Developing Cultural Competence and Overcoming Ethical Challenges in the Informed Consent Process: An Experience from Egypt

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Abstract

Research is conducted in a variety of cultural settings. Ethical standards developed in Europe and the Americas are increasingly applied in these settings, many of which are culturally different from the countries in which these standards originated. To overcome these cultural differences, investigators may be tempted to deviate from ethical standards. To suggest that, without such deviations, the contribution of these countries to medical science would be limited, is misguided.

The argument that research would be impossible without these deviations, which limit the contribution these countries make to medical sciences, is not accepted. To overcome these challenges, it is important for research administrators, managers and investigators to develop the cultural competence that enables them to establish recruitment and consent procedures consistent with cultural, political, and social practices. This paper presents some of the issues and challenges encountered in conducting research in Egypt. It is hoped that, by sharing these experiences, researchers and research administrators will gain insight into the design, implementation, and management of research in different cultural settings.

Keywords: Research ethics, ethical challenges, informed consent, developing countries, Egypt.

Introduction

Research activities are increasing in size, complexity, regulatory oversight, and cost, creating challenges and pressures on the research system. The ethical conduct of research related to health care in developing countries has been the subject of much recent discussion (Benatar & Singer, 2000; Lansang & Crawley, 2000; Bhutta, 2002; Caballero, 2002), particularly with the increase of research in these countries and the need to address their high burden of disease. Special challenges affect the conditions under which this research is conducted, such as sanitation, standards of care, and specific political, legal, and social contexts.

Wherever research is conducted, it must honor the autonomy and dignity of all persons, and fulfill the principles of respect for persons, beneficence, and justice -- the three basic ethical tenets of the Belmont Report. Although these principles were developed in Western societies, they have been widely adopted and play a significant role in research ethics worldwide. Application of these principles to the conduct of research leads to consideration of informed consent, risk/benefit assessment, and the equitable selection of human subjects.

The principle of respect for persons is embodied in the informed consent process, through which subjects, to the degree they are capable, are given the opportunity to choose what shall or shall not happen to them. This principle is honored when the consent process is informed, understood, and voluntary.

When research is justified on the basis of a favorable risk/benefit assessment, the principle of beneficence is honored. Such an assessment addresses the probability and magnitude of possible harm and anticipated benefits. Possible harms, and their corresponding benefits, may be psychological, physical, legal, social, and economic.

The principle of justice is embodied in the equitable selection of subjects, and seeks to ensure that participants neither suffer undue burden nor benefit disproportionately from their role in research.

To apply these principles globally in a way that protects the rights and welfare of subjects, it is essential that researchers have sufficient knowledge of socioeconomic, political and cultural aspects of the local research context. An effective child assent process, for example, requires an understanding of how different cultures define relationships between parents and their children.

Questions that may be considered innocuous in the United States and Western Europe could be offensive elsewhere. Different cultures have different authority structures that influence how researchers address potential coercion.

In this paper, issues and challenges encountered in conducting research in Egypt will be presented to provide researchers and research administrators with insight in the design, implementation and management of research in different cultural settings.

The Egyptian Context

Egypt is a country of about 75 million people, with diverse cultural beliefs and practices. Egyptians are very religious, and religious principles are noticeable in their daily lives. The population consists primarily of Sunni Muslims (about 90%) and Coptic Christians (about 10%).

As an Islamic country bordering the Middle East, Egypt is an Arabic republic. At the same time, as a country of North Africa with a 5,000-year heritage, it is altogether unique. In every major Egyptian city there are traditions carried over from the time of the Pharaohs; other areas retain the tribal customs originated by the many invaders throughout the centuries.

Family ties are strong in Egypt. Egyptian society consists of a mixture of Middle Eastern family values, taken from different religious rules, whether Islamic or Christian. This mixture of values colours Egyptian decision-making in a way that may be difficult for many people in the west to understand. In Egypt, clan obligations unite extended families – grandparents, aunts, uncles, and cousins -- in good times and bad. Clan elders arbitrate disagreements, even those between husbands and wives, and give opinions on topics ranging from farming techniques to religious obligations.

Issues and Challenges

Informed Consent Document Signatures

Populations with limited resources are particularly vulnerable, and the high-risk health conditions under which they live can affect both the researchers' and study subjects' assessment of the risk-benefit ratio (Nuffield Council on Bioethics, 2003). Complex documents and legalistic language make it increasingly difficult for prospective subjects to decide about their participation. Truly independent consent may be limited by cultural context and distorted when populations of limited economic means are offered incentives to participate.

The requirement to document consent through a signature or thumbprint may be difficult for investigators working with culturally diverse populations or with individuals who are socially marginalized or involved in illegal activities. In some areas of the world, both individuals and communities have suffered politically, socially, or economically because they signed "legal" forms that resulted in sanctions against them. Signing a document in some communities is always associated with a major life event, and asking research participants to sign a consent form can imply lack of trust.

Readability and Literacy

Comprehension of information during consent discussions is often influenced by misunderstandings about research. There are often negative connotations associated with the words "investigation" and "study," and a suspicion of "experimenting" or "practicing on my child." In many African languages, there is no word for research or science; the word used is generally the same as the word for medicine. The concepts of randomization and placebos used in clinical trials can be especially hard to explain, particularly when international researchers are working with communities and individuals who may be illiterate.

Influence of Medical Tradition on Consent

In many developing countries, medical doctors enjoy a high status and regard as a particularly knowledgeable group. Patients expect health professionals to make decisions for them and are reluctant to choose when given options about their treatment, as they do not question the medical competence in decision-making about their own care. This attitude is routinely applied to health care research, and can result in reduced participant autonomy. Individuals have limited familiarity with the notion of research and research design and find it unacceptable for doctors to express uncertainty regarding the best option available. This places the principal investigator/clinician at great risk of conflict of interest. In Egypt, it is important to take this medical tradition into consideration.

Influence of Social Structure on Consent

A critical element of conducting research is the process of obtaining informed consent. Sometimes, in non-U.S. communities, people other than the individual taking part in the research may be required to give permission before the potential subject can be asked to participate. These individuals may include a spouse, a head of household, or a group leader. The investigator must design a consent process that honors local custom. However, another individual's permission should not substitute for a subject's voluntary informed consent, unless that consent process has been waived by an Institutional Review Board (IRB) or equivalent local review committee. Unique cultural, religious, and socio-economic factors in Egypt pose many challenges for researchers obtaining informed consent.

Post- Study Communication

Another particularly difficult challenge for researchers in developing countries is what happens when the research is concluded. The Declaration of Helsinki (Principle 30) states, "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study." However, in practice, results are neither communicated to nor discussed with the public. Progress to rectify this issue is desperately needed to ensure concise, accurate IRB study completion standards. In fact, IRBs cannot usually follow up the successive phases of the research and ensure that the succeeding study was properly managed.

Overcoming the Challenges

Understanding and Sensitivity

Research managers, administrators, and investigators involved in international research should have some understanding of, and be sensitive to, the social, economic, and political milieu that affects the context in which their research is taking place. This cultural competence would enable them to establish recruitment procedures consistent with cultural, political, and social practices, while developing sensitivity to the individuality of different cultural groups. Lessons learned from genuinely collaborative efforts in multi-center research could be applied in this context.

Disclosure of information should be sensitive to the local context during the informed consent process, and conducted in the local language, employing culturally appropriate idioms and analogies understandable to prospective participants. This obviously entails a need for collaborative partnership between investigators conducting research and local communities.

Novel Consenting Strategies and Maintaining Voluntary Participation

An experience from Mali (Doumbo & Ogobara, 2005) clearly illustrates the importance of cultural competence. A dynamic approach to obtaining informed consent and to maintaining it over time was developed through a stepwise process. First, permission from the community was sought by a discussion with the group of village elders, who determined that a particular study could proceed. Then focus group discussions were convened with the heads of extended families. Similar discussions were initiated with mothers whose children might become part of the study. Finally, consent of the individual families involved in the research study was obtained. "The consent process was open and better suited to the needs of the population than were more conventional approaches. It generated more confidence by the villagers in the research project and a better understanding for us of the village culture and behavior." the author reported in page 2, second column.

Ethical guidelines for international research offer limited advice on the issue of trust and the need for documentation of consent. However, a number of international guidelines suggest that verbal consent is acceptable when written consent is not feasible, but only when it is properly documented (CIOMS 2002; Council of Europe, 2004; Nuffield Council on Bioethics, 2002, 2005; World Medical Association, 2000; Sims, J. & Kuhnlein, H. V, WHO-CINE Indigenous Peoples and participatory health research, 2003). Audio-taping the consent process or ensuring an independent witness for verbal consent are other options for documentation. When audio-taping is inappropriate or an independent witness is not available, researchers should document in field notes that consent was obtained (Marshal, 2006).

Once subjects have been enrolled, strategies to maintain their voluntary participation need to be considered and reviewed by the IRB. Helpful strategies include additional home visits and educational and social activities. Special consideration and monitoring to avoid coercion is needed in certain circumstances, such as pressure to enroll within a defined period of time, competitive enrollment rates between sites, or payment to the research team for the number of subjects enrolled.

Sharing Information

Local knowledge and the reputation of the research institution influence the decision to participate in the study. Sharing information about the study with credible local organizations – government health services, for example – is important, because the population will check with these sources about the research projects. One way to earn the confidence of the community is to provide medical care while the study is being conducted. In rural regions of developing countries where medical care is limited or nonexistent, the research team must often set up its own clinic. Providing standard care for both study participants and others in the community during a research project where the team is the sole source of medical care can be a form of community compensation. Studies in developing countries should generally guarantee care for volunteers who experience serious adverse events – not only during the study, but after it has been completed. Care must be taken to ensure that the provision of these services does not induce participation in a study that may not be in the community's best interest. This ethical dilemma remains unresolved, and a source for concern. It is often difficult for potential participants to evaluate the risk/benefit ratio of a study. Perceived benefits, frequently including access to good health care, may exert the strongest influence.

Strengthening and Promoting Ethical Committees

The role of IRBs in developing countries should be strengthened and promoted by international institutions to help them resist political, economic, or institutional pressures. This role is strengthened with proper structure and when members' profiles, their independent finance, and their relationships with public institutions are defined.

Adequacy of the Administrative Support for Institutional Review Board/ Informed Consent

It is incumbent upon local investigators to have performed an audit of the resources available for study support. This includes staffing, communications, transport and general access to dispersed study populations. Sufficient resources to address recordkeeping, whether manual or electronic, need to be assured. For example, tailored software is now available for records management of IRB documents. However, the relative adequacy of local financial resources needs to take this into account, and satisfactory alternative means of recordkeeping (and record retrieval) need to be in place.

Focused Training of Research teams

In both wealthy and poor countries, training in research ethics must be enhanced for investigators in all settings, particularly when studies involve participants challenged by poverty or low literacy. Minimally, research team members should be trained to obtain informed consent in a manner that is both culturally and linguistically appropriate. Moreover, capacity building is necessary to insure that IRBs in developing and industrialized nations understand the need for culturally appropriate strategies for obtaining consent to research in international settings.

Studies to Assess Research Understanding

There is an increased need for studies to evaluate subjects' levels of understanding of research components, as well as more systematic investigations on informed consent practices for research conducted in international contexts. Such studies can also evaluate the characteristics of participants and their circumstances that are thought to have a critical influence on informed consent. They will improve our understanding of the process, written information, the experience of subjects and strategies that work best. Comparing data from similar studies in developed and developing countries could also illuminate any differences or similarities in the quality of informed consent in the two settings. Greater attention should be given to the development of approaches and analytical tools for assessing social and ethical challenges to informed consent.

These data will not only give researchers an understanding of how they are doing now, but will also be useful to identify differences in the consent process as it relates to different study populations, study designs, and other factors. It is hoped that through this process, continual changes to improve the consent process by researchers throughout the world will result in better informed prospective study subjects and continued excellence in research. The international research community has to share information and debate questions relevant to ethics of research in developing countries and to foster dialogue on ethical issues among actors in the scientific and decision-making communities involved in medical research, with regard to ethical considerations.

Conclusion

Ethical issues apply globally. The Eastern Mediterranean Region, World Health Organization (WHO) has established basic guidelines for exercising research ethics in the Middle East *(http://www.emro.who.int/his/medicalethics.htm)*. Basic ethical principles are consistent with the rich cultural environment of Egypt. How these principles are applied to research in Egypt must take into consideration the cultural context. Egypt's unique cultural context leads to many challenges that require innovative and creative approaches, some of which are described in this manuscript. Egyptian scientists are eager to adapt and apply the latest scientific advances to their country. Egypt is forming IRBs to support a growing interest in research, and beginning to address its related ethical issues. Egyptian scientists must apply their cultural experiences, must bring in community and non-scientific leaders, and conduct and document healthy ethical discussions about research to find the best methods to adapt global ethical principles into their unique local context. Lastly, these practical experiences and challenges must be shared with other researchers to develop cultural sensitivities among the research community and ensure that the rights of human subjects are protected. Studies to evaluate and assess the level of understanding of research subjects to the research elements can serve as a good monitoring tool.

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