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Scientific research, current guidelines in the European Union and ethical issues

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Abstract. Scientific Research is the main process of evolution of Science. Especially in the Healthcare Sector, the context in which the development of Scientific Research is possible marks both the Legal and the Ethical data of each era. For example, the limits of research, the interventions in Humans, the existence of standards and the continuous control of research data are some of the elements of the ongoing scientific study for the framework within which scientific research can be conducted. In the first part of the present paper, the current in the conduct of Scientific Research in the field of Health at the international level in the field of health are developed through a bibliographic review. The second part of the paper summarizes the rules of the European Union on Scientific Research in Health. Finally, the third part of the work mentions the Ethical issues that have been mentioned in the literature, regarding the conduct of Scientific Research in the Health Sector.

Keywords. bioethics, ethics, Scientific research, Unesco, WHO

1. Introduction

The scientific progress of the 19th century, the inherited perceptions of the 20th but also the political and social changes of the 21st century strongly influenced the ethics of healthcare today. This paper has been prepared with the aim of recording and reporting the applicable rules governing scientific research worldwide and in the European Union as well as to present current ethical issues.

Global biomedicine and global bioethics

The First World War, with the Holocaust, the emphasis on categorization but especially the experiences of the Nazi era led not only to the development of interest in medical ethics but also to its integration into both experimental process and education. Many doctors and nurses were heavily involved in the Nazi program of discrimination, the extermination of the "inappropriate," and the "cleansing of the race."

While in Germany doctors collaborated and contributed to the conduct of Nazi politics, the same was not observed in Denmark, where doctors (often trained at the same universities) did everything they could to thwart Nazi policy. The "Oath of Doctors" in 1946 developed the code of conduct for human research (the "Nuremberg Code") and has undergone several revisions ("The Helsinki Revisions"). The claim that this was the first code of conduct for human research is false: there was a code similar to the Nuremberg Code of 1946, which came into force during the Weimar Republic but was never repealed - simply ignored [4]. Finally, the Universal Declaration of Bioethics and Human Rights, adopted by UNESCO on 19 October 2005, is an important step in the pursuit of universal standards in biomedical research and clinical practice [5]. During the last two decades, several scholars have been involved in the evolution of global bioethics research in medicine [6-8]. Their findings have shown a growing trend towards ethics, law and rule-making around the world [7, 9].

Significant studies dealing with bioethics as presented in the declarations, principles, guidelines and regulations, have highlighted in recent years the problems that may arise when a general set of guidelines is proposed to be applied in countries that differ between their historical, socio - economic context [8]. We are given the opportunity to delve into three basic forms of criticism related to: (1) mismanagement of resources, (2) the cultural dimensions of values, and (3) the so-called "local ethical framework".

The first of these basic forms of criticism focuses on the problem of harmonizing bioethical and ethical practices worldwide due to inequalities that occur at the scientific, technological, cultural and economic levels [8, 10]. This form of criticism demonstrates the material, technological, and institutional parameters associated with ensuring ethical oversight and protection in conducting scientific research in the so-called "poor" countries, which are considered particularly vulnerable.

The second aspect of the critique focuses on the "Eurocentric" basis of bioethical principles, as proposed by documents such as the Helsinki Declaration or the Universal Declaration of Bioethics and Human Rights: environments around the world. They may need to be radically reformulated to take into account the particular ethical context that determines the complex nature of East Asian culture [11,12]. In line of this cultural criticism, developed specifically (but not only) in Asia, is about a perceived "moral imperialism" and requires intercultural consultation based on mutual understanding and respect.

Finally, a third aspect of criticism emerged from the ethnographic commitment to the communities in which biomedical research is conducted. In these critiques, "anthropologists have variously defined the state of ethics as an indicator of the claims of global systemic ethics" [7]. Bioethics is seen as emerging as a response to specific practices and not as something that can be imposed externally. Ethnographic studies of "research groups" show that there is a significant "ethical variability" or "ethical flexibility" depending on the context in which the research is conducted, perhaps more evident in the context of public health scrutiny, raising questions on the aims of a generalized bioethical direction. Each of these three aspects of criticism is based on the imposition of an ethical framework ("Western" or "universal") that is considered foreign, cut off, or alien to a given existing situation [13].

2. The basic principles of ethics and the European legal framework

The European Parliament aimed to ensure respect for human rights in biomedical research and to harmonize the various regulations on bioethics in Europe. This initiative would create the first international convention on bioethics. In June 1996, the Coordinating Committee for Bioethics (CDBI) approved the final version of the draft Convention on Human Rights and Biomedicine, bringing this success one step closer. Unexpectedly, the majority of delegations accepted the 1996 document. In the autumn of 1996, the Parliamentary Assembly of the Council approved the draft and the Assembly was formally approved by the Committee of Ministers. This brought pride and satisfaction to those who fought for the development of an international convention in a potentially controversial field. Therefore, it is time to consider the application of the main articles and to assess what has been achieved [15].

The conceptual and applied view of the basic ethical principles are used as basis for the application of these values in various European countries. The second part of the paper will analyse the findings from the international English language literature regarding the basic principles of ethics and the European legal framework.

The basic principles of ethics can be considered as the basic dimensions of a European legal framework [15]. They are the guidelines for a European constitutional framework aimed to protect human rights. Thus, respect for basic ethical principles implies a transition from bioethics to the enactment of laws that define principles at the constitutional level. In this way the authorities establish respect for the common good in European societies as an expression of a just legal order [16].

It must be understood that the meaning and significance of the principles differ among European countries [17]. Although there are some common guidelines as a framework, these principles are applied differently in each country. The law among the various European countries can be summarized as follows:

Ethics and bioethics in Austria are characterized by a pragmatic positive tradition limited by Catholicism and German-inspired legislation on the protection of human existence and dignity. [20] There is a growing interest in the application of medicine ensuring autonomy and self-determination with a Kantian moral conception of human existence. In Austria there is no ethical law but only some regulations on certain bioethical issues [16].

Belgium can be seen as advocating a pluralistic approach to bioethical issues, in which the concept of autonomy is of great importance [20]. Belgium is called upon to strike a balance between the perceptions of Northern and Southern Europe. Therefore, Belgium is an interesting case in point for the creation of a bioethical legal framework that can be applied throughout Europe.

The situation in Denmark can be interpreted as "weakly regulatory", in which a technocratic bureaucratic legal system has begun to deal with bioethical issues [17]. There is still legal realism and a strong utilitarian tendency in public consultation. In an extensive public debate, views differ from arguments for recognizing the basic principles of autonomy, dignity, integrity and sensitivity as part of a bioethical and ethical law.

French ethics and bioethics are characterized by a strong fundamental approach to basic ethical principles [20]. French laws concerning people apply to people suffering from a disease. Bioethical principles are a big part of the French consultation on the interpretation of basic human rights.

Germany is characterized by a strong and extensive presence of the concept of human dignity in the definition of bioethics and ethics [16]. Autonomy, integrity and sensitivity characterize the respect for the inviolable dignity of every human being. In addition, there is intense public consultation on technological development in biomedical science.

In Greece there is a positive attitude towards new technologies and principles of bioethics, in the light of the Hippocratic view of bioethics and ethics [18]. Due to the influence of Germany in Greek law, the principle of human dignity is enshrined in law.

The situation in Ireland is characterized by the constant pursuit of peace. The Irish constitution is characterized by a strong respect for human dignity associated with the sanctity of the doctrine of life. In particular, the state recognizes the protection of the newborn's life as essential to human dignity.

In Italy the dialogue on the basic principles of ethics is characterized by the opposition of universal and secular bioethics [18]. Also, the American fundamentalist view, the human rights approach, and the personal philosophy have greatly influenced the bioethics consultation. In addition, in the reflection on bioethical law there is a movement which is far from the metaphysical conception of human nature in support of evolutionary theory.

The Netherlands has a long tradition of tolerance and pluralism due to the absence of a prevailing national ethic. This peaceful co-existence and self-determination contribute in the regulation of bioethical issues. Dutch law in patient rights is a very good example of this liberal attitude. This liberal attitude towards euthanasia also confirms this tendency to autonomy.

Norway is an homogeneous country with little pluralism. Norwegian law is characterized by strong Lutheranism and socio-humanitarian respect for human dignity and integrity. This contradicts the values of the progress of a welfare state. Norway has enacted a comprehensive law on bioethics based on the concept of "mixed ethics".

Ideas of human dignity, integrity and autonomy are essential elements of the Portuguese Constitution, which is a modern constitution of a welfare state. But the universal thinking of the population still has a great influence on the basis of social solidarity. In Portuguese bioethics legislation, the basic principles of ethics are particularly influenced by the fundamental social virtues applied in each of the different fields of bioethics.

Following the new constitution of 1975, Spain evolved into a pluralistic society seeking a common framework. The new values are accompanied by the secularization of Catholicism. However, the principles of autonomy, dignity and integrity have a major influence on the regulation of bioethics in the new democratic society. This society has a strong liberal attitude towards bioethical issues.

Like the other Nordic countries, which are characterized by legal realism and pragmatism, the Swedish constitution places little emphasis on human rights. However, in 1975 the term dignity was introduced in the constitution [16]. Therefore, the concepts of dignity and integrity related to the various areas of bioethics are constantly changing the consultation on bioethics.

Switzerland is characterized by the expanded use of bioethical principles, due to the fact that the country has introduced in its constitution the concept of dignity in creation [20]. Bioethics is regulated by the constitution but also locally (provinces), so there is no specific regulation of the various sub-bioethical issues. Therefore personal autonomy is very important, for example in relation to political self-determination.

The framework for bioethics consultation in the UK is shaped by a conflict between utilitarianism and human rights [16]. The regulatory framework is multi-level and society is multicultural. The human rights perspective defends rights such as autonomy, dignity, equality and respect. Further fundamental influence in the United Kingdom is the American fundamentalist approach as well as utilitarianism [17,18].

3. Ethical issues

The Universal Declaration of Bioethics and Human Rights is an important step in the pursuit of universal bioethical standards. Like any other international body of its kind, it has some

shortcomings. However, due to the sensitive nature of bioethical issues, the fact that all states have reached a comprehensive agreement in this area is a significant achievement. Of course, most of the principles of the Declaration are not original, they come from various existing international documents. That is why the biggest advantage of this instrument is to consolidate these principles and integrate them into a human rights framework. In summary, the purpose of the statement is not to invent new bioethical principles or to provide the definitive solution to the growing list of bioethical dilemmas. Its main goal is quite modest: to gather some basic standards to help states in their efforts to promote responsible biomedical research and clinical practice, in accordance with the principles of international human rights law [5].

Based on the analysis of the principles in Europe, it seems that the basic ethical principles of autonomy, dignity, integrity and sensitivity are not abstract concepts. They do not exist in a "theoretical background", but must be considered in the context of justice. We are already in a post-ethical process of reviewing the principles.

Conclusion

By understanding the presence of main ethical principles in European morality and ethics, we can promote them as a basis for future bioethics and ethics initiatives. We may consider the rights of the individual's body as fundamental human rights. The regulation of bioethical issues is considered as a legislative crisis which is governed by the basic principles of ethics. In addition, this leads to the extension of human rights to include rights in relation to the human body and its organs. Finally, the concepts of non-commercialization and anonymity in organ donation of the human body should be included [19].

Based on their pluralistic interpretations in various European countries, ethical principles are very important as guidelines and concerns for the development of a common policy, when it is appropriate - and always in agreement and respect for the principles of the European Union, the institutions and Council of Europe [17]. This understanding of the basic principles helps to develop a new generation of human rights in international bioethics and ethics.

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