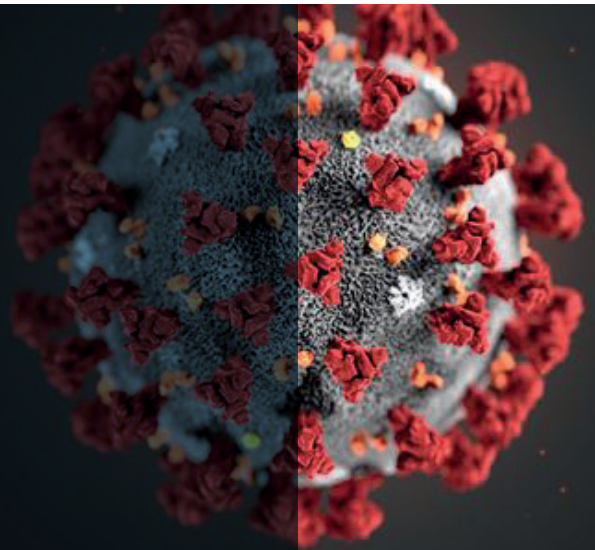




CLINICAL ETHICS RECOMMENDATIONS FOR THE ALLOCATION OF INTENSIVE CARE TREATMENTS, IN EXCEPTIONAL, RESOURCE-LIMITED CIRCUMSTANCES



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Version

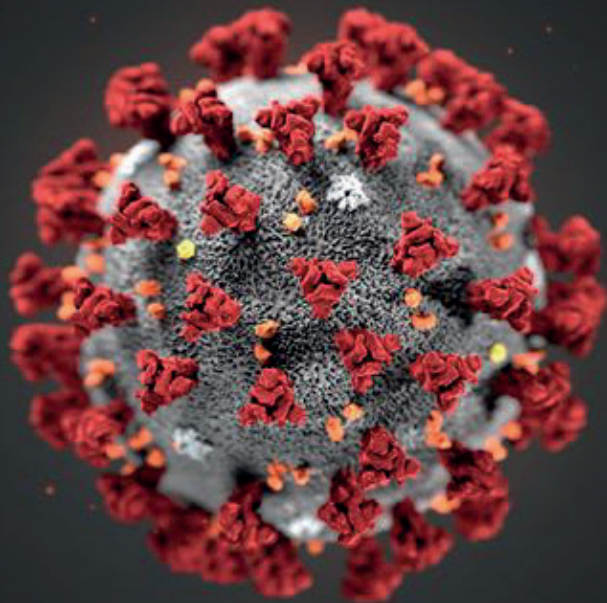
Clinical Ethics Recommendations for the Allocation of Intensive Care Treatments in exceptional, resource-limited circumstances - Version n. 1

Posted on March, 16th - 2020



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CLINICAL ETHICS RECOMMENDATIONS FOR THE ALLOCATION OF INTENSIVE CARE TREATMENTS, IN EXCEPTIONAL, RESOURCE-LIMITED CIRCUMSTANCES

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The predictions of the Coronavirus epidemic (Covid-19), currently underway in some Italian Regions, estimate an increase in many centers of cases of acute respiratory failure demanding ICU admissions. The magnitude of this demand may cause an **imbalance between the real clinical needs** of the population and the **effective availability** of intensive resources.

It is a scenario where **criteria for access** to intensive care and **discharge** may be needed, not only in strictly **clinical appropriateness** and **proportionality of care**, but also in **distributive justice** and **appropriate allocation** of **limited healthcare resources**.

A scenario of this kind can be substantially assimilated to the field of “disaster medicine”, for which clinical and ethical reflection has over time developed many concrete regulations for doctors and nurses engaged in difficult choices.

As an extension of the principle of proportionality of care, **allocation** in a **context of serious shortage of healthcare resources**, we must aim at guaranteeing intensive treatments to patients **with greater chances of therapeutic success**. Therefore, it is a **matter of favoring** the “**greatest life expectancy**”. The **need for intensive care** must be integrated with other elements of “clinical suitability”, thus including: the type and severity of the disease, the presence of comorbidities, the impairment of other organs and systems, and their reversibility. This means, not necessarily having to follow a **criterion for access to intensive care** like “first come, first served.”

It is understandable that the clinicians, by culture and training, are not accustomed to reasoning with criteria of maxi-emergency triage, as the current situation has **exceptional characteristics**.

The **availability of resources** does not usually enter the **decision-making process** and the choices of the individual case, until resources become so scarce as to not allow treating all patients who could hypothetically benefit from a specific clinical treatment.

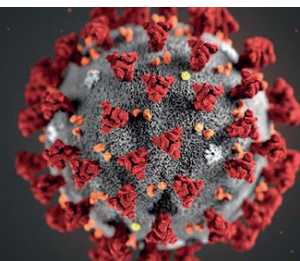
It is implicit that the application of rationing criteria is **justifiable** only after all the subjects involved (in particular the Task Forces and the governing bodies of hospital facilities) and all possible efforts have been made to **increase the availability of resources existing** (especially the Intensive Care beds) and after assessing **any possibility of patient transfers** to centers with greater availability of resources.

It is important that any **modification regarding access policies be shared**, as much as possible, among the **operators** involved. Patients and their families interested in applying the criteria must be informed of the **extraordinary** nature of the measures in place, due to an issue of duty of transparency and maintenance of trust in the public health service.

The **purpose of the recommendations** are also:

- (A) to relieve clinicians from a part of the **responsibility** in the decisions making process, which can be emotionally burdensome, carried out in individual cases;
- (B) to make the **allocation criteria** for healthcare resources explicit in a condition of their own extraordinary scarcity.

From the information available now, a substantial part of subjects diagnosed with infection from Covid-19 requires **ventilatory support** due to **interstitial pneumonia** characterized by severe hypoxemia. The interstitial disease is potentially reversible, but the acute phase can last several days and the ventilatory support may be needed for weeks.





Unlike more familiar ARDS cases, with the same hypoxemia, Covid-19 pneumonia appears to have slightly better lung compliance and respond better to recruitment, medium-high PEEP and prone positioning cycles.

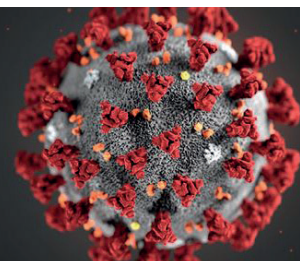
As for the most well known ARDS cases, these patients require protective ventilation, with low driving pressure.

All this implies that the **intensity of care** can be **high** and in need of highly skilled human resources as well. From the data of the first two weeks in Italy, about one tenth of infected patients required intensive care treatment with assisted ventilation, invasive or non-invasive.



RECOMMENDATIONS

- 1. Criteria for ICU** admission and discharge under exceptional, resource-limited circumstances are **flexible** and can be locally adapted according to the availability of resources, the potential for inter-hospital **patient transfer**, the ongoing or **foreseen number** of hospital and ICU admissions. These criteria apply to every patient potentially in need of ICU admission, not only to Covid-19 infected patients.
- 2. Allocation** of ICU resources is a complex and delicate task. A sharp increase of ICU beds in order to admit a rapidly growing number of critically ill patients could not guarantee an adequate standard of care to every newly admitted subject; moreover, it could distract valuable human resources and treatments from the patients who were already admitted in the ICU. Another potential consequence of these exceptional circumstances may be an increase in overall mortality for patients who were not directly affected by the ongoing epidemic, but whose survival may be eventually reduced by the interruption of planned elective surgical interventions, outpatient clinics and shortage of ICU resources.
- 3.** 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. In the worst-case **scenario of complete saturation** of ICU resources, keeping a “first come, first served” criterion would ultimately result in withholding ICU care by limiting ICU admission for any subsequently presenting patient.
- 4.** Together with age, the **comorbidities** and **functional status** of any critically ill patient presenting in these exceptional circumstances should carefully be evaluated. A longer and, hence, more “**resource-consuming**” clinical course may be anticipated in frail elderly patients **with severe comorbidities**, as compared to a **relatively shorter**, and potentially more benign course in healthy young subjects. In Italy, general criteria for ICU admission were explicitly addressed in a 2003 publication ^[1] and in a multidisciplinary consensus document released in 2013 for advanced care planning in patients with end-stage diseases ^[2].
- 5.** The presence of **advance healthcare directives** or advance care planning should be carefully 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**.
- 6.** A decision to deny admission to the ICU by applying a “ceiling of care” should always be motivated, communicated and documented. The decision to **withhold invasive mechanical ventilation** does not necessarily imply that other, non-invasive, modalities of ventilatory support should also be withheld.
- 7.** Under **exceptional circumstances**, when the availability of resources is **overwhelmed** by their need, a decision to deny access to one or more life-sustaining therapies, solely based on the principle of distributive justice, **may ultimately be justified**.
- 8.** A **second opinion** (e.g. from Regional Healthcare Coordination Centres, or from other recognized or designated experts) may be useful when dealing with particularly difficult or distressing cases.
- 9. 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.



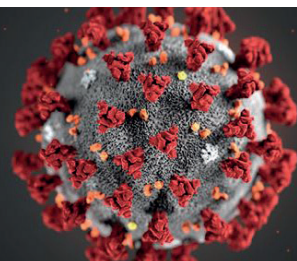


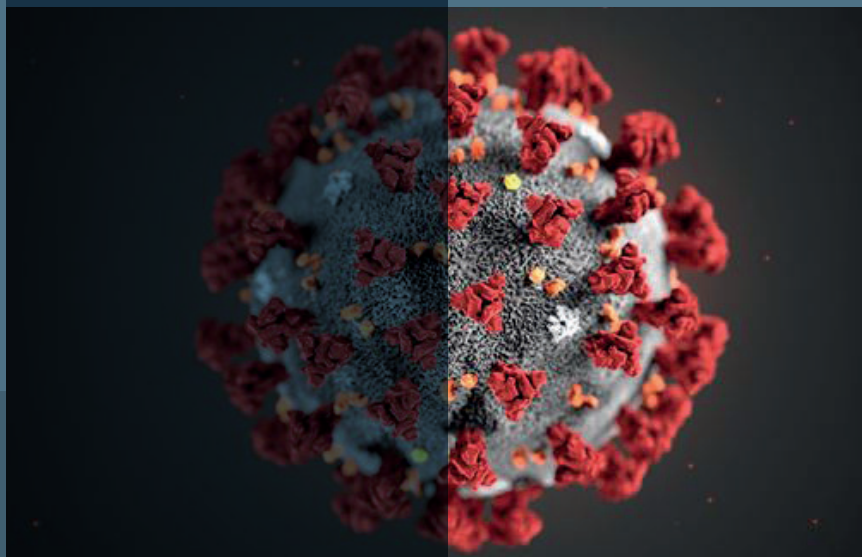
10. **Appropriate palliative** care must always be provided to hypoxic patients when a decision to withhold or withdraw life-sustaining treatments is made. Palliative care should be provided according to national or international recommendations, as a matter of good clinical practice. If a prolonged time to **death is anticipated**, the patient should be **transferred to a non-ICU bed**; optimal palliative care should be provided also outside the ICU setting.
11. Every admission to the ICU should be considered and communicated as an “**ICU trial**”. The appropriateness of life-sustaining treatments **should be re-evaluated daily**, considering the patient’s history, current clinical course, wishes, expected goals and proportionality of ICU care. When a patient is not responding to prolonged life-sustaining treatments, or severe clinical complications arise, a decision to **withhold or withdraw** further or ongoing therapies should not be postponed in a resource-limited setting during an epidemic.
12. 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. The daily practice and continuous reassessment of the patients’ clinical course, their wishes, and the availability of resources will strengthen the decision-making process over time.
13. **Extracorporeal Membrane Oxygenation (ECMO)** is one of the most resource-consuming treatments that can be provided in an ICU setting. As such, it should be reserved for extremely selected patients, for which prompt weaning from extracorporeal support can be anticipated. It should ideally be reserved for **high-volume referral centres**, where the same procedure could be less resource-consuming than in other, less-experienced, settings.
14. **Networking** among healthcare professionals is essential to share clinical expertise. Dedicated time and resources should be anticipated for team **debriefing** and monitoring of **burnout** symptoms or **moral distress** among the healthcare staff once time permits.
15. During an epidemic, the impact of **restricted** visiting policies on families and proxies should be considered, especially when the death of a loved one occurs during times of complete restriction of family visits.



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