Review Article

National Framework for Ethics in Health Research Involving Human Subjects

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Abstract
Bioethics is intrinsic part of medical practice and health research involving human subjects. Many countries in the world have established a well defined national system to govern the ethical aspects in the field of health research involving human subjects. Sudan, with its long history in the field of health research is still lacking national ethical policy for research involving human subjects. Nevertheless, there is some ethical review process, but is still premature. Bioethics as a system may help policy-makers and researchers at the same time to recognize and deal with the ethical dilemmas in health research. To be acquainted with the means and tools needed for protection of human subjects involved in health research. This article suggests establishing a national framework for ethics in health research that involves human subjects. It suggests four components to be included in this framework.
***Key words**: National Framework, Bioethics, Health Research.*

Introduction

Sudan's history with medical research could be traced back to 1903, when The Wellcome Research Laboratory was established in Khartoum as a part of the Gordon Memorial College[1].

In the last two decades, funding for biomedical research to national health research institutions has grown. This fund comes from international agencies and to some extend from local component. As research activities have increased, so has the number of complex questions concerning the social and ethical dimensions of national and collaborative research.

Research involving human subjects is an ancient practice, but serious concern about its consequences and about the protection of human subjects emerged relatively recently. Abuses of human subjects and crimes against humanity pushed the topic of ethics to the forefront. There is a growing global concern about ethics in health research (Seven Global Forums have been held up to now). An African organization for ethics in international health research - Pan African Bioethics Initiative - and other global and regional forums were also established[2]. The major events that pushed research ethics to the forefront occurred at the Nuremberg trials in 1947. The Nuremberg Military Tribunals condemned the Nazi experiments on war detainees in the tribunals' review of "crimes against humanity"[3].

In Sudan, the first attempt to establish ethical guidelines in medical practice was in 1968, when the Sudan Medical Council formed a National Committee for that purpose. The Committee successfully finished its task by the end of that year. It established a set of principles, which is now known as "Principle of Medical Ethics and Medico-moral Problems". This important document however, focused on the ethical problems arising in medical profession and has ignored research ethics[4].

Throughout the history of health research in Sudan it is very difficult to find any reference to research ethics. Nevertheless, there have been a few attempts to articulate an ethical system in health research in this country. In 1979 Sudan witnessed the establishment of the first ethical review committee, established by initiative of a group of doctors and scientists from the national health research laboratory. The mission of that committee was to protect human subjects involved in health research. It also proposed to protect Sudanese citizens from

exploitation by foreign researchers and to meet potential ethical dilemmas in health research[5,6]. This committee got neither political nor institutional recognition. Therefore, it had not developed and had come to an end shortly after its inception. In 1980 The Faculty of Medicine, University of Khartoum established its first Ethical Review Committee.

In 2000 a new Ethical Review Committee was established by the Federal Ministry of Health (FMOH). In 2001 the Institute of Endemic Diseases, University of Khartoum established its first Ethical Review Committee[6].

Although Sudan has apparently long history with research ethics, but still there are so many problems. These can be summarized as follow:

- Research Ethics is lacking political commitment.
- There is neither national system of ethics for health research nor national ethical guidelines.
- Knowledge of ethical aspects, among doctors, researchers, scientists and other health workers involved in research is deficient.
- Informed consent is not well observed in both medical practice and health research involving human subjects.
- Good Clinical Practice is not well observed. Deficient to no ethical review process in the major research institutions[6].

The main purpose of this article is to suggest a national framework for health research ethics (NFWRE). A framework is needed to examine the ethical issues raised when health research involving human subjects is proposed.

National Framework for Research Ethics (NFWRE)

An ethical framework may be defined as: a set of principles that allow us to evaluate the research activities and policies of individuals and bodies such as the FMOH, universities, research institutions, non-governmental organizations (NGOs), international organizations and government agencies. These principles are emerging from general practice of clinical medicine, epidemiology, health sciences and general ethical principles. Here they are offered as basic considerations that anyone concerned to reflect upon or evaluate health research in our country, should take into account. These principles constitute the national framework for ethics in health research. The Proposed NFWRE is consisted of four components. These are political commitment, creating national ethical guidelines, establishment of ethical review process and capacity building.

Political Commitment

Most of health research activities in the Sudan are carried out in governmental agencies or with their collaboration. Since the commencement of health research, ethics has not been a priority component or an important factor in the development of health research system and in the shaping of research policy. Research ethics is not included in the Sudan Medical Council regulations, nor in the Sudan Public Health Legislation or in Sudan Code.

We suggest involving the policy-makers and politicians in the process of research ethics. It may not be understood simply inviting policymakers and distributing scientific information among them or just creating a set of regulations. It may be equally useful for researchers and policymakers to participate together in the policy and research ethics development process. Engagement of politicians in this process would strengthen and accelerate political commitment. The state will take its responsibility not only to protect its citizens from research abuses, but also by allocating funds and fair distribution of this fund[7-9].

National Ethical Guidelines

The upsurge of the global concern in research ethics can be interpreted by the occurrence of international ethical guidelines. The Nuremberg code (1947) delineated the principle of voluntary consent to medical research. Declaration of Helsinki (1964) determines and focuses on the obligations of physicians-investigators to research subjects[10,11]. International Guidelines for Ethical Review of Epidemiological Studies and International Ethical Guidelines for Biomedical Research Involving Human Subjects have also been developed by the Council on International Organizations of Medical Sciences. Operational ethical guidelines for Ethical Committee that Reviews Biomedical Research (WHO, 2000) contributed in the development of research ethics all over the world. They presented a set of basic ethical principles that seemed to be universally valid. International guidelines however, well designed and clearly settled, can replace national laws and regulations. Many countries in developed and developing world have settled their own national guidelines for health research involving human subjects, such as US, Tanzania, Nepal, Uganda, etc[12-15].

There is a necessity to set our own national ethical guidelines for research that involves human subjects. They may relay on the international guidelines and ethical principles, but should take into account the religions, traditions and culture and context of the country. National guidelines are essential for ethical review process, help and direct the ethical review committees to review research and perform their entire functions. They are also needed for direction and prevention of researchers from abusing and exploiting research subjects.

Ethical Review Process

Establishing ethical review process may be a first step for the country to create a platform and bodies for ethical debate, analysis and policy development. Ethical review process usualy consists of ethical review committee(s) (ERCs) and equipped by well trained staff.

Ethical review committee (ERC) is specially appointed committee. The major roles of which are to safeguard, the dignity, rights, safety and welfare of the research subjects and to support and advise researchers[16-19]. In the majority of the countries where ERC of health research has been created, this has been on the basis of recommendation emanating either from professional or scientific bodies, such as Medical Research Council or Ministry of Health. The ERCs have different designations, for example in the USA they are known as Institutional Review Boards (IRB) and they are based in the academic and research institutions, in Canada and other Western European countries as Ethical Review Committees[20,21].

In Sudan not all research or academic institutions have established ethical review process. Where already established, most of ethical review committees are not well equipped for their duties. Thousands of health and biomedical research has been made by various health research institutions including the FMOH. Despite the fact that this research covered the major health problems affecting the poor communities in the country and most of them involved human subjects. Most of this research has been carried out without any means of ethical review. For example the ERC at the FMOH mainly review research protocols that seek international fund[6].

There are two systems of ERCs existing in the world. The first, single system, where there is one ethical review board in the whole country[20]. The other is the multi-boards system, where there are many ERCs in the country i.e. every academic or research institution has its own ERC. Both of them have their capacity to conduct a thorough ethical

review of research proposals. We suggest adhering to the second one. It may seem expensive and impracticable in our country, but it has the advantage of covering the whole academic and research institutions and involving a large number of people in ethical review process.

Capacity Building

The practice of biomedical research involving human subjects requires adherence to the basic principles of bioethics and carries special obligations to individuals and communities, not only those participating in the studies but also others whose health may be affected by application of these studies[22,23]. In countries conducting biomedical research involving human subjects, it is crucial that they have their own programs for training of researchers and other personnel involved in health research[24].

The majority of researchers, scientific investigators and postgraduate students in our country received little to no type of formal ethical training. Moreover even the members of the exciting ethical review committees are not trained in ethical review process. Medical ethics is taught only in 9% of schools' of medicine educational program[25].

Sudan, like many developing countries lacks trained bioethicists to fill the vacancies that would be created in academic institutions. It is in this regard that the efforts made by Research Directorate at the FMOH and the Institute of Endemic Diseases in conducting numerous seminars and one training course on bioethics are noteworthy. Here, one also would like to mention the efforts carried by some international agencies that fund training of developing world bioethicists. Some Sudanese scientists have undergone bioethics training in the developed world and have become pioneers in this field. They have an awesome responsibility of establishing educational agenda.

It must be emphasized that the ethics education program must be based on the international ethical principles and take into account the domestic context. Ethics education is needed for all researchers, scientists, members of ERCs and students of medical and health related schools for moral sensitization and development of ethical awareness regarding the dilemmas arising in deferent aspects of health research activities. It is even unethical to leave them strive on their own and relay on their intuition.

Conclusion

Health research is, by definition, designed to create generalized knowledge that will help to resolve critical health problems and benefit the citizens of the country. Research carries in itself the potentiality of benefiting as well as harming the communities. Citizens of our country are often in vulnerable situations because of their lack of power, lack of education, unfamiliarity with medical interventions, extreme poverty, or dire need for health care and nutrition. These conditions represent a good media for research abuses and/or exploitation. The new approach of research ethics is of concern to the FMOH, Ministry of High Education, Ministry of Science and Technology, Sudan Medical Council, academic and research institutions and NGOs. Indeed, without unified efforts of all the stakeholders in development of research ethics system or an official bioethics policy, it is unlikely that the potential of such framework for the improvement of biomedical research and bioethics will be realized. Indeed such framework must exist and function within the national health research system.

National framework for ethics in health research involving human subjects helps researchers, scientists and policymakers to recognize ethical dilemmas in biomedical research and provides guidelines to overcome these dilemmas. It helps in

particular the ERCs member in the review process and equips them with standard principles and guidelines[26]. The framework is proposed to protect the human involved in the health research and safeguards their dignity, rights, safety and welfare and to support and advise researchers.

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