

LETTER TO THE EDITOR

The establishment of ethical guidelines for biomedical research in Libya

Over recent decades, there has been an upsurge in professional and public interest in how biomedical research and clinical trials are conducted. This has coincided with a growing awareness of the importance of ethical considerations in research. The key ethical principles are to safeguard the rights, well-being, and dignity of research participants, and the obligation to reflect on moral aspects of improvements in health care, science, and technology (1, 2). In this regard, several ethical codes and guidelines have been developed by a number of countries and international organizations (3). The Nuremberg Code (issued in 1947) is considered the foremost contemporary memorandum as it delineated the principles of voluntary consent in medical research (4). Further international guidelines were laid down in the Declaration of Geneva (1948; amended in 1968, 1983, 1994) (5) and the World Medical Association Declaration of Lisbon on the Rights of the Patient (6), which underlined the commitment of the medical profession to the sovereignty of internationally adopted ethical guidelines (6). The Declaration of Helsinki on Ethical Principles for Medical Ethics and Human Rights (adopted 1964; latest amendment 2013) was developed by the World Medical Association (7). However, this declaration was designed in accordance with Western perspectives. The International Ethical Guidelines for Biomedical Research Involving Human Subjects were proposed by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (8). The two latter sets of guidelines proposed a framework of basic values for medical ethics that are considered to be universally shared by other similar bodies (9). However, concerns have been raised that, by emphasizing their universality, these guidelines neutralize factual and legitimate cross-cultural and religious variations in ethical codes (2, 10).

Recently, a review of research ethics in Arab countries of the Middle East noted that only a limited number of such countries had already developed their own national guidelines (11). Furthermore, the same review concluded that most of these guidelines frequently contained inadequacies; therefore, it urged for more efforts of improvement and refinement.

To the best of our knowledge from anecdotal evidence, currently there are no clear ethical guidelines for biomedical research in Libya. There was, nonetheless, a decree issued by the previous Libyan Council of Ministry (12)

whereby a concept, rather than a set of guidelines, was instigated and its privilege transferred to the Ministry of Higher Education. However, we wonder if this decree, which was stated ambiguously, i.e. only the phrase *biological ethics* was mentioned, implemented any guidelines. Based on that, the authors aimed to create a real set of guidelines which can be adopted in biomedical research in Libya.

In practice, researchers planning an investigation place an ad hoc request for a sponsorship letter with the dean of their medical/dental school or the head of department. If the applied fund is obtained, it is usually used to access research premises in studies that require fieldwork rather than to pursue ethical clearance for their particular study. No such document is obtained for retrospective studies that involve access to patients' records. It is unfortunate that some Libyan medical researchers do not even ask for patients' consents to use their data in case reports; one researcher declared that a case report study was rejected by a scientific journal due to the failure to obtain the patient's consent (personal communication, 2016). Libyan law on research policy, which adds another dimension to this sensitive and vital issue, does not require ethical approval to be attained prior to commencing a research project. In summary, research guidelines enforceable by law, which promote ethical research practice, must be established in Libya for the effective maintenance of ethical standards in research.

In this regard, and due to the expertise of the authors, we exemplify our doctrine with the International Association for Dental Research (IADR), which is a non-profit organization, even though the message of our research ethics encompasses all biomedical fields. Its main mission is to promote research and raise knowledge for the development of oral health worldwide, to support and represent oral health research community, and to facilitate the communication and application of research findings (13). The Libyan section of the International Association for Dental Research (LADR) was successfully established in March 2015 (14). The LADR has launched an initiative to establish national guidelines on ethics in research, which take into account the culture and traditions of Libya by involving 'knowledge holders' in the community (15). However, there are many challenges and obstacles that need to be overcome in order to set up ethics guidelines in Libya.

Challenges and recommendations: Ethical guidelines for research offer a valuable framework within which investigations can be conducted with the appropriate medical care. These guidelines help medical and health professionals to identify ethical dilemmas and guide them through the associated decision-making processes.

In Libya, the challenges and difficulties reside in developing such guidelines exceeding those in other developing countries, due to the unstable political situation and the fragile system of governance. For any guidelines to be established, they need accreditation by the authorities to reinforce credibility and empower national and international communication and networking. Another factor is the allocation of the funds required to initiate and follow up the development of ethical research guidelines. This is likely to be further confounded by the lack of a deeply rooted research culture in Libya. Nevertheless, biomedical researchers need to be engaged in the planning of capacity building programs in bioethics, which should include training in research ethics. A comprehensive review of ethics will safeguard public confidence in research and will serve as a foundation for an improved understanding and implementation of related laws and policies.

Reviewing and adopting ethical guidelines are at the top of the Libyan section of LADR priority list. Future plans should include courses and campaigns to raise awareness of research ethics for both researchers and the general public.

Iman Bugaighis
Department of Orthodontics
Faculty of Dentistry
University of Benghazi
Benghazi, Libya
Email: isbugaighis@yahoo.com

Asma El-Howati
Department of Oral Medicine
Faculty of Dentistry
University of Benghazi
Benghazi, Libya

Ahmed S. Ali Elmusrati
Department of Paediatric Dentistry
Faculty of Dentistry
University of Benghazi
Benghazi, Libya

Arheiam Arheiam
Department of Community and Preventive Dentistry
Faculty of Dentistry
University of Benghazi
Benghazi, Libya
School of Dentistry
University of Liverpool
Liverpool, UK
Department of Health Service Research
University of Liverpool
Liverpool, UK

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