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RELIGIOUS, SPIRITUAL, AND TRADITIONAL BELIEFS AND PRACTICES AND THE ETHICS OF MENTAL HEALTH RESEARCH IN LESS WEALTHY COUNTRIES*

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Abstract

This discussion article contributes to ethics reform by introducing the contribution of religious, spiritual, and traditional beliefs and practices to both subject vulnerability and patient improvement. A growing body of evidence suggests that religious, spiritual, and traditional beliefs and practices may provide positive benefits, although in some cases mixed or negative consequences to mental and physical health. These beliefs and practices add a new level of complexity to ethical deliberations, in terms of what ignoring them may mean for both distributive justice and respect for persons. International ethical guidelines need to be created that are expansive enough to cover an array of social groups and circumstances. It is proposed that these guidelines incorporate the religious, spiritual, and/or traditional principles that characterize a local population. Providing effective mental healthcare requires respecting and understanding how differences, including ones that express a population's religious, spiritual, or traditional belief systems, play into the complex deliberations and negotiations that must be undertaken if researchers are to adhere to ethical imperatives in research and treatment.

Keywords

religion; spirituality; mental health; ethics

INTRODUCTION

There are three main layers of ethical dilemmas and moral issues that arise from conducting research on religious, spiritual, or traditional beliefs and practices among the mentally ill. This is particularly an issue in less wealthy countries. For purposes of this article, religious, spirituality, and traditional beliefs and practices will be subsumed by religion and mental health. These dimensions are:

1. working with a mentally ill population,

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2. conducting research internationally particularly in a less wealthy country, and
3. cultural sensitivity.

The complex ethical and moral concerns that arise out of these dimensions may serve as contributing factors to the insufficient body of research in this area.

Vulnerable Populations among the Mentally Ill and the Impoverished

The characteristics of a vulnerable population, in this instance the mentally ill, are a concern for those in the research-oriented community, not just for those in psychiatric research. A vulnerable individual is considered at higher risk to be more easily coerced and unable to give consent because of a lack of understanding or inability to express his or her will. It is not always clear if a person with a diagnosed psychiatric illness is mentally and emotionally healthy enough to be able to make a reasoned independent judgment for individual consent to participate in a study. If an individual is considered vulnerable, mechanisms to minimize additional risks due to their vulnerability need to be considered. In such cases, usually a legal representative or guardian would be requested to make the decision for participation on behalf of the potential participant.

Some individuals within sub-populations, particularly in less wealthy countries, may be considered vulnerable due to economic, social, and/or educational disadvantage such as limited access to healthcare. These limitations may contribute to the coercion of vulnerable peoples in medical studies. If the individuals within these sub-populations are also mentally ill, they can be considered especially vulnerable, exacerbated often by less education, employment, and access to healthcare. In addition, there may also be the complication of diminished decision-making capacity.

Vulnerable Populations among Religious and Spiritual Groups

Individuals that identify with a particular faith or belief tradition which is being persecuted for political gains may feel unable to freely express their will to participate in a study concerning cultural beliefs and practices. There may be fear, either perceived or real, to identify with such a religion from threat of harm from society or the government. Given these circumstances they may be considered a vulnerable population.

Ethical Question Defined

In recognition of the problems of dealing with a vulnerable population, the question to be addressed is if it is ethical for this research to be conducted at all? The simple and short answer is that it depends on the population and research question. It is imperative that the highest ethical standards be carefully and thoroughly considered, planned and executed for the protection and welfare of the population within the region and country being studied.

Research Question—Only in the last two decades has the role of religion in the lives of the mentally ill been studied from a scientific, medical, or epidemiological perspective, and mainly in the United States [1]. Given the lack of access to even basic medical treatment and therapies in certain countries, religious practices may be a valuable coping tool [1]. As seen in refugee camp populations, areas where mental illness is prevalent [2], religion is a source of solace, hope, and may provide a sense of identity for the mentally ill despite the lack of access to mental health care [1, 3]. An understanding of the relationship of religion to mental health may aid in improving mental health within various populations.

Mental Illness: Prevalence and Contribution to Global Burden of Disease

Mental illness is a growing global burden that affects all countries regardless of affluence. Just how large this burden really is has been severely underestimated. Four of the six leading causes of years lived with disability are from mental illnesses [4]. Approximately 450 million people are affected by mental or behavioral problems accounting for more than one-tenth of the global burden of disease [4]. The incidence of mental illness is increasing at a dramatic rate from issues related to poverty, war, urbanization, aging, and discrimination, especially in less wealthy countries, and is projected to increase considerably [5]. Yet among serious cases of mental disorders with substantial role disability, up to a half in wealthy countries and more than three-quarters in less wealthy countries receive no treatment at all due to the scarcity, inequity in access, and inefficiency in resources for mental health [6]. Approximately one-third (32%) of countries do not have a specific government budget for mental health. Of those that do report such a budget, over one-third (36.3%) spend less than 1% of their total health budget on mental health [4].

Fundamental Universal Ethical Guidelines

The guiding ethical principles of research are succinctly stated in the Belmont Report, respect for persons, beneficence, and justice [7]. These guidelines provide the philosophical justification for the legal framework for the oversight of human subjects research in the United States. The guidelines can be applied to international research as well, because they are fundamental and universal ethics. Respect for persons is interpreted as “to ask for consent,” beneficence refers to “do no harm,” and justice is focused on equality.

These three guidelines are deceptively simple yet their application may be complicated in the local environment of a proposed research study. The application of the moral principle of respect for persons is through informed consent, involving adequate information about the study, comprehension, and the voluntariness of potential human subjects. The application of the principle of beneficence is minimization of risk of human subjects, through determination of a risk benefit ratio by the researchers. The application of the principle of justice is through the fair procedures and outcomes in the selection of subjects for research [7].

Potential Ethical Issues with International Research—Awareness and respect for cross-cultural issues is perhaps the most important consideration while conducting international research. The mindset of the researchers can determine whether partnerships are built and can affect the quality of the research obtained. Guidelines and regulations have no meaning if a researcher does not have an awareness and respect for their study subjects, the community, and surroundings [8].

Multiple ethical review committees: The application of ethics in international research can become easily complicated. Often multiple ethical review boards have to approve the research, in the sponsoring country of the researcher and in the host country or countries the research is to be conducted.

Council for International Organizations of Medical Sciences (CIOMS): The sponsoring country's national regulations must be adhered to in addition to international guidelines as documented in such reports as the Declaration of Helsinki, by the World Medical Association and/or the Council for International Organizations of Medical Sciences (CIOMS) guidelines [9, 10]. Though most countries have a national policy and guidelines on research administered through local institutions, it may be particularly difficult for sponsoring and host institutions to monitor and enforce international research due to the lack of global governance of such research.

Many countries lack the capacity for scientific and ethical review of research [11]. Some countries (approximately 30 worldwide) such as Mozambique, Madagascar, Afghanistan, and Paraguay do not appear to have national guidelines, regulations, or laws pertaining to the protection of human subjects [12]. In these instances, the sponsors and researchers have an ethical obligation to provide scientific, ethical review and monitoring of such research. International guidelines such as the CIOMS are designed to prevent exploitation of less wealthy countries. The goal is to conduct research which is based on sound ethical standards for the protection of the participant and community and to prevent exploitation of less wealthy countries [9].

Capacity Building—Potentially vulnerable poor mentally ill individuals living in a less wealthy country may be easily taken advantage of, particularly in countries that lack national mental health policies and community care facilities. The purpose of capacity building is to build up the capacity of the local people in the host country. This may include establishing and strengthening independent and competent ethical review processes and committees, strengthening research capacity, training and education of local research and healthcare staff, building partnerships, and reciprocity for future research [11].

Relevance of Research in the Host Country—It is important to work with experienced researchers and the local community in the host country to help determine an appropriate research question. It is also important to work simultaneously with both sponsoring and host countries' local ethics review committees to develop an ethical research proposal. The researcher may need to raise awareness of community mental health issues with collaborating local researchers and local community gatekeepers, such as elders and clergy, of the benefits of a research study on mental illness for the local people, community, and nation, as mental illness though often chronic, may not be considered by the local community as pressing an issue compared to high mortality physical illnesses and public health concerns such as access to clean potable water.

Ethical compensation: Compensation should not be coercive in its amount. Compensation should be remuneration for time in loss from work while participating in the study [8]. Many mentally ill are unable to work, and thus have limited income and resources, and may be unduly enticed to participate mainly for the study's compensation [13]. In addition, living in a less wealthy country, the social, economic, and political problems compound the problems of the mentally ill, who are often at the poorest ranks of society. Compensation needs to be carefully considered beforehand and tailored to the location and normal research protocols of fair compensation in the community and country, so as not to be coercive.

Researcher potential burden of guilt from global inequalities vs. proactive research ethics to address inequalities: There remains the possibility for researchers to experience guilt and feel a heavy burden of responsibility to change the inequities in less wealthy countries and to perhaps manipulate or alter one's research study to compensate for inequalities [11]. An example of this would be to provide additional resources such as equipment, supplies beyond the capacities of the budget, as well as an overextension of the personal resources of time and effort of the researchers themselves. The researcher needs to use self-restraint and wisdom to realize that research did not cause nor can it fix the inequitable distribution of wealth among nations [11]. Yet the researcher has an ethical obligation for capacity building through sharing of knowledge and research, promoting teamwork, and pending the type of research, this may also include assisting in developing treatments and preventions that are affordable to the local community [11].

Some bioethicists argue that research ethics within the international sphere needs to be more proactive rather than reactive as in the past. Historically, research ethics has largely been

driven by past abuses, such as the Nuremberg Code from the atrocities of World War II and the Tuskegee experiments (where African-Americans were deliberately not informed they had syphilis and not treated for it) which led to regulations regarding research ethics in the United States [14]. Currently some bioethicists are calling for “a new proactive research ethics [which] must be concerned with the greatest ethical challenge—the huge inequalities in global health” [14, p. 826]. Researchers cannot justify the statistic that 90% of all medical research is being conducted on diseases that cause only 10% of the global burden of disease [15]. Scientists have a moral responsibility to not merely conduct research for their own or institution's gain in terms of publications and prominence, but they should be held responsible and accountable to the moral obligation of raising social and political consciousness of global health inequalities, through research findings that may inform policy decisions to promote more equality in health care.

Informed consent becomes more complex and multifaceted: The application of Western informed consent standards abroad creates multiple issues. There may be a language barrier, particularly if the study population is non-English speaking, as there may be misinterpretations even with verbal and written translation. It is important that the oral and written consent forms and survey questions be simple and understandable to the participants, and be translated backwards and forwards to check for inconsistencies in translation. The researchers have a responsibility to ask the potential participant if she/he is willing to give consent to participate in the study only after determining whether the potential participant has sufficient understanding of the involvement and consequences of participation, with adequate time and resources to make such a decision [11].

In some tribal societies, the role of the elders may act as a type of authorized legal representative of the community members. The elders may provide consent for community members [11]. In this situation, the elders may become offended if consent was inquired of each individual in the village [8]. A way to handle this potential problem would be to obtain official consent from the community elders, and when approaching each potential study participant, inform them that the elders have given consent for her or him to participate in the study, and ask the individual if she or he is willing to participate [8]. However, if the potential participant refuses, even though the elder or the legal guardian agrees, the participant's request takes precedence (even among the mentally vulnerable). “No means no,” unless the treatment would potentially save the participant's life [8].

Issues of documentation need to be revised in an application of the Western informed consent to the host country. For example, if the study participant is illiterate, a consent form script would need to be recited and understandable to the potential participant. An “X” may suffice for a signature after the potential participant provides verbal agreement to participate [8]. If the researcher is not able to communicate in the native language of the study participants, a reliable interpreter is necessary, particularly one that has prior research experience.

Mental Illness—The ethical issues of conducting research internationally in less wealthy countries are varied as just previously discussed. Next, the ethical issues of conducting research with the mentally ill are discussed.

Symptoms may manifest differently in different cultures: Psychiatric symptoms may manifest differently across cultures. For example, symptoms of depression may present themselves differently to an African American living in the United States compared to an Indonesian person living in Indonesia [13]. The researcher needs to be informed of cultural norms of the local community in the host country and how mental illness and mental health are perceived in the culture and community. A researcher needs to be careful not to impose

her or his views of the 'mental illness' on the participants. If the behaviors and thoughts are revered in a culture, and not revered in the researcher's culture, the researcher has to use reserve, and attempt to remain objective in conducting the research [13].

Socio-Cultural Factors: Religious, Spiritual, and Traditional Beliefs and Practices—The most important issue in conducting successful international research is to have cross-cultural awareness and respect [8]. This applies particularly when studying cultural factors such as religion in a particular region and country. This research topic may require special ethical consideration for protection of human subjects particularly for the two universal ethical principles outlined in the Belmont document—respect for persons (right to informed consent and confidentiality) and beneficence (minimization of risk) as described in the following paragraphs.

Protection of confidentiality: When conducting research on socio-cultural factors, the researcher has to be acutely aware beforehand of the potential sensitivity of the topic within the study population and the community. This may be particularly relevant when conducting research on religion, which may be a politically charged or dangerous issue in certain countries. Protection of confidentiality of the potential participants would have to be carefully considered before conducting the study. If the individuals in a study are known beforehand to have beliefs and practices which may be at odds with the dominant ruling class or party, the researcher may consider before conducting the study, as part of the human subjects proposal, *not* to share the data but rather share only the study findings (as well as research skills and knowledge to promote capacity building) with the host institution and country, to help ensure confidentiality and minimize risk to the potential study participants.

Potential harm of intervention: If a study is testing an intervention, the researcher has an obligation to carefully consider beneficence, minimization of all foreseeable risk to the patient. Often researchers and ethics review committees assume that a study that is testing a religious or spiritual intervention, such as distant healing or prayer, could not possibly have any harm associated with it for the potential study participants. This assumption needs to be reconsidered.

For example, a study was published in the American Heart Journal, which was one of the most rigorous methodological randomized clinical experiments ever conducted on intercessory prayer and recovery from cardiac bypass surgery [16]. In addition, this study has also been the most publicized and discussed research article in the religion and health field in the popular press worldwide [17]. The intervention groups that were prayed for reported more complications after surgery than the control group. Researchers did not consider beforehand the possibility that the prayer intervention could cause harm to the participants [16–18]. The mechanisms of prayer or distant healing are currently unknown by researchers, thus the intervention may cause harm of which researchers are not yet aware. Patients randomized into one of the intervention groups were informed immediately before the surgery that they were selected to be prayed for. The patient's knowledge of selection to be prayed for in the study, albeit randomly, may have provoked worry to think "I must be so sick that medical technology or the clinician's skill is not enough, so that I have to be prayed for" [17, 18]. This knowledge may have provoked undue stress on the participants. Another factor in the study was that the patients were informed to hide their assignment into a treatment or control group from their clinicians. For patients about to undergo cardiac bypass surgery, it may have caused undue stress for them to be told to keep information secret from their clinicians, whom the patients may have developed close relationships with and are trusting with their lives [17, 18].

Even though a research variable of interest, such as cultural lifestyle factors of spiritual and religious beliefs and practices, may be presumed to have only good and positive health outcomes for an individual, this cannot be presumed.

CONCLUSION

The three universal ethical principles outlined in the Belmont Report of respect, beneficence, and justice are deceptively simple in theory, yet inherently complex in application to real life research. This is especially true when potential study participants are vulnerable at multiple levels, in terms of cognition and social, economic, political, and cultural status as outlined in this article. However, this should not be a deterrent to conducting research on potentially vulnerable populations. Rather, research may be an important avenue to support long-term effective change to improve the health and welfare of vulnerable populations, particularly for the mentally ill living in less wealthy countries. For successful research to be conducted on vulnerable populations, ethical considerations need to be carefully and thoroughly thought out, planned, and implemented, and a push for more adequate implementation of guidelines and oversight at the local, national, and international levels for conducting such research.

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