

The ethical dimension of prioritization and allocation decisions within the context of the coronavirus disease 2019 pandemic

Jakub Pawlikowski

1 Faculty of Medicine, Cardinal Stefan Wyszyński University in Warsaw, Warsaw, Poland

2 Department of Ethics and Medical Law, Medical University of Lublin, Lublin, Poland

Introduction “The plague bacillus never dies or disappears (...) perhaps the day would come when, for the bane and the enlightening of men, it would rouse up its rats again and send them forth to die in a happy city.”¹ – these words spoken by Dr Rieux, a character in Albert Camus’ *The Plague*, have more than metaphorical resonance these days. Their impact is real.

Globally, in the second half of April 2020, approximately 2 220 000 confirmed cases of new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were reported, including an estimated 150 000 deaths in almost all countries.² According to data from China, 6.1% of patients with coronavirus disease 2019 (COVID-19) required intensive care unit (ICU) hospitalization, and almost 60% of people from this group needed mechanical ventilation.³ In Italy, ICU treatment was required in 5% to 10% of patients and 10% to 25% of those who were hospitalized needed mechanical ventilation.⁴ In the United States, it has been estimated that the number of patients who require mechanical ventilation is several times higher than the number of ventilators.⁵ Special attention in clinical protocols and guidelines should be given to the elderly and geriatric care. In the United States, according to data reported to Centers for Disease Control and Prevention (CDC), 31% of cases, 45% of hospitalizations, 53% of ICU admissions, and 80% of deaths associated with COVID-19 were among adults at the age of 65 years or older, with the highest percentage of severe outcomes in those aged 85 years and older.⁶

The pandemic of SARS-CoV-2 infection, which causes COVID-19, has presented serious challenges to many physicians, healthcare providers, and societies. These are not only of clinical or organizational nature but also have an ethical dimension.

There are numerous areas of ethical concern in a pandemic: equitable access to healthcare, the ethics of public health actions taken in response to a pandemic (eg, the surveillance of outbreaks, confidentiality, balancing public health with personal rights including liberty, privacy, and freedom of religion), the obligations of healthcare workers during a pandemic, and the obligations of society toward them in return.^{7,8} The World Health Organization acknowledged the significance of ethical issues in the context of a communicable disease epidemic several years ago, in guidelines published after the SARS epidemic. This document discussed the influence of moral issues on allocation and prioritization decisions, balancing public interest against civil liberties, particularly when it comes to imposing legal restrictions, the range of duties assigned to the medical staff (or refusal to work), stigmatization of certain patients, and the way of conducting research or humanitarian missions during an epidemic.⁹ During an outbreak of an infectious disease, research plays a crucial role in finding new strategies for disease prevention, diagnosis, and treatment. Research ethics committees (in Poland, bioethics committees) have a vital role in reviewing COVID-19 studies and they need to improve the review efficiency, making sure that the standards of ethical review are not relaxed.¹⁰

Prioritization, rationing, and allocation decisions during the severe acute respiratory syndrome coronavirus 2 pandemic Making decisions related to setting priorities and rationing (“allocation” in economic and bioethical parlance) of medical technologies is one of the most vividly discussed ethical problems associated with the SARS-CoV-2 pandemic. The key terms used in this article are defined as follows: prioritization—decisions on who should receive help in the first instance;

Correspondence to:

Jakub Pawlikowski, MD, PhD, JD,
Faculty of Medicine, Cardinal
Stefan Wyszyński University in
Warsaw, ul. Włocławskiego 1/3,
01-938 Warszawa, Poland,
phone: +48 22 380 96 95,
email: jpawlikowski@wp.pl

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rationing—entails restricting access to scarce goods; and allocation—apportionment and distribution of material resources earmarked for specific purposes. A large share of responsibility for such decisions will be taken by those who manage healthcare systems (from central government bodies to hospital ward directors), but the outcomes of their decisions will influence the choices made by individual medical workers and fates of particular patients. It should be added that ethical dilemmas regarding rationing, allocation, and prioritization are not only a consequence of the disease severity and shortage of equipment but also of the concept of justice and other values, the current status of supply chains providing medical equipment, staff availability, and responsible management.

Decisions on prioritization, allocation, and rationing during the COVID-19 pandemic affect many areas: virus testing, hospitalization, pharmacotherapy, and the procurement of personal protective equipment. Decisions can be made at the micro level (eg, regarding the use of particular medical technologies by doctors, such as mechanical ventilation, ordering diagnostic tests for SARS-CoV-2, hospitalization, and pharmacotherapy), at the meso level (eg, when hospital management teams decide how to distribute personal protective equipment or specialist equipment among emergency departments, isolation wards, ICUs, etc), and at the macro level (eg, when governments decide to create hospital networks, send extra funds and specialist equipment to selected medical centers, or indicate a population on which virus testing will be carried out). However, the decision to either refuse to initiate or withdraw mechanical ventilation (or other treatments used in the ICU, such as extracorporeal membrane oxygenation [ECMO]) is the most difficult and exceptionally fraught one, because it usually determines whether a patient will live or die. Furthermore, the decision to start treatment usually commits technical resources for several weeks, which prevents them from being used to the benefit of other patients, yet the situation is escalating so fast and the lives of so many people are at risk that rapid decisions are unavoidable. It should be added that from a psychological perspective, it is easier to make the decision not to start treatment (withholding) than to discontinue it (withdrawing), which underlines the importance of the initial assessment and the need to prepare algorithms of conduct well in advance.

The criteria for prioritization and allocation decisions in medical ethics In medical ethics, decisions on priority setting and the fair rationing and allocation of limited resources should be based on medical criteria, namely those arising from the life- or health-related need to employ particular advanced therapies, and the expected positive outcomes (or benefits) of doing this for patients' health and life. In the World Medical Association's Declaration on the Rights of the Patient (adopted

in Lisbon in 1981), the following statement can be found: "In circumstances where a choice must be made between potential patients for a particular treatment that is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination" (point 1e).¹¹ Assistance should therefore be granted to people who need it to survive and those selected from this group should have the greatest chance of survival. In the event of epidemics or mass catastrophes, the scope of assistance should also be limited to the necessary minimum to benefit as many people as possible.¹²

Of note, the problem of setting priorities, rationing, and allocating is not new to medical ethics. It appeared a few decades ago when decisions needed to be taken at a time when there was limited access to hemodialysis machines or organs for transplants.¹³⁻¹⁵ After many discussions on the relative importance of various nonmedical criteria—such as age, social considerations (eg, family status, social position, leadership role, and contribution to the society welfare), or economic factors (eg, social security contributions paid)—the conclusion was ultimately reached that such decisions should be primarily based on medical criteria.¹⁶

Faced with the need to prioritize, allocate, and ration, decision makers not only have to strike a balance between concern for patients' welfare and the principles of justice but they also need to be aware of which concept of justice they are referring to. In this case, there are several competing approaches, for example, those directed at: individual freedom (libertarianism—resources should be distributed according to market principles); benefit (utilitarianism—resources should be distributed to the maximum advantage of all); equality (egalitarianism—resources should be distributed according to needs, equally, and by balancing out any existing differences); or the good of the community (communitarianism—resources should be distributed for the good of the community). In healthcare systems, 2 or more concepts of justice tend to coexist alongside one another. However, when justice is being pursued correctly, an individual's dignity should never take second place to the dictates of social utility or pragmatism.

The ethical aspects of prioritization and allocation decisions in clinical guidelines on the use of mechanical ventilation in the treatment of coronavirus disease 2019 Relying on medical criteria while making allocation and prioritization decisions is not easy, and developing an appropriate algorithm of conduct poses a serious clinical and ethical challenge during times of chaos caused by the influx of a large number of patients into medical centers, which lack sufficient equipment and human resources. An attempt therefore needs to be made—at the stage when preparations for a threatening epidemic are still in progress—to develop fair selection principles to be applied when the need

arises.¹⁷ In many countries, the serious epidemiological situation has led to the publication of clinical guidelines and experts' statements on making decisions on key issues including priority access to treatment, allocation of medical resources, and, in particular, the way mechanical ventilation and other advanced medical technologies (eg, ECMO) should be utilized.¹⁸⁻²² In Poland, the Experts of the Polish Bishops' Conference on Bioethics announced the statement on the distribution of emergency measures in the event of a pandemic caused by SARS-CoV-2.²³

The guidelines not only provide clinical advice but also discuss relevant ethical considerations: how to maximize benefits; when to discontinue futile therapy (sometimes also referred to as persistent therapy); the moral division into ordinary (obligatory) and extraordinary (optional) measures—the last may be stopped; respect for autonomy (verification of the patient's living will, respecting the patient's or the proxy's decision to discontinue therapy or provide a “do not intubate” order, also stressing the doctor's duty to justify and document this in written form and to inform the patient and his or her loved ones accordingly); collective responsibility for decision making; separating a triage officer/ team from clinicians; prioritizing a specific group (eg, health-care workers as a high-risk group, research participants); not relying on a first-come, first-served approach; openness to guideline verification and swiftly responding to new research data; applying the same ethical principles to all patients, regardless of the fact whether they have been infected with SARS-CoV-2 or not.²⁰ Some of these issues need a commentary.

As stressed above, benefits are best maximized by considering reasonable life expectancy rather than seeking to maximize the length of life—this rule needs to be applied only when 2 or more patients have similar chances of survival. Given the time constraints imposed by a fast-changing situation, it is not advisable to evaluate the projected quality of life or quality-adjusted life-years.²⁰ The British National Institute for Health and Care Excellence (NICE) emphasized that decisions on the use of intensive therapy should be taken based on the anticipated medical (rather than, for example, social) outcomes while taking into account the likelihood of the patient returning to a state of health that is acceptable for them within a prescribed period.²⁴ Instruments that have already been published may be useful.²⁵ Some guidelines use the Sequential Organ Failure Assessment (SOFA) scoring system to determine exclusion criteria (eg, irreversible shock), assessing mortality risk and prioritizing people for mechanical ventilation.²⁶

The possibility that doctors treating terminally ill patients may decide to withdraw futile (or persistent) therapy and discontinue emergency efforts based on the assessment of therapeutic options is provided for by many national codes of ethics and international instruments.^{27,28}

Similarly, article 32 of the Polish Code of Medical Ethics accepts the withdrawal of persistent therapy.²⁹ Patients with respiratory failure who do not receive mechanical ventilation during a pandemic should receive respectful and compassionate palliative care. Administering sedatives and analgesics is ethically and clinically appropriate in this situation.⁷ Also article 30 of the Polish Code of Medical Ethics obliges doctors to provide terminally ill patients with humanitarian end-of-life care focused on quality of life while creating the conditions for them to die with dignity.

In the current exceptional situation, it seems understandable that the creators of the aforementioned guidelines regarded the ICU treatment, and mechanical ventilation in particular, as an extraordinary (emergency) measure whose validity should be reviewed every day and which may be withdrawn if it fails to have any effect and replaced with palliative care. Nevertheless, it should be stressed that under other circumstances, when resources are not in such short supply, ICUs may be part of a basic (standardized) care plan rather than an emergency measure. The above comments apply to ECMO as well, which should also be considered an extraordinary (emergency) measure due to the pioneering nature of this technology as well as its cost, restricted availability, and the small number of medical personnel with practical experience and skills needed to operate it correctly. The guidelines recently published by the Extracorporeal Life Support Organization (ELSO) address the urgent need to adopt optimal standards of conduct in the treatment of patients developing acute respiratory distress syndrome during the course of SARS-CoV-2 infection, who could be qualified for veno-venous ECMO.³⁰ However, it should be borne in mind that COVID-19 is a new disease, so most recommendations are based on poor-quality data and it is likely that some of these could change significantly, as further knowledge is gathered and new experience gained. The authors of the ELSO guidelines are most keen to emphasize that the vast majority of ICU patients will not require such an invasive form of assistance as gas exchange, because mechanical ventilation with the use of a ventilator is the standard treatment in patients with COVID-19 developing acute respiratory distress syndrome. Nevertheless, this technology should be encouraged in medical centers staffed with practitioners possessing the skills required to use ECMO, and the epidemic may even present an opportunity to increase the number of such personnel and expand the use of ECMO both now and in the future.

Collective decision making is crucial in difficult ethical situations. Prioritization and allocation decisions regarding intensive therapy should only be taken by people with appropriate knowledge, skills, and experience.³¹ The ICU staff should support less experienced medical practitioners when they need to make decisions regarding critically ill patients. “Mechanical ventilation teams”

(similar to “Heart Teams” in interventional cardiology) consisting of several specialists, physiotherapists, and nurses, can be considered.

Many guidelines postulate that doctors providing direct patient care should be separated from people responsible for prioritization or rationing by creating a “triage committee” including triage officers supported by a team experienced in intensive therapy. Such committees should make prioritization and allocation decisions and communicate these to clinical teams caring for patients, the patients themselves, and their families. Doctors are not capable of (and often should not even be) considering the welfare of all the existing and potential patients or acting as spokespersons for the public interest. After all, they are unaware of the potential systemic solutions available in the healthcare sector and incapable of objectively assessing the costs of various options for utilizing the system’s resources. Furthermore, when resources are scarce, doctors are inevitably faced with a conflict between the needs of an individual patient and those of other patients or the society at large. Appointing a triage committee is also supported by Robert D. Truog, an anesthesiologist and director of the Center for Bioethics at Harvard University, who believes that bedside clinicians should not be burdened with deciding whether treatment should be withdrawn in their own patients, not out of consideration for these patients’ welfare yet because making such decisions can cause doctors too much moral stress and lead to professional burnout.⁵ In this context, it is worth remembering that, for many years, discussions have been led in Poland about appointing hospital ethics committees capable of supporting physicians who need to make morally difficult decisions.^{32,33} As for making allocation decisions, such committees should primarily include medical workers (not only doctors of various specialties but also nurses, pharmacists, diagnosticians, and physiotherapists), and also clerics, ethicists, psychologists, regional representatives of the healthcare system administration, and even experienced advisors representing patients and the local community.

The first-come, first-served rule may be followed in medical ethics in ordinary situations but not always in extraordinary events of epidemics or mass catastrophes. It can be moderately useful (once medical criteria have been applied) in the case of a continuous scarcity of resources (as in transplantation), but it is of little use in the context of epidemics or catastrophes when there could be a massive influx of patients, including those living near the hospital being at an advantage, and this could cause chaos and even acts of violence.²⁰

The prioritization process should vary according to intervention types and may be modified to use new research data. For example, the priority of access to preventive technologies (like the anticipated vaccine for COVID-19) should be given to people from the group at the highest risk—in

this case, frontline medical personnel—then to older people, and finally to the young, because they are less vulnerable to infection and serious health consequences. However, young people or children could become a prioritized group if epidemiological models indicate that this would be the best method for reducing the virus spread across the population. The ICU beds and ventilators are healthcare resources used in patients in a life-threatening state, so the first patients to benefit from them should be those who have the greatest chance of recovery, which carries the secondary consequence that the beneficiaries will usually (though not always!) be younger people and those with the fewest comorbidities. However, antiviral pharmacotherapy will be most effective in patients who are seriously, yet not critically, ill and also do not meet the criteria qualifying for mechanical ventilation. The experimental use of pre- or post-exposure pharmacotherapy should be primarily directed at those who are infected yet asymptomatic or have only mild symptoms.

It is also of importance to remain open to amendments to the existing criteria and recommendations, because knowledge of the virus is growing fast. The triage algorithm should be reviewed regularly so that it can be adapted to existing knowledge of the disease and its treatment, while avoiding manifestations of discrimination and unjustified inequalities.³¹ Making prioritizing and allocation decisions is associated with the undoubted need for prudence, transparency, and effective communication so as not to undermine public confidence.

Ethically questionable criteria for allocation and prioritization decisions

On one hand, the above mentioned guidelines assist with clinical decision making, but, on the other hand, some of the criteria that were proposed therein (eg, those based on age and social or overly utilitarian considerations) raise serious doubts if approached from the ethical perspective. A critical approach should be taken particularly towards some of the proposed criteria aimed to determine which patients should be admitted to the ICU and when mechanical ventilation should be used. Including age as a criterion in the guidelines of the Italian Society of Anesthesia, Analgesia, Reanimation, and Intensive Care (SIAARTI) (“An age limit for the admission to the ICU may ultimately need to be set.”) aroused particular doubts.¹⁸ The Spanish guidelines (conceived by the Spanish Society of Intensive Care Medicine and Coronary Units [SEMICYUC]) also imply quite clearly that patients should be segregated based on age, but they also contain a vague and very subjective social criterion (“el valor social de la persona enferma” [English: “the social value of the sick person”]).¹⁹

Adopting the criterion of age as one of the principle decision-making rationales is a risky proposition, which is medically unjustified if there is a wide variation in the biological potential among people of various chronological ages. The

statistically higher risk of death in a particular age group is not a sufficient premise for denying a specific individual approach. Would the chances of survival in a 74-year-old patient and another 76-year-old one be really completely different? Or those of a 56-year-old undergoing immunosuppressive therapy and an athletic 76-year-old? Some situations would be even more morally difficult, for example, the one requiring the decision to assist a 50-year-old mother with breast cancer at the cost of withdrawing ventilation from a physically fit 76-year-old. Relying on statistical premises based on mortality risk in a particular age group can be risky, because premises of this kind can also consider such factors as sex (it is common knowledge that men with COVID-19 are at greater risk of death than women) or even place of residence (different mortality rates are being observed in various countries). Chronological age is a simple measurement of how long we have been alive, but, in a clinical assessment, it is how long we are expected to live that is most important, and the latter cannot be determined based on chronological age alone. Age should be a premise for more care, not elimination. The average septuagenarian is not bedridden. People in their 70s run 2 of the 3 branches of the government in the United States and represent the most rapidly growing segment of labor force there; according to life expectancy, a half of the population in the United States will live past 80 years of age.³⁴

These theoretical doubts are being confirmed in accounts by the Italian doctors who admit that they had an impression that age is playing the key role in the decision-making process. For example, an 80-year-old in excellent health (apart from symptoms of COVID-19) was denied access to mechanical ventilation. The exclusion criteria for therapy also had to be altered by lowering the age threshold from 80 to 75 years (which was criticized on the grounds of ageism). Marco Vergano, a co-author of the Italian guidelines, admitted that he was urged, when developing them, to emphasize “clinical reasonableness,” but he was also aware of the “soft utilitarianism,” as he called it, that accompanied the solution he proposed to use in a situation when resources are scarce.³⁵

In fact, criteria that help to statistically differentiate measurements of morbidity or mortality (eg, sex, level of education, income level, and place of residence) can assist with other health problems, but referring to such criteria when making clinical decisions, which could mean life or death for a given patient, would be ethically and medically unjustified. Age or sex can be one of numerous decision-making criteria if either of them could have a clinically significant impact on life expectancy in a particular case. However, information about a patient belonging to a particular age group cannot replace subjective and objective examination as well as comprehensive assessment of an individual’s health and biological condition. Relying on age as a basic decision-making criterion is undoubtedly one of the simplest

methods of selection (in fact, the same could be said for sex or skin color). However, this is not always medically justified, so great caution should be taken when this criterion is applied to ensure that it does not lead to unequal treatment and discrimination on the grounds of age (ageism) or any other medically unjustified reason.

Recently developed protocols expressly call for the rationing and reallocation of ventilators in a utilitarian manner, which aims to save the greatest number of lives.³⁶ Some authors make the morally controversial proposal that therapy should be discontinued if it is needed by another patient with better prognosis (patients should be informed of this eventuality as part of the admission procedure).²⁰ However, ethics and law generally consider each life “to be of equal value.” Withholding or withdrawing therapy due to its futility can be justified, but stopping treatment in a person who has some chance to survive in order to help another patient who may have a greater chance is morally risky. That is why clinicians who withhold or withdraw ventilators without patients’ consent become exposed to risks of criminal and civil liability (due to medical malpractice).⁶ The odds that such liability will materialize in any given instance are likely low, but the risk of liability does not equal zero. For this reason, legal protection for healthcare workers is considered regarding such decisions.³⁷

The current extraordinary circumstances are also revealing the importance, and limited role, of *pro futura* statements of intent. On one hand, patients’ autonomy should, when possible, be acknowledged, and in cases when it is prudent, be respected, which is why the authors of the SIAARTI recommendations correctly suggest the following: “The presence of advance healthcare directives or advance care planning should be evaluated, especially for patients affected by severe chronic illnesses. These plans should be shared as much as possible between the patient, their proxies and all the healthcare staff involved in patient care.” On the other hand, the medical staff would be justified in doubting whether such statements of intent and advance care plans were adjusted to the present circumstances (eg, the temporary need to use a ventilator and disease projections for COVID-19) when they were drawn up. For that reason, in addition to checking statements of intent, it should also be ascertained whether these documents take into account the present circumstances.

From the medical ethics perspective, the most important decision-making criteria include the need for therapy and projected chances of survival, estimated based on premises that take into account the effectiveness of a given treatment and the risks it may present to a particular patient. Such decisions should depend on medical criteria that are as objective as possible and resistant to manipulation (eg, adopting the criterion of chronological age can easily lead to patients or their relatives withholding the truth to

gain benefits). The recommendations should also shield doctors from making choices that are ethically incorrect or discriminating certain patients. Some guidelines that are currently being developed to meet the needs of the moment may contain simplifications or criteria that carry the risk of differentiating between patients without due cause. However, these are a kind of cry of despair and even if they contain errors, it would be difficult to ascribe bad intentions to the people who wrote them. However, it is worth analyzing them in depth, as this can help to ensure that such errors will be avoided in the future.

Conclusion Decisions on the priority of access to advanced life-saving treatments and the allocation and rationing of limited medical resources should depend on medical, rather than social or economic, criteria. Subjective, unclear, and non-medical criteria of prioritization, such as age, sex, and social value, should be avoided. Clinical guidelines, team decision-making, separating clinicians from triage officers, and ethical support are desirable, where possible, so that a single person does not have to take all the responsibility for life and death of others. “Mechanical ventilation teams” consisting of several specialists can be considered.

Of note, even the most precise guidelines are only recommendations. The final decisions are made by such individuals as a doctor or the first responder, guided by their knowledge, experience, prudent consideration of the real-time situation, and their own conscience. No one can relieve such people of the burden of making difficult decisions and when they decide not to make any decision, this should be seen as an indication that things should be left as they are. In such circumstances, prudence takes on the qualities of a special virtue.

Furthermore, difficult decisions involving the need to refuse admission to the ICU or either decline to initiate or discontinue therapy have understandably caused, and will continue to cause, dilemmas, pangs of conscience, reluctance to discuss the situations in question, moral scars, and psychological trauma among people who have made such decisions. Consequently, when the epidemic subsides, such people will require psychological support, spiritual care, and understanding of their colleagues and local community. The current situation also makes it necessary to appeal to those who are organizing the healthcare system—from the state authorities to local councils and hospital directors—not only to provide the appropriate equipment but also to take care of their staff and ensure that the system is properly coordinated on the national and regional levels.

However, the epidemic also gives us an opportunity to develop our humanity, transcend our limitations, and, perhaps at times, scale the heights of heroism. And this applies not only to people caring for the sick, who are risking their lives (and sometimes the lives of their loved ones

as well) and revealing how profound and beautiful the medical vocation can be, but also to the sick—after all, there have been instances of heroic patients voluntarily agreeing to give up their right to mechanical ventilation in order to save others who will benefit more from using it. If we are to gain a moral message from these times of epidemic, let it be a passage from the first sermon delivered by Father Paneloux in Albert Camus' *The Plague*: “No, we should go forward, groping our way through the darkness, stumbling perhaps at times, and try to do what good lay in our power. As for the rest, we must hold fast, trusting in the divine goodness.”¹

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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