Medical ethics applied in Forensic Research: A revisit to ethical guidelines

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Abstract
The knowledge on recent advances in research ethics is mandatory for the forensic community comprising mainly forensic pathologists, forensic scientists and members from the legal fraternity who support the smooth functioning of the medico-legal system. A revisit to the recent developments in medical ethics and understanding the implications towards forensic research would keep Sri Lanka in equal platform with other countries. The main objective of this paper is to revisit the recent developments in medical ethics and to understand the ethical principles applied in forensic research. The review article briefly explores the ethical aspects of research involving clinical patients, research involving dead bodies and skeletons, laboratory investigations in research and publications of research findings. The existing ethical norms in research practice had evolved over a long period of times. The sound knowledge of the internationally accepted ethical principles would make sure forensic researches are developed according to the accepted standards and be more scientifically valid.

Key words: medical ethics, forensic practice, researcher

Introduction
The knowledge on recent advances in research ethics is mandatory for a country like Sri Lanka which profess high literacy rate. The forensic community mainly involves forensic pathologists, forensic scientists and members from the legal fraternity who support the smooth functioning of the medico-legal system. Therefore, a revisit to the recent developments in medical ethics and understanding the implications towards forensic research would keep Sri Lanka in equal platform with other countries.

The ethical norms are interpreted by diverse group of individuals who perceive and make decisions which may result in conflicts. [1, 2] Medical ethics is a collection of moral principles that applies values and better judgments to the practice of medicine and also it can be applied in research involving medico-legal cases. [3]

The individuals who are presenting for the forensic evaluation differ from therapeutic cases. There is always a legal impediment bordering the patients which plays a significant role when it comes to decision making of an individual. Therefore, these circumstances create important ramifications in informed consent and disclosure of information. [4] The forensic physician is not in a position to assure the confidentiality in the obtained information and examination since the law expects sensitive information to be divulged for legal purposes. [5] The same is applicable for the dead where information gathered during the process of autopsy is revealed to the legal authorities.

Research ethics ensure the rights, interests, safety and wellbeing of the individuals and communities who participate in research. Researchers in forensic practice should be able to identify concepts of medical ethics relevant to the conduct of research in forensic medicine. [3]

In Sri Lankan context the medico-legal work is done by a Judicial Medical Officer who at times functions as a forensic pathologist and in some other occasions works as a forensic physician. The interest in forensic
research will provide access to both living and dead victims. Some of the complex cases where a multitude of research ethics would operate are victims of child abuse, sexual abuse, torture victims, prisoners and those presenting with various types of injuries. On the other hand the dead may be used for various research studies targeting internal organs.

This paper aims to provide a background on the ethical principles involved in research by selectively revisiting the literature and applying those ethical norms to forensic research. The authors are more interested in approaching the Sri Lankan forensic community.

**Objective**

The main objective of this paper is to revisit the recent developments in medical ethics and to understand the ethical principles applied in forensic research.

**Discussion**

War crime tribunal at Nuremburg following Nazi medical experiments in world war two had given 10 principles in 1947 establishing first international moral, ethical and legal concepts in medical research which mandated balancing advancement of the scientific research with the rights and wellbeing of the research participants in human research. [6] This ultimately resulted in the “Nuremberg code”. [7]

The 1948 United Nations gathering adopted Universal Declaration of Human Rights stating that human rights should be protected at international level.[8] 1964 World Medical Association adopted the Declaration of Helsinki (revised in 1989) which strengthen the voluntary consent, permit for surrogate consent when the research subject is incompetent, physically or mentally incapable of giving consent, or a minor.[9]

However, there were several examples of unethical research such as Tuskegee Syphilis study (1932-1972), [10] human radiation experiments in U.S. (1944-1974) Willow brook Study injecting live hepatitis virus to the mentally handicapped children(1963-1966) etc. In 1966 Henry Beecher cited 22 instances of violation of medical ethics in his publication ignoring patients’ rights. His influence created a forum to promote specific standards to the conduct of research. [11]

National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research strengthened ethical principles with Belmont report in 1979. [12]There are multitudes of national and international regulatory documents around the world serving the common purpose of protecting human subjects.

All the research which involve human subjects should follow the basic principles of medical ethics as explained in the Belmont report including respect for person’s autonomy, beneficence, non-maleficence and justice.[12] Depending on the ethical dilemma faced by the researcher these principles give different weightage at the time of application to the forensic research.

**A. Research involving clinical patients**

(a) Respect for the participants autonomy

Not only in forensic research but in every medical research investigators are expected to respect the participants as autonomous subjects recognizing their freedom for a proper decision making. Forensic research involving clinical patients especially in the Sri Lankan context where the interaction with a doctor is for medico-legal purposes it had to be very clearly informed that any refusal in participation would not negatively influence the report. This may be more aggravated in prisoners and children who have diminished autonomy. When involving prisoners for research they should have extra protection in participating research.[13] Researcher has an obligation to make sure that participants take their own decisions freely and voluntarily on participation without having undue influence, incentives or cohesion from any one. The same is applicable for sexually abused victims, when they are traumatized their thinking capacity to take a rational decision is compromised. The researcher had to take extra care in respecting the participant’s autonomy.

To take part in any research, participants should have reasonable amount of information from the researcher to make a decision, be able to comprehend information presented to them before decision making. Information includes purpose of research, methods to be used, risk and benefits of participation. Further for medico-legal cases where the participants could be the victims or accused in a particular incident, it had to be clearly told that the outcome of the court cases would not anyways be affected by their participation in the research. Those explanations should be in a language where the participant can understand and in an approach relevant to the cultural setting of the participant. Participant’s right to withdraw from the research without entailing any consequences should be preserved. There should be extended opportunity to clarify any uncertainties before decision-making. If any equipment are used...
for photography, audio or video recording, separate consent is needed explaining purpose of the recording and fate of it. Researchers are bound to protect confidentiality of participants as well as the gathered information; collected information can be used only for the purpose where the participant agreed upon. [14]

(b) Consent in forensic research
Forensic research subjects are particularly vulnerable due to their legal obligations. [15] Participants may think that they have to cooperate with the authorities. Therefore, the consent may be forthcoming without much hassle. Custodial nature of the patient, power relationship of the examining doctor and the patient, capacity for giving consent in some of the instances are unique in forensic context. In the process of obtaining consent in forensic research mental capacity of the person is pivotal. Some of the research in forensic practice has centered on participants who are having limited comprehension. In such a situation respect for persons require consent from parent or legal guardian who has the best interest on the person and if possible assent from the participant. [16] In certain situations where the participants have diminished mental capacity to make decision participation could be justifiable only if the harm or risk is negligible and benefits to the person or the society is greater than the risk or the harm. [17] There are established guidelines to protect other vulnerable participants in research such as children, pregnant mothers, sex workers, refugees or displaced persons, institutionalized persons, elderly, minority group or people who are politically powerless from undue influence on participation in research. If such a person is required in research an informed consent can be advocated explaining the true nature of the research. [9] It is inappropriate to take consent for the research by the examining doctor who has power relationship with the patient which may cause duress. The data which are in registries or public domain such as following a court case can be used without consent of the person however researcher should be cautious enough not to harm or stigmatize the individual by possible identification. [18]

(c) Beneficence
Researcher has an obligation to maximize benefits for the individual or society, while minimizing risk of harm to the individual. Potential risk can be physical, psychological, legal, social, and economical risk. Risk posed to the participant must be adequately justified in the protocol. Scientifically sound methodology which includes recognition of reasonable research question, accurate sample size calculation, selection of participants with proper inclusion and exclusion criteria’s, proper study setting, accurate and promptly reported results reduce the risk posed to the participants. Presence of conflict of interest should be declared by the researchers and consider ways and means of circumventing it to minimize the impact on study. Scientifically sound methodology, accurate and promptly reported results reduce the risk posed to the participants. The duty to do no harm “no maleficence” requires discontinuation of the research if there is threat to the individual or society. Scientifically sound research assesses the risk and benefit ratio well in advance. Researcher is liable to civil and criminal litigation if there is any negligent act causing harm to the participant as a result of research activity. Researcher has the responsibility of termination of research if there is any harm to the individual or society. When conducting research with vulnerable population it should be borne in mind that the outcome is of more beneficial to the society or the participant. [19]

(d) Non Maleficence (Minimizing risk to the participants)
Prisoners need thorough process of risk and vulnerability assessment and measures to minimize cohesion. [14] Special attention to be paid in consent process and data gathering to improve voluntariness. [20] Forensic researchers have to consider the risk of emotional distress in participation which involves bad experiences such as sexual abuse, child abuse and gender based violence. Information elicited during the research may be on mandatory reporting of a crime by any citizen or may be related to the criminal activity of the person which could result further conviction of the person. Not like in therapeutic research the risk of breaching confidentiality may further affect the participant. Therefore, when designing a research project the laws of the particular country must be considered to avoid difficult situations for the researchers.

(e) Justice
Justice demands equitable and equal selection of participants, where a particular group based on religion or ethnicity should not receive potential benefits while compromising a different group of people which may subject to a risky research. Social justice demands appropriateness of giving a burden to an already burdened person. Persons who are under custody, ethnic or religious minorities, dependent patients should not be selected as research
participants because of their accessibility, compromised position or possibility of cohesion. [21] The group who face the risk in participation should gain benefit of application of research. [22]

B. Research involving dead bodies and skeletons
Mostly ethical principles guide research involving living participants. Still Belmont principle of ethics is applicable to the deceased as well. Autonomy of the deceased person to be respected by the way of taking consent from the relatives and confirming that the deceased didn’t express any unwillingness to take part in research during his life. Some research was terminated considering violation of accepted notions of dignity and morality of the deceased. [23] Even though there is no direct risk in using deceased in research, indirect risk should be avoided to the relatives in the form of harming the name of the person. There should be beneficence to the society as a whole. Following completion of research dignified disposal is needed for remains. Further consent and valid justification is required for different usage such as educational purpose or future research [24] when the internal organs or tissues retrieved from a dead person for research purposes similar ethical norms could be applicable. [25]

C. Laboratory investigations in research
Without using identifiable details of the person, general data of diagnostic investigations or histopathological investigation can be used in research. However this has to be reviewed by an ethics committee. [26] Issues arise using research related to DNA fingerprinting where most of the investigation details are related to a person. Not like in therapeutic research DNA finger printing in forensic is related to a legal issue. Therefore maintaining data base for research, preserving samples for future analysis and confidentiality of storage samples need strict adherence to ethical principles. [27]

D. Publication of research findings
The research publications also should adhere to ethical norms where the identity of the participants is not compromised. The publications should not bring any harm to a particular person or group of individuals. The research publications should be scientifically valid and contributing to the social justice. [28]

Limitations
This article is a selective review of the literature related to research in forensic practice. Though there can be conflicting views regarding ethical guidelines the information provided here are considered to be more relevant to the Sri Lankan forensic practitioners.

Conclusions
The existing ethical norms in research practice had evolved over a long period of time. The changes came following unhealthy involvement of human subjects for various research projects resulting in severe harm to the wellbeing of those individuals. The sound knowledge of the internationally accepted ethical principles would make sure forensic researches are developed according to the accepted standards and be more scientifically valid.

Reference
2. Gillon R. Philosophical Medical Ethics. Great Britain: John Wiley and Sons, 1986
9. Declaration of Helsinki IV, World Medical Assembly, Hong Kong, September 1989


