CLINICAL ETHICS RECOMMENDATIONS FOR ADMISSION TO INTENSIVE CARE AND FOR WITHDRAWING TREATMENT IN EXCEPTIONAL CONDITIONS OF IMBALANCE BETWEEN NEEDS AND AVAILABLE RESOURCES

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Predictions of the Coronavirus epidemic (COVID-19) currently underway in some Italian regions estimate that, for the next few weeks in many centers, there will be an increase in cases of acute respiratory insufficiency (requiring ICU admission) of such a magnitude that there will be a tremendous imbalance between the real clinical needs of the population and the actual availability of ICU resources.

In this scenario, it might become necessary to establish criteria for access to (and discharge from) the ICU, based not only strictly on clinical appropriateness and proportionality of care, but inspired also by a criterion, agreed upon as widely as possible, of distributive justice and the appropriate allocation of limited health resources. This kind of scenario is substantially similar to the setting of "disaster medicine," for which ethical reflection over time has developed concrete guidance for physicians and nurses who have to make difficult choices.

As an extension of the principle of proportionality of care, allocation in a context of serious shortage of healthcare resources must aim at guaranteeing intensive treatments to patients who have greater chances of therapeutic success: we are therefore dealing with privileging those who have the "greatest life expectancy." The need for intensive care must therefore be integrated with other elements of "clinical suitability" for intensive care, thus taking into account: the type and severity of the disease, the presence of comorbidities, and the impairment of other organs and systems and their reversibility. This entails that there is not necessarily a need to follow a criterion for access to intensive care, such as "first-come, first-served."

It is understandable that caregivers, by culture and training, are less accustomed to reasoning according to criteria of emergency triage, inasmuch as the current situation has exceptional characteristics. The availability of resources does not usually enter into their decision-making

process and decisions in individual cases, as long as the resources do not become so scarce so that it is not possible to treat all patients who hypothetically would benefit from treatment.

It is implicit that the application of rationing criteria is justifiable only after the involved civil authorities (and the governing bodies of hospital facilities) have made all possible attempts to increase the availability of resources (in this case, ICU beds), and after every possibility of transferring patients to centers with greater availability of resources has been evaluated.

It is important that any change to the admission/access criteria is shared as much as possible among the professionals involved. Based on the obligation of transparency and maintaining trust in the public health service, patients and their families affected by the application of the criteria must be informed of the extraordinary nature of the measures in place.

The purpose of the recommendations is also to:

- (A) Relieve clinicians from part of the responsibility for decisions, which can be emotionally burdensome in some cases;
- (B) Render explicit the allocation criteria of healthcare resources in circumstances where they are extraordinarily scarce.

From the information that is now available, a considerable number of patients diagnosed with COVID-19 infection will require ventilatory support due to interstitial pneumonia characterized by severe hypoxemia. Interstitial lung disease is potentially reversible, but the acute phase can last many days.

Unlike the more familiar ARDS (Acute Respiratory Distress Syndrome), notwithstanding the same amount of hypoxemia, lungs affected by COVID-19 seem to have slightly better lung *compliance* and respond better to recruitment (reclutamenti), medium-high PEEPs, pronation cycles (cicli di pronazione), and inhaled nitric oxide. As is well-known in the case of ARDS, these patients require protective ventilation, with low driving pressure.

All of this entails that the intensity of care can be high, as well as the use of human resources. From the data reported for the first two weeks in Italy, about one tenth of infected patients required intensive care with assisted invasive or non-invasive ventilation.

Recommendations:

1. The extraordinary criteria for admission and discharge are flexible and can be adapted locally according to the availability of resources, the actual likelihood of transferring patients, and the number of actual or expected admissions. The criteria apply to all intensive care patients, not only to those who have been infected by COVID-19.

- 2. Allocation is a complicated and very delicate decision, especially when an extraordinary increase in the need for intensive care beds would make it impossible to guarantee adequate care to individual patients, and would divert resources, attention, and energy from the remaining ICU patients. We can also predict an increase in mortality from clinical conditions that are not linked to the current epidemic, due to reduction in surgical activity and elective outpatient visits, and the scarcity of intensive care resources.
- 3. It may be necessary to establish an age limit for admission to the ICU. It is not a question of making choices merely according to worth, but to reserve resources that could become extremely scarce to those who, in the first instance, have a greater likelihood of surviving and who, secondarily, will have more years of life saved, with a view to maximizing the benefits for the greatest number of people.

In a scenario of complete saturation of intensive care resources, deciding to maintain the standard of "first-come, first-served" would still be tantamount to choosing not to treat subsequent patients who would remain excluded from the ICU.

4. In addition to age, the presence of comorbidities and functional status must be carefully evaluated. It is conceivable that what would be a relatively short course for a healthy individual potentially could become a longer course, and therefore more "resource consuming," for patients who are elderly, fragile or have severe comorbidities.

The specific and general clinical criteria present in the multi-society SIAARTI Document from 2013 can be particularly useful in regard to end-stage organ failure (https://bit.ly/2lfkphd).

Moreover, it is appropriate also to refer to the SIAARTI document in relation to admission criteria for the ICU (Minerva Anestesiol 2003; 69(3):101-118).

- 5. The possible existence of prior expressed wishes of patients in advance directives must be carefully considered and, in particular, how those wishes are defined by those who are already living with chronic diseases.
- 6. For patients for whom access to intensive care is deemed "inappropriate," the decision to establish a limit on treatment ("ceiling of care") should be, in any case, justified, communicated, and documented. The "ceiling of care" with regard to mechanical ventilation must not preclude other forms of less intensive treatment.
- 7. A judgment that access to intensive care is inappropriate, based solely on criteria of distributive justice, finds its justification in the extraordinary nature of the situation (an extreme imbalance between demand and availability).

- 8. In the decision-making process, if particularly difficult or uncertain situations arise, it can be useful to have a "second opinion" from individuals who have experience with this type of situation.
- 9. The criteria for admission to the ICU should be discussed and defined for every patient, as much as possible in advance, ideally creating in time a list of patients who will be given priority for ICU care at the moment in which clinical deterioration occurs, provided that the availability at that moment allows for it.
 - Any prospective "do not intubate" instruction should be present in the medical record, ready to be used as a guide if clinical deterioration occurs precipitously and should be made known to caregivers who did not participate in the plan of care and who do not know the patient.
- 10. Palliative sedation for hypoxic patients with disease progression is to be considered necessary as an expression of good clinical practice, and must follow existing guidelines [presumably only if a decision has been reached not to intubate]. In the event one foresees a long agonal period, a transfer to a non-ICU environment should be planned.
- 11. All access to intensive care must be considered and communicated as an "ICU trial" only and therefore undergo daily reassessment of its appropriateness, based on goals of care and proportionality of care. In the case a patient, perhaps admitted with borderline criteria, does not respond to prolonged initial treatment or has serious complications, a decision to abstain from further treatment ("desistenza terapeutica") and to modify the course from intensive treatment to palliative care—in a scenario of exceptional high influx of patients—should not be delayed.
- 12. As much as possible, the decision to limit intensive care must be discussed and shared collectively with the medical team and in dialogue with the patient (and family); the decision, however, must be made in a timely fashion. Predictably, the need to make such repeated choices will make the decision-making process in each ICU more robust and better adapted to the available resources.
- 13. In the event there is an extraordinary volume of patients, ECMO support—as a consuming resource compared with a normal ICU admission—should be reserved for extremely selected cases; the expectation is that patients will be weaned from the machines relatively quickly. It should ideally be reserved for hub centers that are experiencing high volumes, for which patients on ECMO absorb proportionately fewer resources than they otherwise would in a center with less expertise.
- 14. It is important to "network" by bringing together and exchanging information among centers and individual professionals. At the end of the emergency, when the working conditions allow for it, it will be important to devote time and resources to debriefings and monitoring of any possible professional burnout and moral distress.

15.	The consequences to must be considered, visitation restrictions.	especially fo			