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Criteria for allocation of life-saving resources during the SARS-COV-2 pandemic: ethical implications and aspects of legal liability

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Abstract
The issue of political, institutional and professional liability in the context of the SARS-COV-2 pandemic is currently widely debated and involves several levels of investigation. One crucial aspect relates to the allocation of life-saving resources in situations where there is an imbalance between need and availability and the associated questions of ethical and legal liability. This work looks at the implications of the criteria applied to rationing under extraordinary conditions and the issue of their legitimacy. Considering the European scenario, we describe the approach taken by Italy in proposing criteria for pandemic triage of intensive treatment and highlight certain problems and critical issues. We emphasise that the decision, based on a comparative assessment, to deny treatment to a patient in critical condition, compromising that patient's right to care, exceeds the scope of decision-making autonomy of the professional concerned and requires a theoretical and procedural definition shared at multiple levels of society.

Key words
- allocation of resources
- COVID-19 pandemic
- medical liability
- selection criteria

INTRODUCTION

A public health emergency with a major impact on people's health, such as the SARS-COV-2 pandemic, represents an extraordinary event that requires the timely implementation of appropriate response actions and strategies. From the initial months of 2020, the resilience of the economic and social systems in many countries around the world has been severely tested by the effects of an unknown virus. Healthcare systems have been required to adapt, in some cases revealing pre-existing organisational and structural problems. This unprecedented situation has created the inevitable conflict between protecting individuals and achieving collective public health objectives (ensuring maximum benefit for the greatest number of patients) [1]. Indeed, in a context of medical emergency, the public healthcare perspective is forcibly shifted from the individual to the general population, which is made up of all "statistical lives".

The issue of political and institutional liability during the SARS-COV-2 epidemic has been widely debated, both in relation to the role of preparedness before the event and in terms of the appropriateness of the actions implemented to address the specific situation. One crucial aspect of the discourse on liability, which soon emerged within the collective debate, relates to the conduct of physicians: there has been no shortage of legal suits brought in respect of alleged cases of negligence in relation to COVID-19. Doctors, like all healthcare workers, are those on the front line who have had to deal with the organisational and resource-related shortcomings of healthcare systems, who have had to work at a frantic pace and under stressful conditions, sometimes even without appropriate protective equipment. They have also had to take action in a situation characterised by significant scientific uncertainty due to the substantial novelty of the virus: as highlighted by the Italian National Bioethics Committee: "in fighting the COVID-19 infection, we are operating without consolidated guidelines or good clinical practices, recognised by the scientific community, therapeutic evidence" [1].

In addition, it is a fact that some medical professionals have had to make extremely difficult decisions about the allocation of life-saving resources for patients requiring intensive care treatment, in situations where there is an imbalance between need and availability [2].

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In such a scenario, the "irreducible core of the right to health" is inevitably compromised by the emergency situation and it can become difficult to ensure equal treatment for everyone. A catastrophic event can stress health systems to varying degrees: it may allow the system to continue providing healthcare in the normal way or it may be excessive in relation to the organisational and resource capacities and cause changes to the level of care considered to be standard. In this latter case, there can be a "substantial change in normal healthcare operations and in the level of care that it is possible to deliver (…) justified by specific circumstances and (…) formally declared by a national government in recognition of the fact that crisis operations will be in force for a prolonged period" [3]. To avoid situations where such a change occurs at the mercy of chance, it is essential to have specific preparedness plans in place, based on shared ethical values. The document "Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations" drafted in the United States by the Institute of Medicine (IOM) lists certain key elements that should underpin action plans modifying the normal standard in crisis situations, including i) a strong ethical grounding that enables a process deemed equitable based on its transparency, consistency, proportionality, and accountability; ii) significant integrated and ongoing involvement by all stakeholders (such as, the public, at-risk populations, healthcare providers), where appropriate to promote trust in and transparency of the process and demarcate roles and responsibilities; and iii) careful consideration and possibly resolution of legal issues identified as emerging, including possible liability considerations [3].

This work will analyse, with reference to the Italian legal system, the issue of decisions made by healthcare workers required to choose those individuals who will get treatment in the exceptional case that there are not sufficient resources for everyone. We will analyse the implications of these decision-making criteria in an extraordinary context and will describe the approach applied by Italy to propose criteria for triaging intensive care treatment. We will discuss certain problems in the light of the legal implications of a decision that, in a case such as this, may result in a patient being excluded from access to intensive care treatment.

ETHICAL PRINCIPLES AND CRITERIA FOR SELECTING BETWEEN *ORDINARY* AND *EXTRAORDINARY*

The allocation of limited resources such as organs, drugs or technologies represents a persistent challenge for healthcare systems from both a regulatory and an ethical standpoint. The distribution choices are made in terms of "macro-allocation" – the specific area of competence of health policy – and "micro-allocation" – the scope of action of healthcare facilities and individual healthcare professionals. These choices always imply consideration of economic, political and ethical variables. The issue, which raises the central question of how to allocate the good in question fairly [4], has prompted discussions on both theoretical and operational levels. The general debate on models for allocation of resources – which involves the relationship between principles and the statement of empirical criteria – is complex and multifaceted and is beyond the scope of this work, which will focus on allocation criteria in the *extraordinary* healthcare context represented by the COVID-19 epidemic.

In this scenario, we have been confronted with an important ethical dilemma in terms of the triage of intensive care treatment. As was immediately apparent, there was no internationally shared ethical thinking or useful tools to deal with a complex decision on rationing of life-saving resources. In the debate that has developed, frequent reference has been made to shared ethical values and principles, but that reference alone is not sufficient: principles such as distributive justice (fair allocation of resources), equality or self-determination need to be reflected in operational criteria that are justified and verified, such as practical tools to guide decision-making. Over the course of the COVID-19 pandemic, numerous guides for professionals intended to regulate intensive care triage have been disseminated. However, subsequently, the criteria proposed have proven to be inconsistent, vague or even contrary to shared international principles or local legislative systems [5].

At the European level, the debate has developed not only on to general ethical criteria underlying choices [6] or on the organization of health systems [7, 8] but also, in individual states, in relation to the implications arising from their specific regulatory frameworks [9, 10].

Controversies and contrasts are reported in the absence of national guidelines or coordination [11]. It is interesting to note that the lack of an authoritative guide has been widely experienced despite the proliferation of documents and recommendations disseminated by authoritative sources [12]. Procedural queries about who should be involved in making decisions or what a fair or equitable allocation of scarce resources would look like are still ongoing [13]. On the basis of the existing literature and proposals developed during other pandemics, certain authors have noted that many approaches agree on four key values: i) maximising benefits; ii) treating people equally; iii) promoting and rewarding those with intrinsic value; and iv) giving priority to those who are worst off. However, as has been pointed out, these values in themselves do not constitute sufficient tool for directing the actions of doctors and guidelines should be provided at a higher level of authority. The authors have also analysed these guiding values in terms of the specific situation of the Sars-Cov-2 pandemic, providing recommendations to adjust their application. For example, they have noted that although the criterion of 'causal selection' should not be used, it could be permitted in the case of two patients with the same prognosis [14].

To the general question as to whether, during an *extraordinary* public health event, medical ethics are suspended and values and principles different from the *ordinary* apply, the response is that, under extraordinary conditions, there is no change to the reference ethical criteria of the medical profession or to the principles of a State or to fundamental human rights as these are recognised by international documents, such as the Eu-

ropean Convention on Human Rights (ECHR) [15]. The ethical principles to which healthcare professionals are required to adhere and that are laid down in the codes of ethics remain the same: respect for autonomy, beneficence, non maleficence ("first do not harm") and the principle of justice continue to guide the activities of medical professionals.

The issue of the legitimacy of allocation decisions also represents a question of primary importance in relation to the risks to which doctors are exposed. The legitimacy of interrupting mechanical ventilation treatment where it is clinically indicated will in fact also depend on the details of the triage procedure applied and who it was applied by. As has been clearly noted, there is an important legal difference between: (1) a procedure adopted by a government, and (2) a procedure suggested by a scientific society or committee of medical ethics experts. This is not because the information provided in the second case is intrinsically inaccurate, but rather because there is an issue of authoritativeness to be considered [5].

THE COVID-19 EPIDEMIC AND INTENSIVE CARE TRIAGE

When we refer to *triage*, we mean "a healthcare practice aimed at identifying care priorities by assessing the clinical condition of patients and the risk that they might get worse, so as to ensure that users are treated and to determine the order for access to treatment". It is important to note that this definition, provided in the "National guidelines on *intra-hospital triage"* from the Italian Ministry for Health [16] indicates that the goal of triage is exclusively to ensure the best possible management of the order for access to treatment and not to make a decision as to who can and cannot access such treatment, assuming that all patients requiring care will be treated. Other common triage contexts in contemporary medical practice are those relating to access to intensive care and to waiting lists for organ transplants. In these latter cases, considering the limited quantities of specific resources, whether intensive care beds or organs, it cannot be ruled out that some patients may not be able to access treatment. The fundamental issue in triage is therefore the following: not all those who need a particular form of healthcare will be able to access it immediately and unconditionally.

During the initial months of the SARS-COV-2 epidemic, doctors found themselves alone in having to make difficult decisions about "who to admit and who not to admit", so much so that in Europe, some scientific societies took urgent action through ad hoc recommendations for professionals [17]. Among the first was, in Italy, the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI), which published "Clinical ethics recommendations for admission to and suspension of intensive care, under exceptional conditions of imbalance between needs and available resources" on 6 March 2020 [18]. This document has generated fierce debate because of the problematic nature of some of its content, in particular the indication of the non-clinical, advance criterion of age for triage selection. Against this background, for example, the *European Alzheimer's Association* has highlighted the need for decisions about access to or denial of intensive care services to be based solely on an assessment of the individual prognosis of the patient and not "on the fact that the patient has a specific diagnosis (such as dementia)" or on non-medical criteria or characteristics "such as age, place of residence, gender, gender identity, ethnic affiliation or marital or parental status" or value judgements "such as probable life expectancy, presumed quality of life, potential future contribution to society, etc." [19].

There has been almost unanimous agreement that decisions on the allocation of resources must be transparent: the public must be able to understand the purpose of any triage protocol and how it will be applied and to trust that it will be applied consistently [20].

It is also valuable to consider how the conduct required of professionals has been codified: the question arises as to whether the appropriate instrument to regulate a problem of allocation of scarce resources can be scientific in nature, for example taking the form of a guideline for professionals, or whether it should be political and institutional, for example falling within the scope of a national pandemic preparedness plan. The latter would seem to be the most appropriate way of guaranteeing better assurance about the chosen allocation criteria, given that it involves political institutions (e.g., Ministry, regions) that are authorised to impose organisational rules in relation to healthcare.

During the second wave of the pandemic, and specifically on 30 October 2020, the SIAARTI and the National Federation of Associations of Surgeons and Dentists (FNOMCeO) made public a new document that made a strong appeal to professional ethics [21], which stated that: "If the imbalance between needs and available resources persists, precedence for access to intensive care will be given to those who will be able to obtain a concrete, acceptable and lasting benefit from that care. For this purpose, strict, explicit, consistent and integrated criteria must be applied, assessed on a case-by-case basis, such as: severity of the clinical symptoms, comorbidities, previous functional status, impact of the potential side effects of intensive treatment on the individual, knowledge of dispositions for advance care planning and biological age, which latter criterion may never take precedence". At the same time, those societies called for an addition to the code of ethics for doctors on the issue of tragic choices in the case of extraordinary or exceptional episodes. The document states that the individual right to equal access to healthcare must remain the cornerstone of the protection that the State is required to provide and that, therefore, "the selective use of criteria that legitimise differentiated treatment modalities should be considered only where absolutely necessary". Indeed, the use of such criteria may not be understood as a denial of the non-negotiable principle of the equal value of every human being.

In December 2020, the National Centre for Clinical Excellence, Quality and Safety of Care (CNEC) within the Italian National Institute of Health opened a public consultation on a document entitled "Decisions for

intensive care in cases where there is a disproportion between care needs and available resources during the COVID-19 pandemic", drafted by the SIAARTI and the Italian Society of Legal and Insurance Medicine (SIMLA). The final version, following the consultation, was published on 7 January 2021 in a section of the National Guidelines System dedicated to the COVID-19 epidemic.

SIAARTI-SIMLA DOCUMENT: A COMPARATIVE ASSESSMENT

The objective of the document, which was published in the section "Good Practices in the National Guidelines System", produced by the SIAARTI and the SIMLA, is to offer healthcare professionals "a suitable tool to enable them to respond appropriately to the current emergency situation due to the COVID-19 pandemic, potentially affecting the health of all citizens, if there is an imbalance between demand for healthcare and available resources, with particular reference to intensive care" [22].

According to that document, in the case of a disproportion between patient needs and medical resources, *triage* must be carried out, namely "a comparative assessment of the overall condition of the patients, not to determine whose condition is more serious or who has greater need of care, but to establish who is more likely (or less likely) to overcome the current critical situation with the support of that intensive care with a reasonable life expectancy outside Intensive Care: and thus short-term survival (several months) following discharge from hospital". The document excludes any assessment criterion associated with chronology (the order of arrival of patients), random choice (drawing of lots) or simple personal data, which would not be "in itself a criterion for establishing which patients may benefit most from intensive care". In a scenario where the "*saturation of healthcare resources making it impossible to guarantee that all sick people can receive the treatment indicated*" the following parameters are indicated for the overall assessment of the individual, to determine whether that individual is likely to overcome the critical condition with intensive care support: number and type of comorbidities; previous functional status and degree of fragility; severity of current clinical symptoms; and presumable impact of intensive treatments, especially considering the age of the patient.

Although the document was produced according to the specific procedure laid down in the "guideline recommendations" published in accordance with Article 5(3) of Law No 24 of 8 March 2017 – and drafted by scientific societies entered on the list created and regulated by a decree from the Ministry for Health in accordance with Article 5(1) of that law –, it has been included in the section on "Good Practices in the National Guidelines System".

It should be noted on this point that the good practices mentioned in Article 5 of the abovementioned law are the good clinical and care practices with which healthcare professionals – subject to the specific aspects of the case concerned – must comply "in the absence of the abovementioned recommendations" (Article 5(1)).

This first ambiguity requires a clarification – for the purposes of the legal framework of the document – of the general distinction between "guidelines" and "good practices". It is in fact because the specific case falls within the regulatory framework that there is any legal significance to the document, considering also the scope of decision-making autonomy of the healthcare professional concerned in terms of permitting, excluding or interrupting intensive care treatment.

In the Italian legal system – which is the reference framework for this work –, guidelines, unlike protocols, do not indicate an analytical succession of obligations, but, rather, express general directives, instructions or guidance [23]. Those recommendations (Article 5(1) of Law No 24 of 8 March 2017), created following a systematic review of the scientific literature, offer healthcare professionals an important support tool in clinical diagnostic, prognostic and therapeutic processes [24]. In this situation, dominated by informative contributions, there is scope for decision-making autonomy for doctors, on the basis of the words in the law "subject to the specific aspects of the case concerned" (Article 5(1) of Law No 24 of 8 March 2017). It is the professional operator who selects the behaviour that is appropriate on each occasion, and in the case of a court dispute, that behaviour will be evaluated by the technical experts and the judge. It can thus happen that "although the guidelines indicate a given strategy in relation to the condition being treated", the unique aspects of the clinical case suggest a need "to deviate from the ordinary course of action" [25].

The legal doctrine makes a distinction between these guidelines – which refer to clinical activity – and guidelines of a predominantly organisational nature, drafted not by scientific societies but, rather, by public institutions that sometimes report these in the Official Gazette or in official regional gazettes [24]. Examples we can cite here include the guidelines on the medical emergency No 1/1996, published in the Official Gazette, which are the result of an agreement between the Government and the regions.

In terms of "good practices" – to which the SIAARTI-SIMLA document also relates –Law No 24 of 8 March 2017 makes a distinction between *good safety practices* and *good clinical and care practices*.

The former relate to the safety of care and have stricter content and are more binding (for example, this covers the rule about pre-operative hand washing) [24]. The others, although not being subject to the drafting and publication procedure envisaged by the law for guidelines, are relevant in the absence of the latter, and have the same preventive, diagnostic, therapeutic, palliative, rehabilitative and forensic purposes (Article 5(1) of the Law of 8 March 2017). It can be said that such good practices, which have the same purpose as guidelines, are of the same type as guidelines. They are alike in that they both stem from scientific evidence [24].

In the light of the reconstructed and general findings, we can see the elements of ambiguity in the SIIARTI-SIMLA document which expose its somewhat hybrid nature.

In principle, it is a "guidelines" in accordance with Article 5 of Law No 24 of 8 March 2017, in terms of form and method of legal enacting. In terms of resource distribution, it is also organisational, although it does not involve the public institutions with jurisdiction in this area. Lastly, it is introduced as "good practice" with reference to the *nomen iuris* of the public web section in which it is published; it also could act as good safety practices that could further reduce the decision-making autonomy of healthcare professionals.

Hence the question as to whether the "good practices" for triage activities in the emergency situations described, produced in line with the requirements laid down in Law No 24 of 8 March 2017, can be classified as "guideline recommendations" or in any case as "good clinical and care practices" in accordance with Article 5 of Law No 24 of 8 March 2017.

It is well known that due compliance – by health professionals – with both assumes considerable importance in civil and criminal law, as a result of legislative reform.

In terms of the former, the guidelines or, in their absence, the good clinical and care practices – which are binding subject to the specific of the case – offer a parameter for assessment of the conduct of health professionals, including in the judicial determination of compensation for damages (Article 7(3) of Law No 24 of 8 March 2017) and in general of the extent to which the action performed is not in conformity with the expected action.

The conduct of the medical practitioner is at the heart of civil law discussion on medical services. It is on that behaviour that the specific discipline of medical liability can be based. For reasons of qualified social contact, this does not rise to the level of contractual liability, but neither can it be viewed in the same terms as an act of non-contractual negligence [26].

In relation to the scenario of possible disputes caused by COVID-19, the various foreseeable initiatives envisaged by the doctrine include cases brought against health professionals for imprudent, negligent or inexpert conduct and, with regard to the issue of the limited number of intensive care beds, cases brought against healthcare facilities called to account for organisational and management problems and deficiencies [27].

In terms of criminal law – as we know – the Italian law provides for a limitation on punishability due to compliance with guidelines or, if no such guidelines exist, good clinical and care practices.

THE CASE IN POINT, THE CRITERION OF GREATEST LIKELIHOOD OF SURVIVAL

The possibility of tying the "good practices" in question back to one or other "source" – and in particular to the guidelines or good practices mentioned in Article 5 of Law No 24 of 8 March 2017 – requires a preliminary clarification of the specific aspects of the case.

Let us imagine the case of two patients who both require intensive care treatment on the basis of the guidelines in use on the general conditions for access to such treatment but where, in an exceptional context where available resources are scarce, only one intensive care bed is available. A comparative evaluation of the overall condition of the two patients would be initiated, and priority would be given to the patient who is more likely to be able to overcome the critical condition and has a reasonable life expectancy outside the intensive care unit (short-term survival following discharge from hospital) [22]. However, this would disadvantage the patient less likely to survive and with shorter reasonable life expectancy.

This is a gradually developing case where the final segment is – dramatically – devastating.

To clarify the scope of the criterion being reviewed – greater likelihood of survival – we need to start with the general criteria for admission of patients to resuscitation and intensive care widely applicable in the period prior to the release of the document being analysed here [28].

Particular focus should be given to the criterion of clinical appropriateness, based on three elements: a) reversibility of the acute pathological condition; b) reasonable likelihood of benefits expected from intensive treatment, including in relation to the cost borne by the patient for that treatment; c) reasonable expectation that the critical condition can be overcome [28]. An order of priority is established according to a scale starting with maximum expected benefit (priority 1) and running to minimum or nil expected benefit (priority 4). With regard to geriatric patients, it should be noted that "chronological age in itself is not a criterion to decide appropriateness of intensive care, because it is not always correlated with biological age", and that "evaluation of the clinical appropriateness of intensive care must not in any case be influenced by the negative image that society has of old age" [28].

In the light of these indications, dating from 2003, we can state that, in an exceptional situation involving scarcity of resources, the criterion of the greatest likelihood of survival, viewed in terms of resource allocation, can be considered a logical consequence and development of the criterion – applied under normal resource conditions – of the reasonable likelihood of an expected benefit from intensive care treatment.

The SIAARTI-SIMLA document from 13 January 2021 states that triage represents an independent, subsequent process in relation to the evaluation of the appropriateness and proportionality of intensive care treatment, with appropriateness and proportionality of treatment being the ethical and professional prerequisite for any treatment. The Italian document is not a closed decision-making system: the authors explicitly exclude the possibility that "the outcome of triage for intensive care treatment could be dependent on the score resulting from the use of any instrument or algorithm, even if proposed or used in other countries" [22]. The only tool indicated as appropriate for guiding the triage process is the overall clinical evaluation, performed by the medical/healthcare team on the basis of recognised prognostic indicators. But the dilemma that can arise in cases where short-term survival estimated in several individuals is equivalent or in any situations where prognosis is uncertain – namely in those phases defined by some authors as "bottlenecks"

– seems to remain vague. It constitutes an element of incompleteness, perhaps to be resolved in subsequent documents, which has also been highlighted in relation to similar international guidelines [17].

The SIIARTI-SIMLA document states: "the increase in demand for healthcare (for three admission levels: standard, semi-intensive, intensive) induced by situations such as those caused by the pandemic, does not compromise the necessary adherence, in protecting health, to the constitutional and founding principles of the Italian National Health Service, or to ethical principles and in particular those of universality and equality (non-discrimination), solidarity and self-determination" [22].

A selection criterion based on these principles has been identified: priority is given to the patient who is more likely "to overcome the current critical situation with the support of that intensive care with a reasonable life expectancy outside Intensive Care: and thus short-term survival (several months) following discharge from hospital" [22]. The doctor must therefore carry out a clinical evaluation and determine an order of priority on the basis of the criterion stated, informing the sick person and any legal representatives and family members of the outcome of triage and an estimate of the likelihood of recovery in the case of admission to intensive care.

The document does not indicate practical decision-making criteria in cases where the prognosis is the same and does not provide any information about how to interrupt or reassign mechanical ventilation treatment if this is required.

The comparative assessment – referred to in the document discussed in these pages – to exclude a patient in critical condition from intensive care treatment is destined to create a conflict between perspectives, cultural discourse, scientific knowledge and social systems. It is in this scenario that ethics, economy and law may contend for the power – each from its own sovereign and unconditional point of view – to establish principles and parameters for evaluation that provide decisive guidance for decision-making by healthcare professionals.

It is only natural that each system, being operationally closed, releases *from within* independent criteria for judging the actual facts, using its specific language and operations.

This is not a question of determining a chronological order of priority, a "before" and an "after", but rather – in the emergency situation described – a *criterion*, in the final analysis, for *exclusion*. This is an "after" that can be fatal for the patient to the point of a tragic "never".

Thus, in economic terms, the clinical determination as to greater or lesser likelihood of survival leads to the conclusion, from that perspective, that the intensive care assigned to one or other patient is a more usefully employed resource. This is a manifestation of the criterion of distributive justice [29]. In other words, in terms of resource allocation, the criterion of greater likelihood of survival is translated into and reflected in the criterion – given certain specific clinical conditions – of the most efficient use of intensive care.

It is worth noting that in some legal systems (such as in Australia, New Zealand and South Africa) [17], for the situation described, emphasis is placed on the category of health professions who, especially in this historical period of pandemic, are a resource that is clearly considered indispensable for the system.

From another perspective, we should note that the criterion of greater likelihood of survival may imply a statistical fact, namely a tendency to exclude the most vulnerable patients (elderly and disabled) from access to intensive care treatment.

In Germany it has been asserted by the President of the German Patient Protection Foundation (Deutsche Stiftung Patientenschutz) that this is a reversal of ethical principles, which ultimately penalises the patients most at risk [30].

In this situation, dominated by contrasts and differences, positions in favour of a political and legislative solution to the problem are emerging. Issues have arisen that, on the one hand, because they involve fundamental human rights, call for political intervention, and that, on the other, trespass into the operational realm of the physicians" code of ethics [31].

GUIDING CRITERIA AND LEGAL ASSESSMENT

The legal assessment of the question requires discussion on the final segment of the case described. It could be said – by way of an explanatory observation – that this patient, excluded following the comparative assessment under extraordinary conditions, would have had access to intensive care treatment in a normal situation where there is a balance of available resources. This is because that patient is the holder of a right – the right to intensive care treatment – that the health professional would have effectively provided, on the basis of the criterion of clinical appropriateness.

If that right to intensive care is restricted or even denied for a person in critical condition – and assuming that patient dies – this scenario could potentially be grounds for civil and criminal legal action.

It is necessary – as a general criterion – to assume the alleged proper conduct (in this case, the assignment of the intensive care unit) and then to determine, according to the counterfactual principle, whether that conduct would have had a positive effect on the survival of the patient [32].

A new comparative assessment can then be carried out by a technical expert comparing the clinical condition of the patient excluded and the patient admitted, and referring where appropriate to similar cases where another patient with similar critical aspects survived and then recovered from the illness due to intensive care treatment.

In that context, with its many uncertainties, the most pressing problem now is to find a guiding criterion that is *legally useful*, a criterion that enables the medical professionals involved in *triage* to calculate the legal consequences of their actions. In other words the risk-reducing behaviour of the professional must also be, in the eyes of *third parties* (interpreter and decision-maker), the behaviour that is legally appropriate.

In the absence of a law, the right – as in so many other

cases – remains uncertain and is destined to manifested *ex post*. It will be the judge who interprets Law No 24 of 8 March 2017 and examines the legal relevance of the document, in this case the SIAARTI-SIMLA document, applying his or her own decision-making criterion to what happens in reality.

We cannot exclude the possibility that a judge, not being convinced of the binding nature of the "good practices" in question, might review the legal framework in order to extract *the value content beyond the law* [33] as values that underpin and drive the legal system, giving precedence in such emergency situations, for example, to the principle of equality that could point, in cases where critical condition and severity of danger to life are the same, towards the different, albeit relativised, criterion [31] of "first come, first served".

This is a perspective – the most rigid – that ties in with a line of argument that can be articulated in these terms.

The "good practices" outlined in the SIAARTI-SIMLA document, do not share the same purpose as guidelines and good clinical and care practices in the technical sense, because they are not intended for preventive, diagnostic, therapeutic, palliative, rehabilitative and forensic purposes. In other words, the behaviours referred to or implied in Article 5(1) of Law No 24 of 8 March 2017 do not have the weight – human, ethical or legal – to exclude a patient in critical condition from access to intensive care treatment.

It could therefore be said that the decision, based on a comparative assessment, to deny intensive care treatment to a patient in critical condition – and thus compromise that patient's right to treatment – is conduct that does not fall within the regulatory framework laid down in Article 5(1) of Law No 24 of 8 March 2017.

From that point of view, the document, which does not fall under a regulatory paradigm, would be irrelevant and ineffective in legal terms [34]. Substantial encroachment into matters of political and deontological autonomy would reduce the "good practices" in question to "pseudo-guidelines" [31].

However, it should be noted that this is still a matter of criteria intended to guide the actions of physicians – the only guidelines existing in Italy in this sphere, which have been developed using more streamlined procedures and published in line with the legal provisions – which, because of their form and the formal nature of their presentation, are undoubtedly blamelessly relied on by the people for whom they are intended. In this context, because of the varying interpretative options, two paths can be envisaged here, suggested also by common sense.

a) In questioning the legal framework, the judge will apply the same criteria indicated by the "good practices" in question, either because he or she considers them binding on the basis of Article 1 (which also refers to "the appropriate use of resources") and Article 5 of Law No 24 of 8 March 2017, following logically from the general criteria for admission of patients to resuscitation and intensive care contained in those guidelines, or because he or she infers these criteria from the legal system by some other means (analogy, general principles, the Constitution); b) In questioning the legal framework, the judge will apply criteria different from those indicated in the "good practices" in question. In this case anyway, in any potential claim for damages that suggests a case for damages for loss of opportunity, the judge will take into consideration behaviour based on observance of those "good practices" and resulting from blameless reliance on them (Article 7(3) of Law No 24 of 8 March 2017).

CONCLUSIONS

As noted above, exceptional decisions on the allocation of life-saving resources, affecting the right of access to care, involving various areas of competence and potentially implying non-conventional actions (such as non-application or suspension of mechanical ventilation treatment), exceed the scope of autonomous decision-making of professionals and require a shared theoretical and procedural definition at multiple levels of society.

It is important to emphasise that the decision to exclude a patient in critical condition from access to intensive care treatment should be made as a last resort as part of a logic imposed out of necessity by external events. It could also be a condition of necessity generated by a situation where such access to care is impossible, because of political and economic responsibilities in the local and national management of resources intended for public health. These facts are a matter of political and institutional responsibility in adopting all strategies intended to prevent problems and serious deficiencies in available health resources.

We can discuss the clinical or non-clinical nature of the selection criterion for intensive care in a situation of imbalance between demand for healthcare and available resources, but we cannot doubt the fact that *the reasons for an – uncomfortable – need for a criterion* fall outside the purview of medicine and originate from afar.

We can grasp the underlying sense of the initiatives of the scientific societies in Italy and elsewhere intended to indicate solutions to the problem. This is to put pressure on institutions, to promote a sort of communication with other systems, to reclaim the value of legal certainty under the banner of the law, which is manifested not *ex post* but, rather, *ex ante*.

It is not surprising that the debate that has opened up on the issue is part of a conflict of discourses representing different areas of society, each with an underlying communication strategy, intended to persuade, impact, shake up the many sensitivities of the audience ignited by the pandemic.

Author's contribution statement

FG, CP, LR: conceptualization and argumentation of the paper. FG: legal assessment. FG, LR: drafting the original article.

Conflict of interest statement

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