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## History and development of medical ethics- the international norms

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Medical ethics encompasses a broad field, including ethics in day to day medical practice, in research and publication. The historical development in the context of international norms of medical ethics is presented here, with brief mention of 'research and publication ethics', the latter two being a broad topic in itself.

The development and practice of ethics is influenced by the human development, social norms and moral values which governs our day to day life. The six pillars of human development include: equity, sustainability, productivity, empowerment, cooperation and security. From health perspective, 'Equity' is the idea of fairness for every person, including the right to health care and education.<sup>1</sup> While 'Sustainability' is the right to 'earn a living that can sustain our lives' and to have access to a even distribution' of goods. The 'Productivity' is the full participation in the process of income generation and 'Empowerment' being the freedom of the people to influence development and decisions that affect their lives. The 'Cooperation' is the participation and belonging to communities and groups as a means of mutual enrichment and a source of social meaning. Finally, the 'Security' offers people development opportunities freely and safely with confidence that they will not disappear suddenly in the future.

The ethical behaviors of individuals are connected with the Human Development Index (HDI) of the society they live in. It was developed by Pakistani economist 'Mahbub ul Haq' and adopted since 1990 by the United Nations Development Program (UNDP). It is the most influential and widely used to measure human development. The HDI is a composite measure of Health, Education and Income.<sup>2</sup>

The human civilization has acquired basic 'rights and responsibilities' by being member of a group of family, indigenous nation, religion, class, community, or state and adopted the golden rule of "do unto others as you would have them do unto you" i.e. treat others as you would like them to treat you. The idea of human rights (HR) strengthened through

united nations (UN) after the World War II (WWII) atrocities of Nazi. The UN charter in 1945 re-defined HR 'to protect citizens from abuses by their governments, and be accountable for the treatment of citizens living in their borders', which was influenced by the 'State of the Union Address' by the US president Roosevelt in 1941 that included 4-freedoms- of speech, of religion, of fear and want'.<sup>1</sup> The Universal Declaration of Human Rights (UDHR) adopted by UN in 1948 states that HR is "inherent in all human beings" regardless of their nation, location, language, religion, ethnic origin or any other status and is applicable everywhere, at every time in the sense of being universal and they should not be taken away except as a result of due process based on specific circumstances.<sup>3</sup>

The 4-Basic Principles of Medical Ethics and scope includes 'Autonomy'- voluntary, informed consent from patients, research subjects; the 'Beneficence' - maximize the benefits and minimize risks to patients; 'Non-maleficence'- do no harm; 'Justice' - is mainly the equity for all service seekers.<sup>4</sup> In broader sense, 1<sup>st</sup> the concept of autonomy- is the autonomy of thought, will or intention, and of action i.e. self-rule or deliberated self-rule. Thus, health professionals are required to 'consult and obtain agreement before doing things to patients' i.e. obligation of informed consent to respect patients' autonomy to be able to help them. It also requires not to deceive each other, for e.g. about their diagnosed illness unless they clearly wish to be deceived. This means, that the medical persons are required to communicate well with patients/clients, listening (not just with the ears) and telling (not just with the lips) to give adequate information about intervention and finding out whether patients want that intervention and information. Followed by 2<sup>nd</sup> and 3<sup>rd</sup> concept of 'beneficence, non-maleficence'- to provide net benefit to patients, for which we need to be clear of the risk assessments and harm to patient or society. In recent years, the popular concept in health care is 'empowerment for self-decision making'- but due to the

commercialization of health services, it has become more than 'doing things to help patients and clients' and has resulted in 'being more in control of their health and health care system'. The 4<sup>th</sup> concept of 'Justice' requires us to clearly explain the burdens and benefits of treatments distributed equally among all groups in society, in the spirit of existing laws that is fair to all involved. Justice involves fair distribution of resources (distributive justice), rights and obligations (rights based justice), and respect for morally acceptable laws (legal justice). For greater good of population, there is also the concept of 7-principles, in public health issues.<sup>5</sup>

The modern historical development of ethical guidelines followed after the 'Nuremberg Trials' also called 'The Doctors Trials' in 1947, after the world WWII, in which 23 German physicians (also the administrators) faced criminal charges by American Military Tribunal for war crimes and crime against humanity for the research in concentration camp. The trial found 16 doctors guilty and seven were sentenced to death.<sup>6,7</sup> The Nuremberg code developed and included 10-codes of ethics to guide medical practice and research. The vulnerable population including, prisoner, children, fetus, pregnant woman, comatose patient, student, employee or army personnel requires further consent and protection during medical care and research.

The infamous US Public Health Service Syphilis Study 1932-72 at Tuskegee, Alabama, changed the way we conduct medical research. The study subjects, mostly African American sharecroppers were not told of the motive of research to see natural progression of the untreated syphilis, which became one of the biggest embarrassment for US government, failing to oversee the Tuskegee study in which participants were not treated adequately even after availability of penicillin and laid the foundation for distrust of public health authorities.<sup>8</sup> After this study, the establishment of ethical review committee/review board and approval for research became the norm. On July 12, 1974, the National Research Act established the

existence of IRBs.<sup>9</sup> The act became law. In 1976 the Belmont Report was published identifying 3-core principles of ethics- respect for persons, beneficence, and justice.<sup>10</sup> This is similar to the 4-Basic Principles of Medical Ethics and scope.<sup>4</sup>

The World Medical Association's (WMA) has been in the forefront to bring out the policy statement for research on human participants, famously known as Declaration of Helsinki (DoH) in 1964.<sup>11</sup> The DoH has undergone continuous amendments, the recent 7<sup>th</sup> one in October 2013 includes ethical norms regarding 'need to disseminate research results, negative and inconclusive studies, treatment and compensation for injuries related to research, and research in limited resource settings'. The addition during the WMA Declaration of Taipei on Ethical Considerations in 2016 mentions the Health Databases and Biobanks.<sup>12</sup>

The council for International Organizations of Medical Sciences (CIOMS) guidelines adopted by UN, includes medical ethics guidelines for research on human participants and beyond, for e.g. protection of prisoners against torture, research involving animals, for epidemiological studies, vaccine safety etc.<sup>13</sup> In Nepal, in 1991- the Nepal health research council (NHRC)<sup>14</sup> formally started to guide, train and supervise the research ethics producing guidelines, including formation and functioning of ethical committees. The recent addition of NHRC is the clinical trial registry in the country.

The International Committee of Medical Journal Editors (ICMJE)<sup>15</sup> has been instrumental in the development of guidelines for authors, reviewers and editors of medical journals, with working documents on 'criteria for authorship, disclosure, conflicts of interests, misconducts' and more. Similarly, the Committee on Publication Ethics (COPE)<sup>16</sup> provides guidelines and flowcharts to support editors, publishers and those involved in publication ethics to promote integrity in research and its publication.

Social norms and values have contributed to the development of medical ethics. The 4-cradles of human civilization recognized are 'ancient- Egypt, Mesopotamia, India, China' dating back to 8000-6000 BC and only thereafter came the 2-European civilizations of ancient 'Greece, and Rome'.<sup>17</sup> History of medical ethics in India, reportedly shows 'Atharva Veda' as the principal source for information way back in 1500 BC, and describes the Ayurvedic ethical declarations, qualities required in a student- teacher and other issues.<sup>18</sup> The ancient Chinese medical ethics (ACME) compares well with the 4-principles of biomedical ethics, however because of ancient socio-culture influence, the Chinese society tend to adopt a "beneficence-oriented", rather than the triumphs of "autonomy-oriented" approach of western culture.<sup>19</sup> The anthropology study reflects that different sociocultural influence 'scientific ethical divide between east and the west' and the report further argues, Why should China follow Western philosophy and religion?; Should the ideas of West be considered the universal ones? The literature argues that the basis of medical research ethics in West is derived from 'Greek, Roman, and European philosophy, Catholicism, and is influenced by a history of research abuse on human subjects, and so they may not be true for all, and may not be seen as the bedrock foundation, 'forcing other culture with different philosophical and religious traditions to abide by could be seen as cultural colonialism'.<sup>20</sup> The research argues that it seems logical as to why China, with a very rich-and-older-than-the-West tradition of religion and philosophy, should abide by the West's version instead of having and develop a rich research ethics from its own traditions, which may differ and the 'assumption that the Western view is always "right" is a display of cultural arrogance'.<sup>20</sup>

Finally, we can conclude that 'wellbeing of participants no matter where, when how, should take precedence over interests of science because 'Research is privilege not the right'!

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