Presidential Address

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Ethical Issues in Public Health Research

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Ethics simply relates to morals, correct behaviour, moral principles, or doing morally correct things. In medical science, the practitioners should observe and follow the science of morals and should work within the field of moral science. Hippocrates, the father of medicine, in his Hippocratic oath for physicians, included basic principles of medical morals. Decorum, an essay, attributed to Hippocrates who practised and taught medicine in the Aegean Island of Kos in the 5th Century B.C. gave a warning not to reveal bad news to patients about their illnesses. From the time of Hippocrates till about the 1960s, medical ethics (or healthcare ethics or bioethics) were seen in terms of doctors duties to patients. Traditionally these duties included helping the patients (beneficence) for their illnesses with no harming (non-maleficence) intentions. These principles of non-maleficence and beneficence were interpreted differently in different cultural contexts, and their importance and seriousness started emerging with the development of the patients' rights movement. In 1803 British physician Thomas Percivial introduced the term "Medical Ethics" to the practice of medicine.

This paper examines the basic principles of ethics in health research with special emphasis on the ethical dilemmas inherent in engaging in research in public health medicine.

The Nuremberg Trials of 1946 gave birth to the "Nuremberg Code" which is widely accepted as an important document related to medical ethics. The declaration of Helsinki in 1964 stressed the importance of written consent. Written consent, today is widely accepted as a basic rule to be observed in carrying out health research involving human subjects.

Health research is conducted to acquire more knowledge about a health problem, or to find a possible solution to an existing health problem. Research helps scientists to develop preventive strategies, new treatment schedules or healthcare practices. Health research involves many professional disciplines, including biomedical and social research. In social sciences, health research seeks to acquire new knowledge on why individuals, or a group, behave in a certain way regarding their healthcare and why they do or do not use accepted preventive or promotive measures. In biomedical research attempts are made to utilise the best information available and test the best known health treatments or to introduce better treatment plans than the existing ones. Since there is a possibility that research could be misunderstood or abused by the researchers, the participants in the research process, need to be protected and they should understand fully what is expected of them and what will happen to them when they take part in research processes. The research participants also should have the right to leave any research study if they wish to do so at anytime during the study. Researchers should also adhere to the rule that participants in a study are well treated during and after the study.

The Belmont report published in 1978 by the United States National Commission for the protection of Human Subjects of Biomedical and Behavioural Research consisted of a set of ethical principles and guidelines for the protection of human subjects of research. Emerging from the Belmont Report, Last (1992) in the context of health research, formulated the following principles:

- *Respect for persons (autonomy)* - means concern about human dignity and freedom, the fundamental rights of the individual. It is the recognition of a person as an autonomous, unique and free individual. It also means that we recognise that each person has the right and capacity to make her or his own decisions. Respecting a person ensures that dignity is valued. Individuals should be empowered to make free decisions and be given all the information needed to make good decisions.

- *Non-maleficence* - is the principle of non-harming. The researchers can provide input to ensure that the benefits to the research participants are optimal while the risks are reduced to a minimum. The risks to a person participating in a research study must be weighed against potential benefits.

- *Beneficence* - is the principle of doing good. The principle of beneficence makes the researcher responsible for the physical, mental and social wellbeing of the research participant.

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- *Justice* - in the ethical sense means natural justice, distributive justice, fairness, equity, and impartiality. Justice requires the fair and equal distribution of benefits and risks of the participation in a research study. Recruitment, selection and distribution of participants must be done in a fair and an equal manner. Justice forbids exposing one group of people to the risks of the research solely for the benefit of another group. The principle of justice establishes special protection for vulnerable persons. Justice does not permit using vulnerable groups, such as low resource persons as research participants for the exclusive benefit of more privileged groups.

The above principles are considered universal and they are applicable anywhere in the world. These principles do not have national, cultural, legal or economic boundaries. Everyone undertaking research involving human subjects should understand and follow these principles. Health matters to everyone, to ourselves, our communities, to our country and to the entire globe. As public health physicians we have a collective responsibility to ensure that the correct measures, are in the correct place at the correct time for people to be healthy.

Human experimentation certainly may be the area that has attracted the largest number of international efforts to address the ethical and legal aspects. Article 7 of the International Covenant on Civil and Political Rights lays down that "No one shall be subjected without his free consent to medical or scientific experimentation". The above and related issues have been addressed by various non-governmental and inter-governmental organisations notably by the Council for International Organisations of Medical Sciences (CIOMS).

CIOMS together with the World Health Organisation (WHO) has published the following documents: *Policy, Ethics and Human Values* in 1988, *International Guidelines for Ethical Review of Epidemiological Studies* in 1991, and *International Ethical Guidelines for Bio-Medical Research Involving Human Subjects* in 1993.

Research in human subjects is done and has to be done in all countries, developed and developing. Research involving human subjects should be conducted only with the informed consent of the subjects. The Nuremberg Code identifies four attributes of consent without which consent cannot be considered valid. Consent must be "voluntary", "legally competent", "informed" and "comprehending". Informed consent is essential to research ethics. The CIOMS guidelines have defined "informed consent "as consent given by a competent individual who:

- has received the necessary information (verbally and in writing)
- has adequately understood the information, and after considering the information has arrived at a decision without being subjected to coercion, undue influence or inducement and intimidation.

From the above criteria it follows that in research:

- information is provided
- information is understood
- a decision is made
- comprehension is monitored and maintained

When informed consent is obtained from research subjects, the researchers should:

- provide a description of the research study and the role of the participant, including an explanation of all procedures relevant to the participant.
- describe all reasonable foreseeable risks.
- describe the expected benefits
- explain alternatives to participation such as other studies or services in the area.
- explain procedures undertaken to maintain confidentiality
- provide explanation of compensation for injuries or health problems resulting from participation in the study.
- provide information on incentives, if any and their duration
- provide information on whom to contact about the research if the participant has questions or concerns.
- explain that the participation is voluntary and that the participant can withdraw from the study if necessary.

The informed consent documentation must include a description of any benefits to the participants or others that may reasonably be expected from the research.

Benefits must be presented without overstatement or exaggeration with the intent to induce participation. The provision of health care to which the potential participant is entitled without participating in the research must not be present as a research benefit. Persons with limited access to health care services are vulnerable research participants. Offering health care to individuals who otherwise do not

have access to this care is potentially coercive. Researchers are responsible for ensuring that the potential participant's decision is not unduly influenced by the opportunity to receive health care.

Benefits are commonly presented as available only during the study. Generally when the research is concluded, the benefits also end. The duration of any benefit associated or derived from the research participation must be clear to the potential participant beforehand. What benefits or services will be available to the participants when the research is ended, or if she or he decides to withdraw from the study, should be explained in the informed consent process. This is particularly important in studies of drug or vaccine trials. If the drug or vaccine proves to be safe and effective, the participant must be informed of availability when the study is terminated.

In most research studies, participants provide information they may consider confidential or personal. In the informed consent process, they must be informed about the degree of confidentiality throughout the study and once the study ends. If the researcher's capability to protect any confidential information is limited, the extent of this limitation must be disclosed. Special attention to confidentiality is necessary when public knowledge of participation is potentially damaging to the participants or their community. Confidentiality extends beyond the duration of the study. Any anticipated future use of the information or biological samples collected, must also be provided, including the conditions under which such information might be used.

Interactions among the following factors are the main influences affecting the health of the people:

- environment
- social and economic factors
- life style
- genetic background
- preventive, promotive, and curative health services

Some countries have a compulsory rather than voluntary system of immunization to prevent infectious diseases. Some ethnic groups, and some religious groups resist compulsory immunization. In childhood immunization, parents make decisions on behalf of their children. Parents make these decisions for their children solely with the intention of preventing childhood diseases. Vaccination of children against the wishes of the parents in compulsory vaccination programmes is subject to ethical issues. In the control of infectious diseases, control measures for specific diseases depend on how infectious a disease is and how it is transmitted. For infections that are directly transmitted from person to person, it is ethically justifiable to apply interventions such as forced isolation or quarantine. These measures were carried out in Asia in the recent past to control the outbreak of severe acute respiratory syndrome (SARS). In countries like the United Kingdom and the United States of America, these forceful measures may be considered to infringe civil liberties. In the control of such epidemics, some of the ethical issues that may arise are:

- Equitable access to health care – Allocation of hospital care, drugs and vaccines are likely to cause ethical issues to patients and for the community in the control and the prevention of infectious diseases. The procedures involved and taken by health authorities in the allocation of resources in advance, and during epidemics may also be questioned.
- Ethical and human rights issues in public health actions, which include:
    1. Disease surveillance and dissemination of information
    2. Measures taken to prevent animal to human transmission
    3. Quarantine, isolation and social distancing
    4. International travel and border control

Quarantine is the restriction of activities of healthy persons who have been exposed to an infectious disease during its period of communicability, to prevent transmission during the incubation period. *Isolation* is the separation, for the period of communicability of known infected persons in such places and under such conditions so as to prevent or limit the transmission of the infectious agent. In emergency preparedness like in SARS and in avian influenza, allocation of resources should be done in a fair and ethically acceptable manner. In these situations special attention should be paid to vulnerable groups and for those who are in real need. The benefits of culling of animals (birds and poultry) as done in avian influenza has to be weighed against the economic loss. Killing of animals also raises ethical issues as animals too have a right to live. Restriction of international travel or country border activities too may create ethical issues.

Obligations of healthcare workers play an important role in the implementation of public health activities. Working with the communities is a key concept in public health practice. Which persons are in-

cluded in public health programmes and which persons are not may pose ethical issues in the implementation of community programmes. Obligation of healthcare workers and how and by whom these obligations are formulated and implemented at community level has to be done with great care. Special thought has to be given to get the maximum community support.

Obligations among countries, inter-governmental and non-governmental organizations in public health practice should be carried out in an ethically acceptable manner. Fair distribution of resources and fair justice has to be maintained throughout and during the provision of health care.

Public communication may pose ethical issues in the practice of public health. Which information should be released to the public and which information should be withheld has to be done with meticulous care. Up to what extent and for what duration information should be withheld is of great concern to the public health physicians. The mechanisms to provide information to the public and the medium of flow of information should be ethically acceptable. Since public health professionals always work with communities, the communication strategies adopted by them should be ethically sound.

The multilateral agreements like the Trade and Related Aspects of Intellectual Property Rights (TRIPS) Agreement provides for compulsory licensing and parallel importation. In the interest of equity and social justice , countries should enter into trade agreements in a fair and an equitable manner.

The humanitarian response to any disaster is to help with food, clothing, shelter and medical care. Public health professionals play a major role in the provision of health care during and after disasters. During disasters and after disasters, especially during the immediate, early and late rehabilitation periods great caution has to be exercised to avoid:

- use of expired and outdated medicines
- distribution of unnecessary products
- distribution of products labelled in foreign language that cannot be understood by local staff.
- products which are not registrable in the country
- products that have deteriorated through poor storage
- receiving materials in excess of the needs

All the above facts are of great concern to the public health physicians who carry out immense work during and after disasters. It will be morally wrong to deviate from the correct and acceptable principles even under such challenging situations.

Finally let me place on record a statement from the Helsinki Declaration

"Well being of human beings should take precedence over all other interests, of science and society"

and I conclude my address with:

".....and never do harm to anyone"

(Hippocratic Oath – 4th Century B.C.)

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Bibliography

1. Bankowski Z, Bryant J, editors. Health Policy, Ethics and Human values. CIOMS: European and North American Perspectives;1988.
2. Bankowski Z, Bryant J, Last J, editors. Ethics and Epidemiology. CIOMS: International Guidelines;1991.
3. Bankowski Z, Levin R, editors. Ethics and Research on Human Subjects. CIOMS: International Guidelines; 1993.
4. Detels R, Holland W, McEwen J, Omenn G, editors. Oxford Textbook of Public Health. 3rd ed; 1997.
5. Detels R, McEwen J, Beaglehole R, Tanaka H, editors. Oxford Textbook of Public Health. 4th ed; 2002.
6. Emanuel E, Crouch R, Arras J, Moreno J, Grady C, editors. Ethical and Regulatory Aspects of Clinical Research. Maryland: The Johns Hopkins University Press; 2003.
7. Rivera R, Borasky D, Rice R, Carayon F. Research Ethics Training curriculum: Family Health International; 2001.
8. Rivera R, Borasky D, Carayon F, Rice R, Kirkendale S, Wilson W, et al. Research Ethics Training curriculum for Community Representatives: Family Health International; 2004.
9. Role of ethics in the rational use of Medicines. SEARO Publication series No 46; WHO 2007.
10. Seeberg J, editor. Health Ethics in South East Asia: WHO 2005.
11. The Ethics of Research Related to Healthcare in Developing Countries. London: Nuffield Council on Bioethics publisher; 2002.