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Navigating across international borders: a guide to research in low and middle-income countries for first-timers

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Abstract

Pharmacy students and residents who become involved in research in low and middle-income countries should be aware of potential challenges that may occur when working in these settings. This article aims to describe logistical and ethical issues associated with conducting research in low and middle-income countries (LMIC) and provides recommendations for individuals who are planning to develop and implement a research project in a LMIC. Recommended planning should involve engagement of local stakeholders where the project will take place, researching and contacting an ethical review board prior to submission, and maintaining flexibility when considering issues that occur on the ground. Anecdotal information is provided to enlighten researchers about potential issues they may encounter. Using the suggested tips as a guide will help to ensure that a successful research project and positive learning experience occur.

Keywords: *Global Health, Research, Low and Middle-Income Countries*

Introduction

Globalisation enables transnational research and increases student demand for international educational experiences. In particular, a growing number of pharmacy students and residents are seeking opportunities to develop knowledge and skills in global health. Though many opportunities exist in developing countries such as short-term and mission-based learning, students and residents also look to research in global health as a way to obtain experience and skills internationally. Further, United States (U.S.) colleges and universities are collaborating with institutions globally to develop pharmacy practice within low-resource settings (AACP Global Pharmacy Report, 2011; Oji *et al.*, 2013; HIV/AIDS Twinning Centre, 2015). While these partnerships allow for untold opportunities to develop infrastructure, improve systems, and create best practices, the feasibility of conducting research in low and middle-income countries (LMICs) is challenged by limited resources and poorly developed health systems, further obviating the potential to translate research findings into practice (Cooke, 2009).

This commentary outlines some of the logistical and ethical issues associated with conducting research in LMICs from the perspective of Western researchers. We will highlight the lessons learned from our experiences to help guide future clinicians and researchers when conducting research in these settings. To illustrate these challenges we will present examples from a pilot research study conducted at a government hospital in Malawi (Table I) (Kauffman *et al.*, 2014).

Planning Your Research

Start with the end in mind

When you begin planning your research project, consider what you are ultimately trying to achieve. Evaluate your own motivations for completing the project. Determine if there is an established relationship with the site and plan to engage local partners in your community. Specifically, how and what will the research contribute to the current state of knowledge? Did the site request this project to be completed? Will the project results be useful for the site? If so, how? How will you disseminate learned information to the local community? Is there a commitment to change based on the results of the project? Who is best suited to work on such a project? Will this project take resources away from other necessary programs? If your research will work against local needs and resources, perhaps it is better to conduct a different project or no project at all.

Plan, plan, and plan some more

Next, you will have to consider what you will need to bring this project to fruition. Think about all of the resources that you will need to make the project a success and identify a plan to obtain each of those resources. Will you need to obtain extramural funding to support your project? What organisations are available to assist with funding? Consider foundations, internal scholarships, or mini-grants. Even something simple such as identifying sources of funding to support travel can be a challenge for

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small projects, but research projects often need to start as a pilot study to ensure appropriate risk mitigation. As a learner, consider your time and travel an investment in both your future and the site.

Plan the project implementation in your head and on paper. Go through each step and consider everything you need to make the project happen. Review this more than once and ask for advice. Evaluate whether these resources will be available onsite or if you will need to bring them. When conducting research in a setting with limited access to resources, creating a checklist to ensure you have all of the supplies that you need will help to minimise logistical complications.

Another related aspect to consider is data collection. Methods for collecting data may be challenging in an international setting, especially when accessibility to comprehensive documentation is limited. Developing an efficient data collection tool is critical to facilitating the process of data extraction. As methods of documentation vary from site to site, it is helpful to pilot the research tools prior to going onsite. While you may not be able to pilot the form in the local setting before you arrive, you should have someone familiar with the site review and comment on your form. If you have established partners in the setting, it may be possible for them to pilot the form and provide feedback. Perhaps your data will come from interviews with individuals or groups. Practice your interviewing technique before you arrive to make the most of your time on the ground. Be sure that batteries and chargers will work for recording your data if you plan to use recordings. The concept of 'safari research', in which the researcher from a developed country visits a developing country merely to collect samples or data to be studied elsewhere, is ethically unacceptable.

Engaging Local Stakeholders Before and After You Arrive

Research needs to be responsive to community needs and national priorities (Kass, 2001; Nuffield Council on Bioethics, 2002). While time-intensive and challenging to implement, it is critically important not to overlook local communities in the development of aims and hypotheses and subsequent application of results. The researcher(s) should work collaboratively with local partners to optimise the strengths of each and seek to build their capacity (*i.e.* a collaborative partnership) (Nuffield Council on Bioethics, 2002). Researchers have an ethical obligation to build capacity for local research by

Table I: Insider's Perspective on Research in Malawi

Planning Your Research
In retrospect, I wish I had printed my data collection sheets prior to arriving in Malawi. Accessing a functioning printer was quite difficult, however, since I brought a laptop, I was still able to record data and password-protect my documents. Balancing the potential risk that my computer could be stolen with the possibility of not completing my data collection was a concern, but I took proper precautions and had no issues. This has definitely taught me to plan in advance about the resources and supplies that I will need so that future projects will run more smoothly.
Engaging Local Stakeholders
I engaged with local stakeholders after I arrived in Malawi. I befriended a pharmacist who helped me navigate the hospital and identify additional potential stakeholders. Additionally, I developed a relationship with a hospital administrator who recruited the clerks on the floor to help me identify the data I needed.
Ethical Approval
For our study, the U.S. and Malawi both required ethical approval. I contacted the U.S. IRB prior to submitting the application in order to ensure that I was following their procedures for international projects. Speaking with an IRB committee member firsthand about specific language that should be included helped avoid unnecessary pitfalls. Consequently, acquiring approval from the U.S. IRB occurred seamlessly. On the other hand, the Malawi IRB initially rejected the study application due to insufficient background material, which seemed odd to me since it wasn't a problem with my local IRB. The submission process was challenging to navigate. The application required hand delivery to the IRB office in order to reduce the likelihood of it getting lost in the mail. When I arrived in Malawi, I learned that the application was rejected. While there, I revised the application, and then asked an individual with local IRB experience to review the application. Once the new application was finalised, I hand-delivered the application and subsequently the application gained approval. Plan for everything to take longer than you would anticipate.
Issues on the Ground
Our experience at a government hospital in Malawi revealed that the majority of reviewed medical records were missing valuable data - such as a patient's medication administration record, laboratory results, and progress notes. Keep in mind that documentation requirements may differ significantly from the U.S and standardised processes for medical documentation vary in many clinical settings. While limited documentation is not a challenge unique to this setting, it doesn't mean that it isn't frustrating. As a result, I excluded many patient charts, significantly reducing the sample size and potentially the generalisability of the data. In addition, be prepared to have difficulty reading hand-written notes and charts. I learned quickly to not be afraid to ask for help interpreting records. Doing a retrospective was clearly not optimal, but given time and resources, it made the most sense at the time.
Sharing Information with Local Leaders
The results of the first study were published and the information was shared with the pharmacist at the Malawian hospital. After the initial project was completed, an additional research study investigating the incidence ADRs was initiated at the same hospital. Unfortunately, due to the prospective nature of the study, ethical review board challenges ensued.

supporting community members in conducting research in their own setting, so that the local team can continue to investigate questions without the need for Western partners. Cost-effective and sustainable training models about ethics are needed and outside researchers should consider sharing their resources with local team members (Butta, 2002).

The process of implementing a research project should involve local stakeholders to engender commitment and ensure that local issues are considered from multiple perspectives (Bastida *et al.*, 2010). Stakeholders to consider include: policy-makers, technical experts, representatives from the ministry of health and schools of health sciences, health care providers, and community laypersons of other key groups, such as nongovernmental organisations (Benatar & Fleischer, 2007). If any one of these groups are not involved in the design, the final program may fail to address a meaningful outcome and may not address the needs of the beneficiary community. The goal is to create an environment where decisions about how to proceed within a local context are made collectively. Remembering that local collaborators are experts in their community is essential. Engaging and involving local stakeholders, who represent the interests of the intended community members, will result in a feasible project with outcomes that are sustainable and relevant to the needs of the region.

Ethical Approval

An overview of research ethics

Global atrocities conducted under the guise of medical research dictated the need for a global code of conduct for human research (Lurie & Wolfe, 1999). We urge all students and residents interested in conducting research overseas to review the recommended readings in order to understand the history of injustice performed in the name of science. Regulation and oversight of internationally sponsored research are under review by the U.S. and other agencies following subsequent debate about the appropriate methods for conducting international health research (Angel, 1997).

Some LMICs are developing ethical guidelines to facilitate the ethical conduct of research locally (McIntosh *et al.*, 2008). Others currently lack the capacity to develop local guidelines or deem local guidelines unnecessary given the myriad of international guidelines [*e.g.* Helsinki declaration, the Council for International Organisations of Medical Sciences (CIOMS) guidelines]. Preferences for who participates in research ethics committees in some countries varies – some countries consider it an advantage to have a majority of members in a research ethics committee who are not professionals in the various fields covered by research. Their primary role is to reflect the values of the local communities and the local and national culture. There are often a limited number of people available who have time and knowledge and skills needed to act as an effective member of a research ethics committee. The few who are well trained may be recruited by nongovernmental organisation or international health agencies, further reducing the expertise available for other national research priorities.

Consequently, since many research ethics committees in LMICs countries have a rapid turnover of staff, training programs for committee members may be needed to ensure that needs are met. As U.S.-based researchers, it is essential to comply with the U.S. Code of Federal Regulations and local requirements for any research conducted. The primary issue is often striking a balance between application of guidelines to protect individuals and their rights while addressing broader public health issues to improve community health. Other considerations should be made to ensure that the research is not exploitative. Particularly, stopping treatment and care, once a prospective study is over, has been criticised as exploitation of individuals who have limited access to health care resources as they are usually not in a position to negotiate for better care at the termination of a study.

Obtaining ethical approval

You should determine if a project will need approval by one or more ethics committees (e.g. Institutional Review Board [IRB]) early in your project planning. While this process can be challenging and time consuming, it is the researchers' responsibility to ensure the protection of human subjects (and is essential if the work is to be disseminated broadly through publication). The types of ethical review and approval vary between institutions. Most IRBs will also require site permission letters for completing research outside of their institution. Supplementary reviews by local community councils, nongovernmental organisation, or ministries of health may be appropriate to maintain the collaborative nature of the research. The community should determine whether the risk to benefit ratio is acceptable.

We encourage you to consider all participants in human subject research in LMICs to be part of a vulnerable population even if the IRB does not always require this classification. Local experience with research may be limited; therefore, research participants may be uncomfortable advocating for their rights. In addition, differences in language and traditions can make the informed consent process more complicated. Consent from village elders or heads of household may be required before researchers can invite individuals to participate. Consent forms should be concise and provide clear information on the risks and rights to decline participation. In some cases, asking someone to provide written informed consent is culturally inappropriate. Alternative solutions include using a tape recording or written documentation of verbal consent (Emanuel *et al.*, 2004). When addressing literacy problems, researchers are encouraged to present slides or pictures that are short and simple (Bastida *et al.*, 2010). Be mindful of who is requesting consent. Would the participant feel comfortable or safe declining participation? If not, who would be better suited to obtain consent? Care should be taken to ensure that the interests of women and members

of vulnerable populations are properly addressed by research ethics committees. In male-dominated cultures, it may be necessary for a woman to ask for permission from a male family member prior to making a decision that affects her or her family. It is necessary to ensure accurate and meaningful translation of documents so that individuals understand informed consent if it is needed for the project. Certain concepts and phrases often do not exist or are interpreted differently in non-Western cultures. Researchers should be aware and respectful of these considerations.

It is common to question whether your project should be considered quality improvement (QI) or research. Keep the definition of research clear – "A systematic investigation, including research development, testing and evaluations, designed to develop or contribute to generalisable knowledge" [45 CFR 46.102(d)]. There can be a fine line between the two, but it is better to err on the side of individual rights and safety. In addition, consider whether the definition of quality improvement differs in the country in which you are conducting your project. Is there a mechanism for approval as a quality improvement project? If not, consider if there is an expectation for your project to be submitted for ethical review.

Issues on the Ground

All experiences must be approached with flexibility and adaptability. Expect that your project will not go accordingly to plan and your rollout likely will not happen seamlessly. Flexibility is a key attitude and skill of global health researchers. Depending on your project, you may experience a variety of barriers that may hinder any step along the way. Do not despair, but continue to move forward with perseverance. Prepare creative solutions to address each possible barrier. Relationships built with local staff will make success of the project more likely.

Sharing Information with Local Leaders

Consider who might use the results of the study to make policy or to reform programs. Sharing the results of your research project with local leaders is a key step to demonstrating the value of the project and showing why their support is needed. Consideration for how the research will impact future health care or prevention of disease in the community should be included. It demonstrates the value of research and how it can be used in a positive way to discover what works and what does not work in their community. Disclosing results creates new opportunities for future research and collaboration. However, it is important to be cautious of how they are presented. For example, accusatory and blaming tones can lead to frustration and misunderstanding among community and government officials. Recognise that change may be slow and that this does not reflect negatively on the value of your project. In addition to sharing this information via written report and verbal presentation, researchers have an obligation to answer questions that participants or other community members may have about the implications of their findings. Conducting a public meeting is preferred and if not performed, particularly in the conduct of clinical trials, participants may be unwilling to participate in subsequent research studies.

Recommendations

We recommend the following steps ensure the success of your project.

- Contact your local IRB prior to planning your research.
- Be sensitive to cultural differences between U.S. and low and middle-income countries.
- Engage local stakeholders during the project planning.
- Develop a network of local people in the community to become your advocates and train them to assist you.
- Be patient and flexible in your planning.

By taking these tips and advice into account when developing and implementing a research project in a LMIC, we are confident you and your partners will have a positive learning experience that will lead to improvements health in the local context. Best of luck in your work!

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