*

Research papers compete for publication in highly respected, peer-reviewed journals. To increase your chances of getting your research published, consider your intended message and your audience, and use the appropriate format. If you are submitting a research article for publication for the first time, work with someone who has had experience with this process. Many researchers have valid information, but they do not know how to convey it in a format that is acceptable for publication in a journal or accessible to the readership. Your paper needs to be clear, well-organized, and written in one of the journal's preferred languages (usually English, French, Spanish, or German; some journals will publish manuscripts in more than one language). Your narrative and your data must convince the peer reviewers, expert readers who will evaluate it and will advise the editors on whether it should be accepted, rejected, or revised and resubmitted for another round of review (described further below).

Some common formats for presenting your research include:

Reports of original data: Published reports of original research are the backbone of medical and scientific communications. These typically follow what is called the AIMRD format—**A**bstract, **I**ntroduction, **M**ethods, **R**esults, **D**iscussion. Your abstract will be extremely important. In electronic database searches, readers often scan only the title and abstract, deciding from the abstract whether to read or download the article. Abstracts are usually freely available online even for journals that restrict the longer, full-text access to fee-based subscribers.

Letters to the editor: These letters are an essential aspect of post-publication review. The International Committee of Medical Editors recommends that all biomedical journals provide a mechanism for submitting comments, questions, or criticisms about published

articles. Letters to the editor are usually in the form of correspondence or a column. The authors of articles discussed in the correspondence should be given an opportunity to respond, preferably in the same issue in which the article appears. Published letters comment on an article previously published in the same journal, and replies from authors of the article make for lively and useful exchanges.

7.2 *Peer review*

If you intend to publish your research in a peer-reviewed journal, you will have to follow specific guidelines for writing and submission. Peer-reviewed literature includes works of original research that has been accepted by academic and professional peers for dissemination and discussion. The term peer review refers to the process of screening scholarly writing before it is approved for publication. Review panels that include researchers and scholars evaluate material according to certain criteria, such as the work's significance and the methodology that the investigator uses. Approval for publication does not necessarily mean that the research findings are true, but it does mean that the findings have been reviewed by other researchers who are knowledgeable in the field under consideration. Journal articles, which represent the latest empirical findings, statistical analysis, and theoretical debate within the discipline, are examples of peer-reviewed literature. Some dissertations and some academic books also fall under this category.

TIP: *If you submit an article to a journal and receive feedback from a reviewer to revise and resubmit, be sure to do so. Respond to every point, one by one, in a cover letter, and if you do not take the reviewer's particular suggestion, be sure to explain why. Responding appropriately will help your case when resubmitting.*

7.3 *Open access journals*

Open access publishers provide free online access to view, download, copy, distribute, and use (usually with attribution) peer-reviewed scientific and medical journal articles. The content is searchable and readily available without restriction, thereby promoting increased impact of the research. The United States government has now required that any research study that has been performed using National Institutes of Health (NIH) funding be freely accessible online, even if the journal itself does not offer open access. Although it is widely debated whether open access journals are on par with the prestigious, top-tier scientific and medical journals, open access journals are particularly important in resource-poor settings because they give more health providers access to the latest scientific evidence on which to base their interventions. PIH therefore supports the concept behind open access scientific and scholarly journals.

The Public Library of Science (PLoS) is an example of a major open access publisher that makes scientific and medical journals a free public resource. PLoS journals charge a publication fee to the authors or research sponsors for each article they publish in order to recover part of their costs of providing open access, including those of peer review editing, journal publication, and online hosting and archiving. Authors who are affiliated with one of

PLoS's institutional members are eligible for a discount. These journals offer a complete or partial fee waiver for authors who do not have funds to cover publication fees. Editors and reviewers do not have access to payment information, so inability to pay does not influence the decision to publish a paper.

CONCLUSION

Using evidence-based research to inform your interventions can improve the health and well-being of your patients and the community. Careful planning should precede the decision to conduct a formal research study. If your organization does not have the capacity for a formal study, a small pilot study or collaboration with another institution that is leading a study can help establish the foundation for your organization's future research. An additional benefit of partnering with a local university or medical institution is that it can give local staff an opportunity to acquire additional skills in research methods. Doing so may also afford your organization access to infrastructure, technical assistance, and ethical and administrative oversight required for the study.

Unit 13

Resources

WORKS CITED

Family Health International. (2001). Introduction. In *Strategies for an expanded and comprehensive response to a national HIV/AIDS epidemic.* Arlington, VA: Family Health International.

Mitnick, C. et al. (2003). Community-based therapy for multidrug-resistant tuberculosis in Lima, Peru. *New England Journal of Medicine,* 348(2):119–28.

SELECTED RESOURCES

Developing a Research Plan

Community Tool Box. (2010). *How to conduct research: An overview.* Work Group for Community Health and Development, University of Kansas.
http://ctb.ku.edu/en/tablecontents/sub_section_main_1210.aspx
The Community Tool Box is a global resource for free information on essential skills for building healthy communities. It offers more than 7,000 pages of practical guidance in creating change and improvement.

Research Toolkit (The PRIMER Project). *Better Tools For Multi-Site Research*.
http://researchtoolkit.org/
This free online resource, created as part of the PRIMER project, is a five-part toolkit organized by phases of multi-site, community-university research, from phase-in to close out.

Research Methodology

Bernard, H. R. (2000). **Social research methods: Qualitative and quantitative approaches**. Thousand Oaks, California, Sage Publications, Inc.
This text provides an introduction to both qualitative and quantitative approaches to social research, emphasizing the benefits of combining various approaches.

Managing Data

Introduction to SAS, STATA and SPSS. UCLA: Academic Technology Services, Statistical Consulting Group.
http://www.ats.ucla.edu/stat/
ATS Statistical Consulting Group at UCLA provides a user-friendly site to teach yourself STATA, SPSS, and SAS with step-by-step directions and annotations to commands.

Mamlin, B.W., Biondich, P.G., Wolfe, B.A., Fraser, H., Jazayer, D., Allen, C., Miranda, J., & Tierney, W.M. (2006). **Cooking up an open source EMR for developing countries: OpenMRS—A recipe for successful collaboration**. AMIA Annual Symposium Proceedings 2006; 2006:529–33.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1839638/
This article describes the OpenMRS system, an open source, collaborative effort that can serve as a foundation for EMR development in developing countries. Included is the progress to date, lessons learned, and future directions.

Open Epi (Epi Info Open Source)
http://www.openepi.com
OpenEpi is a free, open-source software for epidemiologic statistics. It can be run from an Internet web-based server or downloaded and run without a web connection.

Research Ethics

Council for International Organizations of Medical Sciences (CIOMS). (2008). **International ethical guidelines for biomedical research involving human subjects**. Geneva: Council for International Organizations of Medical Sciences.
This is a series of international ethical guidelines for biomedical research involving human subjects issued by the CIOMS since 1982.

Farmer, P. & Campos, N.G. (2004). **Rethinking medical ethics: A view from below**. *Developing World Bioethics*, *4*(1):17–41.
Drawing on experience with infectious diseases in some of the poorest countries, this paper argues that a lack of access to modern medicine and the science that informs it is an important and neglected topic within bioethics and medical ethics as most are treatable with already available therapies.

Farmer, P. (2002). **Can transnational research be ethical in the developing world?** *Lancet*, *360*(1):266.
The article examines the task of ensuring that positive gains from research conducted in developing countries benefit the study population, not just the affluent and the organizations undertaking the study.

Marshal, P. (2007). **Ethical challenges to study design and informed consent for health research in resource-poor settings**. Special Programme for Research and Training in Tropical Diseases. Geneva: World Health Organization.
This is a review of the literature that explores relevant social, cultural, and ethical issues in the conduct of biomedical and social health research in developing countries. Ten case vignettes illustrate ethical challenges that arise in international research with culturally diverse populations.

Rivera, R. & Borasky, D. (2001). **Family Health International research ethics training curricula**. 2nd ed. Research Triangle Park, NC: Family Health International.
http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm
The goal of these curricula is to help researchers learn about the development and philosophy of ethics and how to apply ethical principals in a practical way.

Research Funding

The Foundation Center
http://foundationcenter.org/
The Foundation Center is a database of philanthropic activities designed to connect nonprofit organizations to funders in an organized network.

John E. Fogarty International Center
http://www.fic.nih.gov/
The Center supports the U.S. National Institutes of Health by promoting global health through research abroad.

Johns Hopkins Center for Global Health
http://www.hopkinsglobalhealth.org/
The Resources section of this website contains a listing of various funding opportunities, including fellowships, awards, and scholarships, as well as links to external funding sources.

Publishing Your Research

Provenzale, J.M. (2007) **Ten principles to improve the likelihood of publication of a scientific manuscript.** *American Journal of Roentgenology*, *188*(5):1179.
http://www.ajronline.org.ezp-prod1.hul.harvard.edu/cgi/content/full/188/5/1179
The objective of this article is to discuss the reasons that manuscripts fail to be published and to establish some principles for increasing the likelihood of publication.

Wagner, E. (2005). **Getting research published: An A to Z of publication strategy**. Oxon, UK: Radcliffe.
This is a step-by-step guide to the publishing process.

Dissemination of Results

Fernadez-Pena, J.R., Moore, L., Goldstein, E., Decarlo, P., Grinstead, O., Hunt, C., Bao, D. & Wilson, H. (2008). **Making sure research is used: Community-generated recommendations for disseminating research**. *Progressive Community Health Partnership*, *2*(2):171–6.
The Community Advisory Board of the University of California, San Francisco, Center for AIDS Prevention Studies developed this set of guidelines and dissemination strategies to support researchers' intentions to disseminate their findings through nontraditional venues.

Robinson, E.T., Baron, D., Heise, L.L., Moffett, J., & Harlan, S.V. (2010). **Communications handbook for clinical trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results.** Research Triangle Park, NC: Family Health International.
http://www.mmci-communications.org/resources/communications-handbook-for-clinical-trials/CommunicationsHandbookFull.pdf/
This handbook provides guidance to clinical trial staff and research partners on how to anticipate and respond to the special communications challenges posed by conducting clinical research.

Vandenbroucke, J.P., von Elm, E., Altman, D.G., Gotzsche, P.C., Mulrow, C.D., Pocock, S.J., Poole, C, Schlesselman, J.J. & Egger, M. for the STROBE Initiative (2007). **Strengthening the reporting of observational studies in epidemiology (STROBE): Explanation and elaboration**. *PLoS Med*, *4*(10):e297. *http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040297*
The STROBE Statement provides guidance to authors about how to improve the reporting of observational studies and facilitates critical appraisal and interpretation of studies by reviewers, journal editors, and readers. It consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results, and discussion sections of articles.

Peer-reviewed Literature

BioMed Central
http://www.biomedcentral.com/browse/journals/
All original research articles published by BioMed Central are made freely and permanently accessible online immediately upon publication.

Directory of Open Access Journals
http://www.doaj.org/
The aim of the Directory of Open Access Journals is to increase the visibility and ease of use of open access scientific and scholarly journals thereby promoting their increased usage and impact.

HINARI
http://www.who.int/hinari/about/en/
The Programme for Access to Health Research (HINARI) provides free or very low cost online access to the major journals in biomedical and related social sciences to local, not-for-profit institutions in developing countries.

PLoS
http://www.plos.org/
PLoS is a nonprofit organization of scientists and physicians committed to making the world's scientific and medical literature a freely available public resource.

PubMed Central
http://www.ncbi.nlm.nih.gov/pmc/
PubMed Central (PMC) is the U.S. National Institutes of Health (NIH) free digital archive of biomedical and life sciences journal literature.