Summary report on the

WHO-EM/RPC/039/E

Meeting of the Eastern Mediterranean Research Ethics Review Committee

Cairo, Egypt 6–7 November 2016



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1. Introduction

The WHO Regional Office for the Eastern Mediterranean held the annual meeting of the Eastern Mediterranean Research Ethics Review Committee from 6 to 7 November, 2016 at the WHO Regional Office for the Eastern Mediterranean in Cairo, Egypt.

The objectives of the meeting were:

- to follow up on the recommendations of the 2015 meeting;
- to discuss new sections added to the Ethics Review Committee checklists (for principal investigators and reviewers);
- to address new challenges to bioethics in the Region in light of the results of the WHO regional bioethics survey;
- to discuss ethics in clinical practice and decision-making; the outcomes of the meeting on ethics of health policy and system research, held in Zurich, Switzerland, July 2015; and the preparations for the first regional summit of national ethics committees (proposed to take place in Oman in April 2017).

The meeting was inaugurated by Dr Jaouad Mahjour, Director of Programme Management, who read the opening message of Dr Mahmoud Fikri, WHO Regional Director for the Eastern Mediterranean. In his message, Dr Fikri emphasized the importance of this annual meeting in support of health research ethics, setting norms and standards for the proper conduct of research and accelerating translation of research findings into health policy and practice. The 2015 situation analysis of bioethics in the Region had provided opportunities for improved understanding of the challenges and the need to observe bioethics in the Region. It had also identified areas of progress and improvement in bioethics. He noted the strategic importance of the current cooperation of the WHO Regional Office with different stakeholders, including other United Nations agencies, such as UNESCO, in the field of bioethics applications. One outcome

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of such cooperation was the first regional summit for national ethics/bioethics committees, which would take place at Sultan Qaboos University, Muscat, Oman, in April 2017.

Participants included Professor Mohamed Saleh Ben-Ammar (Ex-Minister of Health, Tunisia), Dr Orio Ikebe (UNESCO), and Hoda Atta, Jamila Al-Raibi, Samar El-Feky, Arash Rashidian, Awad Mataria and Ahmed Mandil from the WHO Regional Office for the Eastern Mediterranean.

Professor Ben-Ammar (Tunisia) served as Chairman, while Dr A. Mandil (Egypt) was Rapporteur.

2. Summary of discussions

The meeting discussed the recommendations of the Ethics Review Committee meeting in 2015 which included promoting research on public health priorities in the Region, especially on crises and emergencies. In this regard, a prioritization exercise was conducted among representatives of WHO regional technical programmes to reach consensus on the list of research priorities, according to the five strategic priorities, to be considered for WHO funding through the Research in Priority Areas of Public Health grant and TDR Small Grants Scheme.

The expertise of current global WHO collaborating centres on bioethics/regional technical WHO collaborating centres should be fully exploited by WHO.

A regional WHO collaborating centre on bioethics should be established. A designation proposal was submitted from Pakistan and it is under discussion with headquarters supporting capacity-building activities in bioethics/ethical conduct of health research. In this regard, a regional summit for bioethics is planned to be conducted for the first

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time at the regional level early in 2017 to explore and discuss methods of regional collaboration, with special focus on development and work of national ethics/bioethics committees and bioethics during emergencies and disasters.

An expeditious process is required for proposals on health policy and systems research.

Sections on "conflict of interest" and "informed consent process for vulnerable groups" should be added to current checklists for review of submitted proposals. ERC checklists were updated and new sections were added for pregnant women, minors and research during emergencies.

Regional bioethics survey

The regional bioethics survey draft report was discussed. The survey had 71 respondents from 19 countries (all countries of the Region except Djibouti, Somalia and United Arab Emirates).

Its recommendations included:

- establishing/enhancing the role of national research ethics committees;
- developing/fostering a core bioethics curriculum within the health sciences' curricula of academic institutions and in-service training of health care providers in the Region;
- building capacity of health care providers on medical ethics;
- raising public awareness, especially among patients on bioethicsrelated matters, such as the informed consent process and the importance of bioethics;
- allocating more resources for bioethics-related interventions;
- applying research ethics and monitoring ongoing research;

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- strengthening coordination among different bodies that deal with misconduct or claims;
- enforcing bylaws/regulations for ethics of organ transplantation;
- promoting consistency of regulations and practices between different institutions dealing with bioethics and research; and
- enhancing the role of civil society as a key stakeholder to ensure compliance of concerned bodies, as well as establishing laws according to local needs and context.

Ethics in clinical practice and research

The standards' setting bodies along with guidelines for health/clinical research were discussed. These include: the Council for International Organizations of Medical Sciences; United Nations organizations; WHO/Health Metrics Network; World Medical Association/Helsinki Declaration; Organisation for Economic Co-operation and Development; United Kingdom National Clinical Decision Support Service Board; International Standards Organization; European Standard; European Pre-standard.

Global and national perspectives ethics of health policy and system research

The objectives and outcomes of the 2015 Zurich meeting were presented.

The recommendations of the meeting included:

- developing a framework that categorizes common types or activities of health policy and system research based on the degree of ethical review needed;
- establishing mechanisms to integrate ongoing ethical review throughout the duration of the project;

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- engaging communities in the identification of challenges and risks of research;
- holding health policy and system research at a higher standard of post-study obligation and sustainability;
- explicitly stating the responsibilities of all stakeholders prior to the undertaking of a project.

Ethics in decision-making

The ethics of resource allocation was discussed with special emphasis on accountability and transparency principles, including social values in health care decision-making (content versus process values). Examples were provided on how countries apply such principles in their decisions, for example, Islamic Republic of Iran's social values in health-related national policy documents/health-related priority setting.

Ethical Review Committee checklists

Updates to the checklists in the newly added sections were agreed upon (checklists for pregnant women, minors and research during emergencies). Sections on pregnant women and minors were modified and endorsed, while the section on "research during emergencies" required further discussion. The current status of ethical review of WHO-funded proposals (TDR Small Grants Scheme and Research in Priority Areas of Public Health) and future prospects were presented and discussed.

First regional summit of national ethics/bioethics committees

It is proposed that the first regional summit of national ethics/bioethics committees take place in April 2017 at Sultan Qaboos University, Ministry of Health, Muscat, Oman. Partners of the summit would

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include UNESCO (in light of the agreement between UNESCO Regional Office for Arab States and WHO during the meeting of Regional Directors on 9 May 2016).

The objectives of the summit were presented. These included:

- discussing methods of regional collaboration, with special focus on development and work of national ethics/bioethics committees;
- developing strategies to raise public awareness and provide education on bioethics in Member States, in line with recommendations of the regional bioethics survey conducted by the Regional Office;
- developing strategies to strengthen linkages between bioethics committees and policy-makers (Ministry of Health and Ministry of Education and Science and Technology);
- sharing experiences on relevant health-related ethical issues, e.g.
 ethics during disasters and emergencies, with a focus on
 humanitarian ethics (resilience/response of health systems to
 migration, ethics of supplies, research ethics, ethics of dealing
 with casualties);
- biotechnology cross-roads with bioethics, with special reference to controversial ethical issues emerging from new situations brought about by advances in biology and medicine.

The expected outcomes included reviewing past progress, current actions and future goals in order to generate a list of prioritized recommendations for a short- to medium-term operational strategy. This strategy will allow the WHO Regional Office and UNESCO to proactively develop guidance and potential capacity-building activities on the inputs provided during the meeting.

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3. Recommendations

- 1. Maintain ethical review of WHO-funded proposals.
- 2. Conduct further work on updated versions of the checklists, including new sections for informed consent forms.
- 3. Expand the mandate of the Committee to include bioethics in general rather than research ethics only.
- 4. Support capacity-building on bioethics and research ethics.

