ISSN 1809-1628
REVISTA MULTIDISCIPLINAR
HUMANIDADES E TECNOLOGIAS (FINOM)
FACULDADE DO NOROESTE DE MINAS

RATIONING SCARCE TREATMENTS TO PATIENTS DURING THE COVID-19: SHORT ETHICAL-LEGAL REMARKS ON THE SWISS AND ITALIAN CASES

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Abstract: This paper aims at critically discussing ethical questions concerning the identification and justification of criteria useful to handle the extraordinary situation hospitals have been facing since the COVID-19 emergency was declared. In order to achieve this goal, the paper compares two guidelines released by the Italian and Swiss medical associations as they represent two different approaches to the problem of rationing and allocating resources when they are very scarce.

Keywords: Resource allocation. Rationing by age. Principle of justice. Ethical guidelines.

1. Introduction

The COVID-19 emergency has brought to the fore a crucial bioethical question: how can the principle of justice be best implemented in health care systems? As is well-known, indeed, within the bioethical reflection the principle of justice has a multifaceted meaning and risks not being adequately implemented because of the different, sometimes competing, definitions as well as the difficulty of elaborating on an all-embracing theory capturing the diverse concepts. The minimal meaning of justice which states that equals must be treated equally, and unequals must be treated unequally, traditionally ascribed to Aristotle, has proven hard to apply to a situation where the determining characteristic that COVID-19 patients have in common is being infected by the virus. As a matter of fact, this pandemic has shown how unequal our Western countries are. On one hand, for the poorest of the poor it has been difficult to stay safe as not only has been there insufficient equipment, like masks and gloves to be distributed to everyone, but these persons have no place to go and continue living on the street in dangerous conditions. On the other hand, specific vulnerable categories like the elderly have been systematically and intentionally discriminated against in relation to their access to intensive care treatments based on a misleading way of applying rationing, that is, the policy of limiting access to intensive care units (ICU) when there are not enough resources for everyone.

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Although it is undeniable that current public policies of health protection and health care entail some form and level of rationing, the problem during the COVID-19 emergency is that the process of rationing has relied, in many cases, as in Italy, mainly on one sole criterion: age. This means that rationing by age has been the main guiding principle in setting priorities among allocation criteria during the epidemic. In this specific situation, it could be argued, structuring priorities is difficult, and time is short. Thus, the need for a clearly intelligible strategy is of the utmost importance. If it is true that an extraordinary and unexpected situation may call for quick decisions, fairness and transparency in the selection of criteria should remain, nonetheless, central aspects of the decision-making process in order to avoid ending in criteria and procedures that fall below the cutoff line of the priority list without a due process of analysis. In fact, whereas fairness is usually seen as a fundamental component underpinning responsible systems, transparency in the decision-making process is actually one major tool to enable accountability once this pandemic is over, and it is time for responsibility.

Based on the previous considerations, in what follows I will discuss the procedural strategies for setting priorities used in two different countries, namely Italy and Switzerland. In comparing the *Clinical ethics recommendations for the allocation of intensive care treatments in exceptional, resource-limited circumstances* released by the SIAARTI (Italian Society Anesthesiology, Analgesia, Resuscitation and Intensive Care)[2] with the Swiss guidelines *COVID-19 pandemic: triage for intensive-care treatment under resource scarcity* by the SAMWASSM (Swiss Academy of Medical Sciences)[3], this paper aims at critically discussing ethical questions concerning the identification and justification of criteria useful to handle the extraordinary situation hospitals have been facing since this pandemic was declared. The Italian and Swiss guidelines represent a good example of two different approaches, one being more balanced than the other. Differences in these approaches also depend on the way these recommendations have been written and structured. Indeed, clarity and proper use of language usually contribute to avoiding fundamental misunderstandings about how to act in given circumstances, misunderstandings that can have even more serious consequences in the long term than the pandemic itself. Both language and structure are important in order to avoid ambiguity and vagueness. Proper language as well as a well-structured thought that enables the reader to go from general statements to more specific and directly applicable rules are a

[2] Available at the following link http://www.siaarti.it/News/COVID19%20-%20documenti%20SIAARTI.aspx
[3] Available at the following link https://www.samw.ch/en/Ethics/Topics-A-to-Z/Intensive-care-medicine.html

fundamental feature for succeeding in communication, in general, but even more when time is short.

We can assume that availability of sufficient technological devices, specifically of mechanical ventilators would have helped in this crisis. However, to address this topic requires a broader reflection on how allocation decisions have been made by contemporary health policies, in particular in Western countries. We should therefore analyze reasons for rising costs like insurance costs, new technologies, deteriorating health conditions, and longer life expectancy. These are relevant issues that require an in-depth analysis that is beyond the scope of this paper. My intention here is to stress that focusing on how to structure clear priorities is a prerequisite for a fair and transparent allocation of resources, including technological devices, in emergencies as well in normal situations. As I will point out in the following paragraphs, in many, albeit not all, Italian intensive care units rationing by age has long been a surreptitious criterion of access. And this pandemic has highlighted its use.

2. The Swiss and the Italian guidelines on the COVID-19 pandemic: a comparison concerning rationing scarce treatments to patients

The process of rationing scarce resources may be based on different bioethical arguments and criteria as literature on the topic shows.[4] These criteria may range from age, constituency factors, progress of science, prospect of success, medical utility, mechanisms of chance and queuing, social utility, and triage.[5] Some of these are medical criteria whereas others are not.

In order to remain focused on the comparison between the Swiss and Italian guidelines, I will take into account only those criteria mentioned in the documents: age, chance and queuing, prospect of success, medical utility, social utility, and triage. The aim is to show the difference in balancing these standards, and the arguments used to support one or the other choice.

I will first analyze the single documents and then draw some conclusions. Let us start with the Italian ethics recommendations by the SIAARTI.

[4] Beauchamp T. L. and Childress J. F., *Principles of Biomedical Ethics*, Oxford University Press, 2013.
[5] *Ibidem*, p. 284 ff.

When these recommendations were released, they immediately made the headlines and a heated ethical debate split the country down the middle because age appears to be the main guiding principle selected by the Association. About one month after these recommendations were made public, the Italian Committee for Bioethics (CNB) published an opinion entitled *Covid 19: clinical decision-making in conditions of resource shortage and the "pandemic emergency triage" criterion*[6]. In this opinion, there is no explicit reference to the SIAARTI's recommendations, but there is a clear stance on adoption of the clinical criterion as the only justifiable one in the current situation and a refusal of any other criterion, including age, when it comes to allocation of scarce resources. Thus, the CNB frames the bioethical debate within the constitutional framework by recalling those constitutional principles that should guide the bioethical reflection in this situation[7]. This contextualization is essential to not lose sight of principles and rules already existing and useful to guide any decision-making process regarding prioritization. However, the SIAARTI's recommendations fails to do so.

But let us turn to the analysis of these ethical recommendations. After emphasizing that «the application of rationing criteria is justifiable only after all the subjects involved (…) and all possible efforts have been made to increase the availability of resources existing (…) and after assessing any possibility of patient transfers to centers with greater availability of resources»[8], the document clarifies its twofold purpose: 1) to relieve clinicians of part of the responsibility in the decision-making process;[9] 2) to make the allocation criteria for healthcare resources explicit in circumstances of extraordinary scarcity.

The main problem caused by the pandemic is that the infection requires ventilatory support and though the acute phase can last several days, a ventilator may be needed for weeks. Thus, intensive care units were not prepared to host such a large number of patients requiring

[6] See the following link: http://bioetica.governo.it/en/opinions/opinions-responses/covid-19-clinical-decision-making-in-conditions-of-resource-shortage-and-the-pandemic-emergency-triage-criterion/
[7] The document refers to Article 32 (right to health), Article 3 (equality), and Article 2 (fundamental rights).
[8] SIAARTI (2020), *Clinical ethics recommendations for the allocation of intensive care treatments in exceptional, resource-limited circumstances*, p. 4, online availability see footnote 1.
[9] This is a very delicate point that would require an in-depth analysis I cannot provide here. I want to stress however that a first question we should ask is whether it is really possible to relieve clinicians from responsibility. And in order to answer this question we should not forget that in case like pandemic outbreaks clinicians have to act in the best interests of the patient to the extent possible. If this is true, we should not forget that in health emergencies there are some crucial differences in the role of physicians. As Bernard and Katz observe: «physicians'primary ethical responsibility in a public health emergency is the well-being of the public, not the interests of the individual patients. Physicians need to be clear in their own minds about their altered responsibilities, the heightened public scrutiny of their decisions, and the importance of the perception of fairness. In addition, physicians also need to explain to patients both the changes and continuities in their role. Front-line physicians play an important role in conveying to the public health measures are necessary and fair», Bernard Lo and Mitchell H. Katz, *Clinical Decision Making during Public Health Emergencies: Ethical Considerations*, in *Ann Intern Med*, 2005, 143:7, 493-498, at p. 496 ff.

assistance in such a short time. In light of this complex situation, the SIAARTI lists rationing criteria and gives priority on the basis of age. It states that: «An age limit for the admission to the ICU may ultimately need to be set.»[10] It goes on to say: «The underlying principle would be to save limited resources which may become extremely scarce for those who have a much greater probability of survival and life expectancy, in order to maximize the benefits for the largest number of people. In the worst-case scenario of complete saturation of ICU resources, keeping a 'first come, first served' criterion would ultimately result in withholding ICU care by limiting ICU admission for any subsequently presenting patient.» And it adds that: «Together with age, the comorbidities and functional status of any critically ill patient presenting in these exceptional circumstances should carefully be evaluated.[11]»

The way in which criteria have been presented in the document is of concern. In general, the document is written in a very superficial and ambiguous way and as a consequence it does not fulfill its commitment to clarity, neither in the English nor in the Italian version. Ambiguity in language as well as the lack of a structured plan of how to concretely implement general principles into practice is one of the major deficiencies of this document if compared to the Swiss one. Moreover, there is an oversimplification of the justifications given for selecting age as a main criterion. In addition, age seems to be related to other criteria, but what exactly the role of those criteria in combination with age is remains unclear.

Let me say something about oversimplification first. Simplification, as a process to make something easier to understand, is neither good nor bad in itself. However, it becomes a dangerous strategy when it fails to grasp the main negative implications on a given situation and therefore becomes oversimplification. Ethical problems in biomedical matters are, by virtue of their own nature, very complex as they are extremely nuanced, and their oversimplification may result in an oversight of relevant aspects. In the SIAARTI's document, age-based selection as a guiding principle in the decision-making process is linked to the argument that literature calls the 'prospect of success'[12]. The chance of benefit contributes to not wasting resources, and this is one relevant aspect to be taken into account in case of emergencies like the Covid-19 one. To link rationing to age and to argue in favor of it based on the probability of success means to make this a matter of medical utility. If we can agree that medical utility should figure into decisions to allocate resources, we should not forget that need and prospect of success are not the only arguments that have been proposed to justify age as an allocation criterion. Age is

[10] *Ibidem*, p. 5.
[11] *Ibidem.*
[12] Beauchamp T. L. and Childress J. F., 2013, p. 289.

indeed the weakest criterion among those that can guide the decision-making process even in the case of very scarce resources. It is the one that faces the most problematic challenges as it is the one that risks perpetuating injustice by stereotyping patients, in particular the elderly. We cannot overlook that sector specific ethical decisions «must be shown to be compatible with more broadly based ethical principles if they are to be ethically defensible.»[13] In other words, decisions based on ethical principles in the biomedical field, albeit concerning a special field, cannot be totally detached from the general ethical-legal context, in fact, as Peter Singer reminds us, «ethical conduct is acceptable from a point of view that is somehow universal.»[14] In light of these considerations, we cannot overlook how age is conceived in legal terms today as regards its relevance for equal distribution of benefits.

In the European Charter of fundamental rights as well as in many other legally binding documents like Conventions and national Constitutions in the European context, age is among those features that ought not to be taken into account for distribution of benefits. Indeed, any form of discrimination based on age is forbidden[15]. Age like many other categories, such as skin color, gender, personal status etc. listed in legal rules cannot count to make an individual a person in constitutional terms. This achievement is the result of a long historical process that has redefined equality. It is no longer based on ontological references, which for centuries dictated which groups were beneficiaries and which groups were excluded. In this perspective, equality is no longer a fact, a descriptive concept, justified upon assertions of facts, as was the case for the theories of important thinkers like Hobbes, Locke and prior to them Aristotle. Today, in the European legal framework, based on fundamental rights, equality is a normative concept, a basic ethical principle. It does not state that individuals are de facto equal, it dictates that as individuals are de facto different they have to be treated equally at the legal level.[16] This paradigmatic change is also recognizable in the separation of the concept of person (normative concept) from that of individual (descriptive concept). As individuals we are all different, as persons we are all equal at the legal level. This is the outcome of the process of constitutionalization of the person as Stefano Rodotà has explained on different occasions.[17]

[13] Peter Singer refers this sentence to 'self-interested acts', but I think we can also extend this statement to the use of principles in specific sectors like biomediciine. Singer P., *Practical Ethics*, 2nd edition, Cambridge University Press, Cambridge, 1993, p. 10.
[14] *Ibidem*, p. 11.
[15] As stated in Article 21 of the European Charter of Fundamental Rights and in Article 14 of the European Convention on Human Rights.
[16] Ferrajoli L., *Principia Juris*, Laterza, Roma-Bari, 2007.
[17] Rodotà S., *Il diritto di avere diritti*, Laterza, Roma-Bari, 2012.

The second comment on the prioritization of criteria concerns the statement that «a much greater probability of survival and life expectancy» is the aim «in order to maximize the benefits for the largest number of people.» This last argument is based on a utilitarian strategy intended to achieve maximal benefit to patients and society. The problem is that the majority of the patients requiring treatment in intensive care units range from old to very old. And these also represent a large portion of our population today. Thus, trying to benefit the largest number of people overall by adopting the age-based rationing could be counterproductive as the category with the greatest quantity of individuals would be at a disadvantage.

A third comment refers to the 'first come first served' argument mentioned, which belongs to an impersonal mechanism that literature refers to as chance and queuing. These procedures carry a great potential for injustice in case they become the only guiding criterion. As Beauchamp and Childress observe: «Although admission to the ICU establishes a presumption in favor of continued treatment, it does not give a person an absolute claim.»[18]

And my last comment on the SIAARTI's document points to the statement that clinical criteria (comorbidities and functional status) should be taken into account together with age. But age again seems to be the determining factor in the decision-making process.

Instead, I argue that the clinical criterion should represent the main guiding principle, albeit not the exclusive one, in the process of developing and using criteria for prioritization (triage). Indeed, it is by means of the clinical criterion that we can determine whether a person's illness is included as a case in an outbreak investigation and also evaluate need and prospect of success (medical utility). Age can be an indicator of the probability of surviving and a factor in the prospect of success, and it can be included in the evaluation if it contributes to the likelihood of success. It should not, however, be the main selection criterion in the hierarchy of prioritization because in emergency cases, such as this pandemic, triage may need to be adapted to include nonmedical considerations as well as medical criteria. I am referring in particular to social utility. This is the case when the decision has to be taken to give priority to individuals who have a crucial role in contributing to limit the pandemic. Nurses and physicians belong to this category. If the adopted guiding criterion is age, they may be excluded from or have limited access to treatments. And this would result, as current history has shown, in a social damage as these people are essential in attaining a major social goal.

Considerations regarding the relevance of the clinical criterion in tandem with other elements in the decision-making process are actually not new. Many of the discussions about

[18] T. L. Beauchamp and J. F. Childress, 2013, p. 291.

limitation of the therapeutic effort (LTE) are based on it.[19] It is not, however, my intention to discuss LTE here as it would broaden the horizon of my reflection too far. So let us turn to the Swiss guidelines.

The Swiss guidelines recalls the four fundamental ethical principles guiding decision-making: beneficence, non-maleficence, respect for autonomy, and equity. They underline that «on no account are scarce resources to be employed for treatments which a patient does not wish to receive». After emphasizing respect for autonomy, the guidelines identify the rules of precedence to apply the four fundamental principles. Priority is given to equity. This means no unjustified unequal treatment on grounds of age, sex, residence, nationality, religious affiliation, social or insurance status, or chronic disability. The document calls for transparency and fairness in the allocation procedure. As a matter of fact, the guidelines exclude age in itself as a determining factor[20]. Justification for this position relies on the constitutional prohibition of discrimination. However, age as a risk factor is indirectly taken into account in the triage as we will see. The guidelines exclude the possibility of applying additional criteria like queuing, chance, and social usefulness. In the case of scarce resources, for admission to intensive care units the decisive factor is short-term prognosis based on a clinical evaluation.

After equity two other rules of precedence have been identified in the document: 'preserving as many lives as possible', which follows an egalitarian strategy, and 'protection of the professionals involved' based on a narrow social utility criterion. These are legitimate criteria that integrate equity and contribute to a fair and transparent process.

After presentation of the theoretical framework, the Swiss document puts it in context and provides concrete instructions for health care professionals focusing on triage.

According to the Swiss guidelines, the triage has two phases: admission and continued occupancy under resource scarcity. The different approach to these two phases reflects the attempt to concretely apply the selected criteria mentioned above. The initial triage involves criteria for ICU admission and is divided in two steps. The clinical criterion guides the first step (inclusion criteria) as the requirement for invasive ventilatory support and/or for hemodynamic

[19] See Borsellino P., *Limitation of the therapeutic effort: ethical and legal justification for withholding and/or withdrawing life sustaining treatments*, in Multidisciplinary Respiratory Medicine, 2015, 10:5, 1-5; see also of the same author *Bioetica tra 'morali' e diritto*, Cortina, 2018. For a critical analysis of the Italian context see of the same author *Covid-19. Quali criteri per l'accesso alle cure e la limitazione terapeutica. In tempo di emergenza sanitaria?*, in *Notizie di Politeia*, 2020 oingoing publication.

[20] As stated in the Swiss guidelines: «Age in itself is not to be applied as a criterion, as this would be to accord less value to older than younger people, thus infringing the constitutional prohibition of discrimination. Age is, however, indirectly taken into account under the main criterion "short-term prognosis", since older people more frequently suffer from comorbidity. In connection with COVID-19, age is a risk factor for mortality and must therefore be taken into account.», p. 3

support with vasoactive agents are determining factors to proceed to the second step. At this second level exclusion criteria are listed like availability of advance directives or clinical signs as listed in the document[21]. At this second level, age is mentioned as one criterion among others. The distinction is made between patients older than 85, for whom age is a prognostic indicator, and patients older than 75 for whom age is considered in tandem with at least one additional criterion to be selected between liver cirrhosis, stage III chronic kidney disease, NYHA class > l heart failure and estimated survival time of less than 24 months.

The document clarifies that triage during ICU stay is based on the regular assessment of the patients. In case of no improvement or deterioration in health status decisions of withdrawing or changing treatments have to be made and palliative care ought to be considered. Application of criteria selected for this second phase depends on how scarce resources are. The more scarce they become, the more stringent the criteria are applied. This seems like a legitimate way of dealing with this critical situation as the procedure is not set once and for all, but it is adaptable to changing conditions. This flexibility is a prerequisite for equality to be respected as much as possible. The guidelines divide the triage during ICU stay into three steps. The most relevant aspect of these three steps is that decisions are basically based on clinical criteria balanced with medical utility.

Some general conclusive, albeit not definitive, remarks

The outbreak of the Covid-19 pandemic has shown how fragile the principle of justice is. And how attention paid to its implementation through prudent and wise allowance or allotment when resources are not that scarce is the prerequisite to avoiding major injustices during emergencies. The analysis of the Swiss and Italian guidelines allows us to make some broader considerations on the difficulty of transposing ethical principles from the theoretical level to the practical one. Compared to the Swiss guidelines the Italian ethics recommendations suffer from lack of linguistic clarity, which is one major source of misunderstanding, as well as from a simplistic and superficial approach to difficult bioethical questions concerning concrete implementation of the principle of justice. This in turn has enormous emotive implications for the reader: on one hand, the question of justice is reduced to that of age, which makes this principle seem trivial in the end; on the other hand, because of its triviality this choice sounds frightening and alarming.

[21] Amongst others: cardiac arrest, malignant disease with life expectancy of less than 12 months, end-stage neurodegenerative disease etc.

A second consideration concerns the knowledge of the interaction of ethical principles applied in one specific area with the general ethical framework. First of all, 'ethical' has a broad meaning and includes moral, legal and deontological rules. Secondly, these general ethical principles, albeit adapted to the specific medical sector, cannot however be ignored or changed by a single individual or a sectoral category of individuals. As a consequence, unilateral decisions to apply a controversial criterion such as age cannot be justified as these decisions would violate how equality is interpreted in our legal systems today as referred to earlier. In line with these considerations, the Swiss guidelines make reference to the constitutional framework to fix the borders that cannot be crossed. And this is a valuable feature of that document.

A third remark is directed to the ability that those who write about ethical principles, especially when they are not exclusively theoretical discussions, but aim at being of practical guidance. In case of a crisis, decisions have to be made quickly. This however does not mean that we should lose sight of the complexity of moral and ethical situations. Thus, if the ability to be concise is required when giving instructions for critical situations, this can only be done in tandem with a profound knowledge of how ethical questions are to be treated (terminology and contents). Only experts of the ethical debate in these matters can be expected not to oversimplify and trivialize the process of determining priority.

Eventually, we should realize that, although we could not have foreseen when the outbreak of a pandemic would occur, this is not a totally unexpected event for scientists and politicians.[22] If we agree with this statement, it follows that if we really had committed to transparent and fair procedures of rationing in normal times, we would have faced fewer problems in adapting already existing procedures to emergencies like Covid-19.

As matter of fact, there is no criterion with absolute value. There are choices that have to be made to select the most adequate combination of criteria, all things considered. And this choice reflects how deeply which ethical criteria have been culturally introjected and those

[22] The WHO has released different documents on emergency and pandemic, see for all the 2017 document entitled *A strategic framework for Emergency Preparadeness* available at the following link https://www.who.int/ihr/publications/9789241511827/en/; see also U.S Department of Health and Human Services, *Pandemic Influenza Plan 2017 Update*, https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf
See also Bernard Lo and Mitchell H. Katz, *Clinical Decision Making during Public Health Emergencies: Ethical Considerations*, in *Ann Intern Med*, 2005, 143:7, 493-498; Beauchamp T.L., Walters L., Kahn J. P. and Mastroianni A. C. (edited by), *Contemporary Issues in Bioethics*, 7th edition, Thomson Wadsworth, 2008, especially chapter 9.

which have not. In conclusion, as «No set of criteria is the only acceptable set, (…). public trust and cooperation are crucial in addressing public health crises.»[23]

This means that to set priorities during crises cannot be done unilaterally. In democratic societies, the public cannot be excluded from decisions concerning the destiny of so many people.

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