Logos Universality Mentality Education Novelty: Social Sciences
ISSN: 2284-5747 | e-ISSN: 2458-1054
Covered in: ERIH PLUS, CEEOL, J- GATE, CrossRef, CrossCheck, Google Scholar, Ideas RePeC, Econpapers, Socionet, KVK, WorldCat, ICI Journals Master List - Index Copernicus.

2024, Volume 13, Issue 2, pages: 92-113 | doi: https://doi.org/10.18662/lumenss/13.2/109

Biomedical Research and the Need for Ethics

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Abstract: *The objective of this paper is to determine to what extent clinical research meets moral criteria. We will briefly present virtue ethics, duty ethics, utilitarian ethics, human rights theory, and end we will end with a few words about moral bioimprovement.*

Keywords: *research ethics, bioethics, Kant, duty, consequences, virtue, human rights.*

How to cite: Ginghină, S. (2024). Biomedical research and the need for ethics. *Logos Universality Mentality Education Novelty: Social Sciences, 13*(2), 92-113. https://doi.org/10.18662/lumenss/13.2/109

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Introduction

The objective of this text is to determine to what extent clinical research meets moral criteria, which is why certain theoretical clarifications are required, in fact it is necessary to establish those criteria according to which that field is analyzed from a moral point of view and how they have been defined over time. We must start from the fact that, before being doctors, researchers or anything else, all human individuals belong to a community and respect certain rules of good coexistence with their fellow human beings. For this reason, everything people do to be accepted and appreciated by others in society according to norms and based on the notions of "good" and "evil" subscribes to the notion of morality, while ethics, a branch of philosophy, defines itself as the science of morality regarding how we should behave (Volacu et al., 2021, 13).

It can be said that while morality refers to the general rules of desirable behavior in society, ethics is concerned with establishing norms and principles of conduct applicable to the public and professional environment. In this context, it should be noted that the norms that made up the professional ethical codes are based on the norms and principles of universal morality that the great philosophers of the world synthesized in the form of moral theories to be presented succinctly, theories that sought to identify the criteria according to which people's actions are moral or not.

To this end, each of these theories is the answer to one of the following questions: *What must I do to make my actions considered moral?*, respectively *How should I be?* Thus, two philosophical currents emerged: utilitarianism, according to which the morality of an action is judged in relation to its consequences, and deontology, which establishes the moral character of acts in terms of intention and fulfillment of duty. About what man should be in order to be accepted and respected by others wrote one of the great thinkers of the world, Aristotle, within his theory of virtues. Later, another question of morality was raised, by referring to those on whom the actions of others or the state produce effects, ideas that shaped the theory of rights. All these have created the general and universal framework of norms of behavior in interpersonal relationships, from which the concepts underlying professional ethics were subsequently extracted, by adapting the general to the particular and generating specific norms, meant to meet the requirements of an increasingly divided and evolved society from a professional point of view.

Virtue ethics

By connecting the morality of action with the morality of the agent, the moral theory known as virtue ethics answers the question of *how I should be in* (Campbell, 2017, 33) order for my actions and actions to fall within the scope of morality.

The first philosopher who was concerned with the research and analysis of man was Socrates, who proposed self-analysis, according to the famous dictum *Know thyself* and is attributed to the Athenian philosopher who, according to those who knew him, spoke about what is beautiful and what is shameful in people's behavior. But the one who built around human attributes a genuine theory was the peerless Aristotle, disciple of no less famous Plato, considered one of the most important representatives of Greek antiquity, whose ideas were the foundation of European civilization (Barnes, 1996, 7-12). Encyclopedic spirit, concerned with all fields of knowledge of his time, Aristotle (384-322 BC) approached with the same passion the natural sciences, political philosophy as well as moral theory, to which he gave a privileged place in his work. The study of living things facilitated his understanding of the position that man occupies in nature to which he is connected by his materiality and also by the mortal character of life, realizing at the same time its uniqueness through reason and social life, since only man "grasps the right and the unjust, ... Man is naturally a political creature" (Aristotle, 2001, 37) Speaking of ethics, meaning "matters of character" in Greek (Barnes, 1996, 121), the philosopher recognized its practical character, that of guiding behavior, a discipline whose role "is not to know what it is, but to become virtuous" (Aristotle, 1944, 10- 12). Two fundamental ideas emerge from the pages *of Nicomachic Ethics,* actually two questions and their answers: what is the purpose of our actions and how can we achieve this goal. Regarding the first question, the answer is very simple, namely to obtain good and happiness (Aristotle, 1944,18, 26), so that the way to achieve this goal is, in the philosopher's opinion, to cultivate one's virtues and live according to them, the term can be assimilated, according to David Hume, as "a quality of mind, agreeable or approved by others" (Beauchamp & Childress, 2019, 411).

For an active and inquisitive spirit, happiness could have no other meaning than harmony between character and deed. Studying the human psyche many centuries before the advent of psychology, Aristotle distinguishes two types *of virtues of the soul: intellectual and moral*. Intellectual virtues, for example intelligence, help us understand, acquire theoretical knowledge and practical skills necessary in private life, but especially in

professional life, where there are demands to which we must correspond, these virtues being associated with reason. The moral virtues, on the other hand, represent a balance, an average between reason and sensitivity, these virtues being those that guide us in the direction of moral choices, in the direction of using our skills for noble purposes (Campbell, 2017, 35). Thus, in Aristotle we find four fundamental virtues, namely courage, temperance, prudence and justice, as well as an interesting theory, called the *golden mean,* theory according to which any virtue represents the balance between a moral attribute with meaning *too little* and another that means *too much*, suggesting that a moral decision should be a balanced decision, for the outcome of the action to be a beneficial one (Aristotle, 1944, pp. 45-49).

Christian morality adds to the list of fundamental virtues faith, hope and love, but also humility (Campbell, 2017,35). Regarding Christian love, love of neighbor, help to those who suffer, it can be said that this principle has been taken up by all moral theories, being considered a supreme command, an expression of ethical perfection to which we must strive. In fact, these two virtues, namely love and humility, enriched the moral profile of the doctor, along with modesty, sobriety, promptness, discretion and patience, associated with the Hippocratic model (Beauchamp, Childress, 2019, pp. 34-35).

Many of Aristotle's theories, especially those in the natural sciences, but also some of political philosophy have been challenged by scientific progress and the evolution of political systems, but we can still draw inspiration from his work dedicated to ethics, so that our existence, by cultivating what we have most valuable, will help us choose what is right and honest and thus achieve the happiness of a fulfilled life, for always activity according to virtue will be perfect happiness (Aristotle, 1944, p. 209).

Medical ethics identified in Aristotelian philosophy of virtues those elements that were missing from theories that emphasize the morality of action, whether it is judged from the perspective of duty or whether the emphasis is on consequences, bringing to the fore the moral attributes of the health care professional. The profession of doctor but also that of nurse, whether they work in the field of current medical practice and even more so if we are talking about people engaged in clinical research, have their own moral standards, in accordance with the specifics of their work, with the fact that the people on whom their actions produce effects are vulnerable and, last but not least, in the context of increased expectations from society (Beauchamp, Childress, 2019, p. 33). In addition, it should not be forgotten that the disease, in addition to the physical and mental suffering it produces

to the individual, also negatively impacts the family and even the community (Frunză, 2017, p. 13).

Given the above, we can admit that the moral profile of the doctor has its significance in defining the morality of his actions according to the principles and norms (Beauchamp, Childress, 2019, p. 15), the decisions – often difficult – that he is obliged to make, and let's not forget about building the doctor-patient relationship, so that all the efforts of the medical team materialize in a favorable outcome. In fact, there is a connection between a person's character traits – in this case the doctor – and his behavior, respectively the attitude he expresses in different contexts, by achieving a fair proportionality between reason and emotion, depending on the given situation. Thus, a first meeting between doctor and patient, or a public discussion, possibly to complete bureaucratic formalities, does not imply an affective-emotional involvement from the doctor, being sufficient a calm, relaxed and at the same time respectful attitude (Beauchamp, Childress, 2019, p. 36), taking care that the patient does not feel intimidated by the doctor's personality. But the complexity and diversity of pathology brings before the professional challenges not only medically, but also psychologically, demanding the entire emotional arsenal available to a human being. Thus, a patient who is diagnosed with a serious illness, with a gloomy evolutionary potential and without available therapeutic resources, first needs to feel that the doctor cares about his suffering. In such cases, a detached, cold attitude can amplify the suffering of a man who needs not necessarily a truth spoken in all his cruelty, but rather the compassion of another human being and the slightest hope that someone will alleviate his suffering in the slightest. It is obvious that not only the patient in question, but also his family needs emotional support to go through with less suffering the dramatic situation caused by the illness of a family member, a loved one, close person. Thus, without exaggerating and without falling into a sentimentalist extreme, a doctor is obliged to convey, through his words and attitude, a message of sympathy and solidarity.

There are also situations in which the prospect of improvement or even cure depends on a risky treatment, perhaps surgery or enrollment in a clinical trial. By giving the patient the right to decide on the clinical path to follow, the doctor must know that the patient needs his informed opinion. For this reason, the most appropriate attitude in this context is full honesty, in a spirit of full transparency regarding the risks and benefits associated either with accepting proposals or with rejecting them, without leaving out the known therapeutic alternatives. This creates a climate of trust and mutual respect, the premises of a partnership relationship that will ensure the active

participation of the patient in his healing process. It is obvious that, once the patient's trust is gained, the doctor must make every effort to preserve it, respecting the privacy and dignity of the patient and his family, proving throughout the therapeutic process an adequate professional and moral involvement.

It is known that health professionals are engaged in a process of continuous medical education (to use an established term), the purpose of which is to assimilate the novelties, increasingly numerous and diverse obtained by medical science and research and, finally, to improve therapeutic methods and an increasingly effective control of diseases. Also, the medical world recognizes and respects elites, their performance as a result of the work and involvement of exceptional professionals. Beyond these, however, it should be noted that there is a danger that these top professionals will be affected by a certain elitism, especially if they are the leaders of a team whose members, out of respect and loyalty to mentors, do not dare to contradict them when they make mistakes. Perhaps it would not be meaningless if, regardless of the professional performance achieved at any given moment, every doctor would admit that he can commit errors and that their recognition is by no means a debasement, but a sign of moral superiority, and to understand that modesty ennobles, representing a first step towards correcting the mistake. Sometimes, faced with the courage shown by a patient in struggle with the suffering and anguish caused by the imminence of the end, a professional, no matter how well he controls his emotions, cannot fail to feel admiration, respect and even humility stemming from the feeling of his own powerlessness, of his own limits, as well as the natural aspiration to help him, to offer him everything that knowledge allows him. In most cases, in health-related professions there is a convergence between professional obligations, the purpose of the activity and the moral principles and character of each employee. However, in certain situations, the obligations drawn up by the management of a particular professional organization may conflict with certain principles and moral values of the doctor. It is known that, for example, in many countries, abortion is a legal practice that is performed safely in a medical environment (hospital or private clinic). There are also states, it is true that a fairly small number, in which euthanasia is accepted by law. Under these circumstances, what can a person-doctor or nurse do – if his moral principles do not allow him to participate in this type of procedure? To what extent can personal character and moral principles prevail in the face of material needs, being people who earn their living through their work and for whom losing a job would have a major negative impact on their family? Keeping proportions, of course, one

sometimes wonders whether the employees of the extermination camps could have felt compassion for their victims and whether they would have had the opportunity to refuse to carry out criminal orders. We will probably never know, the important thing is to have learned something from the lessons of the past.

It is no secret that all people like to be admired and appreciated when they act for the benefit of others and it is normal to want this as a factor stimulating self-confidence, but those actions done out of generosity, without expecting anything in return and without constituting an obligation, are more morally valuable (Campbell, 2017, 32).

So, to conclude, we could say that in an increasingly technological society, where medical science imposes new standards of practice, beyond obligations and rigors, we also need human warmth. Therefore, medical ethics is not tributary to any of the moral theories exclusively, but, maintaining balance and drawing inspiration from each, seeks a formula that can respond to the increasingly complex challenges of contemporary medicine, converging towards a medicine at the service of humanity, a medicine that constantly promotes fundamental human rights, responding to its needs and the demands of society. We can admit that good deeds are done by good, generous and involved people, but in order for the result to be as expected, other conditions must be met, such as, for example, professionals endowed with a strong sense of duty.

Kantian heritage

Terms such as deontological norms, deontological codes, professional ethics, belong to the common language and, as such, are known by most people, being assimilated with the moral duties incumbent on different professional categories in order to regulate conduct both between team members and between professionals in a field and the society on which their activity produces effects. Etymologically, deontology, doctrine regarding moral and professional duties in various fields of activity, is of Greek origin (*deon* means duty). Thus, referring strictly to the topic discussed, the *Code of Ethics of the Medical Profession* should be mentioned, but there are also deontological codes of researchers, members of the teaching staff, businessmen, media professionals and examples can continue.

In philosophy, the one who elaborated and analyzed the concept of duty in the context of his work was Immanuel Kant (1724-1804), a central figure of modern philosophy, an outstanding representative of the German Enlightenment, whose ideas continue to have influence in philosophy, ethics, politics, etc. (Rohlf, 2010). It occupies a distinct place among

philosophers who have approached the topic of morality, standing at odds with consequentialists regarding the criterion by which an action is considered moral or, on the contrary. If consequential philosophers analyze morality according to outcome and consequences, Immanuel Kant proposes a different approach, stating that at the origin of a moral action lies a "good will", that is, if the intention behind the individual's action is good; in this way, good will, moral law and freedom assume each other (Baciu, 2000, 127-143). We could consider that the two moral theories complement each other and life gives us enough reason to understand that intention alone is not enough to achieve something truly worthwhile, and also that it is almost impossible to reach a positive outcome based on malicious intentions. Therefore, both theories have influenced and continue to influence ethics applied to various professional areas. In the construction of his moral theory, Kant pays special attention to reason, subjecting it to his analysis and, at the same time, giving it an essential role regarding the origin of morality. Thus, this capacity specific to the human being is meant to raise him above the "sensible" world, respectively the living world (to which all beings, including man, belong), placing him in the "intelligible" world (Sole, 2020, 89). According to Kant, reason is independent of any conditioning, while feelings can divert conduct from the right path (Campbell, 2017, 32). Thus, reason, through good will, will resist temptations and determine moral actions. A special discussion is required about the good will, this true lever between reason and deed, according to the attention paid to it in his work by the author of the deontological theory. Without denying the existence and role of other intellectual or temperamental attributes, Kant draws attention to the danger that, in the absence of a good intention, the individual will use his abilities for evil purposes, while "the good will is an unrestrained good" (Kant, 1972, 11), a guarantee of respect for the moral law, which man, as a rational and autonomous being, elaborates and carries out (Rohlf, 2010). What stands out in Kant's philosophical thought is a new vision, different from what had been written before him, a new way of approaching morality.

Of course, he was well versed in consequential moral theories developed up to that time, as well as Christian doctrine. Acting morally, in the consequential sense, for example, involves achieving an outcome that maximizes either pleasure or happiness and diminishes suffering. Religious morality, on the other hand, provides rewards for those who follow divine commandments as well as punishments for those who break them. Also, the judiciary, over time, has developed laws whose violation is punishable. All this, of course, has its importance, but the German philosopher believes that man is duty, by the reason with which he has been endowed, to act in the

sense of good without expecting any reward and without fear of any sanction. It is what in Kantian philosophy is called "acting out of duty" in order for the action to acquire moral value, but Kant himself admits that it is difficult in practice to have actions whose motive meets that criterion of morality, since most human actions are "according to duty", in the sense that the motive behind them is a selfish one (Kant, 1972, p. 24). Acting out of duty, he believes, implies, on the one hand, overcoming desires and temptations by means of the will and, on the other, acting on the basis of principles whose representation is called imperative (1972, p. 31). In this regard, it can be considered that the most valuable Kantian contribution to the edifice of ethics is represented by the two "categorical imperatives", a concentrated expression of his doctrine (Paton, 1947, 46-57). Thus, what Kant called the "Basic Law of Pure Practical Reason" (Kant, 1972, p. 118) can be considered the principle stipulating the universality and binding of ethics for all rational beings, since the motivation behind every action becomes "a universal law", i.e. a rule applicable to all situations without exception. The second categorical imperative is a law of respect for others, it is a concept that brings together the ideal of Christian love with the modernity of Enlightenment philosophy and represents a veritable bridge to contemporaneity. To treat all people as "ends" not as "means" presupposes acknowledging, on the one hand, that man is an end in himself (Kant, 1972, p. 46) and, as a rational being, has his own autonomy and dignity (Kant, 1972, p. 54). The model of Christian morality, expressed by the command of love for God, near and ultimately even for the enemy, is seen by Kant as a moral ideal towards which human beings can only strive, hoping to attain it one day, aware that God represents perfection, the absolute, while man lives in an imperfect world (Kant, 1972, p. 172). In the more than two hundred years since the publication of Kant's works, they have been analyzed, praised or criticized, but they still represent a source of inspiration for contemporary thought, having a significant weight in applied ethics due to the permanence of the ideas transmitted. Thus, if we were to synthesize, we could draw some conclusions: 1) duty means doing the right thing, not what is pleasant; 2) an action must originate from a rule that can be applied in any situation without exception; 3) All people must be treated with the respect due to rational and autonomous entities. If we refer to the medical field and especially to the more sensitive one of clinical research, it is necessary to analyze to what extent Kantian imperatives help solve ethical dilemmas, genuine challenges that may arise at some point in the activity of any professional.

As for duty, no one doubts that the medical profession works in the spirit of fulfilling it towards patients, but perhaps people who suffer want to

find more than fairness, feel the need for a little empathy, want and hope that the one who treats it cares about them. It should also be argued that, by putting reason at the heart of his theory, Kant excludes from the "kingdom of ends" (Leibniz, 2015, 506) the mentally ill or children. They have less ability to reason, but that doesn't mean they don't deserve the respect of others (Campbell, 2017, 32). With regard to the imperative that it acts be generalizable, one could say, with Kant's justice, that doing otherwise is dangerous, and the recent history of clinical research can provide us with sufficient examples to prove that, with regard to the life and integrity of human beings, no exceptions are allowed. We must also seriously consider the imperative that humanity must always be treated as an end, never as a means (Kant, 1972, p. 47) in order not to be tempted to deny the ethical character of research on human subjects. It is true that, after all, research itself is a method, and therefore a means to a stated end, which is to develop medical knowledge for the benefit of mankind, and that this activity subjects human beings to situations beyond their control. Is it possible to have a common vision that satisfies both parties, namely medical science with its needs and medical ethics with its demands? Kant gives us the answer when he talks about rational and autonomous beings, medical research having the mission to find the formula by which subjects participating in a clinical research benefit from all respect. This formula, called today "The principle of respecting autonomy", one of the four principles of biomedical ethics, having as substrate informing the patient about the project proposed to him, with all possible risks and benefits and, mandatory, respecting his decision (Beauchamp, Childress, 2019, p. 397). And if Kantian philosophy is less accessible to the public, including most doctors, we have all heard of deontological codes, of which, of course, of great interest are those associated with professions in the field of health care and scientific research, and through them we are called to apply in practice the philosophy of the great scholar of Königsberg. Recognizing the undeniable merits of Kantian thought, we must admit that good intention alone and strict fulfillment of duty are not enough if the possible consequences of an activity are not taken into account.

Utilitarian imprint

The moral theory known as utilitarianism had, and undoubtedly continues to have, a consistent weight in ethics applied to different fields of activity, the latter elaborating its own concepts by taking over and adapting the defining elements of utilitarian doctrine, on the grounds that all our actions have a purpose, an end, produce positive effects or, on the contrary,

negative, on other individuals, society as a whole or on the environment (Mill, 2007, 2). Belonging to consequential (or consequential) ethics (Flew, 1996, 348), whose origins can be found in the philosophy of Epicurus and his school (Flew, 1996, 113), utilitarianism has been prefigured in modern times by English philosophers David Hume and Edmund Burke, who are considered preutilitarians; the establishment of utilitarian theory occurred in the eighteenth and nineteenth centuries through the works of Jeremy Bentham and John Stuart Mill respectively, so that, subsequently, other authors, such as Peter Singer, G.E. Moore or Kenneth Arrow, nuanced the utilitarian model without altering its essence. Thus, while for Jeremy Bentham the imperative was to achieve the greatest happiness for as many people as possible with the least pain, a goal detailed by John Stuart Mill, for Peter Singer it is important that everyone affected by an action benefit from it, for G.E. Moore ideals matter, and Kenneth Arrow discusses individual preferences. In essence, utilitarianism is the theory that considers the consequences of an action as the criterion by which that action is moral or not. Thus, in order to be classified as morally correct, an action must have positive, desirable consequences, bring benefits. In the terms enshrined in the classics of utilitarianism, the purpose of an action is to produce happiness or reduce suffering, generally aiming to make the world a better place, so that the interest of others takes precedence over personal interest. Moreover, the interest in the social aspect, in the harmony between the members of society that must become a framework conducive to the realization of each individual is noticeable in both Bentham and Mill, with the difference that, while the former discusses mainly the group, the latter considers especially the individual and his positioning in society. As for John Stuart Mill, he makes an idealistic connection between the morality he promotes and the source that inspired him, namely the Christian teaching of the New Testament, considering that "the golden rule represents the ideal of utilitarian morality" (Biblia, 2008, 1104). Beyond the slightly idealistic character of the English author's statements about an almost perfect society in which individuals live in harmony with each other and act for the common good, the happiness of others at the expense of their own happiness (Mill, 2007, 29), we understand from *Utilitarianism,* published in 1861, that its author was a man devoted to society, responsible, who sincerely believed that the actions of men, If they aim to bring happiness and reduce suffering in the lives of others, they will succeed with effort and sacrifice. Of course, J.S. Mill, like many other philosophers or simply as a human being, was aware that some of humanity's suffering was due to disease, but, in his optimistic manner, he believed that in this case too, there

are solutions if education and science are resorted to, so that through its progress, disease, "This loathsome enemy" to be defeated (Mill, 2007).

If the British philosopher foreshadowed to some extent the progress of science and the favorable consequences for humanity, it may also be remarkable that applied ethics, seeking answers to increasingly challenging moral dilemmas, took the utilitarian model, founded on the principle of the prevalence of benefit over risk, and integrated it into its own concepts (Volacu et al., 2021, 275), moreover, It can be said that utilitarian doctrine remains the dominant theory in biomedical ethics (Campbell, 2017, 21). Thus, the principle of utility measures the effect obtained by a treatment, by the difference between favorable outcome and adverse effects. If there is a degree of certainty in current medical practice, or at least the results are largely predictable, in clinical medical research it is more difficult to predict the consequences (Campbell, 2017, 22). However, the stated purpose of clinical research is to identify increasingly effective treatments with fewer and fewer side effects, thus obtaining an increasingly favorable risk-benefit ratio, which translates the utilitarian criterion of ethical judgment applied to an action. If we refer to the principles of biomedical ethics, this criterion has led to the formulation of two principles, namely benevolence and nonharm (Beauchamp & Childress, 2019, 388, 392). As medicine has always operated on the trial-and-error basis, progress has consisted of gradually or largely eliminating errors in favor of certainties, or precisely these certainties, the evidence needed to apply an effective and safe treatment to as many patients as possible, is obtained from clinical research (Campbell, 2017, 23). At the same time, we are talking about the life and rights of each individual, rights that are imperative to take into account, or this aspect is not discussed by utilitarian doctrine, just as it does not discuss the professional and moral duty that every doctor, as investigator, has towards every human subject. This is why any decision must be carefully weighed so as not to end up in situations of risk or abuses committed in the name of a generous but improperly applied principle. In this regard, it is revealing what happened in the extermination camps during the Second World War, where, in the name of the need to find solutions to increase the resistance of the Wehrmacht soldiers in extreme conditions or under the pretext of studying and preventing the transmission of serious infectious diseases, thousands of human beings were subjected to cruelties difficult to imagine. The usefulness of these so-called researches has never been demonstrated, most of them being in fact criminal acts, committed for the purpose of exterminating individuals considered undesirable by the totalitarian German and Japanese regimes. The disclosure of these genuine crimes against humanity led to the

foundation and adoption of international legislation to regulate research on human subjects, legislation that will be extensively presented in a chapter dedicated to this subject. In essence, such trials are not acceptable, because if this were to happen, "anyone could become the next victim" (Campbell, 2017, 25), the usefulness of the project, even hypothetical, being mandatory to demonstrate each time a new clinical trial is proposed for approval.

If the events that took place in the Nazi and Japanese death camps are extreme cases, it is no less true that there have been situations in which it was difficult to prove the usefulness of a clinical trial - there have been cases in which this was actually impossible - one of the most famous being the Tuskegee trial, also presented in the chapter on the history of clinical research. Whereas the forty-year study of the natural history of a disease known since antiquity, especially when, while the study was under way, penicillin, which proved very effective in the treatment of syphilis, was discovered, was not a contribution to the development of science, that is to say, it proved useless; Moreover, the principle of usefulness cannot be applied without taking into account other principles, such as, for example, the principle of respecting the rights of subjects enrolled in research, whatever the topic researched and the imperative need to obtain results and evidence in order to maximize beneficial effects on future potential patients, is not allowed, violation of the rights of current patients. We propose for example an episode in the controversial history of vaccine development, namely obtaining the measles vaccine. This viral condition has been known for hundreds of years, but the pathogen, the measles virus, was identified only in 1954 in pediatric patients at a Boston hospital. We do not discuss the need to develop a protective vaccine, as measles can evolve severely at an early age, but it is worth mentioning that the first version of the vaccine was studied and tested in 1958 on children with mental retardation (Budiu, 2017). This type of approach expresses a disrespectful attitude towards the rights of beings considered to have less social value than the majority, which is clearly contrary to ethical norms.

In order to conclude, in my opinion, it is necessary to mention that any action involving and subjecting individuals to consequences difficult to anticipate or prevent – such as the participation of human subjects in clinical trials – must be planned, carried out and monitored with the utmost professional and ethical responsibility. Given that medical research is the engine of progress, do not forget that every person's life is an intrinsic value, and it must not be forgotten that every human being has the right to life and to medical care. As long as these principles do not conflict with each other, clinical research can focus on the consequences in the name of a generous

principle of maximizing benefits for as many people as possible. For this reason, reflections on human rights in the medical and clinical research context have imposed themselves in shaping biomedical ethics, a necessary and mandatory complement.

Human rights in theory and practice

The analysis of moral theories that contributed to the elaboration of biomedical ethics cannot end without reviewing and discussing the theory of human rights, whose criterion for assessing the moral character of an action consists in assessing respect for the rights of those on whom that action has consequences. Thus, a complete picture emerges, by integrating and balancing the four moral theories, respectively those discussed so far and referring to the actions and character of moral agents, to which will be added the debate on human rights. "To have a right is a possession which society owes me to protect," a statement belonging to John Stuart Mill (Flew, 1996, 102) and from which we can see the necessary correlation of rights with the obligations incumbent on society or other people. One can therefore define one's right as a justified claim against someone else or against another, the purpose being to protect the individual from abuse and injustice (Beauchamp & Childress, 2019, 401), in the context in which "the simple man of our day is firmly determined to put the individual above the state". A topic of great topicality, the issue of rights is the subject of extensive legislation, but it cannot be omitted that any legislative system must have a moral content (Cobianu & Ciuraru, 2001, 573-581), which is why we will approach the problem here from a philosophical perspective, trying to reveal some moments considered significant in the moral evolution of society to the level where human rights are a criterion for assessing the level of democratization reached by society. The evolution of morality followed the evolution of human society, which experienced successive epochs of suppression of individual rights and freedoms, with power and authority concentrated in the hands of autocrats, while the majority of the population was totally disenfranchised. It was the merit of thinkers such as J.J. Rousseau, J. Locke, Thomas Hobbes or Montesquieu to bring to light through their works that people have not only duties but also rights and that the time had come for society to recognize them. Moreover, man, as an agent of change, had to be valued. The fundamental idea was that, in the same spirit as the great ancient philosophers, man must be recognized rights precisely because he is human, and natural law has principles: life, freedom, interests and equal rights.

From revolutions to international law, four centuries of struggle for the affirmation of human rights

Historically, the seventeenth and eighteenth centuries were marked by three great revolutions: the English Revolution, the American Revolution with independence from the British crown and the French Revolution, which concludes a dramatic chapter and opens new perspectives of affirmation of the human spirit. Ideally, we have three documents that openly proclaim fundamental rights of the human being, in the foreground being the freedom of the individual in relation to society. In the order of their elaboration - and in accordance with the corresponding historical events - we have: *Bill of Rights* (England, 1689), *U.S. Declaration of Independence*., drafted in 1776 and used as inspiration for the first U.S. Constitution, that of 1787, and the Declaration of the Rights of Man and of the Citizen, the document of the French Revolution of 1789. Inspired by the *Bill of Rights* and *the Declaration of Independence,* the document drafted by the French revolutionaries and adopted by the French National Assembly states in its preamble that it was precisely the disregard for sacred, natural and inalienable human rights that led to the violent overthrow of a political regime. Article 1 of this flagship document states unequivocally: people are born free and remain free and equal in rights.

One of the best-known defenders of individual liberty within society was utilitarian John Stuart Mill, who believed that society should not interfere with an individual's personal decisions except to prevent harm to another individual. Thus, according to the English philosopher, "... In matters which concern only himself, his independence is de jure absolute... upon one's own body and spirit" (Mill, 2017, 21).

The two world conflagrations that marked the history of the twentieth century brutally interrupted the democratic trajectory of nations, reiterating the danger of ignoring human rights in the context of an impermissible tolerance towards totalitarian regimes. The magnitude of the suffering caused by war, both on the battlefields and especially among the civilian population, determined the awakening of the humanist and civic spirit of the international community, which led to the adoption by the United Nations General Assembly in December 1948 of the Universal Declaration of Human Rights. Thus, as recorded in this document, "all human beings are born free and equal in dignity and rights" (Article 1). These rights are granted irrespective of sex, religion, race or legal status of the country of provenance (Article 2). It is also stressed that every human being has the right to life, liberty and personal security (Article 3). The

protection of human rights, according to those who drafted it, aims to achieve a favorable social climate for all citizens, so that they have all the conditions for personal development towards assuming social responsibilities, while avoiding revolt, as was the case in the past. Naturally, human rights theory has been the moral foundation for the legal system, including legislation regulating health care, both in terms of current medical practice, but especially in terms of the implementation of health policies and also regulations on clinical medical research. This theory has been supported by the writings of authors such as Henry Shue, Ronald Dworkin and John Rawls. There are also authors who were concerned with combating racial discrimination, such as William du Bois (1868-1963), American sociologist and historian, participant in the creation of the National Association for the Promotion of Black People, author of *The souls of black folk*. Another work that presents the problems resulting from racial discrimination is *Black Skin, White Masks* by Franz Fanon.

Henry Shue's Basic *rights: Subsistence, Affluence and U.S. Foreign Policy*, published in 1980, does not deal with medical ethics, but draws attention to the weight of rights in practical philosophy (Beauchamp, Childress, 2019, p. 404). Thus, the author classifies rights into positive (e.g. rights referring to subsistence, as this requires individuals to receive support from society) and negative rights, the latter being rights concerning the security of the individual (e.g. the right not to be killed or tortured). Transferring these rights to medical ethics, the right to receive medical care is obviously a positive right, while refusing proposed treatment or being protected from risks are negative rights. According to Shue, for rights to be truly exercised by those entitled, it is necessary to correlate them with the obligations of those designated to enforce them. To refer strictly to the medical field, we can exemplify by the obligation to respect the right to autonomy corresponding to that right, as well as the duty of the medical staff to provide services of this nature to those entitled to receive them. It can also be mentioned the moral and legal obligation to protect patients by avoiding unjustified risks, corresponding to the patient's right to have his physical and mental integrity protected.

Ronald Dworkin proposes the theory of rights with the power of an "trump card", developing it in *Rights as trumps* to emphasize the need to protect individuals against abuses by society, balancing individual rights somewhat with those of the group, advocating the integration of moral aspects into legal decisions, basing his conception on the fundamental right of all people to life. It is also worth mentioning the American philosopher

Robert Nozic, author of *The Theory of Justice*, supporter of human rights in relation to the state, rights that are based on the mere fact of existing.

Individual rights versus "greatest happiness for as many as possible"

As mentioned in a previous chapter, the utilitarian principle of "greatest happiness for as many as possible" can be objectionable precisely in that it subordinates the rights of the individual to the social good. If we refer to medical activity, there are situations that impose the limitation of individual freedoms for reasons of protecting the community, as happens in the case of a pandemic when either freedom of movement is restricted or certain rules are imposed, such as the mandatory use of masks, so that in certain situations vaccination is imposed by decision of the health authorities, action perceived as a violation of individual autonomy, of everyone's right to decide for himself (Volacu et al., 2021, 269-296). If in such cases the force of the "trump card" does not act, this approach proves its value in situations where it is necessary to protect the interests of individuals against abuse. These can be, for example, disadvantaged people, vulnerable by age, psycho-intellectual incapacity, deprived of liberty, belonging to minorities, in a word, vulnerable persons or groups. These categories, although they may find themselves in situations that impede the exercise of their rights, must not be abused. Starting from the premise that every life represents a value in itself, the theory of rights combats any discriminatory vision that would place individuals or groups in an inferior position. From the point of view of correlativity, it must be said that, from society, in general, from medical services in the context of the discussion restricted to them, there is an obligation to institute all measures to guarantee the interests of those who cannot protect themselves (Beauchamp, Childress, 2019, pp. 402-407).

Concurrent moral theories versus converging moral theories

It can be concluded, from this review of the four moral theories, that each point of view has its place and importance in the elaboration of practical philosophy and especially biomedical ethics. Thus, morality cannot be discussed in the absence, on the part of professionals in this field, of a solid sense of duty, but at the same time of a tempered, rational and sensitive character, anticipating as much as possible the consequences of each action. Morality implies at the same time a striving for self-improvement, balanced by modesty and prudence, by accepting different opinions, by acknowledging one's own errors. Working in a field with social impact, we must not lose sight of the individual, for whose safety and integrity the

doctor is directly responsible, while pursuing objectives that concern the community.

According to *the Universal Declaration of Human Rights,* all people have the right to a decent standard of living, including access to health services (Article 25), which are a necessary condition for maintaining and promoting health. As for this, scientific progress has made possible the transition from health as the absence of disease to health as a human right, for the promotion of which society is obliged to mobilize all the resources at its disposal.

It can be said that no moral theory holds a privileged place in terms of establishing the agreed and accepted conduct in the sphere of medical activities, but, through their convergence, they can achieve an idealistic framework that expresses the philosophical, profoundly humanistic dimension of the medical profession. Moreover, human civilization itself owes to moral philosophy the systematic conceptualization of secular experience, which has allowed, over time, the elaboration of legislation to ensure the functioning of society. But we must not forget the Judeo-Christian heritage which, together with the philosophy of ancient Greece, was the basis of the edifice called European civilization.

Moral bio-improvement

In the early years of the twenty-first century, a new topic entered the debate of philosophers, as a result of a legitimate concern caused by the disastrous consequences of man's irresponsible actions towards his fellow human beings and towards nature. These actions consist of violence, wars, depletion of natural resources and climate change, phenomena that raise serious questions about the very future of our planet and the human species. As science and technology have experienced a much faster pace of development than moral norms that, in essence, have been perpetuated for millennia, undergoing too few changes, it was considered that the source of the problems is precisely this gap between science and morals (Ojovanu & Leabu, 2021, 91), requiring a radical intervention and much more effective than education. The proposed solution, consisting of various interventions, from pharmacological to genetic engineering, was called *moral bioimprovement* (Ojovanu & Leabu, 2021, 83), its stated purpose being an improvement of morality, followed by the adoption of appropriate decisions. This idea, to intervene at the level of the biological substrate of the human psyche, or even at the much deeper level of the genetic substrate, immediately ignited the spirits, provoking ample debates between supporters of this concept (among supporters being the Australian philosopher of Romanian origin

Julian Savulescu) and opponents of moral bioimprovement, both camps arguing their opinion with passion and intensity. In order to overcome this "empty commitment" (Persson & Savulescu, 2014, 17), Persson and Savulescu argue that practical and intellectual capacities, through genetic or pharmacological means, need to be improved, with which people could become as equal as possible in terms of these capacities (Persson, Savulescu, 2014, p. 80 sqq).

Without pretending to exhaust the subject, we propose approaching it from the perspective of necessity, feasibility and morality, considering moral bioimprovement as a tool through which science and technology intervene in the life of man and society.

The need for moral action on the part of humans, both as individuals and as a society, no longer needs to be demonstrated, as the harmful consequences of irresponsibility manifested by members of our species are seen everywhere. Thus, our world, which should be "the best of all possible worlds" (Leibniz, 2015, 466), is today very far from this picture. Violence, greed, irrational exploitation of resources, pollution and, last but not least, wars for which brilliant minds invent and produce ever more refined tools to kill, all make up a grim picture of self-destruction. With regard to the level achieved by science and technology, it should ensure a longer, safer and happier life for mankind, provided that it is used for this purpose, which, of course, requires high morality on the part of people, whether we are talking about researchers, political decision-makers or ordinary citizens. The interventions proposed by the supporters of moral bioimprovement aim to remove decisions and attitudes considered harmful, in favor of those beneficial to man and society.

Starting from the material, biological substrate of behavior, among the proposed solutions would be the administration of substances with psychotropic effect, or, as the case may be, genetic engineering by which certain genes are removed, presumed to be responsible for immoral behavior. With regard to medication, certain observations are warranted. One of them is that any treatment is indicated for a particular condition, in other words it is administered following a medical diagnosis, which could suggest that those who violate the rules of morality would be sick. It is true that certain disorders in the sphere of psychiatry induce behavioral disorders, translated including (or mainly) into antisocial acts, but let us not forget that in these cases we are talking about a pathological alteration of discernment, while perfectly healthy individuals with integrity discernment knowingly commit reprehensible acts. Another observation would be that these therapies would also have adverse effects, the manifestations of which could

induce other imbalances that would create other problems, instead of solving an existing one. Regarding genetic engineering, as promising as it may sound, science has not yet identified the "morality gene", so there is no intervention at this level. No one has ever been able to predict whether a child will become a scientist, a dictator or a simple man with modest aspirations, because the genetic dowry is only the nucleus around which education, family and society build the personality of the future adult.

In principle, we can agree on the gap between the accelerated pace of scientific and technical progress and the slow pace of moral progress, in which case traditional methods of educating members of society in the spirit of moral principles and norms prove insufficient and with the need to adopt corrective measures. If in this regard we can talk about consensus, the proposed solutions have occasioned an ample debate, both from the perspective of their feasibility, but especially from an ethical perspective (Ojovanu & Leabu, 2021, 98). Admitting that any of the procedures mentioned above had the expected result and that the subject acted upon acquired a superior "morality", translated into decisions beneficial to society, this could be circumscribed to a utilitarian vision, while, from the perspective of other moral theories, things would be different. Thus, according to Kant and deontology, reason is at the origin of moral decisions, the criterion by which it is decided whether or not an action is moral being the intention, the motivation behind any action. Nor is Aristotle's vision found in artificially induced morality and not through education and the cultivation of virtues, which raises serious questions about the human condition, in fact about the essence of humanity.

As Aristotle remarked, of all beings, only man has knowledge of right and wrong, in other words only man discerns good from evil, being endowed with reason and sensitivity, qualities that constitute the very essence of humanity, allowing the evolution of the human species, the emergence and development of society, and it would be too sad to admit that precisely these qualities prove ineffective to counteract the dangers we have created and which could one day destroy us. At the same time, science and technology can provide us with the means to live longer and more fulfilling lives, removing what can affect our health and quality of life. But personally, I don't think the morality of our decisions and actions can be adjusted through interventions on the biological substrate of emotions and reason, as long as our discernment remains upright and we are able to recognize that we are imperfect, evaluate ourselves, and try to be better.

Conclusions

I briefly presented virtue ethics, duty ethics, utilitarian ethics, human rights theory and moral bioimprovement, in order to see to what extent clinical research meets moral criteria.

Considering what we said above, we can admit that the moral profile of the doctor has significance in defining the morality of his actions according to the principles and norms, the decisions – often difficult – that he is obliged to take and let's not forget about building the doctor-patient relationship, so that all the efforts of the medical team materialize in a favorable outcome. The duty of self-improvement, professional, academic, value, or ethical, must be a permanent desideratum of the medical profession.

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