

Brief report of ICMR -WHO Intercountry meeting on Ethics in Health Research, held from 9th-13th September, 2002, at Hotel Le Meridien, New Delhi, India

INAUGURAL SESSION

Dr. Vasantha Muthuswamy, Sr. Deputy Director General, Indian Council of Medical Research (ICMR) and Dr. Adik Wibowo WHO-SEARO welcomed the participants and hoped that deliberation of the meeting will lead us to some tangible results. Dr. N.K. Ganguly, Director General, ICMR highlighted upcoming issues of ethics in biomedical research. While inviting the attention of Mrs. Bhawani Thyagrajan, Joint Secretary, Ministry of Health and Family Welfare he said that for the implementation of various programmes it is essential that the administrators and politicians are given enough feedback. He said that with the new awakening on ethical issues, harmonization of guidelines is required to have major responses. Ethical issues are closely related to affordability and equity. While referring to a study on mother to child transmission of HIV/AIDS, he said that although the poor institutional status of participants posed an ethical challenge, unfortunately nutritional supplements could not be provided to them during the trial. He further mentioned about the ethical issues concerning breast feeding in an antiretroviral trial and issues related to HIV vaccine trial, and the recent trial for cancer & bronchial asthma involving John Hopkins etc. The importance of judgement of ethics committee in such matters was highlighted. He enumerated various experiences of ICMR on ethical issues notable among them being the study carried out 20 years back on cervical cancer. The study was initiated for peripheral level primary diagnosis of such cases which was not available during that period. The informed consent process for this study at that time and subsequently other ethical issues were highlighted by the women activists later but ultimately the issue was cleared by an Enquiry Committee. He spoke on ICMR agenda in the area of ethics aimed at propagating awareness among people about the general issues of research. He also referred to the quinacrine trial carried out in Vietnam, other developing countries including India and further mentioned about the research study done 10 years back on Malaria by ICMR to ascertain which strain of mosquito transmits malaria through human bite. This also encountered ethical problems because of lack of awareness. Necessity of informed consent to be understood by people was stressed upon.

He further informed the group regarding the process of formulation of ICMR's ethical guidelines and supplementary guidelines on G.M. food, stem cell research, Assisted Reproductive Technologies etc. He was sure that various deliberations and case studies discussed during the meeting will benefit all the participating countries for effective implementation of these guidelines in a more vigorous manner after generating awareness among people.

Dr.T.Walia , Acting WHO Representative, New Delhi, welcomed the participants to India to participate in this very important meeting on Ethics in Health Research. He thanked Prof. N.K. Ganguly, the Director-General of ICMR and his team for making this meeting a reality. He pronounced that ICMR is, so far, the leading agency in India working in the field of ethics in health and research. The Council's pioneering efforts have borne fruit and India has developed guidelines on several important issues like national ethical guidelines in health research, use of animals in research, genetics and genetically modified food etc. He felt confident that under the able leadership of experts from the Council, fruitful discussions will be held. He stated that ethics is one of the major concerns our Region is faced with. In the medical profession, ethics has transcended centuries of evolution that can be traced back to the time of Hippocrates. Up to this day, it is the pride of every medical practitioner to honour and uphold the oath. The message conveyed by the oath is very simple and can be summarised as "do no harm".

In 1946 the World Health Organization's constitution stated "The enjoyment of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." This visionary statement is as true today as then and forms one of the guiding principles of WHO's work. In pursuance of this goal the WHO put forward the concept of Health for all. Health for all embodies a deep commitment to equity in health. Equity implies not only equal access to health, but an equal respect for the autonomy of the individual and his or her right as a human being. The good of the individual must always be kept in mind along with the concept of public good or good for many.

Modern concern for human rights and ethics in research on human subjects started with the Nuremberg Code on Experimentation on Human Subjects in 1947. This first international document on ethics in medical research was followed by the United Nations General Assembly adopting the International Covenant on Civil and Political Rights. Article VII states "...no one shall be subjected without his free consent to medical or scientific experimentation".

As early as 1964 the Declaration of Helsinki of the World Medical Association and WHO, which has been widely recognized as providing the fundamental guiding principles for ethics in biomedical research, involving human beings, states that, "In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject, and "in any medical study every patient – including those of a control group – should be assured of the best proven diagnostic and therapeutic methods."

Two factors that have made this debate particularly timely are the advances leading to organ transplants and the advent of HIV/AIDS. Both these have thrown up many issues that have forced the medical profession to take a hard look at ethical and human rights issues.

SEAR provides a unique and highly attractive research environment with its mixture of developed countries' skills, expertise, infrastructure and developing countries' burden of diseases. This unique research environment has attracted many researchers but has also opened the door to potential dishonesty and fraudulent ethical practices in health research. The need for ethics in health research again is therefore urgent.

He felt that this meeting is most appropriate at this point of time. Much has been done internationally in the development of guidelines, on proper conduct of health research involving human participation. The Declaration of Helsinki is the most fundamental guideline for clinical research where the responsibilities of data and of those involved in the clinical research are outlined. It states the principles of ethics in health research. The CIOMS guidelines for biomedical research involving humans focused on the principles involved in research.

However, the various available international guidelines in many circumstances are not always optimally suited to the real life situations pertaining to SEA countries. In the absence of no relevant ethical guidelines, it becomes increasingly difficult to deal with situations especially when research sponsored by a developed country is being undertaken in developing country. There is a danger that the conduct of the research may fail to reflect the cultural and social values of those from the developing countries who participate in it. As discussions went on, and as the situation unfolded, it became abundantly clear that there was a great need to look at ethics in health research from a South East Asia perspective.

Ethics is indeed not easy to understand particularly when it deals with health research. Many medical institutes have started teaching ethics from the first year of education. Past experience has shown that using case studies is one of the best methods to understanding ethics in health research. Compilation and collection of case studies that are very much related to our

daily life, our culture, norms and society are required. One of the objectives of this important meeting was aimed at developing a compiled series of selected case studies from member countries to be used for future training programmes.

It became clear to all the participants that ethics in health research was crucially important and there was no doubt that the development of ethics in health research in this region had to be strengthened. WHO made commitments to assist member countries in various ways including the development of national ethical guidelines, to strengthen the national ethical review committees and to conduct training in reviewing research projects for ethical clearance. It was hoped that this meeting will propose some suggestions on the forward steps to be taken for promoting ethics in health research and wished the participants a successful meeting and a pleasant stay in Delhi.

Dr Rajni Kaul, ICMR, proposed a vote of thanks after which the scientific sessions followed.

SCIENTIFIC SESSIONS

A total of 50 participants attended the meeting which included 11 foreign participants : 2 each from Indonesia , Thailand, Sri Lanka, Myanmar and Bangladesh and 1 each from Bhutan and Nepal (ANNEXURE-II), 5 participants from different parts of the Country , 10 participants from ICMR Headquarters, New Delhi, 4 facilitators and 3 from WHO-SEAR office Delhi.

The objectives of the meeting were:

A) To gain knowledge on the principles of ethics in research, the structure, roles and functions of research ethics committees at institutional and national levels, informed consent in research, evaluation of risks and benefits, research integrity and plagiarism, inducements and special issues of research in developing countries, and international collaborative research

B) To develop a compilation of selected case studies from member countries of South- East Asia to be used for future training purposes.

The Agenda, (ANNEXURE-I) included :

- 1) Presentations on various topics by the experts
- 2) Country presentations on Institutional Ethics Committees / Institutional Review Boards (IEC/IRB)
- 3) Discussion on actual case studies collected by the participants from their respective countries on the topics *viz.* clinical trials and informed decision making including cross cultural issues; evaluation of risk benefit ratio ; ethical issues in standards of care in the context of international collaborative research; inducements and compensation; privacy and confidentiality; ethical issues in social and epidemiological research and ethical issues in publication practices.
- 4) Each country representative presented the status of national ethical guidelines in the respective country and the proposed programs for next 2 years.

VALEDICTORY SESSION

The Session was attended by Acting Director of WHO-SEAR office and Secretary, Ministry of health and family welfare, Government of India. The summary of the proceedings and recommendations were presented by Dr R. Ravi, Vector Control Research Centre, Pondicherry. This was followed by distribution of certificates to the participants and the vote of thanks by Dr. Nandini K. Kumar, ICMR.

Plenary Lectures were made on the following topics by the experts:

- Ethics in Health Research in SEA region
- Historical background and introduction to Principles of Ethics
- Role and responsibilities of Ethics Committees.
- Country Presentations on Institutional Ethics Committees/ Practices & Processes in place.
- Informed decision making and cross cultural issues
- Evaluation of Risks and Benefits
- Ethical Issues in Standards of Care in the context of International Collaboration
- Privacy and Confidentiality
- Ethical Issues in Social Sciences and Epidemiological Research
- Ethical Issues in publication practices
- Inducements/compensation and post-study benefits
- Case studies: at least two on each of the themes of the lectures.
- Introduction of the Nuffield Council Report on “Ethics of Research related to Health Care in Developing Countries”

The General Consensus

- Principle of Informed Consent by **individuals** is inviolable, but there are circumstances when oral consent may be adequate
- Innovative strategies that are culturally specific to the local population would be essential to obtain ‘genuine’ consent.
- Ethics Committees should take into consideration all relevant factors (technical, ethical as well as circumstantial) in arriving at decisions, particularly relevant to risk vs benefit and standards of care.
- The standard of care offered particularly to the ‘control subjects’ should be “ the best currently available”. Where this is not feasible or appropriate, the best care available in the national public health system should be offered.
- Maintaining confidentiality regarding identity and all information which could be linked to participants is essential. Suitable methods may have to be devised according to the situation.
- Subjects participating in research should be compensated for travel, wages lost etc, but these should not be of such magnitude that it becomes an inducement. Particular care should be taken when inclusion of vulnerable groups like students, women, etc are proposed.
- Ethics in publications , especially safeguarding the interests of all investigators, is essential.
- The responsibility of the researcher and the Ethics Committee does not end with the research . •Individuals in the control group should, at the least , be given the treatment / vaccine found successful in the trial .
- It is essential that discussions are held with sponsors for a priori agreement even before trials on drugs or vaccines are started on the access of the population of the ‘trial’ country to the agent being tested, if it is found useful. The Ethics Committee should pay attention to this.
- Adherence to ethical principles is essential in social, epidemiological and health systems research, where it involves patients, controls and population groups, especially in large surveys, mass drug and vaccine trials.

RECOMMENDATIONS

A. For WHO-SEARO

- SEARO should promote training in Health and Research Ethics in each of the member countries, preferably using regional facilitators
- SEARO should facilitate a meeting of concerned legislators of Member Countries, along with biomedical ethicists from the region to accelerate the development of appropriate legislation in the area of Ethics.
- SEARO to facilitate preparation of ethical guidelines for research in Traditional medicine

B. For Member Countries

- All Member Countries should develop National Ethical Guidelines for biomedical and Research. There should be specific guidelines for externally sponsored research.
- Once the Guidelines are developed, appropriate action should be taken to make the guidelines mandatory through legislation.
- Biomedical Ethics should form part of the curriculum for all health and related professionals
- Promote networking among countries and institutions.

C. For Individuals

- All individuals concerned about biomedical ethics should be encouraged to form National Forum. These fora should review the changing pattern of ethical issues and give appropriate suggestions to legislative authorities. They should also actively build up capacity in biomedical ethics.
- All interested individuals in the Region should become members of FERCAP (Forum For Ethical Review Committees in Asia and Western Pacific)

ANNEXURE-II

Intercountry Meeting on Ethics in Health Research 9-13 September 2002, Hotel Le Meridien, Windsor Place, New Delhi

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