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Section on International Organization Perspectives on Person-centered Medicine

Council for international organizations of medical sciences perspectives: protecting persons through international ethics guidelines

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The purpose of guidelines in the field of medical ethics is to help physicians to make the best decisions or follow the right course of action in difficult medical situations. For other guidelines, the purpose is to help investigators, sponsors and Institutional Review Boards (IRB) or the equivalent to design, support or approve only studies involving human beings that fulfil a set of conditions, principally the scientific validity of the project, the protection of the participants and the respect of their rights, including that of giving their free informed consent. They are not algorithms or decision trees to deal with a disease, or recipes to conceive a hypothesis, and then write a protocol to confirm or reject it. All these guidelines are derived from more basic general declarations and codes of conduct. The terminology used in these various documents to define the subjects of their consideration reflects the degree of generality or specificity.

Thus, attention should be devoted to the terminology used in codes, conventions, declarations and guidelines. It occurred to me that some confusion between these numerous fundamental texts exists in the mind of many colleagues. I therefore tried to put some order among them based on the designation of the very subjects they aim to protect. This is also very important since they represent the fundamental texts upon which the Guidelines of Council for International Organizations of Medical Sciences are based and from which they expand to help investigators, sponsors and members of Institutional Review Boards or Ethical Committees to prepare or, as appropriate, examine research projects involving human beings.

These texts are so numerous that, in order to chart this field, I propose, for those not familiar with them, a simple classification starting from the most general texts addressing almost abstract themes to the more specific dealing with the encounter between a physician and a patient, where each acts and responds as a person, so to speak adding more and more flesh and blood to the basic structure.

The first level is that of the most general declarations and conventions that are legally binding for these countries that have adopted, signed and, in some cases, finally ratified them. The Declaration of Independence of the US (1776), the Bill of Rights of the US (1788), the French Declaration des Droits de l'Homme et du Citoyen (1789), the Prussian Directives (1900), the Nuremberg Code (1947), the Declaration of Geneva of the WMA (1948), and the Universal Declaration of Human Rights adopted by the UNGA (1948).

These bills and declarations address the most common denominator, that is to say the human being and citizens. They represent the basic structure or one can even say the backbone upon which more specific texts have been built in the course of the years and to which these texts refer.

The second level adds flesh to this basic structure in defining the conditions to be respected in medical activity and most particularly in medical research. It concerns every patient or healthy participant and is largely based on the best known Kantian categorical imperative and on the fundamental principles, proposed by the North American ethicists Beauchamp and Childress in 1979, of autonomy, beneficence, non-maleficence, and justice, which are so often quoted but are also objects of debate. Among them, one finds the International Code of Medical Ethics of the WMA (1949), the Declaration of Helsinki of the WMA (1964) and its successive revised versions,

the Belmont Report (1979), and the Universal Declaration on the Human Genome and Human Rights of the UNESCO (1997).

The third level concerns specific categories of patients grouped according to their common pathological conditions, mental or physical condition or handicap, socio-economic situation, including gender, age group, etc.

National guidelines issued by various academies, councils or other institutions dealing with ethics have dealt specifically with one or more of these different groups of subjects. For example, the Swiss Academy of Medical Sciences has published >20 such guidelines [1]. They are addressed primarily to physicians but also to the various medical societies in different fields of specialization as well as to the Foederatio Medicorum Helveticorum (better known as FMH), the nurses associations, the health authorities, and courts of justice, which may refer to them in cases of misconduct, although as such these guidelines are not legally binding.

At this most important third level, not only general principles, as already mentioned, apply, but in addition special standards of conduct are expected from the various categories of health professionals, notably physicians and nurses.

Throughout these three levels, great attention should be devoted to the terminology to designate participants in professional actions and research studies. There are differences between almost abstract concepts or anonymous terms, such as human beings, participants, and subjects and those with flesh and blood as persons, patients and victims in the event of natural catastrophes or man-made disasters.

One should not forget that when data are collected and reduced to mere figures and points on a curve, introduced by statistics, there is behind them a person with an identity and in between one or more collections of personal data in current electronic files. Also when organs, pieces of tissues, blood or DNA samples are collected, there is, hidden behind them, a source, that is to say a patient. They can be anonymized or coded in various ways. However, in view of the ease in connecting, merging and transferring electronic files, special precautions should be in place to secure the rights and the privacy of the individuals, and sometimes even of their families. The goal is to not jeopardize their relationship with their next-of-kin, their employer, and their insurance company, *inter alia*. In consequence, the necessity of free and informed consent of the person is central and should be respected whenever feasible. Even after death occurs, one is confronted by problems of identity and anonymity.

All these delicate situations have already been considered in the new revised CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects issued in 2002 [2], but particularly in the newly revised International Guidelines for Ethical Review of Epidemiological Studies [3]. Central to this protection of the person is the requirement that the investigator seek the free informed consent of the participant in any study.

I will now plead for the defense of persons in a world that tends more and more to disintegrate or manipulate them. A person is meant as a unique individual with his or her own self and a complete biography. Not only a biography as it appears in a curriculum vitae to present oneself for a position, a prize, an award or any other distinction, not a medical anamnesis to recount his or her symptoms and the list of ailments of the past. We should always remain aware of the various layers that lie under a CV or a biography: the circles of the family, of friends, of professional colleagues, the ethnic or cultural group to which he or she belongs; also the list of cultural interests, religious beliefs or philosophical attachments, of sports activities and hobbies; and so on, all of which forge a personality.

When only the bare civil status or identity is removed in a research project, as I mentioned, one speak of anonymization and the rest of the personality is preserved; but if one or more of those layers, which I mentioned, that form the totality of a person, are still accessible, there is a danger of harming, whether unintentionally or not, a person or his or her family circle or social surroundings.

On the contrary, when one or more of those layers are purposely ignored, this represents depersonalization. For example, with the new management of hospitals, economists and sociologists have introduced, instead of ‘patients’, the terms ‘clients’ or ‘health-care consumers’, while practitioners are no longer nurses, doctors or physicians but ‘health-care providers’. Thus, sick persons are depersonalized and reduced to economic entities if not straight bar codes or bare social security numbers, not only in hospitals but more and more in private practice under the pressure of insurances companies.

All this should reinforce our determination through Ethical Committees of all sorts, and associations, such as yours, to recognize what a person is; his or her uniqueness, importance and responsive role in society; to protect them

from harm and defend them against unacceptable intrusion; while at the same time one should appeal to their sense of responsibility towards other persons and society at large in promoting, supporting, and rendering possible medical research. Thus, a balance has to be struck between not hindering medical research and not harming the participants. This has always been the aim of CIOMS, as well as most national medical academies.

References

1. Swiss Academy of Medical Sciences. [webpage on the internet]. Available from: http://www.samw.ch/en/News/News.html.
2. CIOMS. International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS; 2002.
3. CIOMS. International ethical guidelines for epidemiological studies. Geneva: CIOMS; 2009.