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**Ethics in health in EMRO: practices and perceptions among health researchers
in the Region**

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Introduction

The huge global disparities in health research and inequities in health were first brought to the global centre stage in 1990 by the international Commission for Health Research and Development¹. Concerned, the international community began to examine ways to resolve the situation and a series of international recommendations, resolves and pledges were made. Eight years later the Global forum for Health Research showed that little was achieved². The situation had even deteriorated, and disparities in economic development, burden of disease and health outcomes continue to grow³.

The exploitation of the weak, the poor and the vulnerable under the guise of health research is not new and violation of human rights and dignity by the unscrupulous in the medical profession is well known both during war as well as peace⁴. In the near absence of ethical standards, norms, practices and regulations in many developing countries, their population still continues to fall victim to unjust and unfair health research and harm^{5,6}. The challenge for the developing countries now is to push ethical issues surrounding health research into lime light, through engaging in national debates aimed at improving equity and justice. Developing countries must forge ahead to strengthen bioethics capacities, link research to the community needs in an transparent and participatory manner and initiate communications between the scientists and the ethicists⁷.

The Regional Committee of the Eastern Mediterranean Region of WHO (EMRO) in its 48th session in 2001 adopted the renewed policy for health research and development⁸. The strategic directions of the health research policy include;

¹ Health Research: Essential link to equity in development. Commission on Health Research for Development. 1990. Oxford University Press ISBN 0-19-520838-2

² The 10/90 report on health research 2000 Geneva. Global Forum for Health Research

³ Evans, T.; et al. Challenging inequities in health: from ethics to action New York. Oxford University Press; 2001. pp 3-11

⁴ Emanuel L, J.; et al. Ethical and regulatory aspects of clinical research. Readings and Commentary. Johns Hopkins University Press. Baltimore & London. 2003 p 1-24

⁵ Lurie, P. and Wolfe, S. M. Science, ethics and future research into maternal-infant transmission of HIV-1. Lancet. 1999 353: 1878-9.

⁶ Bagla, P and Cassus, B. Indian trials troubles Hopkins Science 2001. 293:777

⁷ Bhutta, Z. A. Ethics in International health research.: a perspective from the developing world. Bulletin of the World Health Organization. 1002. 80(2):114120

⁸ Renewed policy for health research and development in the EMRO. 2001 EM/RC48/8.

- Advocacy role within Member States to make increasing investments, focus on priorities, engage key stakeholders and improve health research management systems and environments.
- Support networking among health research institutions
- Develop capacities to carry out health research and provide funding to operational and applied health research.

The Regional Office is following the renewed policy since 2002, and is providing additional financial resources to improve health research capacities with an objective of research as evidence for policy change and practice

During 2002 and 2003, two calls for research were made for research in areas that were identified as priority. The priority fields for research were chosen after a list was drawn following discussions with leading health researchers in the Region, the ministries of health and within the EMRO technical staff. These included health systems research, chronic diseases (including mental health), healthy lifestyles, environment and child health and issues of ethics and equity in health research. Infectious diseases were not included because EMRO supports this field through a special grant (Small Grants Scheme) in collaboration with UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

The proposals were submitted by the principal investigators on a structured format and guidelines developed at the Regional Office and provided to the researchers. During the response to the 2002 research call it was noticed that very few researchers were cognizant of ethical issues and concerns in the proposed research. Indeed many did not make any reference to ethical issues at all while submitting their proposals. During the following year (research call for 2003), a special one page questionnaire on ethics was added in the application form. The researchers were asked whether they needed ethical clearance for their proposal and had they obtained it, and if not, what were the reasons for not doing so? The questionnaire went further to enquire if there was need for informed consent and confidentiality and the researchers were asked to attach the consent form in the application. Information was also sought about the ethical review committee / board that had cleared their proposals and whether it was national or local and how long it had been functioning. It was clearly mentioned in the application guidelines that the proposal will not be considered for funding if the information on ethical aspect was incomplete.

Results and Discussion

During the two rounds, a total of 403 research proposals were received and following a two-stage screening process, 71 proposals were selected for funding (Table 1). Almost 60 % of the research was funded in the fields of health systems research, environment and child health and chronic diseases and healthy lifestyles (Figure 1).

It was observed that there was a significant shift in the number of proposals where the researchers had made a special effort to safeguard ethical issues and practices in their research in the second round. An overwhelming majority of the research proposals submitted in the first round of research (2002) had ignored even to

consider ethical aspects in their research proposals. This changed in the following year, and the percentage of principal investigators who had considered ethical aspects adequately in their research proposals rose almost five fold, from 12 to 57 % (Table 2). The table shows that of the proposals that were short listed, there was a significant difference in the numbers where ethical aspects were considered well described during the first stage screening, between the proposals submitted in 2002 and 2003.

During the 2003, there were 77 (43.3 %) research proposals where the principal investigators felt that their research did not require any ethical clearance (Figure 2). On retrospective examination of these proposals, it was clear that indeed all required ethical clearance. The researchers were apparently ignorant of ethical research ethics and norms and believed that their proposals did not require ethical clearance. The main reasons they cited are shown in Table 3. Some interesting and anecdotal reasons cited by the investigators for not requiring ethical clearance for their research are given in Figure 3 (BOX).

Ethical review mechanism in the Member States of Eastern Mediterranean Region is limited. Barring a few exceptions many countries are now beginning to develop mechanisms to regulate and minimize the exploitation of research subjects. The situation analyses of health research systems carried out in five countries of the EM Region showed that only Iran and Egypt have national (and regional / institutional) ethical review processes. The remaining three; Pakistan, Sudan and Morocco had limited facilities and only institutional ethical review mechanisms existed in one or two institutions in the countries⁹. Saudi Arabia, Kuwait and Lebanon are some examples of EM Regional countries that have relatively well established ethical review procedures for health research both at national and institutional levels.

At the time of designing the research application form during the 2003 research call when specific information on ethical aspects was asked, there was concern that the absence of ethical review mechanisms, might deter research investigators from applying. This presumption seemed to be untrue and in reality served as reminder for the researchers to develop their research proposals where ethical aspects of health research were better addressed. The study showed that 72 % of the research proposals were peer reviewed by local (institutional) ethical review committees (ERCs), another 20 % were reviewed by national ERCs. A small percentage was reviewed by other level committees. Those who had obtained ethical clearance stated that in about 65 % of the cases, the ERCs had been functional for a period between 2-5 years. Another 23 % stated that these were operational for greater than 5 years, and about 12 % stated that the ERCs had existed for less than one year.

In conclusions, the results show that the overall awareness to ethical practice among the health researchers was low. However by reminding the researchers of the necessity and the need for ethical clearance especially when applying for research grants, helps improving the ethical standards. During the second round of research grant, many researchers made a special effort to ensure that ethical principles and

⁹ A study of the National Health Research Systems in selected Countries of the WHO Eastern Mediterranean Region: Egypt, Islamic Republic of Iran, Morocco, Pakistan and Sudan. 2003 ISBN 92-9021-385X

standards were met –something that was missing during the previous year. It was also clear that awareness and knowledge regarding ethical practices in health research among many researchers is weak. In pursuance of the renewed policy for health research in the Region, the Regional Office has begun efforts to assist the countries in building capacities in bioethics and raise national awareness to the need for establishing ethical review mechanisms and regulations.

Table 1. Health Research Proposals on Priority Areas Of Public Health Supported By EMRO during 2002 and 2003

COUNTRY	# Received	# Short Listed	# Approved
AFGANISTAN	1	1	1
EGYPT	62	22	10
IRAN	252	66	24
IRAQ	1	0	0
JORDAN	4	2	0
LEBENON	10	6	2
LIBYA	1	0	0
MOROCCO	20	14	4
OMAN	3	3	3
PAKISTAN	54	28	13
SAUDI ARABIA	2	1	1
SOMALIA	2	1	1
SUDAN	13	5	4
SYRIA	4	3	1
TUNISAIA	4	4	2
YEMEN	20	11	5
TOTAL	453	167	71

Table 2: Awareness to ethical issues and concerns among health researchers in the research proposals submitted to EMRO and short listed at preliminary screening

Ethical issues	Research grant 2002	Research grant 2003
Not considered at all	75 (75.8)	14 (19.4)
Mentioned in passing	12 (12.1)	17 (23.6)
Well considered	12 (12.1)	41 (57.0)
Total	99 (100)	72 (100)

(Parentheses show percentages)

Table 3. Response of the Principals Investigators to the question on ethics in the research application form

	Yes	No	No response	Total
Ethical clearance needed	85 (46.2)	69 (37.5)	30 (16.3)	184
Why no ethical clearance is needed (# 69)				
<i>Obtained authority approval</i>			13 (18.8)	
<i>Just verbal consent adequate</i>			12 (17.4)	
<i>Not dealing with human subjects</i>			8 (11.6)	
<i>Its public health research</i>			6 (8.6)	
<i>Its laboratory tests only</i>			9 (13.0)	
<i>Other rationale</i>			21 (30.4)	

(Parenthesises show percentages)

Figure 1: Total number of on going research proposals funded by EMRO under the Health Research Grant for Priority Areas in Public health

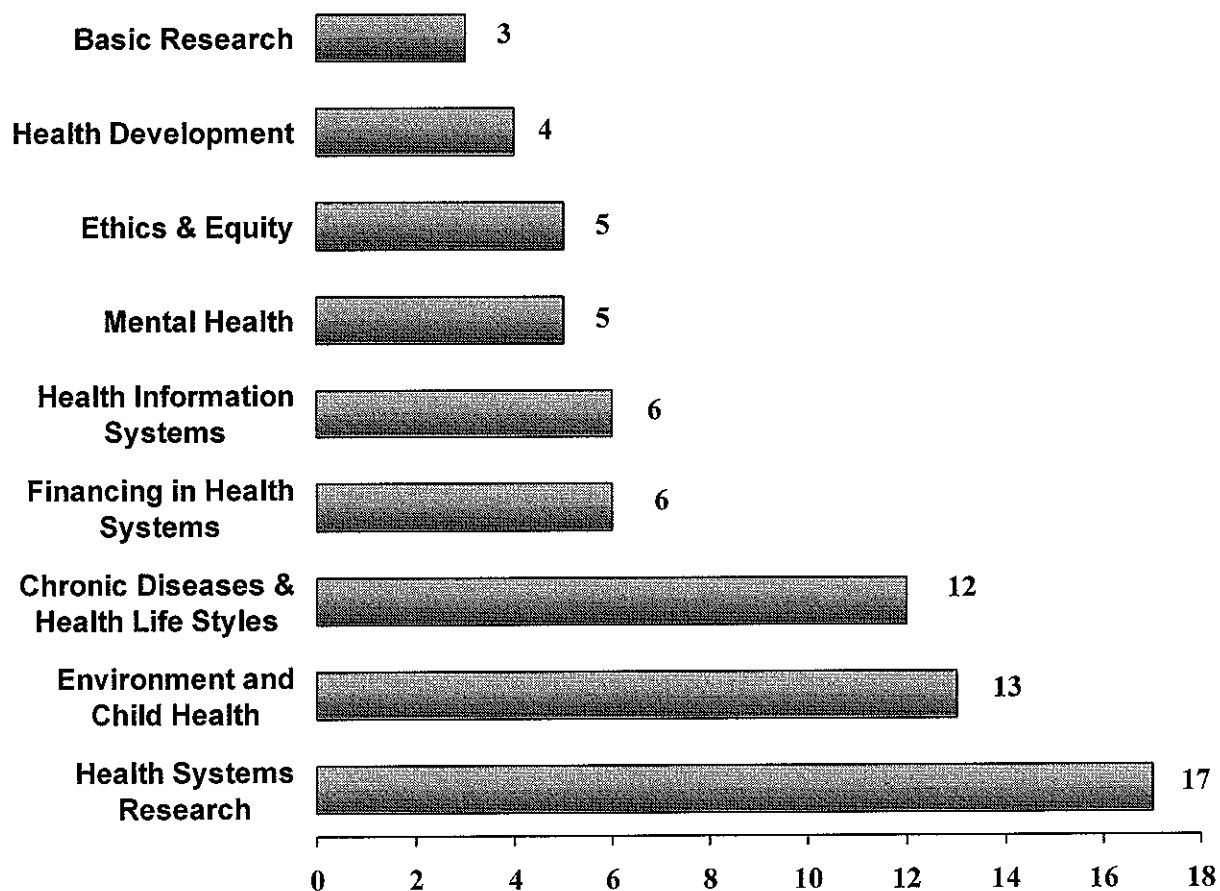


Figure 2. Health researchers' perceptions in research proposals submitted for funding in 2003

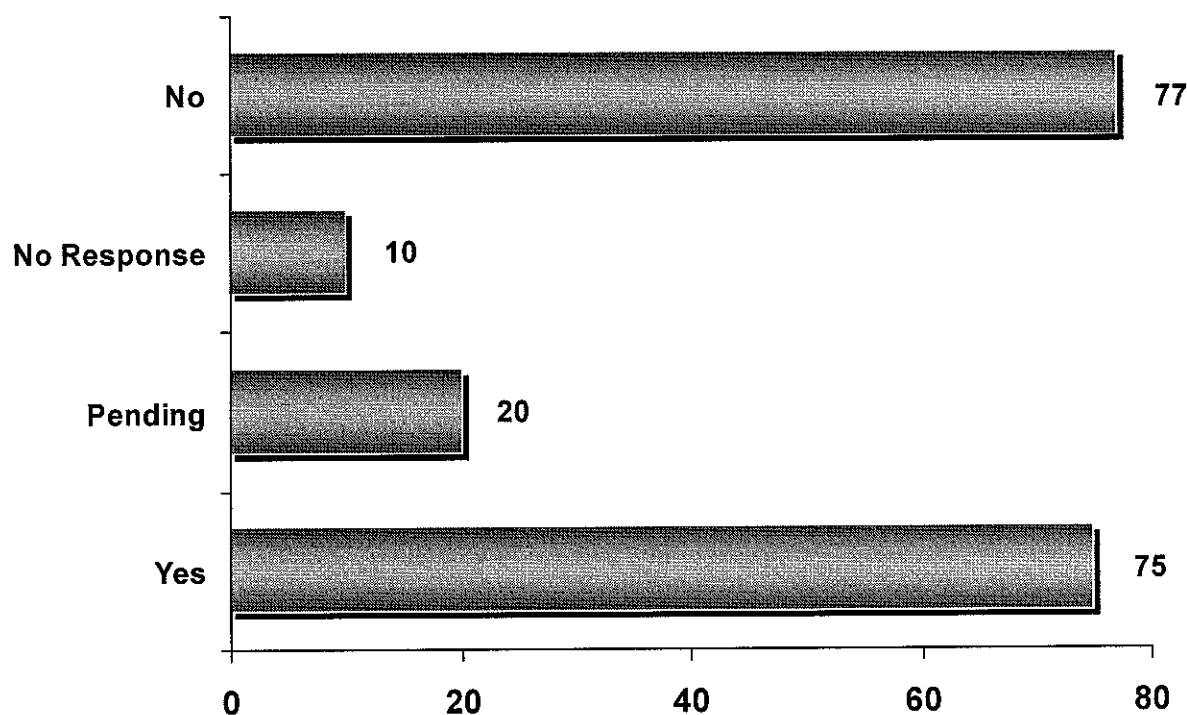


Figure 3. BOX

- ☞ Mothers are cooperating well without consent – *a study involving children*
- ☞ We are taking blood and urine samples only. There are no invasive investigations involved!
- ☞ 5 ml. Blood will cause no harm to the patients – *another study involving children*
- ☞ Semen waste (?) will be used in other additional studies – *a study on male sterility*
- ☞ PCR and are new technologies and these need to be investigated!
- ☞ The vice chancellor is one of the investigators of this study!