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Addressing the Challenges of Conducting Research in Developing Countries

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Abstract

Purpose—To explore the unique challenges that occur when conducting research in developing countries so the reader can consider approaches for providing ethically and culturally-appropriate research strategies applicable for the context of the host country.

Organizing Construct—This article presents an overview of the challenges, which are organized based on the phases of the research period: pre-enrollment, enrollment, and post-enrollment. At each stage, examples of adaptation to meet the challenges are presented and recommendations are posited.

Conclusions—Strategies for research should protect the rights of the most vulnerable and disadvantaged populations while balancing the needs of society at-large, provide culturally relevant ethical informed consent while balancing institutional review board requirements, and conduct research in a culturally-appropriate manner for the host country while balancing the principles of ethical research established by developed countries.

Clinical Relevance—Researchers are implored to focus on the ethical and cultural appropriateness of each aspect of the study process to afford the highest level of research credibility and validity.

Keywords

cultural issues; international health; ethical issues; research trends

Research should be conducted in a manner that is appropriate for the unique community and the culture of the proposed research site. While this may seem straightforward, significant challenges have been encountered when conducting research in developing countries where cultural perspectives often vary significantly from those of developed countries. These challenges include: protecting the rights of the most vulnerable and disadvantaged populations while balancing the needs of the many (Stapleton, Schröder-Bäck, Laaser,

Meershoek, & Popa, 2014), providing a relevant informed consent that is truly appropriate for the culture of study while balancing an institutional review board's set of rules, and conducting research in a culturally-appropriate manner for the host country while balancing the principles of ethical research established by developed countries (Igoumenidis & Zyga, 2011). Beneficence, justice, and respect for the rights of each human being should be expressed throughout the research plan. Ethical research can only be conducted when the unique circumstances and constraints of the host country are considered and the standards of research are upheld, yet adapted, to address these needs.

One might question, why should we conduct research in developing countries? Many developing countries have insufficient resources or a weak infrastructure to support their own research (Igoumenidis & Zyga, 2011). The Global Forum for Health Research reports that only 10% of research funding is spent on 90% of the world's health problems; therefore using funds from developed countries to address health disparities in the lesser developed countries is appropriate to reduce the inequality that exists (Bhutta, 2002). Constituents of the United States (US) or other developed countries might question the exportation of research dollars to other countries. The National Institutes of Health (NIH) support research outside the US when the research has the potential to impact global health issues that affect many countries. Indigenous knowledge may hold keys to scientific advances. Also, the incidence of specific diseases may not be high in the US or other developed countries and therefore no longer a developed-world focus. Researchers must travel to the geographical regions where the diseases are more prevalent and those suffering are in continued need of care. For example, diarrhea remains the second leading cause of mortality for children under the age of five worldwide (Bulled, Singer, & Dillingham, 2014), yet this is a health concern found primarily in developing countries. According to the Centers for Disease Control and Prevention (2014), malaria remains a leading cause of illness and death in developing countries. Clearly, the staggering rates of these diseases warrant further research to reduce mortalities.

The majority of published literature related to conducting research in developing countries is currently written by ethicists. Normative global health ethics seeks to identify "wrongdoings" and readdress those issues in an ethical manner which is appropriate to "specific circumstances and constraints" (Stapleton et al., 2014). In consideration of this ethical framework, nursing must take a pro-active stance and join the conversation in order to lead health initiatives on a global front in a more ethical manner.

Researchers commonly initiate research studies with the best intentions. Unfortunately a lack of understanding by the researchers of the social determinants of health and the unique cultural factors of the community inhibit attempts to attain successful outcomes. A systematic review of 27 studies focusing on improving patient knowledge of informed consent found evidence of comprehension issues related to the meaning of randomization, placebo, benefits, and risks (Montalvo & Larson, 2014). Of the 27 studies, three were conducted outside the US and reported a lack of understanding related to terminology in the presence of low literacy levels. During a community-directed treatment study for onchocerciasis (river blindness) in Tanzania, people failed to participate in the treatment due to a lack of understanding about the cause of the disease, the benefit of the medication, and

fears of sterility and impotence that might be associated with the medication (York, Kabole, Mrisho, Berry, & Schmidt, 2014). Consideration of the low literacy levels in this community and the availability of visual education materials would likely have improved the outcomes of the program. Also, the lack of education for the community-directed distributors of the medication played a pivotal role in the less-than-optimal implementation of the program.

The Declaration of Helsinki, established in 1964, provides guidance on ethical issues in research; however, it offers little guidance to address specific issues that arise when conducting research in developing countries (Bhutta, 2002). This document was originally intended for use by physicians conducting biomedical research and suggests a portion of participants be assigned to a control group. The participants in the control group may receive a placebo; therefore they are not always provided the best treatment. For example, clinical trials regarding the use of zidovudine, in developing countries in 1994, deemed the drug too expensive for developing countries; thus placebos were used in one arm of the study. Clearly, the participants who were placed in the placebo group (participants received no treatment) were not provided with the best treatment. This led to ethical questions about the research associated with preventing mother-to-child transmission of HIV in developing countries (Bhutta, 2002). A great debate exists about what is “ethical” care that should be provided, both during and after the study. What should be provided: the standard of care for a developed country or the standard of care in the host country? Can the host country afford to provide the best care? What happens after the research is over? Can a level of best care be maintained? An updated version of the Declaration in 2008, continues to fuel the debate. The declaration continues to support the use of placebos when no effective treatment is available or there are compelling reasons to support the use of the placebo *and* participants will not be subject to any serious harm. According to Bhutta (2002), it is important to develop a research plan with health interventions that will be available and can be sustained in the host country.

These issues and questions provide a small glimpse of the challenges associated with research in developing countries. The following sections address specific challenges from published literature, as well as the encounters of two experienced researchers working with indigenous populations in the developing countries of Guatemala and Kenya. The following challenges and recommendations are organized based on the phases of the research periods: pre-enrollment, enrollment, and post-enrollment (Woodsong & Abdool Karim, 2005).

Pre-enrollment Phase

The pre-enrollment phase involves determining how to convey the meaning and protocol of the research study, assessing the community for issues that may impact the research study, and demonstrating respect of the potential research participants (Woodsong & Abdool Karim, 2005). An ethical challenge for the professional conducting research in a cross-cultural environment, often within a vulnerable population, is to ensure “truly voluntary and fully informed” consent (Woodsong & Abdool Karim, 2005, p. 412). Challenges related to the informed consent protocol have been encountered in multiple and diverse studies worldwide. According to Igoumenidis and Zyga (2011), “informed consent is the cornerstone of modern ethics, but it tends to lose its true meaning when put in the context of

a developing country” (p. 247). Low education levels often affect the participant’s full understanding of what research entails (Stapleton et al., 2014). In sub-Saharan Africa, researchers participating in the HIV/AIDS Prevention Trials were challenged to find ways to develop informed consents that conveyed basic research concepts in a society where few participants had even the basic education levels to understand what is meant by “experiment” (Woodsong & Abdool Karim, 2005). Many Maasai in Kenya continue to live very traditional lifestyles in a predominately oral society, and have limited or no formal schooling (Strang & Mixer, 2015). While conducting research in Kenya, pre-enrollment involved the careful translation of the informed consent using forward and backward procedures along with community input; training of the translators about the research process and importance of fully informing the participants; and allowing a time for questions by the participant prior to each interview.

Other challenges related to the informed consent arise in diverse cultures. Informed consent is a process and requires community input, formal or informal, depending on the culture of the community. For many countries, autonomous decision-making is not a communal social structure concept (Woodsong & Abdool Karim, 2005). For example, in Maasailand, Kenya, research involvement required the overall, initial permission to be given by the area chief and Maasai elders for the villagers to participate (Strang & Mixer, 2015). When granted permission, the researcher was informed that individual consents were no longer needed. Word had traveled to the villages prior to the arrival of the researcher that they had permission to share their stories. In accordance with institutional review board (IRB) protocol, the procedure to garner individual consents was still fully followed. During a study in rural Guatemala, permission was sought from the *cocode* (local mayor and town council) prior to beginning focus groups or household surveys (Amerson, Hall-Clifford, Thompson, & Comninellas, 2015).

In some cases, informed consent may be more heavily focused on protecting the rights of the researchers from developed countries, and not the rights of participants. Based on the standards of the developed world, the informed consent may be lengthy; may include complicated concepts that are foreign to collectivistic cultures; and is often impractical in an oral society (Woodsong & Abdool Karim, 2005). The standard protocol for informed consent requires an explanation of the study, benefits, risks, incentives, privacy, confidentiality, and contact information for the researchers as well as the sponsoring university. The provision of contact information for the researcher’s IRB, which is located in a foreign country, for all practical purposes, is irrelevant for poor, non-technological communities and participants. In Guatemala, participants often consult their family members before giving their permission to participate in the research. The western concept of confidentiality often seems at odds with their family-oriented culture. Language differences create significant barriers for true informed consent. All words are not completely translatable into another language. Words such as “placebo” and “randomization” may not translate, if no equivalent word exists in the indigenous language (Woodsong & Abdool Karim, 2005). Researchers must consider these issues and balance them with the requirements of the IRB for their institution.

Gaining permission in a developing country with different social structures presents additional challenges. Commonly, patriarchal or matriarchal social structures may require non-research participants to give consent for others to participate. The process of gaining permission frequently is a lengthy process (Woodsong & Abdool Karim, 2005). In Massailand, this process required almost two years. The researcher visited the host country to gain gatekeeper permissions, hear potential community concerns about the research process, confirm interest in and need for the study topic within the community, and seek opportunities for pragmatic use of data gathered for the research participants or community at large (Strang & Mixer, 2015). Prior to the actual study date, this initial effort paved the way for an overwhelming response to participate in a large ethn nursing study of 48 participants from the Maasai community. In Guatemala, this process was reduced to approximately six months by the presence of an in-country host, who served as a liaison with the community (Amerson et al., 2015). This host, with a well-established reputation within the local community, facilitated meetings and introductions to gatekeepers of the village. Also, one of the researchers had been working in the community periodically for over 3 years.

Age of consent varies depending upon the host country and should also be considered in the context of the country of study. In Guatemala, the age of consent is 18. According to NIH guidelines, the age of consent is 21 years; thereby necessitating a waiver from the IRB to allow participants to provide their own consent (Amerson et al., 2015). Indigenous cultures may have alternative definitions of adulthood that do not fit with a chronological age. For example, marriage and motherhood may signify adulthood, while occurring far less than 18 years of age. Within the Maasai culture, it was important to seek the malaria care practices from all generations of malaria sufferers and care givers. To hear the full story, the researcher sought and was granted IRB approval for mothers and fathers age 14 and above (Strang & Mixer, 2015). Not only is age an important consideration, gender practices may influence how consent is given. In certain cultures, male consent must be given for females to participate (Woodsong & Abdool Karim, 2005). Many variations of the consent process must be considered prior to development of a culturally appropriate consent.

Opportunities to gather credible data are the responsibilities of all researchers. In the Maasailand study, villagers were very hesitant to participate in the interviews because as they stated researchers in the past had come, interviewed them, promised to return with information, but never had (Strang & Mixer, 2015). In addition to apologies that previous researchers had not kept their word, much time was spent with the leaders of the village to assure them the researcher would return with the study results and a training seminar on the topic of malaria care.

Enrollment Phase

Ethical considerations continue in the enrollment phase, the research period during which informed individuals agree to participate in the study. Often in a cross-cultural research study, a different language is used with which the research team is not completely familiar (Amerson et al., 2015; Strang & Mixer, 2015). Some have debated that the research team should be representative of the community and culture (Bhutta, 2002). This is not feasible in

many indigenous communities. Finding an indigenous member of the community with the required education levels, language skills, and expertise to conduct or lead the research may be highly improbable. In addition, the participants of an oral culture such as the Maasai do not often read. Ensuring comprehension of the study to each participant is critical, yet may not follow the standard IRB approach to confirm the best understanding. Because participants may find the consent process long and boring with untranslatable terms or concepts, consent should only include essential and relevant information. In countries with low formal education levels, non-readers or non-writers require the entire process to be oral. Consent forms that require a signature or mark from the participant often raise issues of mistrust, especially if the participant cannot read or write. In cultures with an oral tradition, a person's verbal consent is highly valued. As both authors have witnessed while conducting research, asking for a signature to confirm the contract may actually imply an insult to the individual's integrity.

Demonstration of comprehension is essential. Providing a verbal agreement for consent does not always ensure that participants are choosing to enroll for the appropriate reason. Research participants may be influenced by others within their community (i.e., community leaders) or by family members who urge them to participate (Woodsong & Abdool Karim, 2005). Participants may have unrealistic expectations of the benefits or risks. In Guatemala, potential community health workers were informed that minimal reading skills were required to participate as a *promotora* (promotor of health). Even when this was repeated daily, women continued to come to training sessions with less than adequate literacy skills (Amerson et al., 2015).

To assist in comprehension, incorporating community members into the research process is strongly supported by community-based research protocols, but this also can add challenges. Standard IRB protocols require members of a research team (i.e., anyone collecting data) to complete training on human research ethics. However, ethics training in the developed world is not always amendable in a developing world context (Opollo, Opolo, Gray, & Spies, 2014). Members of the community frequently also have low literacy skills and a lack of formal education.

Cultural practices sometimes conflict with the treatment and interventions of the study. Information about voluntary withdrawal must be balanced with acknowledgement of their value to the research program and encouragement not to withdraw. If too many people withdraw, then the research may be jeopardized. During HIV Prevention trials, researchers balanced the enrollment of women to the condom-only groups with the microbicide groups of the study (Woodsong & Abdool Karim, 2005). It was feared that women would withdraw from the condom-only group. Researchers in this study focused on the importance and value to the community of the participants' willingness to remain in the study.

Post-enrollment Phase

The post-enrollment phase is the timeframe when the study is underway and may extend past the actual period of research. This phase ensures continuation of the study and also entails its own unique challenges. If a study continues over a long period of time,

misunderstandings about the research and interventions may occur. Many Maasai informants requested clinics with malaria medicines and distribution of free insecticide treated nets (ITNs), but immediate fulfillment of these were outside the scope of the research study. It was important, during the study period of two months, to listen carefully and quell rumors that certain areas would receive such benefits. In Guatemala, rumors began to circulate that *promotoras* were being paid to provide education to families. This belief led to an expectation that families should also receive payment. In fact, *promotoras* only received a small quota of cell phone minutes in order to communicate with the researchers. Reasonable incentives for the culture, context, host country, and individual's time are important to reiterate during each stage of the research.

Some of the challenges of international research extend beyond the period of intervention. The information gathered and opportunities for care relevant to the data are often difficult to share because: (1) the researcher may have returned to their country to review and determine findings; (2) the cost to return to the research setting may not be included in the research funds; and (3) needed care related to research findings may not be affordable or accessible for the participants. The responsibility of the researcher to address the discoveries of needed professional care for the participants should also be considered prior to the onset of the study.

Recommendations

Each of these challenges, that are more commonly encountered in developing countries, need nurses to acknowledge the dilemmas that arise and promote ethical and culturally-appropriate research in order to fully protect every research participant. In a study conducted with registered nurses serving as research coordinators ($n=266$), scientific misconduct in the form of informed consent violations occurred in approximately a quarter (26.6%) of the research studies (Habermann, Broome, Pryor, & Ziner, 2010). The International Code of Ethics for Nurses (International Council of Nurses, 2012) includes the universal mandate for all nurses to uphold ethical practices, respect the cultural rights of each human being, and provide culturally appropriate information. The code is intended for application in every aspect of nursing practice, including research among vulnerable populations. Researchers can develop partnerships of accountability among international, regional, community, and local persons who share the topic of interest (Bhutta, 2002; Strang & Mixer, 2015). Prior to, during, and post research study; the primary researcher met with international, national, community, and local leaders for the fight against malaria to ensure relevance of study, and shared information, sought research needs, and brainstormed post-research resources for the Maasai community (Strang & Mixer, 2015). Researchers are further encouraged to consider Meleis's eight criteria for culturally competent scholarship throughout all phases of the research process. These criteria address contextuality, relevance, communication styles, awareness of identity and power differentials, disclosure, reciprocity, empowerment, and time (Jacobson, Lin-Lin, Pascucci, & Gaskins, 2005; Meleis, 1996). The authors, whose expertise is working in developing countries, make the following recommendations to conduct an ethical study. The recommendations support and expand upon the three phases outlined by Woodsong and Abdool Karim (2005) and support Meleis' guidelines for culturally competent research.

Pre-enrollment Phase

Externally-sponsored research should be reviewed by an independent reviewer from the host country in addition to the sponsoring country (McMillan and Conlon, 2004). Ethical research practices require an added layer of accountability when data is collected within a developing country (Igoumenidis & Zyga, 2011). Initially, the researcher should consider how best to offer cross-cultural care over the span of the study. This would include cultural and participant factors, such as the cultural context, education level, socio-economic status, and translation needs in relation to informed consent, translation needs, compensation, and benefits to the participants (Igoumenidis & Zyga, 2011; McMillan & Conlon, 2004; Strang & Mixer, 2015). To discover this information, formal and informal community leaders should be involved. This will enhance the overall understanding of the entire research process for both the researchers and the participating parties. Amerson et al. (2015) sought an external review with a non-governmental organization (NGO) working in Guatemala to ensure the protocol was appropriate for the cultural context. This type of input is essential to develop health care interventions which are culturally and economically suitable for the host country (Bhutta, 2002).

Advisory boards and focus groups should be established to represent the concerns of participants prior to enrollment (Woodsong & Abdool Karim, 2005). In Guatemala, meeting with the *cocode* allowed the researchers to seek permission to work in the community, but also to answer questions about the intent of the research and how the information would be used. Community representatives need to be involved in the decision-making process to clarify the types of activities that participants will engage in during the research. It is critically important that researchers make an effort to learn what the community wants and expects from the study prior to the initiation of enrollment procedures. Researchers and community members should agree in advance about the materials and/or interventions that will be shared as a result of the research (Bhutta, 2002). Also, anticipating common health problems that occur outside the parameters of the research protocol may prevent ethical scenarios associated with failure to provide treatment (Merritt, Taylor, & Mullany, 2010). For example, *promotoras* were trained to recognize and make referrals for children who were exhibiting signs of dehydration. While they did provide education, they also performed consultations for children with diarrhea (Amerson et al., 2015).

Researchers should consider the length of the consent and how to include all the necessary information to fulfill ethical standards in a concise manner while incorporating the cultural perspectives of the country. Maasai elders, community leaders, and others in the Maasai community-at-large were consulted by the researcher as to the relevance and cultural respect of the research inquiry guide (Strang & Mixer, 2015). This information was then used to construct important concepts of the informed consent. Researchers may choose to conduct a pilot study with the consent form to determine its usefulness in the target community (Woodsong & Abdool Karim, 2005).

To enhance communication and culturally appropriate interactions during the research period, the use of translators who are fluent in the languages used and an expert in the culture is important. Careful translation of the informed consent in the language of the

participants will enable the highest possible level of comprehension. Consideration prior to IRB approval is necessary to determine the need of a written or oral format for the informed consent. Researchers should consider avoiding the use of signed consent forms when possible. The need for an oral consent procedure should be anticipated during the pre-enrollment phase and researchers should gain an IRB waiver for a signed consent.

To best enable community members to assist in the pre-enrollment phase, to engage in the research process, and to enhance the comprehension of participants; training materials must be adapted to their culture, language, and education level. Materials available through the *Family Health International's Research Ethics Training Curriculum* provide an excellent starting point, but should be adapted to the specific community.

Enrollment Phase

Most developed countries' IRB policies are focused on the rights of the individual, yet this focus may conflict with the values of collectivistic cultures (Woodson & Abdool Karim, 2005). Informed consent should be provided in a manner that allows for the whole family to be involved when appropriate to the culture. If the consent is read to the participants, it is suggested to read each section then follow with a period of questions and answers before moving to the next section of the consent. Allowing interested family members sufficient time to ask questions and to be involved may be more consistent with the norms of the culture.

Community-based research occurs in homes and villages where arrival is public and members of the community at-large may view the research participant as getting special privileges (Merritt, Taylor, & Mullany, 2010). Research incentives may be viewed by others as special privileges; thus creating some level of animosity within close communities. It is essential to keep these cultural variations in mind when conducting research. Compensation and incentives should be relevant to the cultural context. In Maasailand, it was suggested by a Western researcher that each participant should receive an ITN as an incentive for a malaria study. However, the cost of an ITN was equivalent to the pay from three days of work and it had not yet been discovered if the Maasai communities had knowledge of the use or benefits of an ITN. It is often difficult to determine non-coercive compensation in a developing world context (Opollo et al., 2014). A pre-research visit to the Maasai culture revealed that an ITN was actually not a culturally appropriate incentive.

Health problems may be identified during the research study which will not be treated by the research intervention. It is important to foster relationships with local agencies or NGOs who can provide ancillary health care needs (Merritt et al., 2010). For example, some of the Maasai participants did not desire to talk about malaria, but about their current concerns for clean water or of the problem with bed bugs. It is important that the researcher is aware of the closest health care facility to each interview site, so to refer persons for assistance.

Post-enrollment Phase

Both during and following the study time frame, efforts to maintain cultural and ethical practices continue. Researchers should continuously check for rumors or misconceptions

that are occurring in the community that may affect enrollment (Woodsong & Abdool Karim, 2005). Participants may expect special privileges or incentives that were not anticipated or planned by the researchers. Ethics boards may limit incentives, yet communities may expect some type of incentives for their participation. Eventually, the products or knowledge gained from the research should be shared with the local community in addition to higher levels within the host country. Any product developed through the research efforts should be made available to participants in a reasonable manner (Bhutta, 2002). Following the completion of the research in Guatemala, the training materials were shared with the local health post and the regional office. The *promotoras* were urged to connect with the local clinic and continue to assist with training and consultations within the community.

Additional resources provide guidance for researchers working outside developed countries. *The Ethical Aspects of Clinical Research in Developing Countries* provides a framework of 8 principles to be considered when conducting research in a developing country (Emanuel, Wendler, Killen, & Grady, 2004). This report also provides 31 benchmarks to assist researchers to evaluate the ethical appropriateness of their study. A report by the Nuffield Council on Bioethics (2002) provides four principles to guide research in developing countries. These principles include: “(a) the duty to alleviate suffering; (b) the duty to show respect for persons; (c) the duty to be sensitive to cultural differences; and (d) the duty not to exploit the vulnerable” (2002) (p.2).

Finally, it is recommended that nurse researchers and educators provide mentorship and education that develops researchers who are prepared to face ethical dilemmas they may encounter in developing world contexts (Stapleton et al., 2014). Ethics training for an international researcher should be provided prior to any global health study, with a special awareness that good intentions may actually create harm in developing countries (Stapleton et al., 2014). Scientific misconduct is inexcusable, yet is highly suspected to still occur in research, including within the nursing profession. The ethical integrity of every nurse begins with education in ethics of conduct and should cover topics such as peer accountability, plagiarism, and data falsification (Fierz et al., 2014). Research integrity continues as mentors are consulted when unexpected dilemmas arise.

Conclusion

The intent of this article is to stimulate further discussion and thought about how international research should be conducted in an ethical manner within the cultural context of the host country. Researchers are implored to focus on the ethical and cultural appropriateness of each aspect of the study process to afford the highest level of research credibility and validity. Dialogue, mentorship, and co-mentorship among experienced and novice researchers can only benefit the parameters of ethical research and further best practices. Nurses must expand knowledge amongst themselves and others to shed light on the ethical and cultural implications of conducting research in a developing country using the standards of a developed world.

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Clinical Resources

- Family Health International's Research Ethics Training Curriculum - http://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/RETC2_Edition_Concise.swf
- The Ethical Aspects of Clinical Research in Developing Countries - <http://jid.oxfordjournals.org/content/189/5/930.full.pdf>
- The Ethics of Research Related to Healthcare in Developing Countries: A Guide to the Report - <http://nuffieldbioethics.org/wp-content/uploads/2014/07/HRRDC-short-Version-final.pdf>