

Abstract

In late February and early March 2020, Italy became the European epicenter of the Covid-19 pandemic. Despite increasingly stringent containment measures enforced by the government, the health system faced an enormous pressure and extraordinary efforts were made in order to increase overall hospital beds availability and especially ICU capacity. Nevertheless, the hardest-hit hospitals in Northern Italy experienced a shortage of ICU beds and resources that led to hard allocating choices. At the beginning of March 2020, the Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care (SIAARTI) issued recommendations aimed at supporting physicians in prioritizing patients when the number of critically ill patients overwhelm the capacity of ICUs. One motivating concern for the SIAARTI guidance was that, if no balanced and consistent allocation procedures were applied to prioritize patients, there would be a concrete risk for unfair choices, and that the prevalent “first come, first served” principle would lead to many avoidable deaths. Among the drivers of decision for admission to ICU, age, co-morbidities and preexisting functional status were included. The recommendations were criticized as ageist and potentially discriminatory against elderly patients. Looking forward to the next steps, the Italian experience can be relevant to other parts of the world that are yet to see a significant surge of COVID 19: the need for transparent triage criteria and commonly shared values, give the Italian recommendations even greater legitimacy.

Keywords: COVID 19; allocation; resources; rationing; ethics; Italy

Introduction

In late February and early March 2020, while infection rates in China fell, Italy became the European epicenter of the Coronavirus (SARS-CoV-2) 2020 epidemic. At the beginning of May 2020 Italy entered the so called “phase two”, consisting in a progressive reopening of business and social activities while monitoring the eventual raise of the epidemic curve. “Phase two” posed a number of ethical questions, such as finding a new balance between personal liberties and public health; privacy concerns from the use of movement tracking apps; and down the line access to vaccines or improved medications. We think it is, however, important to look back and determine which lessons can be derived from the way Italy confronted the scarcity of medical resources available to confront the epidemic, especially since this experience can prove invaluable for other countries that are still facing the epidemic peak. In the paper we analyze the features of the Italian recommendations, why they raised a heated debate and why it is important to have ethical guidelines and balanced and consistent allocation procedures to prioritize patients.

The recommendations issued by the Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care

In March and April 2020, a huge effort was made by the national government to flatten the epidemic surge by enforcing increasingly stringent containment measures, in order to reduce the impact of the outbreak on the health system. Despite facing a likely major social and economic crisis, the Italian Government imposed a nationwide lockdown on 9 March: prohibition of all movements of people within the whole territory, and closure of all non-essential business activities.

Some think a systematic and strong response arrived too late¹; such measures inevitably have a delayed impact, and hospitals we hit by what has been called a medical “tsunami”, with high caseload punctuated by a stream of deaths.

The enormous challenge for the health system – facing a dramatic shortage of ICU beds and staff – has been how to meet the medical needs of patients affected by COVID-19. Even though authorities state that

no cases of people who failed to get into intensive care have been reported, many Italian physicians working in ICUs in Northern Italy have stated otherwise, as has the Mayor of Bergamo, one of the hardest-hit cities.²⁻⁵ Professionals experienced uncertainty and distress about how to allocate the dramatically scarce resources available, as that situation was unprecedented for everyone: in some hospitals, at the peak of the surge, the rationing involved not only ventilators but oxygen as well.

At the beginning of March, some hospitals around Milan were already collapsing (some of them admitting more than 200 patients with severe respiratory failure every day). As difficult allocation choices were already being made, clinicians (including one of the authors, MV) of the ethics section of the Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care (SIAARTI) were asked to publish guidance on the allocation of limited resources. They worked between shifts to construct the recommendations (Box 1), that sparked a heated debate immediately after the release.

1. 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
2. Criteria for allocation should be flexible and adapted locally in response to available resources, the potential for patient transfer, and the ongoing or foreseen number of admissions
3. An age limit for admission to the ICU may ultimately need to be set
4. Together with age, the comorbidities and functional status of any critically ill patient should be carefully evaluated
5. 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

Box 1: Key elements of SIAARTI recommendations.⁶

The recommendations issued by SIAARTI suggest that, if a choice to ration medical equipment and intervention is needed, the maximum individual benefit in terms of expected life years—likelihood of survival plus remaining likely years of a patient’s life – should be prioritized. According to this principle the recommendations suggested evaluating age, comorbidities and functional status of any critically ill patient. This was subsequently criticized as ageist, as well as “unconstitutional” and discriminatory against elderly patients⁷⁻¹⁰. It was perceived as not consistent with the values on which the health care system is grounded.

According to the SIAARTI guidance, the drivers of decision for admission to ICU should be the clinical picture taking into account “biological” (not mere chronological) age, co-morbidities and preexisting functional status. This kind of “soft” utilitarian approach is already applied in Italy in specific fields of dramatically scarce resources, such as organ transplants¹¹ This approach is justified by the need to maximize the achievable benefit in terms of life years gained, thus optimizing the use of available resources: not only the probability of survival and the “greatest life expectancy” are considered, but also the predicted length of the ICU stay and hence the use of intensive care resources. Nonetheless, this kind of approach is the opposite of the egalitarianism that pervades the wider Italian healthcare system.

Sometimes in pursuing what is good, we run the risk of forgetting what is fair. In emergencies, the patient-centered “duty to care” needs to be balanced with public-focused duties to promote equality of persons and equity in distribution of risks and benefits. Also, individual allocating decisions must be supported by fair institutional processes that may include strategies such as preparing, conserving, substituting, adapting, re-using, and re-allocating resources.¹²

In every single country facing COVID-19 emergency, if no ethical guidelines or balanced and consistent allocation procedures are applied to prioritize patients, there is a concrete risk for unfair choices.¹³ Should the shortage arise with no rationing plan in action, decisions would be left to the ruling of local healthcare and hospital authorities or to the clinician's judgement in the heat of the moment, resulting in approaches both inconsistent and uncoordinated.

One motivating concern for the SIAARTI guidance was the real chance that the prevalent criterion would be "First come, First served". Such an approach appears to remove responsibility for choice over life and death, and can be thought as avoiding having to make ethically fraught choices between patients. We will only point out in passing that from an ethical standpoint, there is no actual difference between action and inaction when they both cause harm and injustice. Choosing First come, First served is to be responsible for the foreseeable, avoidable deaths of many people in a pandemic. Moreover, this approach would also carry the huge risk of social unrest and riots due to the rush to obtain hospital beds, or at the very least hospital overcrowding, with the ensuing risk of further spread of infection.

Major inequities would also arise from a "self-made" utilitarian approach by the clinicians left to their own individual intuitions. The risk of arbitrariness and disparities of judgement is only partially reduced by the recommendations, that do not set specific thresholds and state that cutoffs "must remain flexible". The aim to provide a guidance, not a substitution of the individual clinical judgement.

Last but not least, individual physicians would be, as it happened in Italy, under a tremendous moral distress facing such a terrible task of improvising decisions about whom to treat. They would literally be out on an ethical limb.

In Italy, as elsewhere in the world, we were dramatically unprepared for such a startling emergency, and not just because we had not enough ICU beds, staffing or funding. We were not prepared at all to face such dramatic choices. In retrospect, the SIAARTI recommendations might have been written differently. It would have been better to have had a chance to involve members of the wider community in reflection on how to make decisions in the event of such a health emergency, as was done in Maryland in the USA in 2012-15.¹⁴ In Maryland multiple forums were held with the general public and with health care workers and disaster professionals using a deliberative democracy approach. Input from citizens was then fed into policy recommendations developed by an expert working group. This kind of approach would have given the recommendations greater legitimacy, and might have provided additional support to clinicians.

Conclusions

We don't know what the future will be like after the pandemic, but it is clear that we should try to rethink the whole issue of allocation of scarce resources in emergency conditions, finding out commonly shared and accepted values to construct a contingency plan with sound and consistent ethical guidelines and proper structures – such as triage committees – to help apply guidelines, relieving the individual front-line clinicians of that burden. The approach is similar to other settings, but this is not acknowledged by the general public, or better, by the critics of the triage recommendations.

Now more than ever we are aware that a universal, functional and proactive public healthcare system has the best chances of appropriately facing an unforeseen outbreak of a viral disease. Its full functionality is important at the early stage, when no specific immunization or treatment interventions are available, since it guarantees proper infrastructures to mobilize a testing regime that provides the data that health-policy leaders need to make decisions, and it guarantees a fair and consistent access to supportive care. It will become crucial later, when drugs and vaccines will hopefully be available, to define their price and deliver them widely, effectively and fairly. We do not know yet if this hard time will turn into a global catastrophe, but should learn from the history of past epidemics that one of the highest risks is to give wrong priorities.¹⁵

1. In emergencies, the patient-centered “duty to care” needs to be balanced with public-focused duties to promote equality of persons and equity in distribution of risks and benefits.
2. In emergencies, when medical resources available are scarce, the first-come-first-served approach should be rejected.
3. As the development of rapid ethical guidance in emergency is difficult and politically fraught, an advance planning for intensive care – including decision-making in the event of overwhelming demand – is needed.
4. A political and public engagement/education in the ethics of resource allocation is needed to clarify priorities and values if they are to be reflected in allocation

Box 2: Key lessons from Italy

REFERENCES

- 1 Pisano GP, Sadun R, Zanini M. Lessons from Italy’s Response to Coronavirus. *Harvard Business Review* 2020 Mar 27. [internet]. Available from <https://hbr.org/2020/03/lessons-from-italys-response-to-coronavirus> (last access 04/03/2020)
- 2 [internet]. Available from https://www.ansa.it/sito/videogallery/italia/2020/03/20/coronavirus-borrelli-mancano-posti-in-terapia-intensiva-non-ci-risulta_5746bc30-b752-4ee1-903e-55a515482070.html (last access 04/03/2020)
- 3 Nacoti M, Ciocca A, Giupponi A, Brambillasca P, Lussana F, Pisano M et al. At the Epicenter of the Covid-19 Pandemic and Humanitarian Crises in Italy: Changing Perspectives on Preparation and Mitigation. *NEJM Catalyst* Mar 21 2020. [internet]. Available from https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0080?fbclid=IwAR1LWoRq5zIomshBBUGfp6n0W-n_6TI90VJndf-YYMgGoiRD-FmS2hPH8fo (last access 04/03/2020)
- 4 Rosenbaum L. Facing Covid-19 in Italy - Ethics, Logistics, and Therapeutics on the Epidemic's Front Line [published online ahead of print, 2020 Mar 18]. *N Engl J Med* 2020; 10.1056/NEJMp2005492. doi:10.1056/NEJMp2005492
- 5 [internet]. Available from https://www.corriere.it/politica/20_marzo_11/coronavirus-gori-denuncia-pazienti-lasciati-morire-poi-si-scusa-655be6a2-638e-11ea-9cf4-1c175ff3bb7c.shtml?refresh_ce-cp (last access 04/03/2020)
- 6 Società Italiana di Anestesia Analgesia Rianimazione e Terapia Intensiva. Clinical ethics recommendations for the allocation of intensive care treatments, in exceptional, resource-limited circumstances. [internet]. Available from <http://www.siaarti.it/SiteAssets/News/COVID19%20-%20documenti%20SIAARTI/SIAARTI%20-%20Covid-19%20-%20Clinical%20Ethics%20Recomendations.pdf>. opens in new tab (last access 03/20/2020)
- 7 [internet]. Available from <https://portale.fnomceo.it/anelli-fnomceo-su-documento-siaarti-nostra-guida-resta-il-codice-deontologico/> (last access 03/04/2020)
- 8 [internet]. Available from http://www.quotidianosanita.it/stampa_articolo.php?articolo_id=82299 (last access 03/04/2020)

- 9 [internet]. Available from https://www.quotidianosanita.it/scienza-e-farmaci/articolo.php?articolo_id=82353(last access 03/04/2020)
- 10 [internet]. Available from http://www.quotidianosanita.it/scienza-e-farmaci/articolo.php?articolo_id=82425(last access 03/04/2020)
- 11 Cillo U, Burra P, Mazzaferro V, Belli L, Pinna AD, Spada M, Nanni Costa A, Toniutto P; I-BELT (Italian Board of Experts in the Field of Liver Transplantation). A Multistep, Consensus-Based Approach to Organ Allocation in Liver Transplantation: Toward a "Blended Principle Model". *Am J Transplant*. 2015 Oct;15(10):2552-61. doi: 10.1111/ajt.13408. Epub 2015 Aug 14. PubMed PMID:26274338
- 12 [internet]. Available from <https://nam.edu/duty-to-plan-health-care-crisis-standards-of-care-and-novel-coronavirus-sars-cov-2/>(last access 03/20/2020)
- 13 Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, Zhang C, Boyle C, Smith M, Phillips JP. Fair Allocation of Scarce Medical Resources in the Time of Covid-19. *N Engl J Med* 2020 Mar 23. doi: 10.1056/NEJMs2005114. [Epub ahead of print] PubMed PMID: 32202722
- 14 Daugherty Biddison EL, Faden R, Gwon HS, et al. Too Many Patients...A Framework to Guide Statewide Allocation of Scarce Mechanical Ventilation During Disasters. *Chest* 2019;155(4):848–854. doi:10.1016/j.chest.2018.09.025
- 15 Jones DS. History in a Crisis - Lessons for Covid-19. *N Engl J Med* 2020 Mar 12. doi: 10.1056/NEJMp2004361. [Epub ahead of print] PubMed PMID: 32163699