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Medical Research Ethics in Islamic Context

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Abstract

Medical research has a crucial role in the development of medical knowledge. Ethical behavior is essential within the sphere of human medical research. Numerous regulations about research involving human subjects have been issued, such as the Helsinki Declaration and the Belmont Report. Despite these guidelines, significant abuse of human subjects and a profound violation of the standards of medical ethics were encountered. Most of the currently accepted Western principles of ethics in research are consistent with the instructions of Islam known to us more than 14 centuries ago. Islamic law automatically bans all immoral actions. A researcher who pursues scientific knowledge to cause harm is subject to God's rage. In Islam, injustice is forbidden. Coercing and exploiting vulnerable groups to participate in medical research is incompatible with Islamic law. Researchers should be equipped with knowledge and comprehension of religious perspectives related to human research.

Introduction

Islam opens the door to research. In many verses of the Glorious Quran, God encourages people to learn and look for wisdom to build the earth (Only those fear Allah, from among His servants, who have knowledge(Qur'an 35:28).God states in the Holy Quran."..And follow not (i.e., say not, or do not or witness not) that of which you do not know.." (17; 36).Islam encourages the use of science, medicine, and biotechnology as solutions to human suffering. Thus, Muslims throughout the world may be eager to make use of the latest medical developments.[1] Islam forces the dissemination of knowledge and prohibits hiding it; as the Prophet (peace be upon him) (PBUH) said: "Whoever conceals knowledge which Allah has made beneficial for mankind's affairs of religion, Allah will bridle him with reins of fire on the Day of Resurrection.".[2]

In the golden Islamic era from the 9th to the 11th century, many discoveries and huge advances in science and medicine were revealed. For example, Mohammed Zakariya AlRazi (born in 854 CE) was the first to conduct clinical trials comparing two identical groups of monkeys and humans.[3]

Muslim countries with common backgrounds and ethical concerns should involve themselves in research that suits the local situation. Many underdeveloped countries need research to provide affordable medicines to the low socioeconomic classes, and many researchers feel the deficit in the contributions of Muslims in the medical field.[4]

Clinical research requires that it conforms to internationally recognized ethical guidelines. For Muslim physicians, conforming to Islamic ethical guidelines is an added requirement. Muslim physicians and scientists should monitor externally sponsored research in their own countries to ensure that these guidelines are followed.[5]

Ethical Codes and Unethical Practice

The Nuremberg Code, established in 1948, was the first international document that emphasized voluntary participation and informed consent. It appeared after the Nuremberg Trials of the Nazi Physicians (World War II) who experimented with prisoners of war, gave them lethal drugs, caused pain and suffering to all of them, and

ended in the death of many. All the experiments were not serving any benefit to those researched and of course, were done without any consent. The Nazi physicians had abandoned the traditional ethical commitment of the physician to individual patient welfare. They were committed and found guilty. The Nuremberg trials of the Nazi Physicians opened the eyes to what was happening both in the democratic countries of the West and the heinous experiments of Nazi Germany.[6]

Japanese physicians during World War II undertook biological warfare research on military and civilian prisoners, often causing terrible suffering. Subjects died either because of experiments or were put to death when no longer useful. These crimes were not publicized as were those by Nazi physicians, nor were Japanese physicians tried in the Tokyo War Crimes trials.[7]

The World Medical Association issued guidance in 1964 to help physicians while conducting biomedical research on humans. The Declaration of Helsinki regulates worldwide research ethics and establishes standards for "non-therapeutic research". The Declaration of Helsinki is the foundation for current Good Clinical Practices (GCP). Later, in 1979, the Belmont Report was published, emphasizing basic ethical principles and guidelines for conducting research with human subjects.[8]Many other international laws and regulations were established.

Despite these international ethical codes, there were many irregularities, deceits, and unethical practices that were exposed by Western physicians, moralists, and the media. The occurrence of blatant unethical procedures is disappearing in the West. The drug companies pushed their experiments and unethical procedures in third-world countries. But even there, the international codes are exposing them.[6]

In the 1950s, American prisons hosted an increasing variety of non-therapeutic medical experiments some of which were risky such as injecting live cancer cells to study the natural killing-off process of the human body.[9]The Willowbrook hepatitis study (From 1956 through 1971) involved intentionally infecting healthy but mentally challenged children with hepatitis by feeding them a solution made from the feces of those with activehepatitis.[10]

In a hospice in Massachusettsin the 1950s, handicapped children were told that they would go on an enjoyable trip and would be given lots of delicious food. The children were unknowingly being used in anon-therapeutic experiment whereby they were given radioactive food to examine the effect of radioactive materials on human beings. Much later, each of them was given US$ 60,000 as reparation. This incident remained unknown until eventually, it came to the attention of a journalist, who wrote a book about it which was published in 2004.[11,12]

Post-Awareness Research

In the Cincinnati Radiation Experiment (1960–1972), Eugene Saenger, a cancer researcher at the University of Cincinnati School of Medicine began one of the most notorious human radiation experiments of the postwar era. Over more than ten years, Saenger and his research team exposed approximately 80 patients with terminal cancer to potentially lethal doses of radiation; at least eight of them have died from radiation poisoning. [13]

In Jewish Chronic Disease Hospital (1963), twenty-two chronically ill and debilitated noncancer patients were injected with live human cancer cells. Patients were not told of the cancer injection. The hospital covered up the lack of consent and tried to fraudulently obtain consent. [14] Two years after the investigation, the American Cancer Society appointed the principal investigator as a Vice President.

The Tuskegee Syphilis Experiment (1932–1972) targeted 600 poor and illiterate African American males (399 with syphilis and 201 without). They were told that they were being treated for "bad blood". The study was originally designed to last for 6 to 8 months, but it turned into a long-term study that continued for 40 years. Researchers followed their progress without providing penicillin, which was a known antidote as of 1943. Twenty-nine men died directly from syphilis and 100 others died of illnesses related to syphilis.[15]

Learning from these traumatic and often cruel moments in history gave impetus to developing international ethical guidelines, driving research conduct, and protecting the rights and safety of those participating in studies today.[16]

Islam and Medical Research

Islam is not only a religion; it is a way of life. The Shari'a controls the everyday activities of Muslims. Once an individual freely joins Islam, he is bound by Islamic rules and hence he is obliged to follow instructions and rules in the Quran and Hadith. The rejection of

secularization within Muslim communities does not affect the relationship between Muslim countries and secular states as Islam respects others' beliefs and choices.[17]

Islamic bioethics is an extension of Shari'ah (Islamic law), which is itself based on two foundations: The Qur'an (the holy book of all Muslims and the Sunna (based on the Prophet Muhammad's words or acts). Development of Shari'ah in the Sunni branch of Islam also required ijma (consensus of jurists after the death of the prophet) and qiyas (analogy) using human reason when no clear rule is found in the Quran or Sunna, resulting in 4 major Sunni schools of jurisprudence.[1]

In Islamic communities, religion greatly influences behavior and practice. Teaching human research ethics to researchers in Islamic communities will not be meaningful and effective if resources heavily rely on foreign, word-to-word translated guidelines that do not address the Islamic cultural dimension of ethical human subjects research.[18]Ethical principles and guidelines have been developed by international organizations such as the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS). The Islamic Organization for Medical Sciences (IOMS) in Kuwait convened a meeting in Cairo, Egypt, in 2004 and produced a document advancing an Islamic viewpoint on these principles and guidelines. Dr. Husam Fadel elaborated in depth on these principles outlined in the "International Ethical Guidelines for Biomedical Research (An Islamic Perspective)."[5]

While researchers involved in the design or conduct of research with human subjects are typically familiar with international ethical guidelines, religion's impact on participants' perceptions of human research should not be underestimated.[18]Medical research in the Islamic community should conform to and not violate the 5 maqasidal-shari'ah which are the preservation of religion, life, and health, progeny (curing infertility), intellect, and wealth. If any of the five purposes is at risk, permission is considered to undertake human experiments that would be otherwise morally unacceptable in Islam.[19]

Ethics of Medical Research

Respect for Persons

This principle "incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection."[20]Islam respects autonomy even on the issue of belief. The Qur'an declares that "there is no compulsion in religion" (Quran 18:29) and that each person has the full will to accept Islam or refuse it.

In Islam, a similar principle applies, that is, "no one is entitled to dispose of the rights of a human being without his [her] permission". In the human subjects' research context, this implies that "no one should be involved in a research project without his[/her] free and voluntary consent".[21]This is stipulated in the fiqh rule: "No one is entitled to dispose of the rights of a human being without his permission" and "No right of a human being can be canceled without his consent."This statement is arguably in conformity with the Belmont principle of respect for persons.[5,18, 21]

If a participant may be concerned about the presence of a religiously prohibited ingredient in a trial medication or placebo, the medical researcher should disclose the ingredients to him/her during the process of informed consent.[18]

In Islam, consent is allowed under the doctrine of the ''human temporary custody of life''. This means that the subject and physician or researcher are accountable before God for any decision made, such as consenting to a highly risky experiment that has no potential direct benefit. This is why Islam would object to phase I trials in healthy subjects unless under unique and compelling circumstances with every effort made to protect the participants, detect complications as early as possible, and take the necessary steps to treat them.[19]

Informed Consent

The research should be fully explained to the participants in simple language, that they could fully comprehend. Any questions should be answered. A written document in simple language should be given to the participant. He/she should be given enough time to review it, ask questions, and have free choice to accept or refuse participation; alternatives (in case of refusal) should be explained. Refusal of participation will not in any way affect his/her right to full treatment and management. The participant can withdraw at any time. The researched person even then, will not affect his right to full treatment and management.[6]

The foreseeable risks, discomforts, and hazards should be explained, indicating the probability, magnitude, and duration. The risks should include physical, psychological, social, legal, and economic risks. If any hazard occurs during research, the research should be stopped immediately and the participants should be

informed, treated for any injury, and compensated duly. Many consent documents declare that no compensation will be paid in case of injury or even death. This should be changed, and the Institution Review Board (IRB)should not accept the research until the sponsors agree to treatment and compensation. The subject's confidentiality should be always protected.[6]

Beneficence:

The first main principle of Islamic Medicine is the emphasis on the sanctity of human life which derives from the Qur'an:"If anyone saved a life, it would be as if he saved the life of all mankind" (Quran 5:32.). The verse says: The person who helps to preserve the life of even one person is the protector of the whole of humanity, for he possesses a quality which isindispensable to the survival of mankind. It is reported that Prophet Mohammed (PBUH) said, "There should be neither harming nor reciprocating harm".[22] He also said "Allah likes when anyone does a work, to do it with perfection".[23]

Based on sound logic and clear Islamic teachings, the physician has no right to recommend or administer any harmful material to his patients. The Qur'an says: "And He makes for them good things lawful, and bad things are forbidden"(Quran 7:157).A person who pursues scientific knowledge to cause harm is subject to God's wrath. God says: "And they learn what causes them harm and brings them no benefit, and they already know that whoever purchases it has no share in the hereafter(Qur'an2:102).

Human experimentation can be associated with potential hazards and risks. These risks have to be balanced against the harm caused by the disease and the potential benefit of the proposed new treatment (risk/benefit ratio). When balancing possible harms against benefits, human subjects researchers can apply Islamic rules such as public interest overrides individual interest; accepting the lesser of two harms; necessity overrides prohibition; harm has to be removed at any cost if possible (IMANA Ethics Committee 2005); and "if a less substantial instance of harm and an outweighing benefit conflict, the harm is forgiven for the sake of the benefit".[5]An example of "Necessity legalizes the prohibited" is participation in a phase I trial. When there is an endemic disease with no available successful standard of care, and there is a promising new drug as proven by experimental studies, it would be permissible to expose healthy volunteers to the potential harm of participation in such trials for the benefit of the community if they receive no payment for such a utilitarianattitude.[19]

Islamic law automatically bans all immoral actions as ''Haram'' and automatically permits all that is moral as Mubaah. Walton et al.[24] explored the health beliefs of practicing Muslim women and found that all research participants (100%) strongly agreed that smoking, alcohol, and overeating were harmful to the body. So, while consuming alcohol is a harmful action, and is thus prohibited by Islam, and is even illegal in some Islamic communities, it may be considered beneficial in other cultures.[18]

Justice

The principle of justice is an established principle in Islamic law, and it calls for fairness in all affairs of life, including the context of human subject research. Justice is often regarded as synonymous with fairness and can be summarized as the moral obligation to act based on fair adjudication between competing claims. The Qur'an says: "Indeed We have sent Our Messengers with clear proofs and revealed with them the Scripture and the Balance (justice) that mankind may keep up justice." (Quran 57:25). Researchers should not offer potentially beneficial research only to some patients who are in their favor or select only 'undesirable' persons for risky research. In Islam, injustice is forbidden. Coercing and exploiting vulnerable groups to participate in research is incompatible with Islamic law, as is excluding women of reproductive age from biomedical research.[18]

The Prophet Mohammed (PBUH)said: "There is no special merit of an Arab over a non-Arab except by righteousness and piety".[25]

The Prophet (PBUH) stated: "Ihsan is to worship Allah as if you see Him, and if you cannot achieve this state of devotion then you must consider that He is looking at you."[26]Ihsan which has no equivalent in English means to be good, generous, sympathetic, tolerant, forgiving, polite, cooperative, selfless, etc., In life, this is even more important than justice; for justice is the foundation of a sound society but Ihsan is its perfection. Justice protects society from bitterness and violation of rights, while Ihsan makes it sweet and joyful and worth living.[1]

To apply Ihsan in the research context some points must be considered; investigators are required to be qualified and committed to conducting the research; safeguards for the well-being of the participants should be in place, the data should be accurate and transparent; and the methodology must be correct.[3,27.]

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Medical Research in Vulnerable Subjects:

Vulnerability in research occurs when the participant is incapable of protecting his or her interests and therefore, has an increased probability of being intentionally or unintentionally harmed. The vulnerability can be due either to an inability to understand and give informed consent or to unequal power relationships that hinder basic rights. Excluding subjects from research for the only reason of belonging to a vulnerable group is unethical and will bias the results of the investigation. To consider a subject or group as vulnerable depends on the context, and the investigator should evaluate each case individually.[28]
Incompetent adults should not be exposed to any nontherapeutic research. The consent of the guardian is imperative. The research should be useful to the person(patient) or his group. There should be no other alternative to obtain that information. Prisoners and incarcerated persons should not be exposed to research unless it is going to help the person or group. The consent of the prisoner is legally invalid; however, it should be obtained without coercion.[6]

Volunteers, or so-called volunteers, are easily forthcoming from the poorer, more vulnerable sections of the population who would even risk suffering pain or bearable damage for small payments. This is true of many kinds of research, in addition to research on issues such as organ
transplantation and the like. It is unethical to exploit a subject's poverty and vulnerability in this manner. Medical students, prison inmates, and other such groups have frequently been used for medical experiments in exchange for different favors and advantages.[29]

Research on Children

The participation of children in clinical research is essential because children develop different diseases and respond to treatment in a different way than adults. Nevertheless, many drugs have inadequate information on toxicity and administration regimens for children. Medical research on children has increased in the last 20 years. International ethical regulations for conducting clinical research on children may not pertain to Muslim communities where religious beliefs play a big role in the decision-making process.[3]

Few regulations released details about the participation of children in clinical research.[30]Among the reviewed documents, the guidelines by the Islamic Organization of Medical Sciences—released in 2005 from Kuwait (IOMS, 2005) and updated in 2016—were the most balanced and included all key points of research ethics. The latter from Kuwait documents stated that "Children and adolescents must not be included in health-related research unless a good scientific reason justifies their exclusion."[3]

Among Muslims, three items might add to the inherent difficulties in children's participation: the right knowledge, the uncertainty about religious judgment, and the cultural barriers in the relationship between parents and children.[31]In pediatrics, the research questions should be scientifically sound and lead to the understanding, advancement, or improvement of a medical issue for a larger population.[3]

Children should not be exposed to nontherapeutic clinical research. The consent of the minor is invalid and hence it is obligatory to obtain the consent of the guardian. The assent is the agreement of the child to participate in research when he/she is not competent to provide legally valid informed consent.

Children under seven cannot comprehend the intricacies of medical research. However, children who can comprehend and understand should be informed in simple language and their consent obtained. If they refuse, no research should be done on them, despite the guardian's consent.[6]

Women in Research

Those who call for equality between men and women falsely accuse Islam of not giving womentheir rights. Islam protects women's dignity and rights more than any other regulation, or laws currently used in Western countries. Women are different biologically, physiologically, and psychologically from men. Islam 1400 years ago realized this and looked at women and men equally in issues related to general legal rights and differentiated between them in their financial responsibilities, heritage, family responsibilities, testimonies, and the right to divorce.[32,33]The Prophet Muhammad (PBUH) in his last speech at Arafat Mountain instructed Muslims to take care of women. He stated:"Show fear towards God regarding women, for you have got them under God's security".[34]

The woman in Islam represents the cornerstone of the family, and it is the responsibility of a man to ensure her protection and welfare. Two prerequisites are needed for a female to participate in research: the first is the approval of the family and the second is that the women

must consent to the proposed research project. The approval of the husband is an important pre-requisite becausehe is the protector of the family, and her protection against any harm is a crucial issue. If she refuses, the husband has no right to force her toparticipate.[33]

If participation may be hazardous in case a woman conceives, the investigator should offer her pregnancy testing and provide her with access to effective contraception before the research. The participation is conditional on voluntary informed consent, including information on the precautions taken to spare her and her fetus if she becomes pregnant from any hazards.[5]

Research on Pregnant and Lactating Ladies

Islamically, there is no objection to the participation of pregnant women in biomedical research because of the potential benefit of the research to them and their fetuses. There will always be some risk. Islamically, accepting the possibility of such harm would nevertheless be permissible if the mother or the fetus is likely to gain an absolute or outweighing benefit. When there are potential risks for the fetus, even when they are minor or outweighed, the investigator should also obtain the consent of the father. Ethically and Islamically, the investigators should make an extra effort to explain the trial, the potential benefit to the fetus, and the potential complications before she agrees to participate in the trial.[5]
The research should benefit the pregnant lady, her fetus, or the group. Clinical research should in no way expose the pregnant lady, nursing mother, fetus, or baby to any harm.The lady should avoid pregnancy if the research period is prolonged, and contraception should be used. The consent of the husband or any other member of the family is not enough. The consent of the husband may be essential in research involving reproduction.[6,33]

Conclusion

Research is a potential engine for the development of any nation. Despite the presence of many international regulations, medical research on human subjects is replete with horrendous stories of cheating, maiming and even killing many innocent persons.

Islam emphasizes seeking and disseminating knowledge. Morality and ethics in Islam are of divine origin. Medical research in the Islamic community should conform to and not violate the 5 maqasid al-shari'ah which are the preservation of religion, life, progeny, intellect, and wealth. For Muslim physicians, conforming to Islamic ethical guidelines is an added requirement. Muslims should be the first to broadcast those ideals since saving a life, for a Muslim, would be as if he saved the life of all mankind.

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