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Why do we need bioethical recommendations?

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Abbrevations: CIOMS: International Organizations of Medical Science; WHO: World Health Organization; ICH: International Conference of Harmonization

Opinion

Hundreds of years ago, only three classes of men were not judged about their decisions or their behaviors because they were considered the same as God: The King, The Priest and the Physician. Over time, society understood that all of them are just men with extraordinary power: the power of money, the power of faith and the power of health, respectively. All of them are corruptible. Because of this, society has been trying to control the use of their respective powers. I will not talk here about the king (now the politician) or about the priest. But, what can we say about the physician? Their power was first ruled by the Hippocratic Oath, which remained intact for more than 2500 years. However, during the last decades the main core of this oath has been changing due to the demands of society.

Most of us agree that the crimes committed during the World War II put the society to think about what we are doing with humanity and what kind of future we would like to have. In that sense, soon after the end of the War, the most questionable tasks were those related with physicians. How, when they are supposed to preserve life, do they behave causing suffering and death? Immediately the Nüremberg Jury found guilty all these white-gloved killers and the world medical community accepted the New Rules of the Nüremberg Code for human experimentation. With only 10 simple rules, most of them just common sense, in 1947 it became in 1947 the first Code of Medical Ethics for Human Research. Almost immediately, the General Declaration of Human Rights was signed by 48 of 58 Members of the United Nations assembled at the General Assembly of the United Nations in 1948. During the next decade, it seemed that common sense and humanity had returned to the medical community, however, many "well-conducted investigations" began to be published and soon some of these protocols were questioned due to ethical issues. Taking into account this situation, the World Medical Association prepared an extensive document that was discussed in 1964, during the 18th Annual Meeting in Helsinki. It is known as the Declaration of Helsinki and was the Great Bioethical Document for many years. Unfortunately, it had too many revisions and the main purpose been diluted. Also, the declaration lost power in 2008 when the Food and Drug Administration ceased compliance with the Declaration and replaced it by the Good Clinical Practices of the International Conference of Harmonization.

Once again, it seems that Declaration of Helsinki helped the medical community behave ethically. However, in 1972, the Tuskegee Case was published by the press. Now it was too much for society. They could not accept that such a terrible investigation took place under their noses for 40 years. This time US Congress prepared a document to rule scientific experimentation in humans. This document was the Belmont Report completed in 1978. During the '80s and knowing all this professional misconduct, the Council of International Organizations of Medical Science (CIOMS), in close relationship with the World Health Organization, began to prepare a draft on the International Guidelines for Biomedical Research. The first official document was published in 1993. The last and excellent revision was carried out in 2016. By the same time, in 1990, from the pharmaceutical board, the International Conference of Harmonization (ICH) was born, and during the first decade they were advocated to complete the Good Clinical Practice Guideline to protect the rights of human subjects who participate in clinical trials and ensure the scientific validity and credibility of the

data collected in human clinical studies. The era of globalization began and developed countries needed rules for the trade in medical drugs and health technology.

Therefore, we currently have the Nüremberg Code of the War Crimes Tribunal, the Declaration of Helsinki of the World Medical Association, the CIOMS guidelines of the International Organizations of Medical Sciences and the Good Clinical Practice of the ICH. This means that we have international law, physicians, medical organizations and pharmaceutical industry that try to protect the human being from abuses committed during medical research, and even so, the abuses continue to exist. But it is not the physicians or the industry that abuse human being; it is a human being who abuses another. All these rules could be summarized in a behavior of common sense "respect the other". And this is the first principle of the Belmont Report.

Many of these recommendations have never been used properly, otherwise in some countries, these recommendations served as the basis for legal regulations. But, why do we need ethical recommendations? Kant explained that human beings tend to do the right as a pragmatic fact, to guarantee the survival of the species. Kant called this goodwill. But Kant also recognized that the human being tends to do evil, he called this radical evil. So, everyone must fight continuously between good and evil. Everyone seems to walk the thin line of good and evil. That is why I like to say bioethics is the science of interstice. Bioethical recommendations are a kind of guide to show what could be bad during human experimentation. History taught us that perversion has no limits. Even when these recommendations emerge from international councils, every government must do the effort to promptly convert them into legal regulations. Undoubtedly man is son of rigor.

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