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Medical Liability for Allocation of Scarce Healthcare Resources in the COVID-19 Pandemic: the Italian scenario

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Abstract

Summary: 1. Tragic Choices in COVID times; 2. Criteria for the Allocation of Scarce Healthcare Resources; 3. Liability of Healthcare Professionals and Institutions; 4. Possible solutions?

I. Tragic Choices in COVID times

One of the most painful memories of the first wave of Coronavirus is the messages sent by healthcare workers to friends and acquaintances imploring them to stay home because healthcare facilities of the worst affected areas were about to cave in and doctors were forced to decide who should live and who should die.

As we all know, the Coronavirus pandemic, like other disasters of human or natural origins, created a sudden and unpredictably high demand for healthcare supplies, which the system itself was not able to satisfy.

In a situation of scarcity of resources, not everyone entitled to those resources can necessarily manage to have them. Therefore, difficult decisions ('tragic

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choices')[1] have to be made in order to identify those who will benefit from the scant resource at the expense of others.

In addition, COVID-19 has exposed the weaknesses of the Italian health care system: it has been estimated that in the most critical period between the 5th and the 25th of March 2020, in the provinces of Bergamo-Lodi-Brescia-Cremona (the so-called red zone) for every single bed in intensive care, there were almost ten patients queuing up for it.[2]

Setting aside the sensitive issue of the adequacy of the financial resources allocated for the health care system, what is more concrete and involving from a legal point of view is the discussion about the healthcare professionals' decisions, choosing the beneficiaries of the scarce healthcare supplies.[3]

The discussion focuses on two different issues: i) if it is possible to establish criteria that should guide healthcare professionals in this 'tragic choice' and ii) if professionals can be held liable for making that choice.

II. Criteria for the Allocation of Scarce Healthcare Resources

With regard to the first issue, let me first point out that the Statute n. 833 of 1978, founding the Italian National Health Service, establishes that 'The National Health Service encompasses all the functions, facilities, services and activities directed at the promotion, maintenance and recovery of physical and mental

1 On this issue see G Calabresi, *Tragic Choices* (New York 1978).

2 As is widely known, some patients died at home while awaiting admission. On the loneliness of the dying in the time of COVID-19, see M Foglia, 'La solitudine del morente al tempo del Coronavirus' (2020) 3 Resp. medica 373; P Strang, J Bergström, L Martinsson, S Lundström, 'Dying From COVID-19: Loneliness, End-of-Life Discussions, and Support for Patients and Their Families in Nursing Homes and Hospitals. A National Register Study' (2020) 60(4) Journal of Pain and Symptom Management 4; GK Wakam, JR Montgomery, BE Biesterveld, CS Brown, 'Not dying alone-modern compassionate care in the Covid-19 pandemic' (2020) 382(24) New England Journal of Medicine 8; CL Wallace, SP Wladkowski, A Gibson, P White, "Grief during the COVID-19 pandemic: considerations for palliative care providers" (2020) 60(1) Journal of Pain and Symptom Management 70.

3 For a broader analysis of the issue, see R Pucella, 'Scelte tragiche e dilemmi giuridici a tempi della pandemia' 2020 (3) Nuova giur. civ. comm. 24; G Ponzanelli, 'I danni subiti da CoViD-19 tra regole di responsabilità civile e piani' 2020 (3) Nuova giur. civ. comm. 137; C Scognamiglio, 'La pandemia CoViD-19, i danni alla salute ed i limiti della responsabilità civile' 2020 (3) Nuova giur. civ. comm. 140; C Casonato, 'Health At The Time Of Covid-19: Tyrannical, Denied, Unequal Health' (2020) 3 BioLaw Journal 315.; M Maggiolo, 'Coronavirus and Medical Liability' in E Hondius, M Santos Silva, A Nicolussi, P Salvador Coderch, C Wendehorst and F Zoll (eds.), *Coronavirus and the Law in Europe* (Intersentia 2021); G Smorto, 'The Right to Health and Resource Allocation. Who Gets What and Why in the COVID-19 Pandemic' (2020) 20 Global Jurist (published ahead of print https://doi.org/10.1515/gj-2020-0040).

health of the entire population, *regardless of social or individual conditions, and in a way which ensures the equality of the citizens*'.[4]

So, together with the constitutional principles, the law prescribes that care must be ensured according to universalistic and egalitarian criterion.

However, the terrible emergency triggered by the Coronavirus brings us up against a shortage and the dramatic problem of how best to manage health resources to ensure the right to health referred to in the Italian Constitution.

Indeed, in March 2020 the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Therapy (SIAARTI) issued the document entitled 'Clinical ethics recommendations for the allocation of intensive care treatments, in exceptional, resource-limited circumstances'.[5] The document establishes guidelines on the access to the intensive care units in situations of scarce resources, as happened due to COVID-19 pandemic. The core principle is not new: the basic rule '*first come, first served*' is replaced by the 'clinical suitability' criterion, according to which the patient more likely to have more benefits from the treatment must be cured.

This is the same principle that is applied in *triage* practices, where the severity of the reported disease justifies the priority in healthcare delivery.

However, in a situation where the scarcity of resources not only affects the priority but also the possibility to cure someone, the criterion in the allocation of the scarce resource is identified by the SIAARTI as the chance of survival, depending on the age of the person and the presence of previous pathologies (or, in other words, comorbidities).

On the other hand, the Italian National Bioethical Committee 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 and so on, is deemed ethically unacceptable by the Committee.[6] In other words, such a clinical criterion identifies the current urgency and necessity as the only criterion that must govern the physician's conduct in treating the patient in need of care.

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4 For an outline of the Italian Health Care System, see AP Scarso, M Foglia, 'Medical Liability in Italy' in BA Koch (ed), *Medical Liability in Europe. A Comparison of Selected Jurisdictions* (Berlin-Boston 2011) 329 ff.

5 See Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Therapy (SIAARTI), 'Clinical ethics recommendations for the allocation of intensive care treatments, in exceptional, resource-limited circumstances' (SIAARTI, 16 March 2020) <www.siaarti.it> accessed July 13, 2022.

6 See Italian National Bioethical Committee, 'Covid 19: Clinical Decision-Making In Conditions Of Resource Shortage And The "Pandemic Emergency Triage" Criterion' (Italian National Bioethical Committee, 8 April 2020) <http://bioetica.governo.it> accessed July 13, 2022.

It should be noted that, even irrespective of the pandemic, in Italy the criterion of 'first come, first served' is out of date whenever the circumstances of the case require it: the criterion (so-called triage) operating in Italy assigns a priority of care regardless of the time of the patient's acceptance into the healthcare facility, expressed with colours that represent urgency in healthcare provision.

The most striking aspect is the idea that a fundamental right such as health can be sacrificed, despite the fact that the guidelines make it clear that this represents the *extrema ratio* and that, in any case, the physician's professional autonomy always allows him or her to consider each individual case in its precise specificity without being bound by rigidly prefixed parameters.

However, it is necessary to ask whether it is really a 'sacrifice'. Sacrificing health is an active conduct, implying a voluntary act or a decision; but if in a healthcare facility for every ICU bed there are ten applicants and the bed can be assigned to only one of those ten, can we really say that the health of the other nine has been sacrificed?

The real issue then is not that of 'sacrifice', but that of the inevitability of the situation and the impossibility of resolving it any other way.

III. Liability of Healthcare Professionals and Institutions

Now, it goes without saying that: first, those 'guidelines' are not mandatory (as they are not laid down by the lawmaker nor administrative bodies); second, they cannot – as a general rule – protect any physician or medical institutions from civil or criminal liability.[7]

This brings us to the second issue, namely if health professionals can be held liable for making that choice.

Art. 5 of the law no. 24/2017[8] on medical liability provides for 'good clinical practices and guidelines' and establishes that: 'The healthcare workers, in the execution of health services […], must abide by the guidelines issued by private and public bodies as well as by the scientific societies […]. In the absence of the above recommendations, the healthcare workers must adhere to good clinical care practices'.

7 For detailed information, see Pucella (n 3) 28.

8 Law 8 March 2017, no 24, entitled 'Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie'.

Now, should the SIAARTI recommendations be equated to the guidelines laid down in Art. 5 of the Statute above mentioned,[9] on the one hand the health professionals' criminal liability should be excluded and, on the other, the civil consequences should be determined in relation to their abidance to these guidelines.

However, in my opinion, the two sets of rules cannot be placed on the same level because they have a different *ratio* and functions: L. 24/2017 guidelines define the adequacy of a possible and due performance, meanwhile the SIAARTI recommendations concern the decision imposed by the scarcity of resources, where the performance of the healthcare professional becomes impossible because he or she cannot deliver the service to all those who need it.

Therefore, negligence is not an adequate standard to evaluate the healthcare professionals conduct and guidelines are not the right instrument to justify sacrifices of the right to health.

Some scholars have suggested the application of art. 2236 ICC according to which whenever the performance to be carried out involves 'the solution of technical problems of special difficulty', the debtor is not liable for damages, except in cases of intent or gross negligence; or art. 2045 ICC on the state of necessity. However, in my view, these qualifications are also not completely satisfactory, because the performance of the healthcare professional is not just limited but rather impossible.

Others have claimed that, rather than the healthcare professionals, the healthcare facilities should be liable for negligence, identifying the misconducts in management deficiencies, such as the insufficient sanitisation of hospital environments, inappropriate isolation protocols or ineffectiveness of treatments. However, the burden of proof would be extremely hard to satisfy in the event of a lawsuit.

Think about the single patient trying to prove that he or she was infected during the hospitalisation or the non-COVID patient trying to prove that the cancellation of their scheduled surgery for the benefit of patients in life-threatening conditions was determined by negligent misconduct. Nor do claims for the ineffectiveness of treatments appear to be actionable because the virus is almost totally unknown (at least it was at that time), therefore it was inevitable that off-label treatments would have been delivered.

Hence, it is my belief that the most appropriate interpretation seems to be the impossibility of performance for a cause not imputable to the debtor, according to art. 1218 ICC.

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9 For a more in-depth discussion see A Pisu, 'Diritto alla salute e responsabilità medica alla prova del CoViD-19' (2020) 1 BioLaw Journal 407.

In relation to healthcare facilities, liability could be almost objective (in terms of strict liability) when the lack of resources could have been foreseeable and therefore avoidable. In any case, it would be difficult to charge healthcare facilities with an order to compensate damages because, even though at the beginning of this year the gravity of the situation was clear, it would still have been impossible for them to properly prepare to fight it.

The impossibility of performance due to the scarcity of resources obliged healthcare professionals to take non-avoidable tragic choices. Of course, the recommendations that I mentioned previously cannot create priorities among rights that cannot be reduced (such as the right to health); they rather define guidelines to help healthcare professionals in taking such choices, identifying those who can have access to the treatments and those who cannot.

There is no doubt that health care providers must ensure the necessary care for every patient entrusted to them. There are several principles that regulate this: the most important is expressed in Article 32 of the Italian Constitution, which protects health as a fundamental right of the individual and interest of the community.

But then the protection of the patient is ensured at the level of the contractual relationship, that is, the contract of hospitalisation, which binds the patient to the public or private health care facility that treats him or her.

The patient is, therefore, entitled to care that is adequate and proportionate to his or her needs. The most problematic aspect concerns the situation in which the health service cannot be assured (or cannot be fully assured) for reasons that are not attributable to the healthcare staff member or the healthcare facility; here the problem is to understand whether the combination of circumstances that has put healthcare systems in every part of the world under stress constitutes a circumstance marked by unpredictability and in the face of which it was not possible to take countermeasures to avoid the very serious complex of harmful consequences that the world's experience had delivered to us.

The prevailing opinion is that the disruptive force of the COVID-19 pandemic, together with the lack – for a long time – of an adequate medical response, constitutes that condition of impossibility of performance which, under art. 1218 ICC (or by reason of the state of necessity, as others have held), makes neither the physician's failure to perform nor his or her conduct criminally punishable.

This conclusion could be reached even though some scholars argued that a pandemic was not a totally unforeseeable event, and it is noted that every patient could be cured, perhaps by being admitted to another healthcare facility (even in a foreign country) where the one of first admission is congested.

Obviously, a different situation is the one that may concern cases of non-compliance of medical provision: think of the hypothesis of non-COVID patients

admitted to the same hospital environments where COVID patients were; the case of doctors who, having tested positive for the virus or having come into contact with positive family members, nevertheless went to the workplace; or the case of failure to adequately sterilise environments; in these cases, liability is justified by applying the ordinary criterion of fault.

In conclusion: the 'tragic choices' that Italian doctors have been forced to make are not 'exceptions' to the duty to treat patients.

The 'exception,' in fact, presupposes a faculty of choice between conduct (that which is due) and its deviance (that which was held); in the case at hand, however, the doctors were precluded from this possibility of choice and the only possibility granted to them was to choose how to 'measure out' the scarce resource made available to them.

Here a principle highlighted by the Italian Constitutional Court intervenes: '[…]it is not, as a rule, the lawmaker that can directly and specifically establish what therapeutic practices are permitted, with what limits and under what conditions. Since the practice of medical art is based on scientific and experimental acquisitions, which are constantly evolving, the basic rule in this matter and constituted by the autonomy and responsibility of the physician who, always with the consent of the patient, makes professional choices based on the state of knowledge available'.[10]

It seems, therefore, clear that the criteria by which to allocate the very scarce intensive care resources in a time of medical emergency can only be established at the medical-scientific level, while respecting constitutional principles in all cases.

IV. Possible solutions?

There have been legislative proposals to recognise the healthcare professionals' impossibility of performance in order to exclude their liability. However, it is most desirable to simply exclude the right to sue them, as the Italian Association of the Professor of Civil Law proposed in the prospective *de iure condendo.*[11]

Once the right to claim for damages is excluded, questions arise as to whether there is space for a right of indemnity.

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10 Constitutional Court, 26 June 2002, no 282, in *Foro italiano*, 2003, 2, 1; Constitutional Court, 12 July 2017, no 169, <www.biodiritto.org> accessed July 13, 2022.

11 See the document entitled 'Una riflessione ed una proposta per la migliore tutela dei soggetti pregiudicati dagli effetti della pandemia' <https://www.civilistiitaliani.eu/iniziative/notizie> (Associazione Civlisti Italiani) accessed July 13, 2022.

In the past, for instance, following liability for post-transfusion contagion in hospitals (infection by blood derivative/blood transfusion or damage arising from compulsory vaccination), the Italian Parliament passed a regulation (Statute 25 February 1992, no 210) which granted the right of indemnity to victims of contagion (such as viral hepatitis and/or HIV). The indemnity was paid for by the State and does not prejudice any tortious claim against the tortfeasors.

However, the right of indemnity appears to be, on one hand, strictly related to the principle of solidarity, and, on the other, it seems to implicitly attribute the harmful event to a management wrongdoing.

In conclusion, it should also be noted that the chain of causation seems weak. Facing the high number of dead people promptly treated, there is no proof that the impossibility to receive the treatment due to the state of necessity was the actual cause of death of those who did not receive those treatments.

This would necessarily call for the application of the *more-probable-than-not* rule and the *loss of chance* criterion.

What is certain is that the pandemic's impact was so strong that we were not able to properly contrast it, and COVID-19 has placed patients and healthcare professionals on the same level, eventually turning the latter into the first.[12]

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12 Pucella (n 3) 31.

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