BIOMEDICAL RESEARCH ETHICS

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Biomedical research – opportunities and ethical challenges

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Abstract

Purpose: The principal purpose of this paper is to analyze the main opportunities and challenges in biomedical research, thus contributing to improving compliance with ethical norms within the context of continuously expanding research, such as to ensure better quality of patient care and reduce the risk of research not observing the totality of patient rights. *Background*: Since antiquity finding ways to give care to people has represented not only an opportunity, but also a challenge materialized in experimenting and self-experimenting – a constant part of caregivers' activity. Medical research, whether fundamental or applied, is not only essential to evolution in medicine, but also the way towards increasing the quality of individual lives. *Content*: The article undertakes to analyze the main ethical norms governing medical research, starting from historical experience and literature search. *Discussion*: The growing number of people engaged in medical research over the last years has turned bioethics into an increasingly applicative science, capable of developing practical standards to ensure the moral advancement of the medical profession. *Conclusions*: The bioethics of the last years has been more and more tied to the reality of medical practice, as well as to that of scientific research, contributing increasingly to the integration of moral elements into medical activity and to the development of research in interdisciplinary bioethics. Bioethics and more so bioethical education need to be correlated with the transition from research itself for the purpose of publishing and career advancement to research based on altruism and the desire to contribute to the wellbeing of patients.

Keywords: bioethics, medical research, ethical norms.

Introduction

Biomedical research unfolds in an area where progress is not a purpose in itself, in a field where the individual and not the community as an abstract concept is of importance. For this reason, even if enthusiasm and ambition could determine researchers to become less careful about their behavior towards their fellow human beings, the development over time of clear ethical rules has prevented scientists from turning into research machines that neglect the main purpose of medical research, which is ensuring optimum care conditions for each individual.

Bioethics, although appearing to be a relatively new science, that over the last decades was structured on the fundamentals of scientific research in the filed [1], is based in reality on concepts defined as early as the age of Hippocrates [2]. The increasingly acute need for knowledge in health care, for producing new drugs, the development of new surgical techniques, as well as the appearance of new diseases determined bio-ethics to move towards the central concern of those involved in both fundamental and applicative medical research [3], thus rendering bioethics an integral part of day-to-day activity.

Warren Thomas Reich, editor-in-chief of the "Encyclopaedia of Bioethics" defined bioethics as "the systematic study of the moral dimensions – including moral vision, decisions, conduct, and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting" [4].

As Selye [5] pointed out, researchers are concerned about the impact of their activity from the ethics point of view, as the constant struggle for visibility and the desire to obtain results as any cost and under any circumstances have yielded the need to define universally valid moral values.

Recently the field of bioethics has evolved due to the necessity of establishing a balance between the rights of the individual and those of the community within the context of globalization. Bioethics has become increasingly a modality of improving the ways humanity seeks solutions to the global health issues [1].

The current evolution of bioethics is tied to the emergence and growth of a body of experts in the field, whose development is related to the standards that need to underlie medical ethics and mostly to the moral values that need to be the milestones of our entire life (Figure 1).

Bioethical aspects in interdisciplinary research

Documents like the *Magna Charta Libertatum*, the *Habeas Corpus Act*, the Universal Declaration of Human Rights and other relevant documents of the European Commission do nothing but regulate the moral dimension of medical ethics, as formulated over the centuries by personalities like René Descartes, Hans Selye, Jeremy Bentham, Tom Beauchamp or James Childress [6]. After World War II and more so after the unfolding of certain abusive research the acute need arose for regulations, for moral barriers and even organizations, bodies to ensure compliance with ethical standards, particularly in the case of interdisciplinary research [7, 8].

In the last years, medical scientific research has become increasingly interdisciplinary, and the interest in medical bioresearch has remained no longer an attribute of physicians, but has included biologists, sociologists,

psychologists, anthropologists and even engineers. The area of research has expanded from producing new drugs to the development of new materials used for medical equipment, the design of new laboratory tests, the development of medical software applicable in current practice and research. The emergence of nanomaterials and nanotechnologies, the inclusion of artificial intelligence and robots into medical practice has led not only to increasing patient lifespan and quality of life, but also to the raising of new ethics issues.

Ethical codes need to be further adapted such as to regulate fields like human genetics, cloning, transplant or assisted reproduction, ensuring protection to any individual from unjustified risks and the strong interests prevailing in the commercial area [7].

Figure 1 – ***Medical ethics and research: standards and expertise.***

Conflict of interest, inadequate conduct and informed consent

As Lemmens and Singer mention: "A conflict of interest occurs in a situation in which professional judgment regarding a primary interest, such as research, education or patient care, may be unduly influenced by a secondary interest, such as financial gain or personal prestige. Conflicts of interest exist in every walk of life, including medicine and science" [9].

Revealing possible sources of conflict of interest is not only proof of correctness in scientific research, but also an element of reassurance related to the thoroughness of the conducted research and proving the researcher's awareness of the need to separate financial benefit from the involved financial resources.

A conflict of interest exists only when values like honesty, objectivity, altruism or social benefit are not assumed by the researchers, and thus financial resources made available by companies or individuals can influence research and the way results are presented [4, 10].

In order to ensure that ethically adequate research is conducted, each involved person needs to express their informed consent, even though this sometimes may prove difficult to obtain [7].

Informed consent obtained prior to initiating any study needs to be followed – over the entire duration of that study – by assurance that all new information will be made available to the person involved in the study, as well as by the possibility of this person to resume the initially received information.

The development of alternative mechanisms like the electronic informed consent can facilitate the understanding process of the benefits and disadvantages brought about by the participation in medical research, as the informed consent is "a consent based on autonomy, authorizing in an individual way a medical intervention or involvement in a particular research, being the one that must be legally obtained in institutions, as social rule…" [11–13].

Electronic informed consent has the advantage of ensuring access to information over the entire span of the study.

Securing the agreement of the ethics commission for the modality of obtaining informed consent and the design of the study remains one of the principal ways to avoid the conducting of abusive studies or of studies entailing a clear unbalance of the benefits – adverse effects relation.

Confidentiality – a fundamental right and at the same time an obligation of researchers

Access during research to individual personal data needs to be limited such as to ensure confidentiality and the individual's right to privacy. International legislation provides clear rules prohibiting including of identification data (name, telephone number, address, photographs revealing facial traits, etc.) in studies [7].

While patients believe that their personal identification data are made anonymous within the study, in reality their personal information reaches a much larger number of people, beyond their physician.

Because of the risk of such information reaching also other persons, many data concerning the person involved in the study need to be removed: personal numerical codes, names, addresses, telephone numbers and e-mail addresses. Such data have to be stored securely, and if transmitted electronically a secured medium needs to be provided [14].

Conscious of the necessity of ensuring the balance of the individual's right to confidentiality and the possibility of using information for the greater good of communities' health, those responsible for ethics need to ensure an optimum climate so that research provides a balance of the two research directions that sometimes can be antagonistic [15].

From theoretical to applicative ethics in scientific research

While for a very long time medical ethics had been considered a theoretical discipline, it subsequently proved to be an interdisciplinary research area itself, due to technical progress and medicine including elements of robotics, artificial intelligence or nanotechnologies, as well as to the use of classic research methods in biomedicine involving test animals or clinical trials [6, 16].

The main European and worldwide regulations consequent to an analysis of bioethical situations are provided by documents like the declarations of Tokyo (1975), of Manila (1981) or of Hawaii (1983), the Belmont Report (1979), Beauchamp and Childress' "Principles of Biomedical Ethics" (1979), the Oviedo Convention on Human Rights and Biomedicine (1997), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), the UNESCO Universal Declaration on Bioethics and Human Rights (2005), Animals Deserve Absolute Protection Today and Tomorrow (ADAPTT 2012), the European Union (EU) Directive 2010/63/EU on the protection of animals used for scientific purposes (2013) and WMA Ethics Manual [17–20].

Day to day ore data are included in medical research area and de-identification must be made related to excluding the name, address, personal images, hospital discharge, and postal code. De-identification is a major strategy for respecting the privacy of the patient, but in the same time is correlated to re-identifies data only in a very clear defined condition.

Related with *HIPPA Privacy Rule* identifier list elaborate by Iain Hrynaszkiewicz *et al.*, the data that must be protected are: names, postal address (including street, zip), telephone and fax numbers, all element of dates (except year), e-mail, social security numbers, medical records numbers, account numbers, vehicle numbers, biometric identifiers, full face photographic images or other unique identify numbers [21].

Romania – bioethical and legislative aspects in medical research

Developing individual ethical abilities is essential, considering that human nature is often contradicting, altruism, generosity, humanitarianism, charity, honesty or respect for fellow human beings alternating with egoism, lack of empathy and self-sufficiency.

In addition to the National Ethics Committee, at local level, in medical units, in universities of medicine and pharmacy and in faculties of medicine there exist ethics committees capable of implementing Law No. 206 of 27 May 2004 that provides: "The moral principles and procedures designated to respect them are those stipulated in the Code of ethics and professional deontology of the research-development staff, elaborated by the national authority for research-development" [22].

Indirect regulations concerning medical research can be found also in the Civil Code that provides: "The interest and wellbeing of humans need to prevail over the sole interest of society or of science" [23].

Even though it is still early days for differentiated analysis systems of various types of scientific medical research, and the number of specialists in this area is small. Clinical experience needs to be completed by theoretical one, and the arrival of ethics advisers available to both researchers and patients can represent an efficient solution for supporting those engaged in scientific research.

Romania, like other countries too, undergoes a dynamic process of developing and strengthening structures that ensure the training of specialists in ethics, as well as the development of research complying not only with the legislation in force but also with the moral norms that govern our life.

One of the most important ethical issues of medical research that can raise severe problems is the possibility of Romania being used as a research base for foreign corporations or bodies undertaking to avoid the restrictions imposed in their own countries.

Within this context the role of legislation, of the ethics committees and of the specialists in this field is to minimize unethical research, and including people of different backgrounds (clerics, sociologists, educationists, etc.) into such ethics committees can ensure the independence of these structures.

Conclusions

Interdisciplinary medical research has become increasingly complex over the last years and the number of researchers has grown exponentially, requiring global and overarching approaches to the concepts of bioethics.

The main result of the evolution of science and of globalization was the development of medical interdisciplinary research. It is the mission of bioethics to tie medical research to reality, increasingly based not only on theoretical knowledge but also on personal experience.

In a dynamic society like the one we live in, bioethics cannot be but dynamic, and its evolution requires the development of increasingly complex guides to set the milestones for the activity of us all [24].

Research ethics is strongly connected to respecting rules first stated by Charles Darwin: "… My success as a scientist, no matter how great, was determined by spiritual qualities and complex and varied conditions. Among these, the most important were the love for science, unmeasured patience to reflect upon a certain subject, diligence in observing and gathering facts as well as inventiveness and common sense…" [7].

Bioethics plays the role of a "guide for the dialogue between positivist science and humanities" [25], ensuring a harmonic development in the interest of each individual, while favoring the evolution of scientific research.

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