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REVIEW

Medico-legal and ethical considerations on resource limitation and clinical decisions during the COVID-19 pandemic[☆]



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Abstract The COVID-19 pandemic has raised ethical and medico-legal problems, which include the equitable allocation of health resources, especially in relation to the prioritization of patients and the rationing of resources. Priority setting is always present in healthcare systems and depends on the theory of justice applicable in each society. Resource rationing has been necessary in the COVID-19 pandemic, and therefore consensus documents have been published for decision-making based on four fundamental ethical values: maximization of benefits, treating people equally, contributing to creating social value and giving priority to the worst off, from which specific recommendations derive: maximize benefits; prioritize health workers; do not prioritize attendance on a first-COME, first-served basis; be sensitive to scientific evidence; recognize participation in research and apply the same principles to COVID-19 patients as to non-COVID-19 patients.

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PALABRAS CLAVE

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Consideraciones éticas y médico-legales sobre la limitación de recursos y decisiones clínicas en la pandemia de la COVID-19

Resumen La pandemia por COVID-19 ha suscitado problemas éticos y médico-legales, entre los que destaca la asignación equitativa de recursos sanitarios, sobre todo en relación a la priorización de pacientes y el racionamiento de recursos. El establecimiento de prioridades está siempre presente en los sistemas sanitarios y depende de la teoría de justicia aplicable en cada sociedad. El racionamiento de recursos ha sido necesario en la pandemia por COVID-19, por lo que se han publicado documentos de consenso para la toma de decisiones sustentadas en cuatro valores éticos fundamentales: maximización de los beneficios, tratar a las personas igualmente, contribuir en la creación de valor social y dar prioridad a la situación más grave. De ellos derivan recomendaciones específicas: maximizar beneficios; priorizar a los trabajadores de la salud; no priorizar la asistencia por orden de llegada; ser sensible a la evidencia científica; reconocer la participación en la investigación y aplicar los mismos principios a los pacientes COVID-19 que a los no-COVID-19.

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Introduction

On 11 March 2020 the WHO declared that COVID-19 had become a pandemic.¹ Since then, as medical professionals around the world have confronted their professional responsibilities in the fight against this pandemic, a range of ethical problems have emerged. They are hard to resolve, and include the fair assignation of limited available medical resources.^{2,3}

It must firstly be remembered that all medical actions, and therefore clinical-medical decision-making on the fair assignation of medical resources, must be governed by the ethical principles of medicine established by Beauchamp and Childress⁴: the principle of autonomy, beneficence, absence of malice, and justice. The principle of autonomy refers to the individual capacity of everyone to deliberate and freely decide, i.e., to take decisions about themselves in connection with aspects that concern them. The principle of beneficence refers to the moral obligation to act in a way that benefits others, promoting their well-being and legitimate interests. The principle of absence of malice, which is also known as *primum non nocere*, refers to the obligation not to harm or prejudice patients, while also preventing any possible harm. Finally, the principle of justice refers to the obligation to treat each individual as corresponds to them, understood essentially as a principle of medical policy and the fair distribution of medical resources. The aspects associated with the principle of justice expressed by Beauchamp and Childress will therefore be of key importance in resolving the ethical and medical-legal problems arising from the fair assignation of resources during the COVID-19 pandemic.

The approach to the said ethical and medical-legal problems makes it necessary to differentiate between three different concepts. These arise within the context of medical care, and they centre on clinical-treatment decision-making. They are the concepts of therapeutic futil-

ity, leading to limited therapeutic effort, the prioritisation of patients and the rationing of resources.

Therapeutic futility and the limitation of therapeutic effort

The limitation or suitability of therapeutic effort, which includes the limitation of life support treatments,⁵ is a measure that is often applied in the context of critical patients. It refers to the decision for a specific patient not to commence a life support treatment or to withdraw it if one has commenced in the belief that it offers no significant benefit apart from prolonging the process of dying. In this case, there is no doubt that there is no moral obligation to supply futile treatment. The problem lies in determining whether or not a specific therapy is in fact futile.⁶

The factors that determine whether a medical act is futile refer to three different aspects: the strictly technical aspects, the ethical questions and the social implications. In any case, futility refers to a medical procedure that it is not worth administering as it is of very little use, or one with a remote probability of achieving an effect, or when the patient believes that it will not produce any benefit, or, simply, when its excessive cost compared to the negligible probability of its achieving the desired effect means that it would be unwise to use it.⁷

In this case, the principle of the absence of malice demands that we strive at all times not to cause harm to the patient. This takes the form of mitigating and palliating suffering, even if this accelerates the process of dying. The patient may decide how their end of life should be managed. If it is medically indicated then palliative sedation may be selected, accepting the consequences of this.⁸

Thus even though it may sometimes seem confusing, it is clear that although there are cases where therapeutic effort is limited in patients affected by COVID-19, the COVID-19

pandemic has not altered medical decision-making in connection with suppositions of futility.⁹

Patient prioritisation and resource rationing

Prioritisation involves establishing an order in medical care, while rationing involves assigning a resource to one patient rather than another one. It is not about resources that would be futile for the patient in question, but rather about accepting the loss of opportunity arising from this decision in terms of the evolution of a pathology.

Triage is habitually used in emergency services, with the aim of prioritising patients. Triage is a structured form of working which make it possible to swiftly evaluate the severity of a patient in a way that is rule-governed, valid and reproducible. It aims to prioritise the order of medical care, determining the place and measures which a patient needs.¹⁰ However, triage is also a process that manages clinical risk and patient flows appropriately and safely when demand and clinical needs overwhelm resources.¹¹ The severity of disease, the speed of its progression, waiting time and pain are considered to be the most important and widely used criteria for prioritising patient care in emergency departments. A good prioritisation system also has to include the utility of healthcare, to guarantee equity, so that the need for the selected treatment must also be taken into account.¹²

Over and above specific scenarios, such as the emergency department, healthcare systems always set priorities in medical care, and this involves macroassignment processes as well as the microassignment of medical resources. Resource macroassignment refers to the resources assigned by the Administration. Resource microassignment refers to the way in which within clinical contexts it is decided who, how, when and for how long patients will receive care.¹³

Thus two of the most controversial aspects in the decision-making process when setting priorities are: firstly, defining how this is to be decided, i.e., the type of methodology to be used to determine the ranking of priorities and ensure that it is socially valid. They have to fair according to Aristotle's definition of distributive justice, treating equals as equals. Secondly, the role of experts in the decision-making process regarding priorities must be defined, as well as the degree to which the population will take part in the decisions about what to select.¹³

Respecting the first question, the response will be determined by the theory of justice in which we start by delimiting the principles that have to govern the distribution of medical resources. Determining the scopes and limits of what it is fair to demand depends on the way in which the right to medical care is defined and specified, together with the creation of criteria for the distribution of medical resources.

There are different attitudes to this question, and they basically consist of the libertarian, egalitarian, utilitarian and community viewpoints:

The libertarian perspective is governed by the principle of commutative justice (everyone receives according to what they have given). This legitimises the segmentation of medical care and charity as means of attending to the health problems of the population. Access to medical ser-

vices depends on spending power and the capacity to take out medical insurance, governed by market laws.

The egalitarian perspective is based on the equality of persons and the need for social institutions to counterbalance the lack of opportunities caused by the fact of having become sick. This theory considers equality of access to the medical system to be the premise for achieving a fair medical system. Within this context of egalitarianism, some versions make the right to healthcare conditional on individual responsibility for the cause of disease,¹⁴ i.e., the healthcare system recognises that it must only compensate individuals for unexpected risks, not for those they run because of their lifestyle decisions.

The utilitarian viewpoint defines the value of the right to healthcare and clinical interventions solely in terms of their measurable outcomes, "results" or efficiency. Nevertheless, it is not clear, even from different religious perspectives, who should measure these results or how this should be done.¹⁵ The number of years lived adjusted for quality of life, for example, gives units to measure health results that unit survival with quality of life. From this point of view, distributive justice in healthcare must always be governed by its cost-benefit ratio, so that the moral obligation to do something that is not economically optimum never arises.

Finally, the community viewpoint considers that each good or set of goods is a sphere of distribution, and that each one of these spheres has its own appropriate criteria and guidelines. On the one hand, this implies considering the "social meaning of healthcare", which is determined culturally and is therefore dynamic and subject to constant interpretation; on the other hand, it is necessary to accept that there is no single principle of distributive justice that governs all social goods, but rather that there are a series of constructed principles that constitute different "spheres of justice".

In our social context, where the theory of egalitarian justice predominates, the socially valid scheme of priorities for assigning medical resources includes aspects such as patient age or quality of life, and these criteria are strongly supported socially.

Respecting the second aspect, the role of experts in the process of deciding on priorities has to be defined, together with the degree to which the population takes part in decisions on the microassignment of resources. Rationing resources to certain patients rather than others while accepting the consequences of this decision must take place on the basis of standardised medical criteria, using decision-making algorithms agreed in clinical practice guides.^{16,17} In many cases decisions on establishing priorities involves tragic choices, so that society has to set moral limits. These decisions therefore have to be based on democratically informed deliberations, in which all of the agents involved take part. Bioethical professionals should therefore emerge as the figure able to promote dialogue between the world of medicine and the community, confronting ethical dilemmas even in emerging clinical situations.¹⁸

Nevertheless, we must admit the need for an immediate response in a situation such as the COVID-19 pandemic. This is especially complex due to a demand that surpasses the available resources, so that experts have to decide on priorities. This decision-making process has to be based on

medical criteria which must be socially validated, and this is hindered by the lack of an immediate social debate on this question.

The COVID-19 pandemic and resource rationing for patients

During the COVID-19 pandemic, medical professionals have had to deal with scenarios in which sufficient resources were not available (beds in intensive care units, ventilators, ECMO (extracorporeal membrane oxygenation . . .) for the number of severely ill patients,¹⁹ so that the decision on resource assignment depends on who has the best chance of living or dying.²⁰

Medical resource rationing is fortunately very rarely necessary outside catastrophe medicine, where there are far fewer available resources than necessary and they have to be rationed. However, even in these circumstances the question is not free of ethical debates and clinical arguments.^{21,22}

Therefore, and in a prudentially similar way to what happens during care in the case of major catastrophes, the COVID-19 pandemic has brought about a global state of emergency. For example, in Italy there was insufficient time to test or verify plans or protocols for COVID-19 infection, at least at large scale. The speed with which the scenario evolved made it necessary to adopt easy and pragmatic solutions, even for critical and delicate matters given the lack of resources for everyone.^{23,24} Medical resources rationing has since then been the case in many countries. Resources have had to be rationed even in countries such as the United States, which theoretically had longer to prepare, due to the devastating effects of the pandemic.^{25,26}

Foresight makes it possible to plan for future scenarios, including ethical debate on the assignment of resources. The implementation of algorithms for critical decision-making should be a part of the preparation for a pandemic in any part of the world, and these algorithms should include more than the most evident prognostic factors: fragility, comorbidity and functional state.²³ The fact is that an additional hindrance to implementing decision-making algorithms in the COVID-19 pandemic has been the urgency with which decisions about clinical practice and organisational protocols are being reconfigured. This was necessary due to gradually increasing knowledge about the infection, giving rise to uncertainty in patient care and leading to a considerable degree of variation in treatments.³

In Italy, it should be underlined that in the initial phase of the medical crisis the Italian Society of Anaesthesia, Analgesia and Intensive Care (SIAARTI) drew up a series of ethical recommendations for treatment assignment in exceptional situations with limited resources.²⁷ This document aroused strong reactions in the medical-scientific community, in the academic world and in the media. Nevertheless, it was also supported by a large part of the medical community.^{24,28} Doctors were not surprised that the patient age criterion, which is socially accepted, started to be adopted implicitly in the decision-making algorithm for the assignment of scant medical resources due to the growing number of severe patients.^{23,29} In fact, the SIAARTI document mentions patient age in two critical recommendations: 1) ‘‘It may necessary to set an age limit for admission to intensive

care. This is not simply a selection associated with values, but rather the reservation of extremely limited resources for those who have the greatest possibility of survival and those who may live for more years once saved, to maximise the benefits for the highest number of people’’, and 2) ‘‘The presence of comorbidity and functional state must be carefully evaluated as well as age. It is possible that short admission in healthy individuals may be prolonged, and that therefore resources should not be consumed in the case of persons who are elderly, with fragility or severe comorbidity’’.²⁷ In spite of the implicit acceptance of Italian medical professionals to use the age criterion, disagreements arose in the academic world about this situation, and more specifically about whether it is incorrect to prioritise younger patients with COVID-19.³⁰ In fact, in Spain the General Board of Official Spanish Doctors’ Associations (the *Consejo General de Colegios Oficiales de Médicos de España*) (CGCOM) and other associations drew up different protocols in reaction to the crisis in care caused by COVID-19, giving rise to a certain degree of discomfort due to their references to age. Currently, the documents by organisations such as the Bioethics Committee of Spain,³¹ the Central Professional Ethics Commission of the CGCOM³² or the Spanish Society of Intensive and Critical Medicine and Coronary Units³³ use a text that confirms the age criterion as being of undeniable importance in prioritisation, although it is not exclusive, and they underline the difference between prioritisation and refusing or restricting care.

Lastly, it should be remembered that the rationing of medical resources must be exceptional, and it is only justifiable if all of the parties involved (hospitals and institutions. . .) have attempted to increase resource availability and have also evaluated the feasibility and safety of transferring patients to other hospitals.²⁹

Consensus documents for decision-making

In ethical terms, the novelty of the current emergency due to the COVID-19 pandemic lies in the extraordinarily high number of people who are personally affected by the results of the assignment of scarce resources. They have suddenly realised that the principle of ‘‘equals should be treated equally’’ (the Aristotelian definition of distributive justice) may no longer be applicable. Given this dilemma, and based on the fact that by definition ethical dilemmas have no correct answer,³⁴ we have to design a protocol-governed strategy for action that makes it possible to assign resources as equitably as possible.

The assignment of resources and therefore also their prioritisation and rationing in the COVID-19 pandemic should thus be based on strictly medical criteria. These have to be supported by clinical decision scores¹⁹ and they have to be socially validated even when we know that in these circumstances, the principle of patient autonomy may be restricted.³⁵

Thus in Spain^{33,36–38} and at an international level^{25,39–42} many consensus documents have been published on ethical recommendations for decision-making in this exceptional crisis situation. They are revised at regular intervals, given that knowledge of the disease is evolving very quickly.³⁴

All of the said recommendations have the aim of supporting medical professionals when making difficult clinical decisions. They supply criteria that are approved by professional associations which make it possible share responsibility in situations that involve a strong emotional charge, specifying criteria for the assignation of resources in an exceptional situation of scarcity.

There is agreement on the need to prioritise the assignation of life support measures for those individuals with the highest probability of surviving their critical situation and recovering their project for the future. This decision is based on biological parameters that are guidelines, although others should also be taken into consideration. The capacity of a patient to tolerate the high level of physical, metabolic and cognitive demand involved in intensive therapy over the short to medium terms must be evaluated. This aspect is highly important, and it is not usually taken so much into consideration, and it may lead to therapeutic obstinacy.³⁸

Lastly, guideline documents may be prepared at local level, and experts underline the importance of a higher level centralised committee regularly revising clinical decision-making documents prepared by different committees or workgroups to ensure that inequalities do not arise.³⁴

Fundamental ethical values for decision-making

Proposals for resource assignation in pandemics and other scenarios involving a total scarcity of resources agree on four basic ethical values: the maximisation of the benefits produced by the scant resources in question, treating everyone equally, contributing to the creation of social value and prioritising the most severe situation.^{25,33,43,44} It is obvious that a single basic value is not enough to determine the rationing of a resource for one patient rather than another, as an ethical framework containing multiple values is needed. This framework has to be adapted, depending on the resource in question and the context in which the medical intervention takes place.

Specific ethical recommendations for clinical decision-making

It has been suggested that six specific recommendations can be derived from the four basic values described above for the equitable assignation of medical resources during the COVID-19 pandemic²⁵: maximise benefits; give priority to healthcare workers; do not prioritise care in order of arrival; be sensitive to scientific evidence; recognise participation in research; and apply the same principles to patients with COVID-19 and those without COVID-19.

It is primordial to maximise benefits in a pandemic. For example, this involves the possibility of withdrawing a ventilator or ICU bed from a patient when they would give another patient a greater therapeutic benefit. Patients and their families must be aware of this possibility.^{29,34} The clinical suitability of admission to the ICU is a recurring aspect in

the debate during the current pandemic, and decisions on this involve detailed analysis of the probability of survival and discharge from hospital. This analysis must be based on clinical judgment of the physiological reserve of the patient and their capacity to recover. Patients are therefore classified in one of three priority groupings: high, moderate or low, and this will determine which patients are admitted first.⁴⁵

The second recommendation involves prioritising healthcare professionals for the interventions intrinsic to COVID-19 (testing, personal protective equipment, ICU beds, ventilators, treatments and vaccines). All of these facilities must be available for first line medical care workers and those who maintain critical infrastructures, particularly those who are at high risk of infection and whose training makes them hard to replace.^{46,47} These elements are essential parts of how our society responds to the pandemic, and prioritising them benefits the population as a whole.

The third recommendation is not to prioritise medical care according to the order in which patients arrive. However, due to the pressure in reaching a decision, in circumstances when information is lacking, random selection is preferable to attempting to make more precise prognostic judgements within a group of more or less similar patients.²⁵

Being sensitive to scientific evidence involves not only prioritising resources in a restrictive way for those patients with the worst prognosis, as it also has a positive meaning. For example, when prioritising access to future vaccines for the most vulnerable individuals (after healthcare workers), with the aim of saving as many lives as possible, given that COVID-19 evolution is significantly worse in older people and those with chronic diseases.

Lastly, recognising participation in research means prioritising resources as well for those people who are performing research into therapies for COVID-19. Their acceptance of risk during their research work will help future patients, so that they should be rewarded.

The role of medical professionals

The difficult role of professionals in the microassignation of medical resources was described above, and this creates an additional emotional charge over and above the current complex care situation.

Some experts recommend distributing functions in teams, separating clinical professionals who provide care for the sick from those who, with the help of an expert team, work on the triage of resource allocation.^{25,34,43,48} The latter will then report on their decision to the clinical teams, the patient and their family.

In any case, as well as the information on the ethical basis and recommendation that documents such as the current review may make, or the protocols drawn up by the different bodies mentioned in this paper, as is the habitual practice in decision-making for complex questions at the level of care, we recommend team discussions to support decisions and to share the enormous emotional burden arising from more complex ethical decisions, and perhaps even urgently consulting the ethics assistance committee.

The professional responsibility of medical workers in resource prioritisation

Medical professional responsibility consists of the obligation of doctors to remedy and satisfy the consequences of their actions, omissions and voluntary and involuntary errors, within certain limits, committed while doing their job.⁴⁹ Analysis of medical praxis in each specific case requires study of the specific circumstances in each situation (*lex artis ad hoc*).⁵⁰

Medical care now faces a praxis scenario that is not usual, and professionals act within the framework of a medical organisation conditioned by the crisis in care due to the pandemic and new regulations. This may give rise to claims against the action of professionals being transferred to the system itself or public authorities.

In the current situation movements such as the one promoted by the Humanising Justice⁵¹ association have arisen. These underline that during this crisis professionals have been working without sufficient resources for the conventional exercise of their profession, under conditions contrary to conventional health at work. They have done so in a crisis and in unsuitable conditions in connection with the demand-satisfaction equation. Many professionals have intervened in ways usually reserved for specifically qualified professionals, and that they have worked in installations that cannot strictly be considered medical. Due to these considerations, they suggest forms of institutional rather than individual or professional responsibility.⁵²

It is within this scenario that the prioritisation of resources emerges. This question may have arisen beforehand in emergency situations or major accidents, when urgency is the core concern. The difference now is that it is not urgency but rather the lack of medical material or instruments for treatment that makes it necessary to prioritise and apply rationing,⁵² in a close association with the legal concept of loss of opportunity.⁵³

Another question will be to determine the degree of responsibility of the public authorities, or to apply grading, proportionality and responsibility criteria to the working of the administration.⁵²

Conclusions

Although it may be that there is no way to prevent a COVID-19 pandemic in a globalised world, verified information is the most effective way to prevent panic caused by the infection.⁵⁴ In the same way, faced with ethical problems that may arise in care during extraordinary situations such as those deriving from COVID-19, as well as to mitigate disinformation and the resulting uncertainty, exemplary transparency is needed regarding the criteria for allocating medical resources and especially sensitive clinical decisions. It is necessary to clearly explain the circumstances that give rise to rationing, if it exists, to patients, family members, medical professionals, the community and the media, as well as the form it takes.⁵⁵ The current crisis in care leads to an especially complex scenario that means doctors have to work in a different way in comparison with their usual practice. This has to give rise to an active and intense ethi-

cal debate, the results of which should be included in plans for care during future emergencies.

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