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The New Challenges for Medical Ethics

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Abstract

The evolution of medicine confronts healthcare professionals with new ethical challenges. Elements such as professional secrecy, patient benefit, justice in the distribution of resources are put in crisis by the evolution of medical procedures. Today, doctors must make life-and-death decisions about many patients. As the resources are not enough for all patients, the 'first-come, first-served' criterion crumbles under the weight of the overwhelming demand for treatment. Consequently, they can no longer make treatment decisions based only on proportionality and clinical appropriateness criteria. They must take into account the availability of resources and prioritise patients with 'the longer life expectancy'. This amounts to saying 'the weakest will die' ... with the doctors' consent. While the guidelines issued by scientific societies may well protect doctors from lawsuits, the choice of who to treat and who to let die is left to the conscience of the individual doctor; and it is a choice sharply clashing with the Hippocratic oath and with professional and personal ethics. This and others are a real ethical problem.

Keywords: medical ethics, professional responsibility, availability of resources

1. Introduction

Biomedical ethics has made giant strides over the past decades and has come to be recognised as integral to medical education. This has encouraged the growing inclusion of the teaching of medical ethics, together with that of the human sciences, in the syllabi of medical and nursing schools. In the 1980s, increased awareness of ethical issues shone a light on some excesses of medical research and medical paternalism which conflicted with ethical principles. The 1990s saw the establishment of the first medical ethics committees in hospitals, overseeing both research and clinical practice. Since the 2000s, the various bodies regulating the doctors' right to practice have issued regulations, guidelines and recommendations laying down formal ethical rules for medical practice, together with a system of penalties for infringement of these rules.

Many social and cultural factors have contributed to the increase in ethical concerns. The increase in individual civil liberties, codified in various Charters of Citizens' Rights, has fuelled a growing drive to claim new rights in previously unexplored areas. The development of biomedical technologies has created new frontiers, such as the attempt to shape one's own medical fate, as in the case of the actress Angelina Jolie, who chose to undergo preventive double mastectomy and subsequent ovariectomy because she carried a gene that greatly increased (over 80%) her risk of developing an aggressive and often fatal type of breast cancer, or the decision of a

British manager to have his prostate removed for the same reason. In the meantime, the constant budget cuts have increased the need to make very complex choices.

Recently, the Covid-19 pandemic has confronted us with specific ethical dilemmas, in particular the choice about who to treat or not to treat in a health emergency with scarce resources.

The growing ethical concerns have highlighted the fact that doctors only receive very basic training in medical ethics during their studies and practical training. Some studies even show that the awareness of ethical issues of students and trainees decreases as they advance in their studies [1, 2].

Most doctors trust their ethical judgement and believe that their decisions are morally sound. Yet most doctors lack adequate training and theoretical knowledge of ethical issues to support their beliefs and choices in a manner that stands up to scrutiny. The ethical judgement of most doctors is based on their professional life experience, personal opinions, beliefs and values, but few know the theoretical foundations of biomedical ethics and moral decision-making.

The first part of this paper outlines the key theoretical concepts framing ethical decision-making by physicians. Next, the principles governing the ethical decision-making process are presented. This is important because ethics is not only about the medical decision, but also about the process for reaching that decision. Certain issues in the application of ethical principles and the challenges brought by current events to medical ethics are also discussed.

2. Historical overview and remarks on the relationship between medical ethics and bioethics

The birth of bioethics as understood today is closely linked to the giant strides made by the biomedical sciences and technologies (most notably molecular biology and genetic engineering) around the 1970s.

The gradual unlocking of the mechanisms of life, coupled with the possibility of manipulating and modifying living beings, enabled a number of procedures that gave rise to widespread ethical concerns: medically assisted reproduction, tissue and organ transplantation, genetic intervention, the possibility of artificial life independent of 'natural' life, euthanasia, cloning, etc.

The word *Bio-Ethik* was coined by German Protestant pastor and ethicist Fritz Jahr, who used the term to propose a new bioethical imperative that extended to all living beings Kant's categorical imperative of respect for all persons [3, 4].

However, the current meaning of bioethics can be ascribed to American oncologist Van Rensselaer Potter, who used this term in a paper entitled *Bioethics: the science of survival* [5] and later in his best-known work *Bioethics: a bridge to the future* [6].

According to Potter, building an ethic based on scientific knowledge is necessary to ensure the very survival of *Homo sapiens*, which could be threatened if research were allowed to proceed unchecked and unfettered. Potter rejected merely speculative knowledge and stressed the need to connect ethical values, traditionally confined to the realm of the humanities, with biological facts and thus build a 'bridge to the future'.

Potter himself defined bioethics as the 'knowledge of how to use knowledge', to highlight the distinctive nature of this discipline as a dialogical meeting point between the natural sciences, the social sciences and philosophy.

In his subsequent book, entitled *Global Bioethics*, Potter made the by now well-established subdivision of bioethics into three branches: medical ethics, environmental ethics and animal ethics [7].

It is interesting to note that originally, the scope of bioethics was not restricted to medical practice, even though in subsequent years this came to be considered its main, if not exclusive, area of concern. Indeed, differently from Potter's definition of bioethics (later followed by Jonas in his work *The Responsibility Principle* [8]) the term has mostly been applied in the narrower sense given to it by Dutch obstetrician Andre E. Hellegers, co-founder of the Kennedy Institute, who considered bioethics as ethics applied to the biomedical sciences [9]. This narrowing of the scope of bioethics from its original reflection on the ethical problems relating to life, '*bios*' in all its complexity, is partly due to the fact that the two centres where bioethics research and teaching were first developed (the Kennedy Institute in Washington and the Hastings Center in New York) focused on medical issues, specifically, on medically assisted reproduction. This meant that issues such as the treatment of animals or environmental risks were not considered to fall within the scope of bioethics proper.

The close links between the different facets of bioethics and the high complexity of the problems addressed require constant cross-disciplinary dialogue among scientists and scholars from a range of disciplines such as philosophy, law, economics, sociology, ethology, psychology and anthropology [10].

The interdisciplinary nature of bioethics is also in evidence in the current definition of this discipline, contained in the 2nd edition of the Encyclopedia of bioethics: '*Bioethics is 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*' [11].

The relationship between ethics and science is certainly at the heart of philosophical reflection and may be summed up in one question: should we do everything we can do?

In the United States, the debate on ethical issues had already started long before the breakthroughs in genetics: it was prompted by news of gross abuses committed in several clinical trials, namely at the Jewish Chronic Disease Hospital in Brooklyn, the Willowbrook State Hospital in New York and in the famous 'Tuskegee Study of Untreated Syphilis in the Negro Male' which began in 1932 and continued until 1972 [12].

However, the historical roots of bioethics and, in particular, of medical ethics, can be traced further back in time by a deeper examination of the relationship between science and ethics.

The atrocities committed in the experiments on concentration camp prisoners in Nazi Germany dramatically revealed, well before the later events that prompted the appearance of the term 'bioethics' in the literature, the need to investigate the relationship between ethics and science.

The Nuremberg Code was the first document to enshrine in specific rules the ethical principles that govern research on human subject. The Code, which although it never attained legal value has a universal moral value, established for the first time the following standards for human experiments:

- The voluntary consent of the human subject is absolutely essential: this means that the person involved must be given detailed prior information about the nature, purpose, duration, means and risks of the experiment;
- the experiment must be justified in terms of necessity, anticipated results and avoidance of injury;
- the risks of the experiment must be carefully weighed against the expected benefits;

- the personnel conducting the experiment must be appropriately trained and qualified;
- appropriate equipment and facilities must be used;
- it must be possible to bring the experiment to an end at any time on the initiative of either the human subject or the scientist.

Thus, the Nuremberg Code is a landmark document in the development of medical ethics, paving the way for a gradual and profound revision of the doctor-patient relationship in order to shed the traditional paternalistic approach in favour of the principles of consent, shared decision-making and therapeutic alliance.

Following the Nuremberg trial and the consequent drafting of the Nuremberg Code (1946), several international instruments on human rights were drafted, starting from the Universal Declaration of Human Rights (1948), which laid down the first legal principles of bioethics. The Declaration contains strong statements on the right to life and physical integrity, together with other fundamental civil and political freedoms. In so doing, it opened up a new legal and regulatory path for bioethics and inspired and influenced the subsequent development of international legislation.

The global and regional documents, charters, declarations and conventions that followed explicitly refer to the Universal Declaration of Human Rights as the foundation of their statutes and precepts, including the WMA Declaration of Geneva and the International Code of Medical Ethics of 1948 and the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects of 1964 (with its several subsequent amendments).

However, with regard to the aims of bioethics, it would be reductive and historically incorrect to limit its statutory, founding aims to the need to fix the ethical boundaries for the technical progress of science. As Mori [13] pointed out, what the Nuremberg trial itself so dramatically exposed is the need to set limits not to the technological advances of science but to the abuse of those advances. Thus, Mori reminds us that the core problem of bioethics is not to trace the boundaries of technological advancement, pitting science against ethics, but to identify the reasons that justify a specific moral judgement. Thus, as remarked by Schiavone [14], a crucial premise for any ethical approach to be legitimate and justified is that any critical reflection on scientific areas and disciplines should originate and develop within science itself and the scientific and technical advances achieved by it, instead of referring to a source of regulation outside science.

Far from being a system distinct from science and which attempts to stem its progress, bioethics aims to pursue critical and coherent reflection on human dignity, as an instrument of moral control (in the secular sense) over science in terms of its impact on human beings and the environment.

The subject matter of bioethics (which concerns itself with the sphere of '*bios*', i.e. living beings) is associated with the theme of the destiny of human beings, and thus is an emotionally charged topic, inevitably subject to strong pressures. Bioethics is constantly at risk of sliding from the role of neutral and unbiased observatory – to the extent that such a role can effectively be achieved and maintained – onto the dangerous terrain of ideology and its associated dogmatic views.

Returning to the question of the origins of bioethics, it should be noted that ethical reflection in medicine dates back to long before Potter's text. The Hippocratic oath is significant evidence of this. The oath, which evidently reflects the philosophy and culture of a time when the medical profession had a hieratic character, contains the seed bioethics in its principles of *non nocere* (i.e. 'do no harm' to the patient) and 'beneficence' as cornerstones of the doctor's activity.

Hippocrates (460-377 BC)	Hippocratic Oath
Sefer Asaph ha-Rofe (6th century AD)	Oath of Asaph (Book of Asaph the Physician)
Moses ben Maimon (Maimonides, 1135-1204)	The Physician's Daily Prayer (Maimonides)
Mohamad Hosin of Shiraz (1770)	A Physician's Ethical Duties
Military Tribunal of Nuremberg, 1946	Nuremberg Code
World Medical Association, 1948, 1968, 1984, 1994, 2005, 2006, 1949, 1964, 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, 2013, 1968, 1970, 1983, 2006, 2018.	Declaration of Geneva International Code of Medical Ethics Declaration of Helsinki (on Medical Research) Declaration of Sidney on the determination of the time of death Declaration of Oslo on therapeutic abortion Declaration on terminal illness
European Court of Human Rights Council of Europe, 1950.	European Convention on Human Rights Protocol N. 14 (CETS No. 194)
Supreme Soviet of the USSR, 16 March 1971	The Soviet Union Medical Oath
United Nations, 1971	Declaration on the Rights of Mentally Retarded Persons
1975, 1984	Declaration on the Protection of All Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment
1975	Declaration on the Rights of Disabled Persons
American Hospital Association, 1973	Patient's Bill of Rights
Council of Europe, 1976	Recommendation on the rights of the sick and dying
1979	Draft recommendation on artificial insemination of human beings
State of California, 1976	Natural Death Act
Hospital Committee of the European Economic Community, 1979	Charter of the hospital patient
Tribunal for Patients' Rights, Italy, 1980	<i>Carta dei 33 diritti del cittadino</i> (Charter of the 33 rights of citizens)
International Conference of Medical Professional Associations and Bodies with similar remits, EEC, 1982	European Guide to Ethics and the Professional Conduct of Doctors
World Medical Assembly (WMA), Marbella, Spain, 1992, 2005, 2015. 70 th WMA General Assembly, Tbilisi, 2019	Statement on Physician Assisted Suicide WMA Declaration on Euthanasia and Physician-Assisted Suicide
Council of Europe, (Oviedo), 1997	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164)

Figure 1.
Main documents on medical ethics.

The Western world has adopted this approach and has formulated codes of medical ethics and laws inspired by ethical principles to regulate the exercise of the medical profession. These sets of rules are regularly updated in response to cultural and ethical developments and to the growing demand for professional standards to safeguard not only the interests of medical professionals, but also, and most importantly, those of their patients.

In this regard, medical ethics and standards of professional conduct play a major role in the physician-patient relationship. This is the setting where protecting the patient's fundamental rights is crucial and where the risk that medical practice may infringe the individual's rights protected by the Constitution is highest. Indeed,

since ancient times, the power imbalance inherent in the patient-provider relationship has required a framework of principles and rules specifying the physician's duties, in order to protect the patient (**Figure 1**).

3. General principles

Ethical theories can be grouped for simplicity into two main currents.

One is **teleological ethics**. Teleological theories focus on the purpose of the decisions taken and on their positive and negative impacts, and assess the consequences of the action [15]. These theories are deductive and pragmatic. Among the best known are John Stuart Mill's utilitarianism [16] and American principlism [17]. The latter is undoubtedly one of the most widespread currents in medical ethics, at least in the United States, and will be discussed below. These theories focus on doing good for each individual, but also for the community.

The second current is **deontological ethics**; this differs fundamentally from the teleological approach in that its focus is not on achieving a good outcome but on doing what is morally right. The deontological approach is based on a series of '*prima facie*' principles; it is an inductive principle focused on processes rather than on the final decision and it refers to the theories of Kant and Habermas [18]. Deontological ethics recognises absolute prohibitions, which admit no exceptions for any reason, override other duties, are fixed '*a priori*' and are unchangeable. However, since conflict may arise between different duties, priorities must be identified in the hierarchy. Thus, a shift occurs from a hierarchy with absolute '*a priori*' duties to an ethics with '*prima facie*' duties, which also requires examination of the circumstances.

Teleological ethics and deontological ethics are two alternative ethical theories that determine the moral good or evil of an action.

The key difference between the two theories is that teleological ethics weighs the good or evil of an action according to its consequences. By contrast, deontological ethics determines the good or evil of an action on the basis of an examination of the action itself. Its vision is based on rules that determine the action.

Application of these two theories to end-of-life care can help to clarify the difference between them. Under the teleological framework, doctors who practice assisted dying focus on the purpose of decisions. They respect the patient's choice to end her suffering when there is no hope of improvement. By contrast, under the deontological approach, doctors may refuse to provide assisted dying care on the basis of the *a priori* principle that doctors are trained to treat and not to take life. These are two diametrically opposed positions, which require different ethical frameworks.

General principles that state universal values of common morality also contribute to the basic reasoning on medical ethics. Beauchamp and Childress [17] have identified a model consisting of four moral principles that constitute the most common framework for achieving what is 'good' and what is 'right' in healthcare. 'Principlism' is a basic framework because it identifies four fundamental principles that come into play in most medical decisions, across the different medical specialties, countries and continents. These principles do not constitute a moral system or theory, but offer a framework for reflection on the moral problems encountered, and provide a starting point for making a moral judgement and assessing the procedure to be followed. The main principles are:

- respect for autonomy/the individual
- beneficence

- non maleficence
- justice.

The principle of *autonomy* refers to liberal thought, which has always emphasised individual rights and freedom of choice as an expression of the individual's free will. The patient is recognised as possessing critical thinking and decision-making skills that must be respected. The model that emphasises the autonomy principle aims to oppose and overcome the paternalistic approach that has long dominated the doctor-patient relationship. The paternalistic model was based on an asymmetric relationship between the doctor (acting as a good parent) and the patient, who was treated as a 'child', unable to make decisions because of his lack of scientific and, especially, medical knowledge. This model has been discarded by reversing the patient's role, from a passive one, to that of an autonomous person, capable of self-determination according to the principle of individual autonomy. The principle of autonomy ensures that the patient is involved in the medical decision-making process and protects his right to choose, accept, refuse or stop treatment. This is an absolute right of the individual, even where the refusal or interruption of treatment might cause adverse health consequences or even death. Autonomy implies respect for an individual's physical and mental integrity. A person cannot be forced to receive treatment against her will. The patient cannot be subjected to any physical or mental coercion. The principle of autonomy also underpins the patient's right to accurate and exhaustive information on the proposed treatment. Recognition of this right has led to development of the informed consent procedure. However, for certain specifically identified medical conditions that pose a public health threat, the government has the coercive power to impose treatment; this can occur, for instance, in the case of acute psychiatric patients or highly infectious diseases. However, even in these cases, the dignity of the person must always be respected. To apply these rules, doctors must know the legislation in force in the country in which they work; in any case, they must take all proper actions to minimise the need for coercion and maximise the patient's consent.

The principle of *beneficence* states that the patient's well-being is the ultimate goal of care. This principle lies at the heart of medicine, whose mission is precisely to prevent, diagnose and treat illness in order to promote the patient's health. It is a question of proposing a treatment that is proportionate to the patient's needs and whose benefits for the patient outweigh its possible harms. This principle means that doctors may act in the patient's best interest also by refraining from acting and/or by acting prudently, always from the viewpoint of the benefit for the patient. Traditionally, this principle has been focused on 'objective' good, i.e. the outcome considered to be good by the doctor. However, cultural and ethical developments have gradually led to add to this principle that of autonomy, supporting a more subjective interpretation of the patient's 'best interest'.

The principle of *non-maleficence* has been well known to doctors since the time of the Hippocratic precept of *primum non nocere*. Non-maleficence encompasses two key concepts. The first is that of not causing harm to patients, even before doing them good. The second is the need to properly assess the risks and the benefit/risk balance of a treatment, and hence to refrain from prescribing a treatment that, although effective, could be harmful to the patient.

The non-maleficence principle is reflected in a number of legal provisions regarding wilful medical malpractice, where the patient was intentionally injured, or negligent malpractice, where the harm was caused by negligence, inexperience, recklessness or failure to comply with laws, regulations, orders or standards.

The principle of **justice** requires that all people be treated fairly. It is difficult to provide a single definition of justice, as various theories have produced different versions. Egalitarian theories stress the importance of universal access to basic necessities [19]. Libertarian theories affirm the right to social and economic freedom [19]. Utilitarian doctrines require the balancing of the two principles in order to maximise public and private utility [17]. Moreover, the principle of justice includes the concept of distributive justice, which states that resources should be allocated so as to ensure that access to care is not affected by socio-economic, ethnic or other factors which could favour certain sectors of the population to the detriment of others. The problem of resource allocation arises at different levels. For example, a national government decides which share of funding to allocate to finance social and healthcare relative to other sectors such as education, labour, transport. Moreover, the healthcare budget is in turn distributed differently among the different specialties. Thus, in practice, implementing the distributive principle raises complex issues; for instance, to what extent can expensive experimental treatments be justified in patients who have not responded to conventional approaches? Some of these treatments can cost more than €100,000 per year and clearly erode the sums available to treat other patients.

These four principles are not independent of each other. Rather, they interact in all medical situations of varying complexity, engaging in a dialectical relationship which requires their careful balancing. The clinician's art is to fully understand how to best weigh these factors on a case-by-case basis, to reach the most appropriate decision for the individual patient.

4. The decision-making process

In modern biomedical ethics, the process by which a decision is reached is as important as the decision itself. This is why it is necessary to have a clear approach that takes into account the problems to be addressed and all the persons concerned.

Figure 2 shows a decision making process according to Jonsen's four box model for decision making which evaluates four fundamental variables: medical indications, patient and family preferences, quality of life and contextual features [20].

The approach proposed here is one example, among the many available, of a framework to guide the decision-making process. The approach is based on a series of questions, which are set out and explained below.

1. What are the facts, the circumstances? This question prompts a description of the clinical problem, concurring factors and psychosocial and environmental aspects. The starting point is awareness that the interaction is not with an illness, but with a sick person with a life history, family, affections, job and deep personal, existential and ideological values. Each participant will, in their own way, experience the impact of the decision. Clearly, at the centre of the decision is the patient, being the person that will ultimately make the decision and bear the consequences. The available options should be assessed from a clinical standpoint, considering the likelihood of success of the option chosen. For example, what are the chances that a patient with aggressive cancer will survive mutilating surgery which may have major adverse effects? Besides the purely clinical assessment, the human and emotional costs involved must also be considered.
2. What is the 'spontaneous' option? What do the patient, their family members, the treating physician, the nursing staff and the medical team want? What is

Medical indications	Patient and family preferences	Quality of life	Contextual features
The principles of beneficence and non-maleficence	The principle of respect for autonomy	The principle of beneficence, non-maleficence. And respect for autonomy	The principle of justice (loyalty and fairness)
What is the prognosis including survival, function, and quality of life?	How much informations does the patient want about prognosis?	What are the most important things for the patient at this time (eg. survival, pain control, family wellbwing, etc)?	Is significant moral distress among staff members present, and how is this affecting care?
How certain or uncertain is the prognosis?	How involved does the patient want others (friends, family) to be in decison-making?	What is the patient hoping for?	Are there important family dynamics that must be considered?
What are the treatment options?	Does the patient have decision-making capacity?	What is the patient fearful of?	Are there financial or economic factors that must be considered, such as access to hospice care?
What are the potential benefits and burdens of disease-focused treatment?	If the patient does not have decison-making capacity, who is the appropriate surrogate decision maker?	What is the patient expecting?	Are there religious or cultural factors?
What are the potential benefits and burdens of palliative-focused treatment?	Has the patient previously expressed preferences in an Advance Directive or physician order for life-sustainig treatment (POLST)?	If tradeoffs between duration and quality of life need to be made, wich side should be more heavily weighted?	Are there problems related to allocation of resources?
		Are there quality-of-life-states (eg. permanent coma) where it would not make sense to continue life-sustainig treatment or disease oriented care?	How does the law affect treatment decisons?
			Is there any conflict of interest present?

Figure 2.
Jonsen's four box for medical decision-making.

- the impact of pressure from fellow doctors or hospital managers, for instance in the event of a shortage of inpatient beds. What is the possible impact of pressure from the media?
3. What are the values at stake for each of the parties concerned? To answer this question it is necessary to draw up a personalised list of the hierarchy of values at stake, in the specific clinical situation, for the main parties concerned, mainly the patient, but also her family members (clearly where they have a say) and the medical team. For example, in the case of surgery entailing the risk of serious adverse effects and disability, the patient might refuse the surgery if she feels that the degree of beneficence, as perceived by her, is not adequate; the patient might instead wish to retain her current physical status, refusing a procedure that she considers to be invasive and destructive; this because the patient fears that after surgery, she might not recognise herself as the person she was before. On her part, the doctor may feel that the surgery will enable the patient to survive with what the doctor considers an acceptable quality of life (beneficence/maleficence). In other cases, the reverse may happen: the patient and his family members may want the surgery to be performed

no matter what, even if its positive impact may be minimal or zero (patient autonomy vs. doctor autonomy vs. fair allocation of resources).

4. What is the moral dilemma? The matter here is not to choose the best course of action, but to identify clearly the moral dilemma faced by the doctor and the whole team, spelling it out in the most explicit and detailed way. What must be decided is not whether to operate on a patient who demands a treatment that will yield little or no benefits, but whether to prioritise the patient's autonomy, and what he considers to be beneficial, or to prioritise the professional autonomy of the doctor, expressed through his clinical judgement on a procedure that he considers to be maleficent (a useless operation that will cause suffering to the patient) and to entail an unfair allocation of resources.
5. What are the alternatives? All too often, emotionally charged situations lead to a polarisation of views between just two possibilities. In the example in point 3, the only two options considered are surgery versus non-surgery. Instead, all options should be considered and presented to both the patient and his family members: chemotherapy, palliative care, home care, etc.
6. Which was the initial spontaneous choice? It is always advisable to return to the first spontaneous choice and assess whether the position of the main parties has evolved, and whether they have moved closer or farther apart from each other or have otherwise changed their views. If a change of position did happen, it should be considered whether this could help to reduce the conflict.
7. Making the decision. The decision must be made after consultation with the main parties involved, first and foremost the patient, but also his family members (where their involvement is authorised by the patient), the medical team, etc. It is important to have an open attitude and to truly listen. The patient must be seen not only from a medical point of view, but as an all-round individual with a life story, beliefs and concerns. As J. F. Malherbe [21] said, the patient remains the protagonist of his illness and not just the object of treatment. One should not hesitate to consult a colleague to get a second opinion, or even the hospital's ethics committee. After exhausting all these steps, a decision must be made. The decision must be justified by taking into account the medical evidence for each situation, but also the ethical issues specific to the situation. It is essential to specify which elements justify the principles that were given priority in the decision-making process.

5. Issues in implementing ethical principles

In theory, the description of ethical principles seems to give a clear overview of medical ethics and the procedures to be followed when making treatment decisions.

However, in clinical practice, the application of ethical principles is increasingly complex and is often affected by issues that complicate the decision-making process and come into conflict with ethical principles. Some issues arise when different principles clash with each other; others are linked to patient-specific situations, while yet others are linked to the organisation of services.

With regard to the conflict between principles, a common opposition may arise between the principles of autonomy and beneficence, for example in terminal cancer patients. According to the principle of autonomy, the patient should be told that her

condition is now terminal, to allow her to freely choose among treatment options and decide what to do with the time she still has to live. However, under the principle of beneficence, one might argue that providing such accurate information might cause deep pain, and hence be harmful to the patient, affecting negatively her will to live and her quality of life in the time left to her. Moreover, the conflict between the two principles is not an abstract one; on the contrary, it is experienced by the parties to the decision-making process, with real consequences. The principle of autonomy can be interpreted in very different ways by doctors. For example, some doctors might resort to the legacy of medical paternalism and feel authorised to deliver all the bad news to the patient; other doctors could rely on the principle of autonomy to avoid making difficult decisions by shifting the responsibility onto the patient and/or her family members, placing a heavy emotional burden on the patient; still other doctors may not provide the full set of options to their patient to prevent her from making decisions that the doctor does not consider beneficial to her, resorting to a sort of 'palliative paternalism' [22] and thereby arbitrarily reducing the patient's free choice.

Conflict may also occur between the principles of beneficence and non-maleficence. An example is found in pain management for terminal patients, where the use of opioids relieves pain and meets the beneficence principle, but may shorten life, thereby violating the non-maleficence principle. Both principles are not absolute and are often combined, as in the above example, giving rise to the 'double effect' phenomenon, a term that in bioethics refers to an action that can have more than one result and contrasts two principles [17].

1. Other issues in the application of ethical principles arise when healthcare systems have to contend with limited resources. In these cases, the first ethical problem is patient selection for access to and discharge from care, which clashes with the principles of beneficence, non-maleficence and justice [23, 24]. The American Medical Association [25] has provided guidance on the ethical implications of the allocation of organs for transplant, which may be helpful in the task of determining priority of access to scarce and costly medical resources. The AMA paper has identified five criteria related to the patient's Medical Needs, which should be considered when making resource allocation decisions: likelihood of benefit
2. the improvement in quality of life
3. the duration of the benefit to the patient
4. the urgency of the patient's condition
5. only in some cases, the amount of resources required for successful treatment

These criteria help to maximise three primary goals of medical treatment: number of lives saved, number of years saved and improvement in quality of life. A hierarchy of objectives prioritises the goal of saving the greatest number of lives. [25] While the AMA document makes an important contribution to ethical decision-making, many questions about distributive justice and discrimination against older people remain open.

Furthermore, major social changes have affected the organisation of health systems and have further complicated the application of ethical principles. The globalisation of modern society, with its marked contradictions, inequalities and injustices has also inevitably affected healthcare systems. The undoubtedly successful McDonaldisation phenomenon, [26], characterised by efficiency, productivity, cost reduction, procedural standardisation and control, has also influenced the

organisation of healthcare services. The double pressure to cut costs and make a profit has impoverished the healthcare system, hitting hardest the most vulnerable and deprived citizens and generating major inequalities in the access to healthcare services: this has deeply affected the ethical principle of justice and beneficence and has altered the doctor-patient relationship [27].

6. Current issues

In 2020, the whole world was struck by the Covid-19 pandemic. The pandemic disrupted life for every person with an unexpected, novel situation and caused an unprecedented humanitarian emergency. Its sudden outbreak has put the health systems under massive strain, causing a number of ethical problems for healthcare staff and managers, and giving rise to real challenges to basic ethical principles.

Compounding the existing problems in applying ethical principles, the pandemic has brought about new complex scenarios and issues, which have not always been addressed appropriately and in line with ethical principles.

The first moral dilemma posed by the pandemic relates to the strain on healthcare quality caused by the surge in demand. The pandemic has spread quickly, catching the health structures unprepared to handle the rapid increase in workload. At the height of the crisis, the number of patients rose dramatically and the hospitals soon ran out of beds. The number of healthcare workers (doctors and nurses) was also insufficient to deal with the surge in cases. Many health workers faced the additional workload with great dedication and sense of responsibility, aware that their patients' lives also depended on their willingness to put in the extra hours. They prioritised the beneficence for their patients over their personal well-being. Many healthcare workers fell ill and many died [28]. At the peak of the pandemic, medical and nursing staff worked 12–14 hours a day wearing uncomfortable face masks, visors and coveralls. It is fair to assume that fatigue and stress at work may have affected the quality of care, hence the actual beneficence for patients. It can also be presumed that the quality of the care provided at the start of a work shift was higher than that provided by the same worker after 12 hours of gruelling work. Thus, the actual working conditions undermined both the principle of beneficence and the principle of justice, according to which all patients must be treated equally.

Moreover, the spike in patient numbers was so high that it produced an imbalance between the healthcare needs of the population and the availability of intensive care resources. The situation that came about was and still is an exceptional one, to the extent that it has been classified as 'disaster medicine' [29]. With regard to intensive care, in addition to the criteria for access to and termination of care, traditionally based on the appropriateness and proportionality of care, the criteria of distributive justice and appropriate allocation of limited health resources had to be applied. The 'first-come, first-served' criterion for access could not be applied. Healthcare workers were forced to carry out an unusual triage, in which they often had to apply the criterion of 'greater life expectancy'. In Italy, SIAARTI (the Italian Society of Anaesthesiology, Analgesia, Resuscitation and Intensive Care) issued 'Clinical ethics recommendations for the allocation of intensive care treatments, in exceptional, resource-limited circumstances' [29]. The recommendations are solidly grounded in ethical principles, to relieve clinicians from the burden of making subjective decisions, and establish explicit resource allocation criteria [29]. (SIAARTI). Robert et al. highlighted the ethical issues in patient management in intensive care units during the pandemic in France [30]. Despite the guidance provided, the dramatic pressure of the situation often forced physicians to grapple alone with the final decision about who should get life-saving care. While admittedly it was

necessary to make a selection among the patients, we must also note that a dramatic discrimination occurred by age group, comorbidity and patient type. Elderly patients, patients with comorbidities and frail patients were often denied access to the ICU.

The pandemic emergency also gave rise to other issues. Many patients could not even reach the hospital and died at home while waiting for an ambulance that never arrived. In those cases, the decision was not guided by any particular and specific recommendations, but was simply left to chance: the lottery of life decided for them.

For the patients' protection, during their stay in hospital, the patient-family and healthcare worker-caregiver connection was severed, counter to more than 20 years of research and care practice aimed at improving those relationships for the patient's benefit [30]. Many patients were left to face death alone, without the comfort of family members, without any spiritual or religious care. As hospitals were overwhelmed, much was attempted to provide the benefit to the body but little was done to provide psychological and emotional care; healthcare moved back from caring for the whole person to focusing on the illness alone.

Yet other decisions have impacted ethical principles and good clinical practice in the management of chronic patients. For a long time now, the healthcare system has placed emphasis on prevention and early diagnosis programmes, educating the public about the importance of health screening and monitoring. The emergency has deeply disrupted this approach. Many cancer patients have been unable to attend their routine checks, and the same has happened to patients with heart conditions or diabetes. The principles of beneficence and non-maleficence have been severely compromised. An increase in deaths due to cardiovascular diseases has already been recorded, and the number of deaths secondary to cancer is also expected to rise [31].

7. Conclusions

The above overview confirms that the practical application of ethical principles in medicine is fraught with difficulties that may complicate the decision-making process. The current pandemic is confronting us with novel organisational, social and ethical challenges.

As a rule, major changes in healthcare occur at a much slower pace, giving us enough time to process them, adapt and make decisions. Today's explosive crisis calls instead for urgent emergency measures. The assessment tools we have used so far have been made obsolete by the extraordinary pace of the crisis. In the health sector, clinical guidelines have traditionally been the gold standard for good clinical practice, in addition to providing some protection from medical liability. However, many guidelines have lost their relevance in the pandemic, which has created an unprecedented health situation for which no specific guidance could be prepared. The dramatic developments have put ethical principles under strain in various circumstances and cases. Moral dilemmas have severely affected the emotional resilience of clinical staff; in the near future we will have to deal with the moral distress they experienced.

Ethics, once a discipline of interest to scholars, has nowadays taken on a prominent role in the social debate. However, moral questions must be addressed and analysed critically, in order to define not only what is right, but also why it is right [32].

Hopefully, we can draw some lessons from this tragedy.

The rationalisation of healthcare resources – through major budget cuts, the push for standardised care processes according to the McDonaldization model,

the emphasis on hi-tech and highly specialised care – has not withstood the test of the pandemic. While of course it is hard to say which model would withstood the Covid crisis, it remains a fact that the current one failed, and this requires some reflection.

First, we should strengthen the human dimension of the physician-patient relationship. The focus on performance and profit has reduced the time available for listening to patients and their family members; as medical professionals, we have contributed to the achievement of the productivity targets set by the health authorities, but we have not always respected the ethical principles of an authentic doctor-patient relationship based on caring for the individual as opposed to simply treating a medical condition. Health professionals should take the brave step of fostering the relationship with their patients and prioritising quality over quantity, eschewing the industrial assembly line model: people are not machines and do not function like machines.

Social systems as a whole should revisit their resource allocation models. For a long time now, policy makers from all sides have made major cuts to health care; the pandemic has shown that ‘sick countries’ with difficulties in the delivery of health-care are also countries with persistent economic problems. The share of public spending allocated to healthcare should be fairer, instead of treating the health service as the poor relation.

During the pandemic, we helped the patients with the greatest chance of survival, but we were unable to help the frailest ones. We went back to the model of Sparta, the ancient Greek city where frail male infants were tossed off a cliff, to train the others to become strong and valiant warriors. However, the Spartan model was not the one that prevailed in ancient Greece, nor the one that produced the greatest protagonists of classical culture. Healthcare systems, with the contribution of medical ethics, should develop care models that protect the frailest and shelter them from ‘competition’ for survival in which they would be doomed from the start.

We should also send the message that medical ethics is not just a matter for the individual health professional but is the responsibility of the whole community. The pandemic is teaching us that the responsible behaviour of each of us plays a key role in preventing the spread of the infection. The principles of medical ethics, beneficence and non-maleficence should be better known, understood and applied not only by health workers but by all persons.

Last but not least, the expectations placed on doctors today are very high, if not excessive, as concerns both clinical skills and patient relations. Although ethical issues are now on the front line, there is still very little training in biomedical ethics for health professionals. The development of science and technology require that physicians be knowledgeable of ethical issues pertinent to end-of-life care [33, 34]. It is crucial to invest more in this of training, to ensure that the new generations of doctors and other health professionals, within their respective roles, are better equipped to face the new challenges for medical ethics.

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