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The contribution of ethical reflection during the Coronavirus pandemic. A comparative analysis

Mario Picozzi[1], *Paolo Severgnini*[2]

[1] Center for Clinical Ethics; Biotechnology and Life Sciences Department, Insubria University, Varese Italy; [2] Department of Anesthesia and Critical Care, ASST dei Settelaghi, Macchi Foundation; Biotechnology and Life Sciences Department, Insubria University, Varese, Italy

Abstract. The Coronavirus pandemic has deeply marked all ordinary health care activities and has dictated matters usually faced by the medicine of disasters. The most critical and dramatic dilemma has been the triage and the urge to select patients for Intensive Care Unit (ICU) because there was no place for all at the same time. The need to decide in a very short time has made this decision even more complex. The data of the Italian situation and namely of Lombardia reveal it clearly. Worldwide, there have been many different views on triage, sometimes with very peculiar emphasis. In this paper we will illustrate the contributions of the Unites States compared to the European ones. We have critically analyzed different views and we have highlighted that nevertheless there are several shared elements such as clinical criteria, if we consider only them we might underestimate the uniqueness of the patient, including vulnerable ones. There is a huge gap between the US view and the European view when it comes to the appointment of the final decision maker in triage. We propose the criteria of proportionality as a guide line to take decisions in triage because it allows to integrate collective public health objectives and the principle of ensuring protection for the individual patient. Finally, we envisage the potential role of ethics consultation in this pandemic scenario.

Key words: Covid-19 disease, triage, proportionality, clinical ethics consultation

Introduction

The Coronavirus pandemic has deeply marked all ordinary health care activities and has dictated matters usually faced by the medicine of disasters. The most critical and dramatic dilemma has been the triage and the urge to select patients for Intensive Care Unit (ICU) because there was no place for all at the same time.

The need to decide in a very short time has made this decision even more complex.

The data of the Italian situation and namely of Lombardia reveal it clearly. Worldwide, there have been many different views on triage, sometimes with very peculiar emphasis.

In this paper we will illustrate the contributions of the Unites States compared to the European ones. We have operated a choice among many articles and guide lines about this matter, and we have prioritized those most quoted in literature. We have critically analyzed different views and we have highlighted that nevertheless there are several shared elements such as clinical criteria, if we consider only them we might underestimate the uniqueness of the patient, including vulnerable ones.

There is a huge gap between the US view and the European view when it comes to the appointment of the final decision maker in triage. We propose the criteria of proportionality as a guide line to take decisions in triage because it allows to integrate collective public health objectives and the principle of ensuring protection for the individual patient. Finally, we envisage the potential role of ethics consultation in this pandemic scenario.

The situation in Italy

In Italy we have detected the first patients with a COVID-19 disease at the end of February 2020. In the following months there have been more and more people infected with a sensitive increase of hospitalizations to face the serious breathing syndrome caused by the virus (Fig. 1) (1).

Lombardy has been particularly hit by the virus, with a remarkable increase of patients in need of a ICU recovery (Fig. 2) (2) (Fig. 3) (3).

The clinical evolution of the disease and its manifestation has been very different. Same patients Covid-19 affected were coming to the Emergency Department just presenting the most severe grade of respiratory distress, with PaO2/FiO2 ratio <100 mmHg, requiring immediately breathing assistance through the use of Noninvasive ventilation Continuous Positive Airway Pressure (CPAP) and intubation with invasive approach in case of deterioration of gases exchange.

The greatest number of patients showed up with respiratory dyspnea, fever, cough; they didn't develop early respiratory distress in few hours, but same time in few days, same time in few weeks.

The number of patients hospitalized was growing day by day and daily same patient started to need respiratory assistance. Fortunately, in the most of cases the patients were treated successfully with noninvasive devices like helmet, to ensure bio-restraint with a filter at entrance and at exit way, in CPAP and with increased oxygen amount. These patients were located in different wards, infectious disease ward, internal medicine ward, pneumology ward, with the restriction of surgical activities. Same cases didn't have benefit from CPAP and they needed invasive assistance with tracheal intubation and mechanical ventilation, sedated in Intensive Care Unit. The mortality rate for these patients intubated will raise the 45% in most of ICU and for patients aged or with co-morbidity will arrive over.

Our experience attests that in early days the clinical course of COVID-19 patients in ICUs follows a very differentiated path which makes it difficult to predict an evolution. There are elderly patients who stabilize in the first days and then take a sudden turn

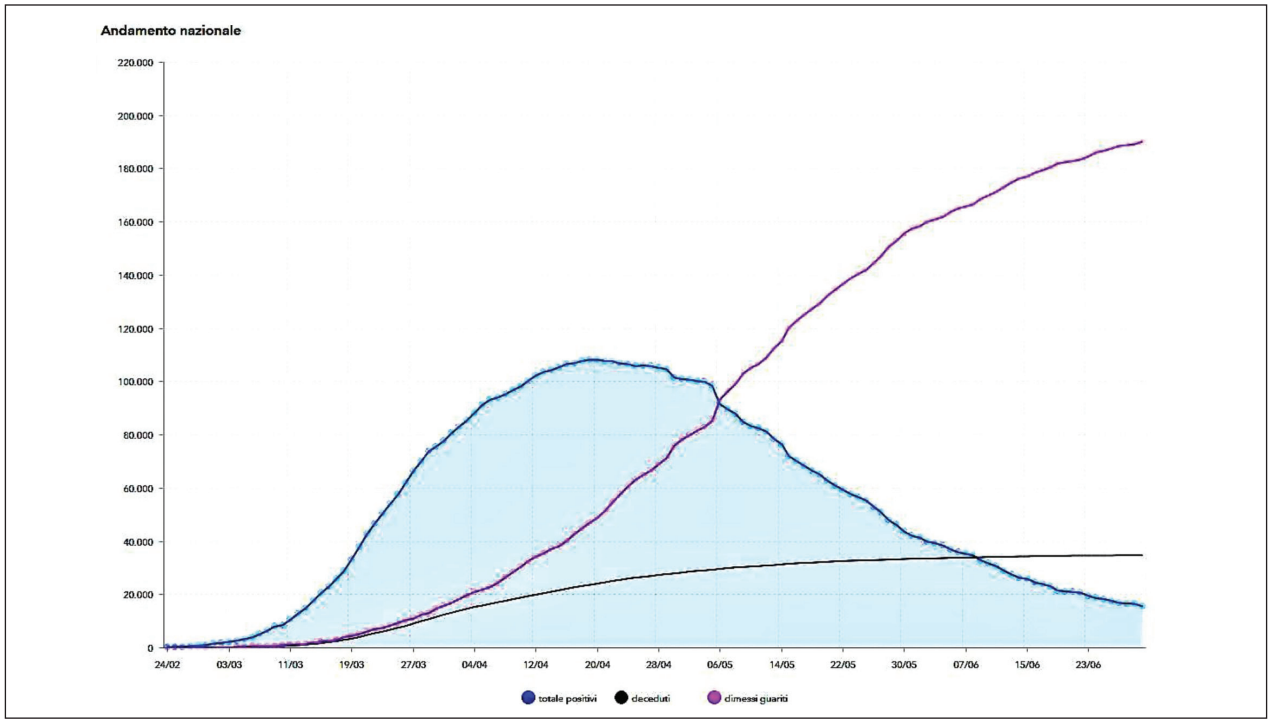

Figure 1. Trend in Italy - people positive, healed, deceased from 2020, Feb 24th thru 2020, June 30th.

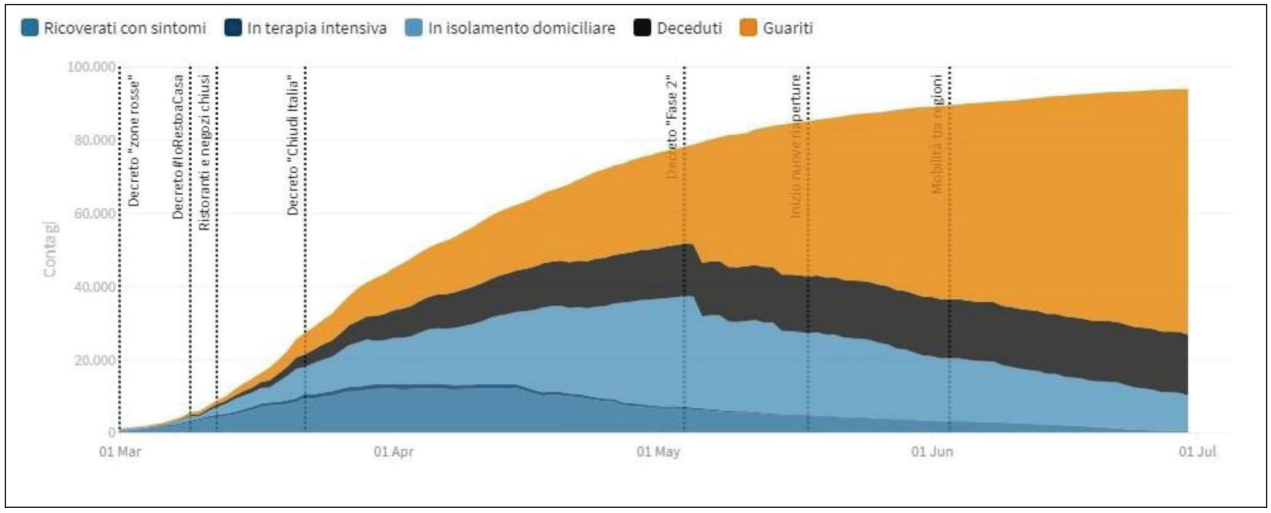

Figure 2. Trend in Lombardia – positive patients hospitalized, in ICU, confined at home, deceased and healed till 2020, June 30th. Temporal indication of restrictions and special measures.

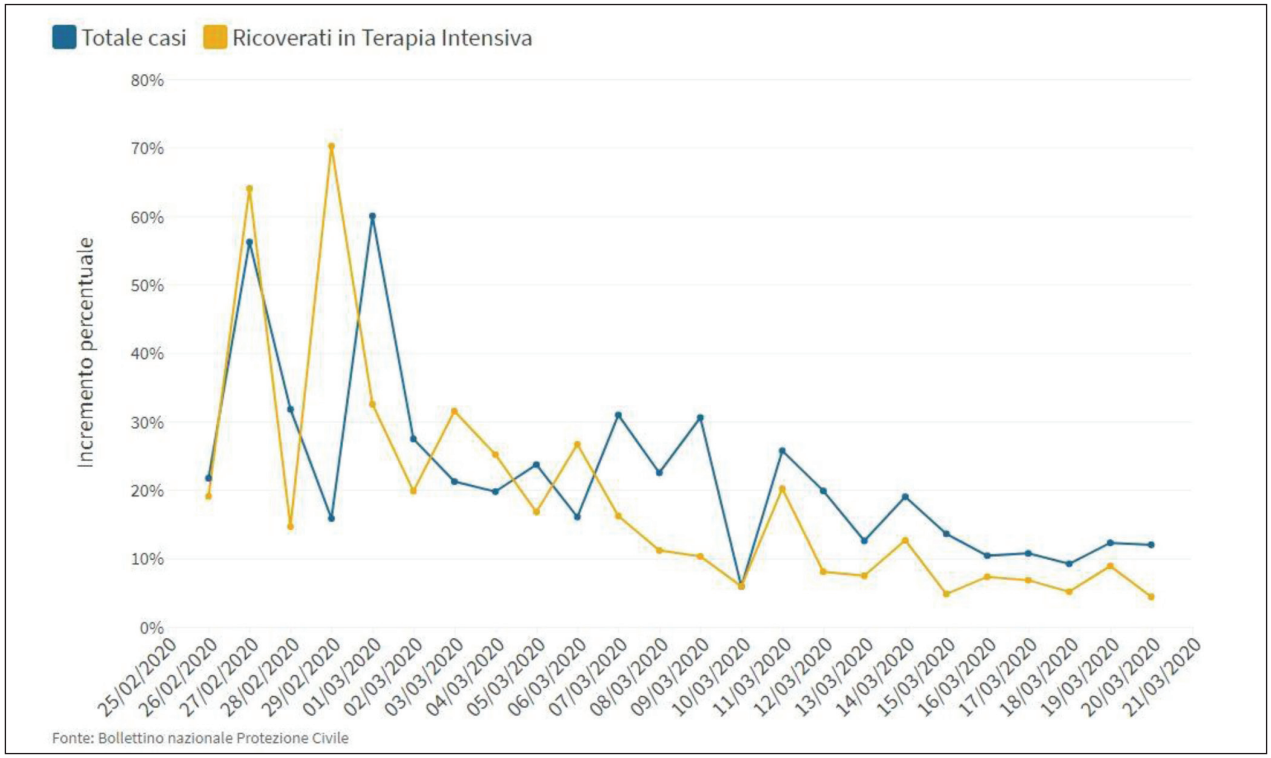

Figure 3. Percentage increase of patients admitted in ICU with severe acute respiratory syndrome coronavirus 2 in Lombardy related to the total number of patients admitted in hospitals between February 25th, 2020 and March 21st, 2020.National Civil Protection Department.

for the worse. There are young patients who get over the acute phase after 20 days in ICUs, entering a rehabilitation phase in other units and after a few days there must go back to ICUs for unexpected deterioration. Because of this complexity, in order to ensure the best allocation of available resources, patients require continuous monitoring along with the review of all decisions already taken.

Triage: comparative analysis

During the acute period of the pandemic, we have seen many hospitals facing a new dramatic dilemma: which are the decisional criteria to be used to select patients for ICU when those who could benefit of an ICU treatment are more than ICU places available?

This is a very dramatic, difficult and complex decision with a tough impact not only on patients and their relatives but also on care givers and the Health Institution besides society as a whole.

The Italian National Committee for Bioethics (ICB) affirms: "We must evaluate how to manage the inevitable conflict between collective public health objectives (to ensure maximum benefit for the largest number of patients) and the ethical principle of ensuring maximum protection for the individual patient in exceptional situations: a dilemma difficult to solve in the concreteness of choices, as shown in the extensive literature on the subject" (4). The decision of triage is the last resort, when all possible alternatives are no longer feasible: the use of therapeutically approaches less intrusive when appropriate, increase of beds, transfers to other hospitals. (5,6).

If we analyze several publications about the triage, we can notice different proposals associated to some geographic areas.

In the US, the most important ethical principle is the maximizing benefits. This entails giving "priority saving the most lives and at maximizing improvements in individuals' post-treatment length of life" (7). To realize this purpose, they use clinical criteria, specifically the short-term prognosis. To define priorities, the clinical indications are described as follows: "The color (blue, red, yellow, or green) determines the level of access to a ventilator. Blue code patients (lowest access/palliate/discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care are provided. However, if more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy. Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy" (8). Non-clinical factors cannot be used because they are discriminatory: "Prioritizing individuals according to their chances for short-term survival also avoids ethically irrelevant considerations, such as race or socioeconomic status" (9). This choice ensures a balance between "the need to protect vulnerable populations with the principle of treating all patients in need of a ventilator equally" (8), granting an objective approach that may be viewed by the public "as fairer than decisions based on more subjective criteria" (9). Only when "all available clinical factors have been examined and the probability of mortality among the pool of patients has been found equivalent, only then may young age be utilized as a tie-breaker to select a patient for ventilator therapy" (8). The matter of the age as a criterion for selection has been thoroughly debated. In the US there is a certain convergence towards a view which affirms that: . "Saving more lives and more years of life is a consensus value across expert reports" (7). As a consequence of this statement they "make it justifiable to give priority to maximizing the number of patients that survive treatment with a reasonable life expectancy and to regard maximizing improvements in length of life as a subordinate aim" (7). In this perspective, they give reasons for "removing a patient from a ventilator or an ICU bed to provide it to others in need is also justifiable and that patients should be made aware of this possibility at admission" (7, 10). In the event that there were several patients with same prognosis and same age, "equality should be invoked and operationalized through random allocation, such as a lottery, rather than a first-come, first-served allocation process" (7).

In Europe, the Italian view is certainly important as Italy has been the first European country to face the pandemic. In the contribute titled: *Recommendations*

for the allocation of intensive care treatments in exceptional, resource-limited circumstances of the Italian Society of Anesthesia. Analgesia, Resuscitation and Intensive (SIAARTI), they declare that: "we must aim at guaranteeing intensive treatments to patients with greater chances of therapeutic success favoring the *greatest life expectancy*. In this sense, the need for intensive care should be integrated with other aspects, including: the severity of the disease on one hand, the severity and number of preexisting comorbidities on the other" (6).

In Italy we have discussed a lot about age as a non-clinical criterion in Triage. The ICB evaluates: "the clinical criterion to be the most appropriate reference point for the allocation of the same resources: any other selection criterion, such as for example age, sex, condition and social role, ethnicity, disability, responsibility for behaviors contributing to the pathology, costs, is deemed ethically unacceptable by the Committee" (4). With regard to the matter of the age, SIAARTI clarifies: "An age limit for the admission to the ICU may ultimately need to be set. The underlying principle would be to save limited resources which may become extremely scarce for those who have a much greater probability of survival and life expectancy, in order to maximize the benefits for the largest number of people" (6).

We notice a considerable affinity between the US and the SIAARTI views: they both focus on clinical criterion, even if the age as a non-clinical criterion has a secondary role in the US stance.

This is also confirmed because the US views tends to reduce the evaluation of the effectiveness of a short-term intervention, while SIAARTI associates the effectiveness to the life expectancy.

The criterion of proportionality in triage

We think it is correct to use the criterion of proportionality to carry out the triage (11, 12).

Also, ICB seems to assume this criterion as a landmark, even distinguishing between appropriateness and proportionate: "Clinical appropriateness means the medical evaluation of the effectiveness of the treatment in relation to the clinical need of each individual patient, with reference to the severity of the onset of the pathology and the prognostic possibility of recovery. This treatment must always be proportionate, that is, consider the balance of benefits and risks with respect to the patient, considered from the point of view of both the objective and subjective clinical dimension (perception of pain and suffering, perception of the invasiveness of treatments, etc.)" (4).

During this severe pandemic, the care for the single patient must necessarily be part of a wider evaluation of the care for other sick people, considering the criterion of justice. The criterion of proportionality considers both the clinical indications than the preferences of the patients, together with the duties, that is the implications on the patient any third party, single, group or community (12). For this reason, the criterion of proportionality enables to integrate collective public health objectives and the principle of ensuring protection for the individual patient. We do not agree with the statement of the SIAARTI document when it is said that "the criteria for access to and discharge from the ICUs should include also principles of distributive justice and appropriate allocation of limited healthcare resources, in addition to clinical appropriateness and proportionality of care" (6, 13).

The criterion of proportionality allows a choice on a case-by-case basis, without falling into arbitrariness. In literature, there are many recalls to the need of analysis that is attentive to the uniqueness of every person even in the dramatic scenario of a triage. The Comité de Bioética de España states that "any criteria or protocol adopted to allocate scarce resources can never be applied mechanically or automatically: every human being has the right to consideration" (14). Similarly, also the SIAARTI document highlights that "ICU admission criteria should be discussed and defined for each patient as early as possible" (6). The position of the Conselho Nacional de Etica para as Ciências da vida (de Portugal) is more precise as the ethical analyisis case by case is parallel to a clinical analysis: "In situations where there may be limited resources, namely medical equipment necessary for the maintenance of life, careful ethical consideration is required, case by case, in parallel with the assessment of respective clinical criteria" (15).

The idea of an analysis case by case is very significant especially in a pandemic: from one side it is necessary to refer to general criteria to ensure same

treatment and possibilities to every citizen; on the other hand it is clearly necessary to operate a choice keeping into account the uniqueness of every single patient. Proportionality combines several criteria, it enables an accurate case-by-case evaluation, considering the patient's changing conditions and the clinical progression attempts, without discriminating the most vulnerable subjects. The clinical criteria refer to the urgency and efficacy of the intervention: they enable the staff to evaluate what the patient's prognosis will be if they undergo invasive mechanical ventilation operations to be implemented in the ICU. The efficacy of the intervention depends on the patient's previous comorbidities, such as severe diabetes, heart disease, nephropathy or liver disease. In this perspective "Age, in turn, is a parameter that is taken into consideration in view of the correlation with the current and prognostic clinical evaluation but it is not the only parameter or even the main one" (4). As illustrated before, age is considered in relation to a clinical profile and not as an independent criterion, to grant everybody a treatment with the same opportunities. However, we need to recognize that an older patient usually has more pathologies than a younger patient; as a consequence, the prognosis of the former is likely to be less favorable than the latter. Thus, if we ground our decision on clinical criteria only, when we compare two patients, the most vulnerable will always be at a disadvantage.

If we contemplate the whole existential and clinical situation, a young handicapped patient would not be penalized as everybody might think; on the contrary he would benefit from this approach. In most cases, if we ground a decision on clinical criteria only, because of his comorbidities the final evaluation would penalize him when compared his situation to other patients. If we used equity as a yardstick based on just a few clinical indicators, as a matter of fact we would always discard the most vulnerable patients. Piccinni et al correctly affirm that: "we are aware that this approach fatally introduces parameters such that some health care resources are allocated to certain people in preference of others (specifically of more fragile and vulnerable subjects, because the age and the comorbidity are related to the survival rate)." (13).

Therefore, the risk of positions illustrated by M.Z. Solomon et coll. is real; they affirm: "Near-term survivability, moreover, can be assessed independently from disability. Consider two patients with Down's syndrome, one with adequate cardiac function, the other with cardiovascular disease. Down's syndrome is an inappropriate triage consideration, but worse baseline cardiac function confers lower survivability with Covid-19. Cardiac dysfunction could therefore be integrated into the scoring system, but only if the criterion applied to all patients, not just those with Down's syndrome. Patients with adequate heart function, irrespective of physical or mental disability, would then have the same triage score. Patients with preexisting cardiovascular disease would receive lower scores because they're less likely to derive benefit from the intervention, not because of disability" (16). We agree with the statement that affirms: "rationing decisions should not be based solely up on age or disability" (17): however, this implies that differences among people must be recognized and not repressed (18); only in this way we can practically realize an actual and not just declared equality. The patient' history and will would seem impractical to use in times of pandemic, given the urgency of the situation. Reality has shown, at least in our experience, that it was not impossible to retrieve the patient's history. Some patients arrive in the Emergency Room in very critical clinical conditions which impose an immediate transfer to the ICU; however, most of them are first admitted to other departments for a diagnostic classification. That is the crucial time to make a good decision through an interdisciplinary and shared judgment by those in charge of the patient, a decision that needs to consider the patient's history.

The patient or the patient's relatives can tell one's history. In this evaluation we need to examine the treatment burdens, in particular the patient's ability to withstand the invasive therapies if one were to be hospitalized in ICU. In its document SIAARTI takes the same stance: "ICU admission criteria should be discussed and defined for each patient as early as possible. Ideally, this would include the creation of a list of patients that should be considered for ICU admission in case of clinical deterioration, given the availability of ICU resources when admission is needed" (6).

The resolution based exclusively on few and stringent clinical criteria - such as a short-term prognosis - entails a decision which will not be open to ambi-

guity with reference to equality and equal treatment and is easily applicable even with an algorithm (19). However, this method cannot keep into account the differences among people to make them actually equal. This position sounds abstract and not appropriate to put in relation and to integrate the collective public health objectives and the principle of ensuring protection for the individual patient, the respect of principles of autonomy and the need for solidarity (20).

Who decides the triage

The team in charge to assess the proportionality of the intervention and therefore the adequacy of the transfer to ICU must be composed by the doctors responsible for the patient's care, both those who are currently managing it (for example the infectious disease specialist or the pulmonologist) and those who will have to manage it (the intensivist). Since they are aware of the actual situation in their respective departments, the inclusion of all these professionals ensures a shared valuation compatible with the overall scenario of the entire hospital.

In this perspective, for several reasons it is not acceptable that the demanding and dramatic moral decision to allocate ventilators is taken by an outsider committee composed by people who are not directly involved in the care of the patient. US authors defend this view. Their considerations are the following: "The angst that clinicians may experience when asked to withdraw ventilators for reasons not related to the welfare of their patients should not be underestimated — it may lead to debilitating and disabling distress for some clinicians. One strategy for avoiding this tragic outcome is to use a triage committee to buffer clinicians from this potential harm. We believe that such a committee should be composed by volunteers who are respected clinicians and leaders among their peers and the medical community. Advantages of this approach are that it allows the physicians and nurses in charge to maintain their traditional roles as fiduciary advocates, including the opportunity to appeal the initial decision of the committee when appropriate. While working together to ensure consistent and unbiased decisions across patient groups, the committee also has the flexibility to consider factors that may be unique to a given situation. As circumstances change and the availability of ventilators increases or decreases, the committee can adjust its rationing criteria to produce the best outcomes. Finally, when a hospital is placed in the unavoidable but tragic role of making decisions that may harm some patients, the use of a committee removes the weight of these choices from any one individual, spreading the burden among all members of the committee, whose broader responsibility is to save the most lives" (10, 7, 17). The World Health Organization also shares this view: "To the extent possible, the interpretation of allocation principles should not be entrusted to clinicians who have pre-existing professional relationships that create an ethical obligation to advocate for the interests of specific patients or groups. Instead, decisions should be made by appropriately qualified clinicians who have no personal or professional reasons to advocate for one patient or group over another" (21, 8). A recent research about the components and their background has highlighted that in the policies considered: "Eighteen (78.3%) of these 23 policies specify that this physician should be trained in critical care and 7 (30.4%) emergency medicine, and 11 (47.8%) specify that this physician should be the chief medical officer or the officer's designee. The other most commonly required or recommended disciplines to compose the body are nurses (20 policies [87.0%]), ethicists or ethics committee members (16 [69.6%]), chaplains (8 [34.8%]), and respiratory therapists (8 [34.8%]). Two (7.7%) policies require or recommend a community member. Nine (34.6% of all policies) exclude individuals who are providing direct patient care from making triage decisions, and an additional 4 (15.4%) recommend that these individuals be excluded" (22).

The thesis of a triage committee composed by physicians with a role outside direct patient care is not to be found in European articles. SIAARTI affirms that: "The decision to withhold or withdraw life-sustaining treatments must always be discussed and shared among the healthcare staff, the patients and their proxies, but should also be timely" (6). The US paradigm does not seem appropriate for the following reasons. The first reason concerns the meaning of giving care, which necessarily means attention to the patient. How can the

physician be deprived of his responsibility to provide care by an external committee? Secondly this perspective would sanction the reduction of the medical act to a technical performance. In complex cases, this would legitimate that a doctor does not take on the inevitable moral responsibilities of his profession. Finally, it is said that being involved also emotionally, does not help in making good decisions. But a good decision is made not because we neutralize the subjects, but rather because we also identify and interpret one's emotions to reach an ethically pertinent judgment. When in front of crucial and demanding choices, doctors usually do not ask to be relieved of their responsibility but they want to be accompanied and not left alone.

We agree with the following perspective: "If doctors are left to make decisions about prioritization on their own, they face great difficulty in justifying these decisions. This is because it would be up to the doctor to demonstrate that it was necessary to make a choice between patients. A national policy is urgently required to ensure that the maximum benefit may be derived from the limited number of ventilators that are available" (23). Also, SIAARTI acknowledges that "Other purposes of the recommendations are to share with clinicians the responsibility in the decisions making process, which can be emotionally burdensome, carried out in individual cases" (6). However, the policy does not exempt the physician by his responsibility, mainly moral, to interpret the general indication of a specific framework towards a certain patient.

In this frame, the role of the ethics consultant comes in as a member of the clinical team; his task it to help and facilitate the attending physicians to take responsibility for the decision (24, 25).

The need of a shared choice among caregivers is often recalled in literature, especially in case of a pandemic when decisions are urgent and dramatic: "It is also important that the therapeutic decision concerning the different patients to be treated, according to the severity of their pathology, is as far as possible the result of consultation between several doctors, to ensure comparison between different points of view and the most correct choice possible, and, just as importantly, to allow the sharing of the responsibility and burden of a decision that will always be agonizing" (4). The risk is to reduce the sharing only to clinical aspects, so that the doubt about a choice is only technical and not moral. The position of SIAARTI is not very clear on this: "A second opinion (e.g. from Regional Healthcare Coordination Centers, or from other recognized or designated experts) may be useful when dealing with particularly difficult or distressing cases"(6). The Comitè Consultatif National D'Ethiquè "considers that health care teams need ethical support, which could be provided by an *ethical support unit*, assisted by regional health agencies and guided by the experience of ethics committees, while drawing on the expertise of the clinical ethics groups of teaching hospitals" (20). Even if attentive about ethical matters and the need of an expert support, the French position is still quite generic. The position of the Comité de Bioética de España is similar (14).

With regard to the communication to relatives, those who defends the idea of an external committee give the following reasons: "In addition to removing the responsibility for triage decisions from the bedside clinicians, committee members should also take on the task of communicating the decision to the family. The treating clinicians may be motivated to try to comfort the family by telling them that mechanical ventilation is not being provided because it would be futile and by reassuring them that everything possible has been done. Though well intentioned, such inaccurate representations could ultimately undermine public trust and confidence. Having the committee members communicate these decisions would ensure that the message is clear and accurate, helping to prevent confusion or misunderstandings" (10).

Instead, we think that thanks to the health shared path we have proposed, the attending physicians is the most appropriate person to disclose their decision to the patient and his relatives through a participatory and empathetic communication.

The proposed decision-making process would also help to soothe the severe moral distress felt by many care givers in this pandemic phase (26). The moral dilemmas at the root of this experience must be thoroughly handled within the department through debated and shared decisions (27) and not simply delegated to a psychotherapy outside the working context.

In this perspective, we achieve to give reasons for the role of the ethics consultant (28). Differently, he

would have a role only when defining the guidelines prior an epidemic (29) and he would be totally absent in the direct management of triage during the epidemic itself. This is McCullough's position who affirms: "The task of bioethicists and bioethics organizations in response to the COVID-19 pandemic and those that will follow it is simple: Call for organizational leaders and government officials to support physicians who already know what should be done about severe scarcity and how to do it by deploying the professional ethics of triage The role of clinical ethicists is restricted to contributing to the rapid and reliable organizational adaptation of existing triage guidelines into organizational policy. The resulting policies will require only deliberative clinical judgment about the interpretation and clinical application of objective triage criteria. The skillset of the clinical ethicist does not include deliberative clinical judgment, making clinical ethics consultations in individual cases unnecessary" (30).

Conclusion

The Coronavirus pandemic has raised complex and dramatic dilemmas. There is a fundamental issue which permeates the general debate and specifically the bioethics discussion: to face this situation, do we need exceptional measures and therefore new criteria or do we apply ordinary criteria adjusted for the new situation? Hence, are physicians adequately trained and educated to face such a scenario?

If we leaned towards the first option, we would answer that physicians are not adequately trained and educated to face a pandemic.

The perspective we have proposed, i.e. the criterion of proportionality, allows us to give an in-between answer which holds a tension between these two polarities. This criterion imposes to learn from every single case and context in a circular approach between an individual profile and a general overview. Therefore, since it is not possible its deductive application, we need to develop a thought with a profile of novelty, because of the exceptionality of the situation.

The more complex the situation is, the more a multidisciplinary and shared approach is required. This way we will be able to integrate the general view in the definition of national and domestic policies with the specificities of each and every case (12).

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Correspondence:
Mario Picozzi
Director Center for Clinical Ethics
Insubria University, Varese, Italy
E-mail: mario.picozzi@uninsubria.it