



COVID-19 IN ITALY. CLINICAL EMERGENCY AND BIOETHICAL PERSPECTIVES

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ABSTRACT

Italy is the European country with the second highest number of novel Coronavirus disease 19 (COVID-19) deaths. Several factors interfered with the spread of this phenomenon, both clinical, political, and bioethical. In this scenario, where the need for care goes far beyond the capacity of a health system able to cope with it, what should be the criteria for an equitable distribution of the available resources? The mass quarantine required physical distancing in order to limit the spread of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, and contextually created additional problems for the organization Italian National Health Service. The delicate ethical questions posed by the current emergency are beginning to unveil some proposals for solutions in literature, which, although still insufficient for understandable reasons, is increasing.

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1. Introduction

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) outbreak is dramatically changing the picture of National health services of the large majority of Countries involved worldwide, putting the whole system in crisis [1,2]. Intensive care beds and ventilators were not sufficient, nor, in some cases, were essential medicines and personal protective equipment for health workers available during the increase of the epidemic curve in several countries, even those with developed sanitary systems. The scarcity of healthcare resources puts patients affected by the novel Coronavirus disease 19 (COVID-19) at risk and the delay of treatment for patients with urgent needs such as cancer, diabetes, and heart disease, contributed to a consistent excess of mortality due to COVID-19.

Moreover, disruptions in the healthcare system are likely to cause more deaths of people with a variety of urgent health needs than those diagnosed with COVID-19 [3].

In this scenario, where the need for care goes far beyond the capacity of a health system able to cope with it, what should be the criteria for an equitable distribution of the available resources?

The first answer is, undoubtedly, preventing the spread of infection [4,5]. During the first phases of the outbreak, mass quarantine policies minimized the number of new infected cases of SARS-CoV-2 infection, relieving the pressure on intensive care units and on healthcare systems.

In this case, the problem becomes social as well as clinical. It involves not only health care structures but also the entire civil community. Since the mass quarantine required social distance between individuals, if on the one hand it reduces the chain of contagion, on the other, it creates additional complications such as the problematic balance between the protection of public health and individual civil rights [3]. It also generates a widespread paralysis of the production system, with its inevitable economic and social problems.

Leaving out the broader political-social and legal issues related to measures of containment and prevention of contagion, focusing attention on the problem of treatment in the regime of scarce resources, where the item "resources", of course, not only corresponds to clinical instrumentation (suitable environments, beds, drugs, personal protective equipment, ventilators) but also to the availability of human resources and, therefore, of health personnel.

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In the presence of a rapidly spreading pandemic such as COVID-19, these problems can always arise regardless of the diversity of socio-health contexts, and it is the so-called "last-bed dilemma". In Italy, public discussion began when, in the Lombardy region, the emergency of COVID-19 brought health facilities to the brink of collapse, and the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI) published the "Recommendations of clinical ethics on admission to intensive treatments and their suspension" [6,7]. It goes without saying, as specified in the SIAARTI document, that the selection of patients represents the last chance in contexts in which everything possible has already been done in terms of macro- and micro-allocation of healthcare resources. There is an efficient network of links between hospital wards, which, in the event of lack of means and staff, allows any patient transfers to centers with higher availability [8].

The issue of triage, not exclusively, of course, not only includes what the criteria for selecting the recipients of the treatment should be, but also who should establish them and possibly answer them in the event of medico-legal disputes [8].

2. Who decides? Ethics committees and medical staff

According to some recent proposals, clinicians who establish the triage criteria and clinicians who apply them in clinical circumstances should be different subjects [8]. Hopefully, a requirement drawn up by an ethics committee will be that a procedure shall not be performed by the same medical personnel who treated the patient, especially in the case of suspension of ventilation already in progress.

Such a division of labor would have numerous advantages:

- 1) relieves clinicians from a responsibility which, however lucidly and prudently exercised, can be emotionally too burdensome;
- 2) increases the probability that the criteria are weighted and impartial;
- 3) makes communication between caregivers and family members more transparent;
- 4) avoids the impression of arbitrariness that could result from a decision made by an individual operator based on purely subjective assessments.

Not surprisingly, the first ethics committee in history was created precisely to establish a just distribution of scarce health resources. In 1961, at the Medical School of the University of Washington in Seattle, the problem of an equal distribution of limited health resources arose for the first time. Dr. Belding Scribner developed a hemodialysis machine, which was needed for far more patients than those that could be treated [9]. The problem of which criteria to follow to exclude patients who, although in need of treatment, could not benefit from it, presented itself dramatically. Measures such as the cost-benefit ratio from the clinical point of view were immediately insufficient, since, even after making a selection based on this criterion, there were still too many candidates with the same possibilities to benefit from the treatment. This issue generated the necessity of making a selection of candidates based on criteria that were not only medical. Thus, in 1962, the first hospital ethics committee was created, formed by a group of scholars, mainly non-doctors, called to establish distribution criteria for the appropriate use of scarce therapeutic resources. Since, in such a situation, it was a question of deciding who should live and who, instead, should die, it would not have been right to leave the doctors alone, since such a tragic responsibility had to be shared by the whole community. Otherwise, as a journalist who investigated the Seattle case written, "society would have forced doctors to play the role of God for themselves" [10].

The historical affair of the Seattle committee is also useful for understanding some implications of the current emergency. To the objection that triage committees in the context of COVID-19 can be labeled "death committees", the reply is that they would be exactly the opposite since their goal is to save as many lives as possible in a situation that does not always allow all to be saved [8-11].

Of course, one might wonder what the actual medico-legal and ethical value of a committee's judgment should be. It is reasonable to think that such a scenario could cause divergences between the opinion of a committee and the doctors involved on the front line. A criterion decided impartially, away from the patient bed, could take on an unexpectedly different meaning in the ward. Moreover, as far as a division of labor can be organized, clinical decisions are never the final link in a sort of assembly line. If this were the case, patients would rely not on the professionalism and conscience of a doctor, but on an anonymous ethical agency which, upstream, establishes criteria that the doctor, dealing with the individual patient, should be able to evaluate in each situation, not abstractly. Otherwise, the risk can arise that health professionals will become executors of actions decided elsewhere, and that the ethical responsibility of the choices made (instead of being shared) will end up being dispersed. From this point of view, ethics committees should have the only consultative function, not a deliberative one [12]. Moreover, if the committee members were to decide, they would be the ones to bear civil and criminal liability for the caregiver's actions.

3. Which selection criteria?

Whether it is a remote ethics committee or a physician in a position to deal with it, in the ward, the problem of which criteria must be followed to exclude some patients for the benefit of others is, without a doubt, the thorniest and most dramatic.

The equitable distribution of scarce resources is, as is well known, a problem of distributive justice. The principle of justice requires us to "give everyone their own". In our case, it implies guaranteeing each patient, not only those affected by COVID-19, the care they need. However, when the means available are not sufficient to cure everyone, it is necessary to choose; the question is, with which criteria?

A first criterion is the "random" one of the "first-come, first-served": the patient who arrived earlier is treated first and so on. The advantage of this criterion is to exempt doctors from making a difficult and potentially unjust choice. The disadvantage is that those who arrived earlier may have a less urgent need for treatment than those who come later, finding themselves in a clinical situation that causes a saturation of the resources, not related to the gravity of the individual clinical condition. Think of the case of a cardiopathic patient over eighty who occupies a bed for a long time with poor prospects of therapeutic benefit, and two other younger patients who, although both treated one after the other, could instead recover their health and free the bed faster than the elderly patient.

A second criterion, connected to the example just made, is that of "fair therapeutic savings": choose that patient by saving who does not require depleting resources necessary to save others [13]. This criterion would make it necessary to treat, other things being equal, a patient, even if not severe, of an infectious disease than a more critical one but who, like the former, is not a potential danger of contagion for others.

Then there is the "prognostic" criterion: those who, other things being equal, have higher prospects of survival and/or recovery are treated for first. Even the SIAARTI, in its Recommendations, refers to this in terms of "life expectancy". Based on this criterion, a young patient with a lower probability of survival/recovery could be excluded in place of an elderly

patient who has a higher probability. The prognostic criterion is linked to that of therapeutic savings, since treating those who have the greatest prospects of benefit means avoiding the waste of a resource. All things being equal, the prognostic criterion becomes the criterion of "healthy life years", or QALYs (Quality Adjusted Life Years): it is decided to treat the patient who, once saved and/or cured, will have prospectively more years to live in good health condition, compared to others. Between a young person and an older adult, the elderly should almost always be excluded. Alternatively, if it was necessary to decide between a forty-year-old patient with a healthy twenty-five-year-old prospect, and two younger but disabled people, each of whom had only a healthy ten-year-old prospect, one should decide to treat the former. In the overall calculation, in fact, the healthy years obtained by treating the first would be higher than those obtained by treating the other two.

When the cost-benefit criterion is applied not individually, but distributively and comparatively between different patients, it results in the "maximum aggregate benefit" criterion. It is a question of treating according to the principle of the most significant benefit for the most considerable number of people. In the current pandemic situation, a certain percentage of those infected are found among healthcare workers. All other things being equal, according to the criterion of the maximum aggregate benefit, a patient who is also a doctor will have to be treated first, since, once cured, he can, in turn, treat other patients on the waiting list, optimizing the benefit received. The maximum aggregate benefit criterion has not only clinical but also social relevance. Moreover, this criterion is characterized by two variants: a perspective and a retrospective. In the first one, we look at the more significant social benefit, which, prospectively, is guaranteed by treating one patient rather than another. For example, it was decided to give precedence to all those people whose survival depends on the well-being of other people, as in the case of parents with dependent minor children. In the retrospective variant, however, we look at either the acquired social merit or irresponsible conduct. As an alternative, whether to heal the victim of an accident or the drunk driver who caused it by going through a red light at a high speed; healing the former is preferable. In the current pandemic situation, think also, and more realistically, of the alternative: whether to treat a patient who has not complied with the hygiene and safety standards provided for in quarantine or an unjustly infected patient while he was at home.

Many people contest the criterion of "value" or social "merit", considering a random selection of candidates a more appropriate solution [9]. Only in this way, it is said, can reducing people to their social function or unjustly punishing certain behaviors that are not always fully deliberate be avoided; respecting their dignity, and the equal right to receive the necessary care. Furthermore, randomly assigning the beneficiaries of therapy not available to everyone, we would no longer decide whom to exclude - with an inevitably arbitrary and, therefore, unjust - choice - recurring to a random assignment.

4. The case of suspension of treatment aimed at "freeing resources"

Each of the listed criteria has advantages but also criticisms. Among many, the prognostic difficulty, especially when biomedical evaluations fade into ethical and social assessments, as in the concept of "quality of life" or in the idea of "life expectancy", where the concepts of "quality" and "life" often have psychological, subjective and social meaning, not only medical or biological.

Despite the perplexities expressed by the Italian National Federation of Orders of Medical Doctors and Dentists (FNOMCeO) in the SIAARTI

Recommendations, it seems that specific criteria, in any case, must be adopted. In the situation in which we find ourselves, in fact, in which no one patient should be excluded from the appropriate therapies and that caregivers should take care of everyone, in the same way, and at the same time, the risk is displayed as purely rhetorical, because it hides the fact that, often, instead, caregivers must choose. Furthermore, it is certainly better to do it in the light of criteria which, however questionable and perfectible, are at least transparent and publicly controllable, rather than doing it under the table. A selection of patients based on the relationship between costs and benefits already occurs in times of peace. Why it should not be acceptable even in times of "war", such as those we are now living in with COVID-19, is illogical.

In this regard, the decision to administer treatments to some patients rather than others takes on particularly onerous importance in the case of treatments already started. The particular emergency we are experiencing could suggest suspending the assistance to one patient and making it available to another. Only that, in such a case, one could not appeal to any of the two medico-legal justifications that could authorize the decision, namely per the request of the patient himself or his representative on the one hand, and the judgment of the uselessness of the treatment on the other. Although in the case that survival chances may be low, and, in the absence of the needing to treat additional patients, the treatment would have been started or continued anyway [8]. The question, at this point, is the following: Is a ventilation treatment considered disproportionate and now useless for the patient himself or because only by defining it as such will it be possible to justify its interruption to be destined for patients with higher prospects of recovery? As it is easy to understand, the risk is that, in a regime of scarce resources, we have been led to consider "persistence therapeutic" cases that, in the regular regime, would not have been considered as such. The judgment of persistent therapy, in such a context, would no longer be individual but comparative: it no longer concerns only the care given to the individual patient but a fair distribution of care among multiple patients. According to some, there is nothing questionable about this; on the contrary, others argued that, in some cases, without the pressure of other needy patients, caregivers would be led to consider ordinary care when, in reality, they represent clinical obstinacy.

In Italy, the issue of persistent therapy overlapped with that of the right distribution of care, especially when we had begun to speak, albeit reluctantly, of the possible exclusion of the elderly from COVID-19 treatments. The registry criterion that leads to the preference of young people is an unconscious clinical translation of cultural discrimination, to which elderly people are already subjected. The reason for preferring the young person is that, by caring for an older person, an apparent injustice would be committed, because the young person would be deprived of many more years of life, than those the older adult would lose. In addition, the elderly in general have already consumed more health and social resources, which a just "diachronic" distribution would require to allocate, for compensation, to the young person; without considering the fact that, from an economic-social and social security point of view, in the health sector, the elderly consume more and produce less, the young vice versa.

Whatever the assessment of these reasons, we might recall the writings of the emperor and philosopher Marcus Aurelius, who states that:

You cannot lose another life than the one you're living now, or live another one than the one you're losing [...]

The present is the same for everyone. In fact, no one could lose neither the past nor the future, since what man does not have, how could he be stolen from him? [...] Both those who die very young and those who die very old lose the same thing: only the present is, in fact, what one can be deprived of, since only this is possessed, and what is not possessed cannot be lost [14].

Of course, it could be specified that while the future has not yet occurred, the past is contained in the present of the memory, so one could even say that letting an old man die means letting "more" life to die than let die a young man, who still had not lived it. Marco Aurelio's quote, on the other hand, goes in the direction of equality of every life. Moreover, this is also confirmed in our legal system and our moral and deontological sensitivity. Then, the means of preserving life are limited. Thus, it may require making choices which are not choices of life and death, but of care. The caregiver is not omnipotent, although an absolute misunderstanding of his precious power could lead one to believe he is. The doctor takes care of life; however, they cannot prevent death. Therefore, when someone dies because he has had to cure another, he cannot be accused of having "let him die". An omission is morally and legally such when there is a clear duty to act. Since "ad impossibili anemo tenetur", when not everyone can be cured, the caregivers are responsible for the appropriate use of the available resources, not for the unwanted consequences that this proper use on some, reflects on others.

5. Beyond medicalization and towards the culture of prevention

The COVID-19 pandemic emergency is highlighting some significant contradictions of our social perception of medicine. That there are still no tested treatments for COVID-19 and that hospitals have collapsed seems to have indirectly returned doctors to their human frailty, well beyond the tendency, under normal conditions, to judging them as responsible "over every limit". And not just because of those potentially infected on the front line of healthcare combat. Never as in the times we are living, have doctors appeared to us, to use the suggestive image that comes from Greek mythology, as "wounded healers". That is, people from whom the necessary help is expected, of course, but those who are also willing to "forgive" if, despite their efforts, cannot guarantee it.

This more forgiving attitude, in the particular circumstances we are experiencing, perhaps also arises from a sort of sense of guilt towards the doctor. Those who, under compulsory quarantine, are infected, may, in fact, have become ill from imprudence or human negligence, not only due to natural causes. So, if before, any medical failure was attributed to the doctors, now it seems that even the citizen, in a renewed solidarity of destiny, has understood that he has to take on his responsibilities. Assessing humanity to both doctors and patients, the COVID-19 emergency seems to have canceled the distrust that poisoned their relationship, sending defensive medicine and medico-legal disputes to the attic for now [15].

As seen above, in context of the current emergency, an adequate cost-benefit assessment of care goes well beyond the individual patient being treated, touching on aspects of social life that go beyond the strictly clinical setting [16]. Thinking of the relationship between quarantine and overload in intensive care units: the better the social measures for the prevention of contagion, the fewer the problems of equitable distribution

of resources for the treatment of the infected [17].

From this point of view, the emergency is also revealing, as never before, the limits of medicalization, that is, the tendency to deal with problems that are not only medical but above all ethical and social, through medical criteria. We all see it: COVID-19 is more effectively countered "upstream" by virtuous social and targeted political behavior than, "downstream", by intensive care.

Italy's health system has 3.2 hospital beds per 1,000 people (as compared with 2.8 in the United States) [18], this number was not sufficient to meet the needs of so many critically ill patients at the same time. Moreover, the overall numbers of caregivers and emergency system resources appeared inadequate to face the COVID-19 emergency.

The choice of canceling elective surgery procedures, modifying operating rooms in small ICUs, and concentrating on the activities of the hospitals to reallocate resources, granting emergency and oncologic treatments exclusively, allows for widening the total capacity of the health system. Thus, although some efficacy is demonstrated in this early stage, it would not be possible to continue in the long term, where patients' demand for elective surgeries, elective procedures, and diagnostic exams, should be granted.

In this long-term scenario, the possibility of building "ex-novo" and dedicated COVID hospitals could represent the most practical alternative. COVID hospitals, allocated in every region, could work as a reservoir for intensive or semi-intensive beds, freeing ICU beds and resources from non-COVID hospitals. Moreover, COVID hospitals could contribute to essential scientific and epidemiological functions, providing data in real-time.

6. Conclusions

Once the emergency has ended, a lesson should also be drawn for peacetime: before delegating it to health workers when it is now lost, the good of health should be prudently safeguarded firsthand. Moreover, if it is true that health is priceless but has a cost, after COVID-19, it is clear that this cost should also be understood in terms of the social responsibility of prevention, not only in terms of tax contribution to health; as the necessary "lockdown" to which we are all responsibly called, without exclusion, is dramatically demonstrating.

Abbreviations

COVID-19 = Corona Virus Disease 19; SIAARTI = Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care; Quality Adjusted Life Years = QALYs; FNOMCeO = Italian National Federation of Orders of Medical Doctors and Dentists; ICU's = intensive care units.

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