Principles of Biomedical Ethics

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Abstract: The text presents the principles of biomedical ethics (the principle of respect for autonomy, the principle of beneficence, the principle of non-harm, the principle of justice) and shows how principlism has influenced perceptions of what is right (good) in medical practice – both in everyday medicine, as well as in clinical research – and to what extent bioethics has provided answers to the moral dilemmas of medicine of the 20th and 21st centuries, a medicine supported by advances in science and research. It is shown that although the principlist approach is not perfect, it represents a successful attempt to bring together the great moral theories developed over time and to create, by balancing them in a new formula, a scheme that represents at the same time a guide moral and an analytical key to human behavior and actions in health care.

Keywords: ethics, bioethics, ethical dilemmas, principles, autonomy, beneficence, non-harm, justice.

1. Introduction

The principlism applied to biomedical ethics involves addressing two main aspects, namely that of guiding moral conduct in current medical practice, clinical research and policies in the field of health, on the one hand, and that of the analytical framework of the behavior and actions of doctors, researchers and factors of decision in the light of the principles originally enunciated in the Belmont report. Beauchamp and Childress develop the ideas from the report and bring before the medical community a system that is intended to be exhaustive and at the same time accessible and applicable in most concrete situations. Again the idea is expressed that common morality concentrated in the form of moral theories, although it cannot provide answers to the many challenges of the world and even less of contemporary medicine, remains the source of fundamental principles, each great philosophical current containing valuable ideas that must be brought to light and integrated into a unitary system, adaptable to concrete situations. It is no secret that the education of doctors, during the six years of college and the three to five years of residency, is focused especially on the biological, more recently on the increasingly complex technology, while the social sciences humanities are given too little space and not enough attention, which is why young specialists are not prepared to look at man in his bio-psycho-social integrity, which sometimes makes it difficult to communicate with the patient and his family, to understand the sick man not only from the perspective of a medical condition but as a being that feels, thinks and has its own value system (Nita, 2020, pp. 213-216; Nita, 2023, pp. 8-9). For a good professional, one of his goals is to approach his patients from the perspective of the concept of "evidence-based medicine", which is not a bad thing in itself, it's just not enough (Astărăstoae, 2020a). Of course, all doctors have heard of Hippocrates and all take the famous oath at the end of the six years, but even Hippocratic medicine, despite its charm due to its two thousand four hundred years of continuity, cannot respond to all the challenges generated by biotechnologies, clinical research and examples may continue (Gavrilovici, 2007, pp. 15-16).

The moral theories that were the basis for the elaboration of the principles of bioethics (namely utilitarianism, deontology, the theory of virtues and the theory of human rights) emphasize a criterion of ethical analysis of human actions and behavior, namely the criterion of utility, that of duty, the moral qualities of the agent, as well as respect for fundamental human rights. Principlism recognizes the contribution of each of these theories and proposes a concept that allows them to be balanced. Bioethics, an
interdisciplinary field, addresses all aspects related to life, including the impact of human actions on the environment, but research is a field to which bioethics prefers, because the rapid progress recorded has also brought the greatest challenges, which has required the establishment of safety limits, beyond which one cannot go (Campbell, 2017, p. 120). Between the original edition of Principles of Biomedical Ethics and the eighth edition, published in 2019, the authors brought certain updates, so in the last edition we find four principles, as follows: the principle of respect for autonomy, the principle of beneficence, the principle of non-harm and the principle of justice (see also Țirdea & Gramma, 2007, pp. 18-26; and Ojovanu & Leabu, 2021, pp. 49-60 - which also presents several principles).

2. The principle of respect for autonomy

We find this principle also in the Belmont report, but under the title of "respect for persons" and, in essence, both formulations have the same meaning, as they refer to: the respect that any doctor is obliged to show to all his patients as of autonomous beings, capable of deciding according to their own wishes and interests (Ojovanu & Leabu, 2021, pp. 51-54). By implementing this principle and acting in accordance with it, medical paternalism is put to an end, an approach that dominated medical thinking and practice until the second half of the 20th century (Astarăstoae, 2020b). Moreover, the paternalistic model is not specific to medicine, it has been applied for a long time in politics as well, in the form of "paternal" governance by the state that takes such care of its "sons", while DEX defines paternalism as a system social based on the prestige of the elderly. In the Hippocratic medical tradition the practice was, among other things, to hide from the patient a painful truth about his health condition, and this approach was maintained for a long time, the only moral justification being that of not causing the patient unnecessary suffering if his situation is serious and cannot be remedied. Thus, in Medical Ethics, Sir Thomas Percival supported the paternalistic approach in 1803, on the grounds that the doctor knows what is best for his patients (Astarăstoae, 2020b). Moreover, generations of doctors educated before the 1990s are familiar with expressions like "you, doctor, know what's best to do" or "I'll leave it to you". The maintenance of the paternalistic model was made possible by the convergence of several factors, including the discrepancy between the level of medical knowledge of the majority of the population and the scientific expertise of doctors, the recognition of their authority and the belief that they, doctors, can only have the best intentions towards patients. These aspects have undergone changes in the last fifty to sixty years, changes that have reduced the discrepancy between the two categories. Thus, the population had more and more access to medical
information on multiple channels, starting with the written media, television and, currently, the Internet, these sources being available especially to the younger generations, through which parents are also connected to news, to progress. On the other hand, revelations of abuses committed by representatives of the medical corps both during the Second World War and in other circumstances have eroded the unconditional trust of patients in people in white coats. Respecting a person’s autonomy refers specifically to respecting their decision, regardless of whether this decision agrees with the doctor’s opinion or, on the contrary, is opposed to it. Thus, the paternalistic model is replaced by a model that can be called "contractual", the patient and the doctor becoming two partners who assume responsibility for their own decisions and actions. Critics of this approach may object to the fact that the patient should not be "forced" to assume responsibilities, but, upon a careful analysis of the evolution of science, medicine, but also of society whose members are increasingly aware of their rights and are willing to defend them, we can consider this approach to be the correct one (Gavrilovici, 2007, pp. 16-17).

a) Informing the patient in order to enroll him in a clinical trial

Each patient's right to be informed about his situation in terms of diagnosis, prognosis as well as therapeutic options corresponds to the obligation of the medical team to provide this information (Beauchamp & Childress, 2019, p. 414). If in medical practice it is sometimes resorted to, justifiably, to hide a painful truth and the disclosure of which would not bring any benefit to the patient - we are talking about situations with an inauspicious prognosis and lack of therapeutic resources -, in clinical research things are completely different. Given that a patient's participation in a clinical trial may represent the patient's only chance to improve the prognosis, there is no acceptable reason why the truth should not be revealed to a patient who is potentially eligible to become a subject of investigation. The information process is initiated as soon as possible, through an open and honest discussion, completed by making available to the patient the document called either agreement or consent, to be studied with the family or any other trusted person the patient. If the preliminary discussion and, subsequently, the provision of answers to the possible problems raised by the patient is the responsibility of the team at the medical center (hospital, clinic, institute, ambulatory office, etc.), the provision of information and the drafting of the document that will be submitted for approval to an independent committee of ethics rests with the sponsor, through its team of experts. In the spirit of respecting the principle of autonomy, the document on the basis of which the patient is to make a decision must contain certain information, considered essential. Thus, he has the right to know that he is proposed to
participate in an experiment during which he will undergo investigations - some invasive, such as biopsies or venipunctures - and a treatment whose outcome is to be determined. It is also important for the potential subject to know that, independently of the will of the team physicians, he may receive either the experimental treatment, usual treatment, or no active treatment at all if assigned to the placebo arm. In order to effectively clarify things, the information must also refer to the therapeutic alternatives to which the patient can resort in case of non-acceptance to participate in the trial or in case of premature withdrawal. Regarding this theme, the patient must be firmly assured that nothing is imposed on him and, very importantly, that he has the right to withdraw from the study at any time if he so chooses. The language in which this document is written must ensure understanding by the patient, which is why it is recommended to avoid loading the text with technical, specialized terms, which could put a person without medical training in difficulty, causing them to give up start reading that document (Ţirdea & Gramma, 2007, pp. 101-110).

b) Competence of potential subjects to understand the information and to decide on enrollment in a clinical trial

The term competence, in the context of clinical trials, refers to the ability of an individual to understand his own medical situation as well as to process the information transmitted through the consent document, which presupposes a cognitive-intellectual function unaltered by congenital pathological processes or acquired. In fact, intellectual competence is an essential component of individual autonomy, along with the social component, affecting any of them causing the reduction of autonomy.

Experience has demonstrated cases of violation of the rights of individuals who could not express their opinion, being subjected to serious abuses, which is why it was necessary to identify solutions to guarantee the protection of patients who, for reasons independent of their will (this is mainly of pathologies that affect their mental capacity, such as the sequelae of vascular accidents, severe congenital or acquired mental disorders) cannot be considered competent, so they cannot decide on participation as subjects in a clinical trial. In such cases, the essential question for a doctor to answer is whether it is beneficial for that patient to participate in the study in terms of improving his health. In this way, another principle of biomedical ethics is resorted to, that of beneficence, so that, from the assessment of the situation, the patient's interest prevails over the scientific interest. In the situation where it turns out that enrollment in the trial is beneficial for the patient, it is resorted to obtaining the informed consent from a legal representative, a person from the patient’s entourage who will act in the patient's interest and take
responsibility for some decisions in his place (Țîrdea & Gramma, 2007, pp. 106-110).

c) The voluntariness of the decision

It is essential that a patient's decision to accept or, on the contrary, reject proposals from the medical staff belongs to him voluntarily, as a natural consequence of understanding the information provided by the document made available by the sponsor through the investigator, in accordance with own wishes and interests and, most importantly, in the absence of any influence exerted by the study team (Banari, 2022, pp. 156-170, especially 162-163).

In order to truly respect the patient's right to autonomy, it is absolutely forbidden to exert any type of influence on a potential subject, being clear and complete information on the possible benefits, risks, as well as the other available therapeutic options in the form of therapies already in practice is sufficient current medical. Threats, blackmail or manipulation are not allowed, nor are attempts at material co-interest (Goldby et al., 1971).

As a conclusion, we can note that the principle of respect for individual autonomy, expressed with a binding title in the Nuremberg Code and later developed to its current form, with all the nuances that have become necessary as a result of the diversification of clinical research and its expansion beyond the initial study (the use of tissue samples requires a separate consent from the patient, according to the updated legislation) had a decisive impact on the doctor-patient relationship model, causing the replacement of medical paternalism by a freely expressed agreement between partners who know their rights and assume their responsibilities. This principle brings to light both the Kantian morality according to which "autonomy is the principle of human dignity" (Kant, 1972, p. 54) and the conception of J.S. Mill, according to which "over his own body and spirit the individual is sovereign" (Mill, 2017, p. 21).

3. The principle of non-injury

The individualization of this principle of biomedical ethics occurred as a result of the identification of the difference between doing good and not doing harm, so this principle means the obligation of any member of the medical body to avoid actions with evil intent in medical practice and clinical research (Miroiu, 1995, pp. 68-89). The origin of this principle can be found in antiquity, in the well-known Hippocratic Oath, where the physician solemnly undertakes to refrain from "anything harmful" to the patient, as well as from committing "every voluntary act of evil and corruption." Hippocratic medical ethics absolutely prohibited the prescription of a substance with a lethal or abortive
effect, as well as the disclosure of confidential information about the patient or his family (Campbell, 2017, p. 177). The modern version of the Oath, entitled the Declaration of Geneva (Campbell, 2017, p. 178), expresses this principle in the form: "I will not use my medical knowledge for the purpose of violating human rights and civil liberties, even under threat being." Adopted in 1948 by the World Medical Association, revised over the years, that text reflects the spirit of the Universal Declaration of Human Rights, adopted the same year by the United Nations General Assembly. Protecting the life and physical and mental integrity of patients is the fundamental objective of the medical profession, sometimes difficult to achieve due to those factors that medicine cannot, at a given moment, effectively control. Thus, both in current medical practice and in the conditions of a clinical research, the patient's condition can deteriorate at any time, from minor discomfort to irreversible disability or death. These unwanted events can arise from various causes, such as the negligence of the doctor and his team, the superficiality in correctly estimating the real condition of the patient and the risk to which he is subjected, as there can be objective factors related to chance that cannot be control, regardless of the doctor's good intentions (Gavrilovici, 2007, pp. 17-18).

From a professional and administrative point of view, each situation of this type is evaluated and subjected to measures according to gravity, but from a moral point of view, those acts committed with the intention to do harm, to cause suffering are truly reprehensible. Moreover, the principle of non-injury was imposed as a result of the revelations regarding the experiments that flagrantly violated the most basic moral norms, true crimes committed premeditated and with the worst intentions, without omitting those unethical trials - perhaps of a gravity reduced compared to those during the war, but harmful by causing unnecessary suffering in the absence of any benefit, and especially through the lens of that unethical mentality, a mentality according to which "geniuses" are allowed anything, including arbitrarily disposing of the lives of human beings viewed either as "acres of skin" or as cobia ("human guinea pigs"). The right to life is sacred and inviolable, a right that no one is allowed to knowingly violate, let alone a medical professional, for any reason (Ojovanu & Leabu, 2021, pp. 55-56).
4. The principle of beneficence (or beneficence)

Formulated as such by the Belmont Report, this principle brings back to the fore the fundamental objective of the medical profession, that of doing good, of acting by virtue of vocation, natural abilities and those acquired through study with the intention of preventing, removing or relieve suffering from disease and prolong life whenever possible (Gavrilovici, 2007, pp. 18). Doctors apply this principle every day, to every patient who crosses their threshold and asks for their help, turning to the evidence regarding the best medicine or the most effective method, consulting national and international guidelines and protocols, looking for the appropriate solutions for each case in part. Medical research projects the benefit into the future, onto a population whose individuals may develop a pathology for which current solutions do not provide satisfactory results or, simply, solutions do not yet exist. If the intent to provide benefit by identifying increasingly effective and safer remedies cannot be questioned (at least not today, when there are mechanisms to prevent the slide into harmful research), attention turns to protecting the subjects enrolled in clinical trials, for this purpose making every effort to avoid unjustified risks. Both in current medical practice and in clinical research, there is objectively and inevitably a risk-benefit ratio, resulting from the evaluation of the intensity, severity and frequency of adverse reactions resulting from the administration of a particular drug in relation to the benefits obtained through the effect on the disease treated (Ojovanu & Leabu, 2021, pp. 54-55).

The difference between the two fields of medical activity – both subject to ethical analysis – lies in the degree of certainty, of defining both risk and benefit. The difficulty is all the greater when the substance is less known, as happens in phase I trials, and as information accumulates, aspects related to the usefulness or, conversely, the harmfulness of a product are also clarified. If from the perspective of a final result what is required are the statistical data, from the point of view of the investigating clinician each individual represents a value in itself and it is the doctor's obligation to protect him. The principle of beneficence in clinical research applies from the moment a study protocol is drawn up, through the purpose stated, through the methods used and through the disclosure of the information accumulated in the previous stages. An essential role in the process of ensuring the protection of the interests of potential subjects is held by the control exercised by the ethics commissions, which have the right to reject a protocol if there are elements that suggest an unacceptable risk to the participants.

Cumulating to some extent the two principles - of non-injury and beneficence - a framework of moral conduct is outlined in such a difficult field
of research, a model that seeks to harmonize, on the one hand, the scientific interest in the perspective of a medicine effective and safe, and on the other hand, to avoid as much as possible the suffering, sometimes irreversible damage or even the death of those enrolled in clinical trials. Moreover, above the interest of science are the interests of the individual, the protection of his life, integrity and dignity. Nor does bioethics provide answers to all questions, it does not solve all dilemmas that may arise, but it is a guide to correctness, honesty and truth. By acting in this way, part of the risks can be prevented, as many patients as possible will be saved from unnecessary suffering, and the results obtained will be for the benefit of society.

Regarding the aspect of benefits for each individual participant, let's not forget that it is also not defined due to the possibility of allocation to the arm with standard medication or placebo. In clinical research, each subject is advised, through informed consent, of the likelihood of receiving either one type of treatment or another, with the investigator not having the opportunity to intervene in this regard. It seems that this aspect of the placebo treatment contradicts the principle of beneficence, but the investigator has several mechanisms at his disposal to lessen the impact on his subjects. It should be noted that, in accordance with the regulations in force, in trials in which patients suffer from a serious, life-threatening condition, the use of placebo as the only medication was abandoned, preferring the standard medication for the comparator arm.

5. The principle of justice

The fair, correct and equitable treatment of human beings was discussed primarily in a social and political context, considering a long period in human history of inequality, of dividing individuals into privileged and disadvantaged social classes, in rich and powerful countries in contrast with other small and poor ones. Along with the evolution of society, humanist and Enlightenment ideas led to the emancipation of the human spirit and the ever firmer proclamation of human rights, until the level reached in the twentieth century, when great philosophers of the world addressed this theme. In medicine, beyond the theory, the application of this principle needs to be evaluated, as it has different nuances, between the generosity of the theory and the practical reality there may be differences due to financial limitations most of the time (Gavrilovici, 2007, pp. 18-19).

Thus, to ensure respect for the right to life and medical care, each state has developed its own mechanisms to protect the most vulnerable citizens. As far as clinical research is concerned, the main challenge is not the lack of resources, but the opportunity or, as the case may be, the risks involved in
enrolling subjects in clinical trials and the need to ensure fair and equitable treatment of trial participants in relation to risks and benefits. Inevitably, research cannot only provide trials with maximum benefit at minimum risk, although consistent efforts are being made in this direction.

Therefore, some of these may expose the subjects to considerable risks, which, for the sponsor and the investigator, may raise the problem of enrolling a sufficient number of subjects, respectively meeting the target required by the protocol to reach the threshold of statistical significance. Other trials, in contrast to the first ones, offer the opportunity of an innovative treatment with real benefits for the participants, a situation in which the number of those who want to participate may exceed the proposed requirement. For both types of trials, the protocol establishes eligibility criteria, criteria according to which future subjects will be selected. These are based on medical and scientific considerations, in accordance with the objectives of the study, being the only ones by which the population of subjects is selected. Acting in the spirit of the principle of justice is synonymous with enrolling in clinical trials subjects who belong to the population indicated by the protocol, after rigorous verification of inclusion and exclusion criteria (Ojovanu & Leabu, 2021, pp. 56-59).

Discrimination of any kind is not allowed (for example based on race, religious beliefs, sexual orientation or economic or educational level), which means that patients belonging to categories that we could call disadvantaged will not be marginalized if people belonging to these categories would benefit from participating in the study. Things must be looked at in the same way when it comes to a study that indicates a high degree of risk. Under these conditions, enrollment encounters certain difficulties, which leads to the extension of the interval until reaching the target. It is the kind of clinical studies in which the tendency to force the recruitment of subjects can be manifested by approaching disadvantaged categories of the population, resorting to unethical means of influencing the voluntary decision. If we are talking about people with subsistence incomes, it might be tempting for them to accept exposure to a risk in terms of health or, in some cases, life, at the price of pecuniary rewards that would provide his family with food for a period of time or money to pay utilities. It is also unethical to enlist people whose condition makes them vulnerable to various coercions and manipulations, forced to accept what others would not accept (for example, persons deprived of liberty, who are either under pressure from the authorities are either promised a reduced sentence or simply the enlistment is decided without those concerned being consulted).
6. Conclusions

As a result of the above, some conclusions can be drawn about how the principlism of biomedical ethics has influenced perceptions of what is right in medical practice – both in everyday medicine and in clinical research – and in to what extent bioethics has provided answers to the moral dilemmas of 20th and 21st century medicine, a medicine supported by advances in science and research. It must be stated that the principlist approach is not perfect either, but it represents an attempt, for the most part successful, to bring together the great moral theories developed over time and to create, by balancing them in a new formula, a scheme that represents at the same time a moral guide and an analytical key to human behavior and actions in the field of health care. Placing the rights and interests of each individual patient first, paying maximum attention to the freedom to decide what is allowed to the doctor by the patient and to refuse what goes against a person's own value system, the principle of respect for autonomy has an essential impact in the doctor-patient relationship, definitively demolishing the paternalistic model, transforming the patient into a partner of the doctor, whose opinions must be respected in all aspects of life and health, with special emphasis in the field of clinical research. Regarding the principle of non-harm and that of beneficence, it can be said that traditional medical ethics was built around them, but, in the context of the challenges raised by clinical research, these principles acquire new valences, in that they draw attention to the need for a balance between the good general and individual and on the obligation to protect the individual by avoiding unnecessary risks and by properly managing the risk situations that can sometimes arise, so that the patients' lives are not put at risk.

As for the principle of justice, it naturally imposed itself in the context of debates on the non-discriminatory treatment of individuals and groups, condemning racial attitudes and in general any type of subjectivism in medical practice in general and in clinical research in particular. This principle proclaims the equality of all people in terms of the right to life, to health care and to every chance that medical science offers.

In order to be able to discuss ethical behavior on the part of health professionals, the analysis of their actions must prove the application of all the stated principles simultaneously, even if sometimes they are faced with a dilemma resulting from the conflict between two principles. Most often, the doctor has a choice between acting for the benefit of the patient, although he does not agree with the option offered by the doctor, a situation in which the principle of beneficence enters into competition with the principle of respect
for autonomy, which obliges the medical side to respect the patient’s decision, regardless what would this be?

In the case of clinical research, the doctor might be tempted to force the patient’s enrollment in a clinical trial that he considers advantageous for him, but he is constrained both morally and legally to respect the patient’s decision, including the refusal to enroll in the trial proposed as well as that of early withdrawal from the study if the patient considers this to his advantage.

Biomedical principlism offers a model of ethical conduct and concise and comprehensive analysis at the same time, focusing in the form of the four principles moral philosophy, Hippocratic doctrine, Christian morality and contemporary legislation in a continuous dynamic (Beauchamp and Childress, 2019, pp. 99-313). Of course, even the principlism of biomedical ethics cannot provide answers to absolutely all the concrete situations that can arise in the activity of medical care and research (note that these two fields are increasingly interconnected), but it represents a scheme that the doctor can build, by capitalizing on their own skills in conditions of respect for their peers, a deeply moral, highly scientific and at the same time humane relationship.

References


