

Recommendations on COVID-19 triage: international comparison and ethical analysis

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Abstract

On March 11, 2020 the World Health Organization classified COVID-19, caused by Sars-CoV-2, as a pandemic. Although not much was known about the new virus, the first outbreaks in China and Italy showed that potentially a large number of people worldwide could fall critically ill in a short period of time. A shortage of ventilators and intensive care resources was expected in many countries, leading to concerns about restrictions of medical care and preventable deaths. In order to be prepared for this challenging situation, national triage guidance has been developed or adapted from former influenza pandemic guidelines in an increasing number of countries over the past few months. In this article, we provide a comparative analysis of triage recommendations from selected national and international professional societies, including Australia/New Zealand, Belgium, Canada, Germany, Great Britain, Italy, Pakistan, South Africa, Switzerland, the United States, and the International Society of Critical Care Medicine. We describe areas of consensus, including the importance of prognosis, patient will, transparency of the decision-making process, and psychosocial support for staff, as well as the role of justice and benefit maximization as core principles. We then probe areas of disagreement, such as the role of survival versus outcome, long-term versus short-term prognosis, the use of age and comorbidities as triage criteria, priority groups and potential tiebreakers such as 'lottery' or 'first come, first served'. Having explored a number of tensions in current guidance, we conclude with a suggestion for framework conditions that are clear, consistent and implementable. This analysis is intended to advance the ongoing debate regarding the fair allocation of limited resources and may be relevant for future policy-making.

KEYWORDS

comparison, COVID-19, ethics, guidelines, public health, triage

1 | INTRODUCTION

A pandemic caused by a newly discovered coronavirus (SARS-CoV-2) is raising dilemmas worldwide in relation to health-resource limitations. To address the possible shortage of acute medical-care capacity, national and international medical societies have drawn up guidance for dealing with scarcity.

In everyday medical practice, a therapeutic decision to admit a patient to the intensive care unit (ICU), including various stages of care escalation (intubation, circulatory support, dialysis, extra-corporeal membrane oxygenation), requires a medical indication and incorporates the patient's will. Where resources are not limited, this decision is generally made with a focus on the potential benefit to the individual patient, unless the patient opts out of the treatment. If a

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therapeutic goal cannot, or is unlikely, to be achieved within the framework of the ICU, it is possible to not start (withhold) or to end (withdraw) the therapy. For example, a decision to withdraw ventilation or dialysis may be acceptable if there is little or no expected benefit.¹ Such decisions should be made in a team with the involvement of the patient and relatives. Intensive care teams around the world have adopted these standards over the past decades and have found ways to implement them, often with input from clinical ethicists.

In crisis situations, such as pandemics, the admission and decision-making processes can change significantly if there are insufficient resources for care, as each decision taken for one patient may affect the decision-making for other patients. Triage in crisis situations comprises the selection of patients who will receive treatment, meaning that those not selected may not receive treatment from which they could benefit. The basic values underlying triage decisions in crisis situations generally include prioritization of medical urgency, capacity to benefit and fairness.² For COVID-19, various guiding principles have been suggested, in particular the maximization of benefit and justice, including considerations such as treating people equally, promoting instrumental value, and giving priority to the worst-off.³ Triage decisions thus include medical factors, such as the severity of the health condition and likely outcome, as well as fairness in resource allocations and ethical issues.

1.1 | Maximizing benefit

Maximizing benefit under conditions of scarcity can mean different things: it could refer to saving as many people as possible, to saving the greatest possible number of life years, or to saving the greatest amount of quality-adjusted life years (QALYs), with the resources available. Depending on which criterion is applied, resource allocation will look quite different. Saving as many life years as possible would favour young people, whereas maximizing QALYs would favour those with a capacity to lead long, healthy, independent lives.

Maximizing benefit gives back a sense of control in a desperate situation: although it may be impossible to help all patients, it is still possible to save those who will benefit most.⁴ The application of this guiding principle is not straightforward, however, and depends not

only on how the medical assessment of benefit and its probability are operationalized but also on sociocultural and ethical norms concerning which benefits matter.⁵ Defining benefit for application in triage in a pandemic, for instance, requires weighing short-term against long-term prognosis, including the impact of age and comorbidities as potential triage criteria. The question of whether people who are of instrumental value (e.g. healthcare workers) should be prioritized⁶ is an additional consideration compatible with the overall idea of maximizing benefit. In order to enable the necessary therapeutic decisions to be made consistently and fairly, criteria for maximizing benefit in triage situations must be clearly and transparently defined.

Although the focus here is on triage, it is important to note that in crises such as the SARS-CoV-2 pandemic, benefit can most effectively be maximized not at the level of triaging those who have fallen seriously ill but at the population level, where disease prevention in the general and vulnerable populations, and in the healthcare workforce is key. This includes ensuring that measures are in place to protect the most vulnerable in society, who have often traditionally been marginalized or in whom the social determinants of health have enhanced their vulnerability, as well as to support treatment teams with appropriate protective equipment (PPE) and potential prioritization for vaccinations, if available. A reward for individual commitment, such as prioritization of vaccination for healthcare workers, or allocation of the most effective masks (FFP2, N95) to those with greater exposure to respiratory droplets, can motivate people to contribute in a crisis.⁷

1.2 | Justice

The principle of justice in triage can be understood to mean that all patients with a comparable prognosis should have equal access to necessary medical care in the event of a crisis, based on predefined medical and ethical criteria. There is some controversy as to how to proceed in a next step, regarding the allocation of limited therapy to patients with the same prognosis. Whereas some have argued for a 'first come, first served' rule, others favour a lottery or randomization in order to avoid disadvantaging those who arrive later for reasons that are beyond their control (e.g. a delayed diagnosis).⁸

Other criteria for distribution, such as preferential treatment based on merit, are often rejected based on objections such as arbitrariness and the societal implications of connecting survival to certain distinctions or social roles.⁹ Giving priority to the worst-off,

¹Sprung, C. L., Woodcock, T., Sjøkvist, P., Ricou, B., Bulow, H. H., Lippert, A. ... Schobersberger, W. (2008). Reasons, considerations, difficulties and documentation of end-of-life decisions in European intensive care units: the ETHICUS Study. *Intensive Care Med.*, 34(2), 271–277. <https://doi.org/10.1007/s00134-007-0927-1>, <https://www.ncbi.nlm.nih.gov/pubmed/17992508>.

²Barilan, Y. M., & Brusa, M. (2016). Triage. In H. ten Have (Ed.), *Encyclopedia of global bioethics*. Cham, Switzerland: Springer International Publishing.

³The category 'worst-off' can be understood in different ways, those who are most ill, those who are in the most difficult situation including e.g. social circumstances or, more controversially, those standing to lose most from remaining untreated such as young people; Emanuel, E. J., Persad, G., Upshur, R., Thome, B., Parker, M., Glickman, A., ... Phillips, J. P. (2020). Fair allocation of scarce medical resources in the time of Covid-19. *N. Engl. J. Med.* <https://doi.org/10.1056/NEJMs2005114>, <https://www.ncbi.nlm.nih.gov/pubmed/32202722>.

⁴Barilan and Brusa, op. cit.

⁵Daugherty Biddison, E. L., Faden, R., Gwon, H. S., Mareiniss, D. P., Regenberg, A. C., Schoch-Spana, M., ... Toner, E. S. (2019). Too many patients...a framework to guide statewide allocation of scarce mechanical ventilation during disasters. *Chest*, 155(4), 848–854. <https://doi.org/10.1016/j.chest.2018.09.025>.

⁶Persad, G., Wertheimer, A., & Emanuel, E. J. (2009). Principles for allocation of scarce medical interventions. *Lancet*, 373(9661), 423–431. [https://doi.org/10.1016/s0140-6736\(09\)60137-9](https://doi.org/10.1016/s0140-6736(09)60137-9).

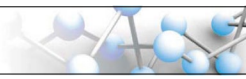
⁷Emanuel et al., op. cit.

⁸Barilan and Brusa, op. cit.

⁹Ross, W. (2012). God panels and the history of hemodialysis in America: A cautionary tale. *Virtual Mentor*, 14(11), 890–896. <https://doi.org/10.1001/virtualmentor.2012.14.11.mhst1-1211>.

TABLE 1 International guidelines - synopsis

	Australia/ New Zealand (AUS/NZ)	Belgium (BEL)	Canada (CAN)	Germany (DEU)	International (SCCM)
Issuing body	Australian and New Zealand Intensive Care Society (ANZICS)	Belgian Society of Intensive Care Medicine	Canadian Medical Association	Several intensive care professional associations/ Academy for Ethics in Medicine (AEM)	Society of Critical Care Medicine (SCCM)
Status	Guidance	Advice	Policy	Clinical and ethical recommendations	Recommendation
Maximizing benefit	Derive maximum benefit for all people from the available resources	Avoid disproportionality Maximize ICU bed capacity	Save the most lives and maximize improvement in individual post-treatment length of life Balance between lives and life-years must be applied consistently	As many patients as possible to benefit from medical care	The greatest good for the greatest number Overall likelihood of benefiting from the intervention
Equality	All patients	All patients evaluated according to the same criteria	No difference in allocating scarce resources between patients with COVID-19 and those with other medical conditions	All patients who require intensive therapy Social criteria not permissible	All patients evaluated in the same way, regardless of their diagnosis
Equity	No discrimination	Avoid discrimination	-	No discrimination	No discrimination
Short-term survival	Likelihood of patient response to treatment and survival	Medical urgency	Prognosis of life expectancy likelihood of survival	Short-term survival prognostic score (SOFA)	Determine scoring criteria
Long-term survival	Likelihood of long-term patient survival	Comorbidities Frailty Severe cognitive impairment in elderly	Prognosis	Long-term prognosis Comorbidities General frailty (clinical frailty scale)	Comorbidities
Life-span	Possible if a situation arises where patients are similarly ranked	'Age in itself is not a good criterion to decide on disproportionate care' Age should be integrated with other clinical parameters	Giving priority to younger patients and those with fewer coexisting conditions	No (de)prioritization 'solely because of biological age'	-
Additional criteria (priority groups, tiebreakers)	Deprived and disadvantaged groups Adults with caring responsibilities Individuals who undertake front-line patient care	In case of comparable medical urgency: 'first come first served' or lottery	Random allocation, such as a lottery in patients with similar prognosis Priority to front-line workers	-	Shift from 'first come, first served' to lottery Waiting list
Fair decision-making	+	-	+	+	-
Patient will	+	+	-	+	(+)
Re-evaluation	+	+	(+)	+	+



Italy (ITA)	Pakistan (PAK)	South Africa (ZAF)	Switzerland (CHE)	United Kingdom (GBR)	United States of America (USA)
Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI)	Centre of Biomedical Ethics and Culture (Karachi)	Critical Care Society of Southern Africa	Swiss Academy of Medical Sciences/Swiss Society for Intensive care (SGI)	British Medical Association	Expert Panel Report of the Task Force for Mass Critical Care and the American College of Chest Physicians
Clinical ethical recommendation	Guideline	Guidance	Guidance	Guidance	Guide
Maximize benefit for the largest number of people	Decisions should be made to maximize the utility of available resources	Save most lives Save most life-years	Preserving as many lives as possible	Greatest medical benefit to the greatest number of people	Benefit to the greatest number of people Maintain the function of the healthcare system
All patients (COVID and non-COVID) who require intensive therapy treated according to the same criteria	All patients including those already admitted	All patients	All patients requiring intensive therapy treated according to the same criteria	People with an equal chance of benefiting from a resource should have an equal chance of receiving it	All current and new patients presenting with critical illness
-	Free from all forms of bias and discrimination	Distributive and procedural justice	No discrimination	Be aware of discrimination	Equitably, with no preference to any particular group
Probability of survival	Expected outcome medical criteria	SOFA score priority scale	Short-term prognosis is decisive	Medical utility	Acute illness likelihood of benefit
Comorbidities and functional status	Comorbidities should also be taken into consideration	Comorbidities Clinical frailty scale	Comorbidities Exclusion criteria (stage B)	Comorbidities Frailty	Comorbid conditions and acute illness using standardized assessments
Life expectancy Age limit 'may ultimately need to be set'	Age limits should take into account other health variables when making allocation decisions	Life-cycle considerations (priority for younger patients in same priority group)	Age 'not in itself' a criterion but affects short-term prognosis Exclusion > 85 years from admission to ICU (if no ICU beds available)	A simple 'cut-off' policy with regard to age or disability would be unlawful, as it would constitute direct discrimination	A system based on age alone, ..., does not account for differences in baseline mortality risk because of underlying health
Proportionality of care No 'first come first served'	Principle of reciprocity 'First come, first served' not recommended	Individuals who are vital to the public health response	Explicitly rejected: other criteria such as lottery, 'first come first served', social utility	No 'first come first served' Priority to those working in essential services	Prioritize key groups (e.g. staff, research volunteers, children and pregnant women) Avoid lottery and 'first come first served'
-	-	-	+	+	+
+	Not mentioned	+	+	+	+
+	+	+	+	+	+

(Continues)

TABLE 1 (Continued)

	Australia/ New Zealand (AUS/NZ)	Belgium (BEL)	Canada (CAN)	Germany (DEU)	International (SCCM)
Termination of treatment	-	Disproportionate care (poor long-term expectations) Discuss decision not to initiate or to withdraw life- sustaining therapies with patients/relatives	Removing a patient from a ventilator or an ICU bed is justifiable	Futility Therapy goal unrealistic Patient-centred decision	Worsening condition after a reasonable period of maximum treatment (futile)
Protection and support	Principle of reciprocity	Psychological support for triaging physicians	Advocate for personal protective equipment Peer support and practise self-care	Psychosocial support of teams	Mitigate burnout and stress
Additional recommend- ations	Child's best interests Support for patients belonging to groups subjected to social deprivation and disadvantage	Measures to maximize ICU capacity Advance care planning (e.g. nursing home residents) No out-of-hospital CPR on 'elderly patients' during pandemic	Encourage advance directives	Palliative care	End-of-life care service

another potential distribution criterion, is hard to reconcile with the idea of maximizing benefit, assuming the worst-off are not or at least less likely to benefit. Triage guided by benefit maximization would rather favour the group that is severely affected and needs treatment urgently but is still well enough to be likely to profit from treatment. In fact, the conventional triage process (e.g. in mass disaster) explicitly advocates excluding those who are least likely to benefit from treatment as well as those not in urgent need of care if resources are constrained.

Whereas justice in general invokes equality, meaning that everyone should receive the same treatment, equity—another concept relevant to triage—emphasizes the need to avoid discrimination, and to address 'remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification'.¹⁰ Equity may mean different treatment for different needs, which is challenging to achieve in the context of triage, where advanced age and comorbidities may impact survival and benefit maximization.

Given the multitude of potential criteria for operationalizing justice in concrete allocation decisions, procedural approaches have

been suggested, to work towards a consensus that is acceptable to all those affected by the decisions to be taken.¹¹

Overall, two major principles constitute the normative basis of triage guidelines: benefit maximization and justice. For the purpose of our analysis we will focus on equity and fair process, and list any additional considerations mentioned in the guidance texts.¹²

2 | TRIAGE GUIDELINES FOR THE SARS-COV-2 PANDEMIC

Italy was one of the first countries to experience a large number of patients who were critically ill at the same time, which led to a shortage of ventilators and intensive care resources.¹³ Although there may be nuances to this claim and more evidence is needed,

¹¹Daniels, N. (2004). *How to achieve fair distribution of ARTs in 3 by 5: fair process and legitimacy in patient selection*. Retrieved from <http://www.who.int/ethics/en/background-daniels.pdf> [accessed Mar 27, 2020].

¹²The terms 'justice', 'equality', 'equity' and 'fairness' are used differently in academic discourse. Variation and at times a certain vagueness or unclarity was also prevalent in the guidance texts we studied. Many of them were put together quickly with a focus on practical utility, and terminology may not have been a prime concern.

¹³*Clinical ethics recommendation for the allocation of intensive care treatments, in exceptional, resource-limited circumstances, SIAARTI, 2020*. Retrieved from <http://www.siaarti.it/SiteAssets/News/COVID19-documentSIAARTI/SIAARTI-Covid-19-ClinicalEthicsRecommendations.pdf> [accessed Mar 20, 2020].

¹⁰Health equity. Retrieved from https://www.who.int/topics/health_equity/en/ [accessed Jun 3, 2020].

Italy (ITA)	Pakistan (PAK)	South Africa (ZAF)	Switzerland (CHE)	United Kingdom (GBR)	United States of America (USA)
Decisions to withhold or withdraw life-sustaining treatments 'must always be discussed and shared among the healthcare staff, the patients and their proxies'	The outcome will not be favourable DNR status Withdraw therapy: peers, including hospital administration, must be involved	Futility Long-term outcome Withdraw therapy	Staged approach to definition of 'ICU treatment no longer indicated' Change therapy goal	If prognosis worsens, IC should be withdrawn and offered to another patient reasonably believed to have the capacity to benefit quickly	Fail to improve Limiting and withdrawing critical care resources are justified by the utilitarian principle of providing the greatest good to the greatest number of people
Debriefing	Personal protective equipment Mental health support team Principle of reciprocity	Reciprocity: heightened priority for those whose work supports the provision of acute care to others	Protection for health professionals	Reciprocity: those who take on increased burdens should be supported Responsibility to protect staff	Psychological and moral support
Every admission to ICU considered and communicated as an 'ICU trial' subject to daily re-evaluation Offer non-ICU bed or palliative care	Compassionate end-of-life care and appropriate personnel	Appropriate clinical care of patients who cannot receive critical care Palliative care Involve family	Resuscitation 'not recommended' (Stage B) Transparent decision-making Offer palliative care	Where patients are dying, the best available end-of-life care. Open and transparent decision-making	Best supportive care Pediatric considerations

access to ventilation therapy in COVID-19 was by default perceived as a matter of life or death, so that scarcity of respirators and ICU beds received special attention.¹⁴ In the initial stages, overwhelmed by the acute crisis, care allocation decisions had to be taken in the absence of formal triage guidelines. This led to much distress on the part of individual clinicians and teams who continuously had to make allocation decisions at the bedside. Under conditions of scarcity, stress and fatigue, there may be errors and inconsistency in the decisions taken.¹⁵ Not all countries have had to face the dire scarcity faced by Italy, but over the past months, in anticipation of demand escalation, triage guidance has been developed or adapted from former influenza pandemic guidelines in various countries.¹⁶ This body of guidance documents aims to facilitate the decision-making process in triage situations, enhancing transparency and objectivity, and lifting some of the moral responsibility from individual clinicians' shoulders. In this article, we provide a comparative

analysis of triage guidance from Australia/New Zealand,¹⁷ Belgium,¹⁸ Canada,¹⁹ Germany,²⁰ Great Britain,²¹ Italy,²² Pakistan,²³

¹⁷Guiding principles for complex decision making during Pandemic COVID-19. Retrieved from https://www.anzics.com.au/wp-content/uploads/2020/04/ANZI_3367_Guiding-Principles.pdf [accessed Apr 10, 2020].

¹⁸Ethical principles concerning proportionality of critical care during the 2020 COVID-19 pandemic in Belgium: advice by the Belgian Society of Intensive care medicine - update 26-03-2020. Retrieved from http://www.siz.be/wp-content/uploads/COVID_19_ethical_E_rev3.pdf [accessed Apr 1, 2020].

¹⁹Framework for ethical decision making during the coronavirus pandemic. Retrieved from <https://policybase.cma.ca/en/permalink/policy14133> [accessed Jun 2, 2020].

²⁰Marckmann, G., Neitzke, G., Schildmann, J., Michalsen, A., Dutzmann, J., Hartog, C., ... Janssens, U. (2020). Decisions on the allocation of intensive care resources in the context of the covid-19 pandemic: Clinical and ethical recommendations of DIVI, DGINA, DGAI, DGIIN, DGNI, DGP, DGP and AEM. *Med Klin Intensivmed Notfmed*, <https://doi.org/10.1007/s00063-020-00709-9>.

²¹British Medical Association (BMA). COVID-19 - ethical issues. A guidance note. Retrieved from <https://www.bma.org.uk/media/2226/bma-covid-19-ethics-guidance.pdf> [accessed Apr 16, 2020].

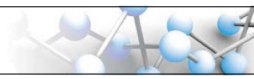
²²Clinical ethics recommendation for the allocation of intensive care treatments, in exceptional, resource-limited circumstances. SIAARTI, 2020. Retrieved from <http://www.siaarti.it/SiteAssets/News/COVID19-documentiSIAARTI/SIAARTI-Covid-19-ClinicalEthicsRecommendations.pdf> [accessed Mar 20, 2020].

²³Guidelines for ethical healthcare decision-making in Pakistan. Retrieved from http://www.situt.org/bioethics/CBEC_COVID-19_Guidelines_for_ethical_healthcare_decision-making_in_Pakistan_April_2020.pdf [accessed Apr 15, 2020]; COVID 19 Guidelines for ethical healthcare decision-making in Pakistan http://covid.gov.pk/new_guidelines/01June2020_Guidelines_for_Ethical_Healthcare_Decision-Making_in_Pakistan.pdf [accessed Jun 1, 2020].

¹⁴Truog, R. D., Mitchell, C., & Daley, G. Q. (2020). The toughest triage - allocating ventilators in a pandemic. *N. Engl. J. Med.* <https://doi.org/10.1056/NEJMp2005689>.

¹⁵Ryus, C., & Baruch, J. (2018). The duty of mind: ethical capacity in a time of crisis. *Disaster Med. Public Health Prep.* 12(5), 657-662. <https://doi.org/10.1017/dmp.2017.120>.

¹⁶The guidance documents we studied call themselves 'guidelines', 'recommendations', 'guide', or, most commonly, 'guiding principles'. The legal status may differ slightly in their countries of origin, but overall they seem to have the status of non-binding professional advice.



South Africa,²⁴ Switzerland,²⁵ the United States,²⁶ and the International Society of Critical Care Medicine (SCCM),²⁷ all published in English in March and April 2020. Unfortunately, guidance documents from severely affected countries such as France and Brazil were not available in English at the time of the analysis.²⁸

For the purpose of our comparison, we focused on guidance that explicitly deals with triage and clinical decision-making situations in the context of the COVID-19 pandemic. Most of the guidance documents were developed by medical association or intensive care societies. We did not include guidance issued by individual centres or universities,²⁹ with the exception of the guidance documents from Pakistan, which have recently been adopted at a national level. We excluded documents that were issued pre-COVID or that provide general strategies on how to deal with a pandemic without providing concrete guidance for allocation (World Health Organization (WHO),³⁰ Centers for Disease Control and Prevention (CDC),³¹ Ontario,³² Australia³³). Guidelines focusing on medical therapy for COVID-19 were also excluded. Our analysis builds on a much briefer synopsis published previously.³⁴

In the following, we identify and explore ethically relevant similarities and differences among the guidelines as well as some inconsistencies (see Table 1).

2.1 | Areas of consensus

2.1.1 | Maximizing benefit

Utilitarian considerations tend to predominate in triage situations. Almost all guidance documents explicitly justify a shift in the decision mode from an individualistic approach to a triage decision-making in the context of the pandemic. The goal is to achieve maximum benefit for as many as possible (AUS/NZ, CAN, CHE, DEU, GBR, ITA, PAK, SCCM, USA, ZAF) and to save the maximum number of lives (CHE, ZAF) with the resources available at the time of the decision.³⁵ The Belgian recommendations do not to provide an explicit moral justification for their triage criteria but rather focus on the concept of avoiding disproportionate care.

Triage plans often contain different levels depending on the degree of resource constraints. Different structures, processes and prioritization criteria may be foreseen for different stages.³⁶ All guidance documents that were reviewed show responsiveness to different situations of scarcity and emphasize that triage decisions only apply in the case of a lack of resources that precludes taking care of all patients according to usual best practice standards. Crisis plans specify steps for different stages (e.g. stage A, limited capacity of ICU beds; stage B, no free ICU beds) (AUS/NZ, BEL, CHE, DEU, SCCM, USA).

2.1.2 | Equality and equity

Reference to the principle of justice can be found in all guidance. The principle of equality is invoked by stipulating that triage decisions should apply to all patients with the same prognosis, with or without COVID-19. In a pandemic with a mass influx of sick people and limited resources, consideration must be given to how to treat people equally.³⁷ Equitable access to healthcare is described in the sense that there should be no discrimination, i.e. no unjustified unequal treatment, on grounds of characteristics such as age, race, sexual orientation, disability or socio-economic status.

2.1.3 | Consideration of medical criteria

All guidance texts except that from Canada include medical criteria in triage decisions. There is typically a gradation in prioritization decisions depending on the extent of scarcity. In order to continually adapt treatment strategies to current resources and to an individual patient's condition, regular re-evaluation is recommended in all documents.

Various scores are recommended to assess mortality risk and to estimate the probability of survival of the acute event. Some guidance texts use the sequential organ failure assessment score (SOFA) score (DEU, ZAF), while others discuss or reject the SOFA

²⁴Allocation of scarce critical care resources during the COVID-19 public health emergency in South Africa. Retrieved from <https://criticalcare.org.za/wp-content/uploads/2020/04/Allocation-of-Scarce-Critical-Care-Resources-During-the-COVID-19-Public-Health-Emergency-in-South-Africa.pdf> [accessed Apr 4, 2020].

²⁵COVID-19 pandemic: triage for intensive-care treatment under resource scarcity. Retrieved from <https://www.samw.ch/de/Ethik/Themen-A-bis-Z/Intensivmedizin.html> [accessed Mar 24, 2020].

²⁶Maves, R. C., Downar, J., Dichter, J. R., Hick, J. L., Devereaux, A., Geiling, J. A., ... Christian, M. D. (2020). Triage of scarce critical care resources in COVID-19. An implementation guide for regional allocation: An Expert Panel Report of the Task Force for Mass Critical Care and the American College of Chest Physicians. *Chest*. <https://doi.org/10.1016/j.chest.2020.03.063>, <https://www.ncbi.nlm.nih.gov/pubmed/32289312>.

²⁷COVID-19 Resources Society of critical care medicine crisis standard of care recommendations for triaging critical resources during the COVID-19 pandemic. Retrieved from <https://www.sccm.org/getattachment/179d65cb-9076-4cf2-a06a-3ae7c928e634/Triaging-Critical-Resources> [accessed Apr 28, 2020].

²⁸For a very helpful overview, see <https://prioritiesinhealth.org/guidelines>.

²⁹Guidance from pioneering institutions has influenced a number of national medical societies' guidelines, in particular the framework issued by the Department of Critical Care Medicine, University of Pittsburgh, which some guidelines explicitly refer to; see https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy_2020_04_15.pdf.

³⁰COVID-19 strategy update. Retrieved from https://www.who.int/docs/default-source/coronaviruse/covid-strategy-update-14april2020.pdf?sfvrsn=29da3ba0_19 [accessed Apr 20, 2020].

³¹Strategies to allocate ventilators from stockpiles to facilities. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/ventilators.html> [accessed Apr 25, 2020].

³²Ontario health plan for an influenza pandemic 2013. Retrieved from http://www.health.gov.on.ca/en/pro/programs/emb/pan_flu/pan_flu_plan.aspx [accessed Apr 14, 2020].

³³Australian health sector emergency response plan for novel Coronavirus (COVID-19) (Publication Number 12723). Australian Government, Department of Health. Retrieved from https://www.health.gov.au/sites/default/files/documents/2020/02/australian-health-sector-emergency-response-plan-for-novel-coronavirus-covid-19_2.pdf [accessed Apr 14, 2020].

³⁴Jöbges, S., & Biller-Andorno, N. (2020). Ethics guidelines on COVID-19 triage-an emerging international consensus. *Critical Care*, 24(1). <https://doi.org/10.1186/s13054-020-02927-1>, <https://www.ncbi.nlm.nih.gov/pubmed/32375855>.

³⁵Country abbreviation follow ISO alpha-3 standards, see https://www.nationsonline.org/oneworld/country_code_list.htm

³⁶Barilan and Brusa, op. cit.

³⁷Persad et al., op. cit.

score because it has not been validated for the SARS-CoV-2 pandemic (AUS/NZ, USA). The clinical frailty scale is also proposed as a tool for estimating the general clinical condition of the patient (BEL, DEU, GBR, ZAF). The presence of severe comorbidities may exclude patients from ICU (GBR). Exclusion criteria, for patients who are not to be considered for triage, are specified in the guidance from Switzerland.

To identify those patients who would benefit most from the scarce interventions, taking into account the probabilities of short-term survival (which is not yet well known in COVID-19) and some determinants of long-term survival,³⁸ including comorbidities, life-span considerations and the patient's current clinical condition, is suggested by all guidance texts (AUS/NZ, BEL, CAN, CHE, DEU, GBR, ITA, PAK, SCCM, USA, ZAF).

2.1.4 | Life-span considerations

All guidance documents agree that age as a criterion alone, despite its objectivity, is not enough for a triage decision. Age must be correlated with comorbidities and prognosis. However, the Italian recommendations comment that an age limit 'may ultimately need to be set' for intensive care therapy. The Swiss guidance also stipulates that in the event of an absolute scarcity of intensive care capacities (where no free ICU beds are available), people over 85 years of age should not be admitted to the ICU. Prioritization of younger patients over older patients is described in the guidance from Australia/New Zealand, South Africa and Canada in cases of similar ranking, as a 'tiebreaker'.

2.1.5 | Fair decision-making

Fair decision-making is an important aspect of ICU triage. Key factors involved in any decision-making regarding admission into the ICU include: patient preferences (expressed in person, through an advance directive, or through surrogate decision-makers); whether the patient stands to benefit from receiving the treatment; and if the potential benefits of care outweigh the burden of treatment.³⁹ Under conditions of scarcity, these usual criteria are superseded by an additional layer of triage criteria that involves evaluating similar considerations across multiple patients and/or using different thresholds for resource allocation.

³⁸Williams, T. A., Dobb, G. J., Finn, J. C., Knuiman, M. W., Geelhoed, E., Lee, K. Y., & Webb, S. A. (2008). Determinants of long-term survival after intensive care. *Crit. Care Med.*, 36(5) <https://doi.org/10.1097/CCM.0b013e318170a405>.

³⁹Bassford, C. (2017). Decisions regarding admission to the ICU and international initiatives to improve the decision-making process. *Critical Care*, 21(1), <https://doi.org/10.1186/s13054-017-1749-3>; Pragasam, D. G., & Pershad, S. (2019). Decision-making in ICU – A systematic review of factors considered important by ICU clinician decision makers with regard to ICU triage decisions. *Journal of Critical Care*, 50, <https://doi.org/10.1016/j.jcrrc.2018.11.027>, <https://www.ncbi.nlm.nih.gov/pubmed/30502690>.

Ongoing revision and adjustment of decision-making is important during a patient's ICU stay, as the patient's condition evolves over time, affecting whether a specific treatment should be continued, escalated, withdrawn or withheld. Common reasons for termination of therapy include lack of anticipated benefit and an unfavourable harm-benefit ratio. In a triage setting, an additional reason might be that someone else is expected to benefit more from the ICU bed. Most guidance recommends that at least two physicians participate in decision-making regarding termination of therapy, either in an interdisciplinary or in a special triage team, which should include senior physicians (AUS/NZ, BEL, CAN, CHE, DEU, PAK, SCCM, USA, ZAF).

Almost all guidance explicitly recommends offering palliative care to patients whose treatment is withdrawn or withheld. The importance of advance care planning is a key element in various documents, facilitating informed patient choice and avoiding unwanted intensive care interventions (AUS/NZ, BEL, CAN, CHE, DEU).

Transparency in decision-making, which is explicitly mentioned in most guidelines, allows patients, surrogates and relatives to comprehend how clinical decisions are reached. More generally, transparency is defined as providing an 'open flow' of information for public access,⁴⁰ helping the public to understand how and why certain decisions are made in clinical settings. In this sense it is important for the public to understand triage criteria and processes for decision-making.

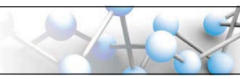
2.1.6 | Patient will

All guidance documents mention that the patient's wishes regarding ICU therapy must be elicited and if possible respected. For instance, Australia/New Zealand guidance calls for 'discussions about goals of care, patient and family preferences, and the acceptability to the patient of critical care interventions if offered'.⁴¹ Other guidance, such as from the United States,⁴² points to the deviation from the typical informed consent scenario in which all possible options are laid out to a patient.⁴² In triage situations, not all treatment options can be offered to all patients who might benefit from them. The focus on patient will in the triage guidance is therefore on the patient's or surrogate's right to reject intensive therapy (AUS/NZ, BEL, CHE, DEU, ITA, PAK, ZAF). Some guidance recommends promoting advance directives, so that reflection occurs calmly before an individual has fallen ill (BEL, CAN, CHE, DEU).

⁴⁰Bonavia, T., & Brox-Ponce, J. (2018). Shame in decision making under risk conditions: Understanding the effect of transparency. *PLoS ONE*, 13(2), <https://doi.org/10.1371/journal.pone.0191990>.

⁴¹Guiding principles for complex decision making during Pandemic COVID-19

⁴²Maves et al., op. cit.



2.1.7 | Re-evaluation of triage decisions and changes in the therapeutic goal

All guidance discusses the possibility that, depending on the prevalent resource constraints, therapy may need to be restricted. Withholding some treatment does not mean withholding all therapy, and even intubation with ventilation does not mean that survival is guaranteed. The decision for or against artificial ventilation is also based on knowledge of the potential benefits and harms for a given individual. Some texts explicitly mention futility as a criterion for re-directing the therapeutic goal (AUS/NZ, BEL, DEU, PAK, SCCM, ZAF), whereas others refer to the concept of proportionality and disproportionate care (AUS/NZ, BEL, ITA, USA). If a change in the therapeutic goal is deemed necessary, this decision must be transparent and well communicated to the patient, family and team. The provision of optimal palliative care is recommended in accordance with medical standards requiring physicians to provide the best available care, including accompanying the dying.⁴³

2.1.8 | Burden of triage and staff support

All guidance acknowledges the extraordinary physical and moral burden on medical staff in the context of pandemic triage prioritization, including physical and mental exhaustion imposed by decisions such as withholding and withdrawing. Many texts recommend psychological support for medical staff under these circumstances (BEL, DEU, GBR, ITA, PAK, SCCM, USA).

Synthesis: The guidelines reflect a shift in prioritization of ethical principles guiding clinical decisions under conditions of scarcity, such as during the current COVID-19 pandemic. Whereas in everyday medical practice, with sufficient resources, principles such as universal access, minimizing harm, patient autonomy and proportionality of benefits and harm take centre stage, priorities shift in triage situations towards maximizing benefits and the just distribution of scarce resources. Various medical scores incorporating clinical condition, comorbidities and prognosis are used to assess the patient, not only, or not even primarily, with a view to the best possible individual treatment, but also for triage purposes. With a view to this departure from usual standards, fair and transparent decision-making based on well-defined criteria is vital to ensure individual and public cooperation and to ease the moral burden on healthcare staff. Procedural aspects, with clear lines of accountability, and professional communication are also key.⁴⁴ Decisions on termination of therapy during resource scarcity must follow accepted protocols and criteria, especially when they reflect medical futility or disproportionate care. All patients should have the option to receive palliative and supportive care, and, if

possible, choose their preferred place of care (e.g. hospital, nursing home, hospice, home etc.).

2.2 | Areas of disagreement

With the exception of the Belgian recommendations, which stress the avoidance of disproportionate care and the maximization of ICU capacity as a key concern, guidance documents focus on maximizing benefit by 'lives saved' or 'life years saved'. The quality of life years saved is rarely explicitly mentioned—there are just some hints, such as severe cognitive impairment in the elderly being a consideration in addition to frailty BEL. Some focus on short-term prognosis CHE⁴⁵ and list exclusion criteria for different stages of resource scarcity. Others highlight the importance of long-term prognosis, including parameters impacting long-term prognosis such as comorbidities and life-span BEL. Most consider both, naming parameters for short-term prognosis as well as for long-term prognosis (AUS/NZ, BEL, CAN, CHE, DEU, GBR, ITA,⁴⁶ PAK, SCCM, USA, ZAF). The Canadian text explicitly mentions the need to balance saving more lives against saving more years of life, stressing that different models are conceivable but need to be applied consistently.

Guidance documents concur that decisions regarding rationing of resources should be made based on objective medical criteria, such as comorbidities and frailty, to identify those patients who would benefit most from the scarce interventions. However, when two patients may benefit equally medically, guidance documents invoke different criteria to fine-tune maximization of benefits. Some argue for giving particular consideration to specific patient groups, such as younger patients (AUS/NZ, CAN, ITA, ZAF), disadvantaged populations (AUS/NZ), or workers central to the public health response, including healthcare professionals, frontline and ancillary staff, who place themselves at higher than average risk, and could, if treated, return to work and continue providing necessary care to the community (AUS/NZ, CAN, GBR, PAK, USA, ZAF). Reciprocity and instrumental value are offered as potential reasons for prioritizing health workers. Guidance documents stress that such preferential treatment provided to hospital staff should be objective and transparent in order to avoid causing public mistrust. Other guidance documents emphasize the need for special protection against infection but also against physical and psychological stress (BEL, CHE, DEU, GBR, ITA, PAK, SCCM, USA).

There are two potential tiebreakers that are highly controversial. 'Lottery' (random allocation) is advocated by some (BEL, CAN, SCCM) and explicitly rejected by others (CHE, USA). 'First come, first served' (waiting list) is considered an option in Belgium but is

⁴³Ryus and Baruch, *op. cit.*

⁴⁴Department of Health, Ireland. *Ethical framework for decision-making in a pandemic*. Retrieved from <https://www.gov.ie/en/publication/dbf3fb-ethical-framework-for-decWoSon-making-in-a-pandemic/> [accessed May 6, 2020].

⁴⁵The Swiss guidelines (CHE) explicitly emphasize a focus on short-term prognosis yet include triaging criteria such as moderate dementia, a severe and irreversible neurological condition or estimated survival of less than 24 months, which seem to involve a more long-term perspective.

⁴⁶The Italian guidelines do explicitly argue for a preferential treatment of younger patients but state that a patient's age should be evaluated together with other factors and that an "age limit for the admission to the ICU may ultimately need to be set.

not recommended by others (CHE, GBR, ITA, PAK, SCCM, USA). No guideline suggests prioritization based on merit or social status. There is no explicit recommendation regarding triage of patients with the same prognosis in the guidance from Germany.

2.3 | Tensions and vagueness within guidance documents

Professional societies have done a remarkable job in coming up with guidance so quickly. Some inconsistencies, tensions and vagueness remain, partly in controversial areas such as the role of age as prognostic factor for short- and/or long-term survival, or determining membership of a priority group or criteria to be used as a tiebreaker in the case of all other relevant criteria being equal. These areas might be clarified in subsequent versions, as a more robust consensus develops or with feedback about practical experiences and needs.

A major issue concerns the overall allocation models and their operationalization. It is sometimes difficult to discern how the various allocation factors and considerations play together and how they are determined. Some guidance documents use a traffic-light chart (SCCM) or a combination of a traffic-light chart with a scoring system (ZAF), while others use neither chart nor scores (AUS/NZ, CAN, CHE, GBR, ITA, PAK, USA).⁴⁷ Whereas scores (e.g. SOFA) may be biased or otherwise imperfect, the avoidance of scores leaves more room for arbitrariness, when criteria for short-term and long-term prognosis remain unclear.

Hardly any of the guidance documents mention age as a hard criterion for triage decisions, and all aim to avoid discrimination. However, most documents cite long-term prognosis as a decision criterion for triage, which inherently include age and comorbidities as important contributing factors. The frailty scale—a measure of comorbidities in the elderly—is recommended as a tool to establish prognosis by various guidelines. Taking into account comorbidities favours not only younger over older patients but also non-disabled over disabled people. In addition, the social determinants of health place people with lower socio-economic status and certain ethnic groups at a double disadvantage, as they not only suffer more often from comorbidities but also are affected by increased exposure to and mortality from COVID-19.⁴⁸ There is therefore a clear tension between maximizing benefits and aiming at non-discrimination of groups who are characterized by more fragile health. Focusing on short-term survival as a first-order criterion and invoking other criteria that are more susceptible to systematically disadvantaging

certain patient groups (such as long-term survival) could ease tensions in cases of a tiebreak.

Another interesting finding is the absence of explicit quality of life considerations among (benefit-maximizing) triaging criteria, which are mainly focused on survival in many guidance texts. This is understandable given the intention to avoid discrimination, which a quality of life criterion would likely imply. At the same time, it can be expected that prospective quality of life after an ICU stay would be a key criterion for individuals in their decision-making for or against ICU treatment, and this would also affect benefit-maximization strategies. The consideration of advance directives in the triage process may be a way to address this discrepancy.

Some guidance mentions the prioritization of health workers as an ethical principle, not only with a view to their instrumental value but also as a matter of reciprocity, acknowledging their readiness to help others. This statement should be critically reviewed with regard to justice and the principle of treating everyone equally, as non-health professionals may have exposed themselves in an altruistic manner but would not get preferential medical treatment.

3 | FRAMEWORK CONDITIONS FOR ETHICAL TRIAGING

Triage guidance for the SARS-CoV-2 pandemic aims to support medical teams in their difficult decision-making under stressful conditions. Decisions made under scarcity, time pressure and fatigue can lead to errors. Predefined criteria and protocols help to avoid arbitrariness in the decision-making process.⁴⁹ In many countries, the anticipated triage situation has not (yet) occurred, but the fact that guidance is in place likely reduces clinician stress, helps hospitals prepare, and can be used to raise awareness in communities. Triage for COVID is currently complicated by the fact that there is still some uncertainty as to which therapies are most helpful, and therefore the prevailing standards of ICU therapy are used. Access to experimental therapies should be governed by research protocols that have gone through ethics approval and should not fall within the triage protocols.

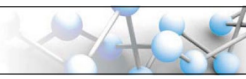
The comparative review of various national guidance documents may help policy-makers in other countries to decide quickly on the recommendations they wish to adopt. Ethical guidance must be not only clear and consistent but also implementable and contextually appropriate. As our analysis has shown, current guidance converges to a large extent, covering the following elements.

1. The core principles of a triage decision should be justice and maximization of benefit.
 - a. Include all patients, new and current, COVID and non-COVID, in triaging considerations.

⁴⁷This may be partly due to the fact that some documents are conceived as frameworks or advice rather than as guidelines.

⁴⁸Patel, J. A., Nielsen, F. B. H., Badiani, A. A., Assi, S., Unadkat, V., Patel, B., ... Wardle, H. (2020). Poverty, inequality and COVID-19: The forgotten vulnerable. *Public Health* <https://doi.org/10.1016/j.puhe.2020.05.006>; Chowkwanyun, M., & Reed, A. L., Jr. (2020). Racial health disparities and Covid-19 – Caution and context. *New Engl. J. Med.* <https://doi.org/10.1056/NEJMp2012910>.

⁴⁹Ryus and Baruch op. cit.



- b. Do not discriminate by age, race, disability, sexual orientation, religion, insurance status, wealth, social status; pay due attention to vulnerable groups (older adults, minorities, people with disabilities). Life-cycle considerations can be used as a tiebreaker.
- c. There must be a clear definition of maximizing benefit in the different stages of scarcity. It is important to distinguish between first-order criteria (e.g. short-term survival) and second-order criteria (e.g. long-term survival) that are used when there is a tie.⁵⁰ Also, flag criteria that should not be used.
2. Create preconditions for fair process through explicit criteria and triage protocols, transparent decision-making, documentation and the possibility for appeal.
 3. Allocate responsibilities for taking and communicating decisions clearly.
 4. Develop a procedure to distinguish different levels of scarcity (e.g. limited availability of ICU beds versus no ICU beds available) and the implications for decision-making (e.g. admission triage versus resource management through discontinuation of treatment).⁵¹
 5. Consistent assessment of short-term and/or long-term survival through medical criteria, tests and validated prediction scores.⁵²
 6. Regular re-evaluation, including available resources and clinical development, preferably by an independent triage committee rather than by the treatment team; rules for deciding on withdrawing or withholding therapy should be transparent and designed to minimize bias and avoid unintended negative consequences.⁵³
 7. Consider patient wishes into account when making decisions, which in triage cases is largely limited to respecting a refusal of intensive care therapy. Information about likely outcome and burden of treatment should be reviewed with the patient or with surrogate decision-makers in advance (advance care planning).
 8. Ensure palliative/supportive care availability for intensive care receive non-intensive medical care and, if appropriate, palliative care.
 9. Provide adequate protection of personnel in this physically and psychologically stressful situation.
 10. Review and evaluate triage guidance after and during the ongoing pandemic in order to create learning opportunities and trust.

This list of ethically relevant elements, which has been synthesized from newly developed COVID-triaging guidance in different

countries around the world, provides a basis for a framework to support clinical decision-making under scarcity. We will need to learn from practical experience in different settings how guidance can be improved to help health professionals make well-founded decisions in the interests of their patients and the populations they serve.

4 | OUTLOOK: COVID TRIAGING FROM A GLOBAL HEALTH PERSPECTIVE

With the COVID-19 pandemic, triage has become a (potential) reality in health systems that are used to plenty, and, at times, even perform too many procedures. Acute shortages of resources in high-income countries such as Italy, when faced with the SARS-CoV-2 pandemic, led to the rapid development of triage guidance to inform medical decision-making, improve uniformity and reduce clinician distress through sharing and justification of the decision burden. Such triage, although hard to accept from an individual or a family-member perspective, is acceptable at a population level. In countries with poorly equipped health systems, it is commonplace to make triage decisions with limited resources. Low- and middle-income countries, with more than 80% of the world's population, are expected to be severely affected by a pandemic with SARS-CoV-2. The number of available intensive care beds varies greatly among countries.⁵⁴

Triage processes and resource scarcity are highlighting many weaknesses in all health systems, which have often been overlooked and remained unaddressed because the crises were occurring at the individual and not the system level. The world is slowly realizing that there is major global inequity in access to care for COVID-19. Some countries do not have the basic capacity to ramp up the oxygen supply for patients with shortness of breath, and even if an ICU bed is available, ventilators and dialysis machines may not be. What is less acknowledged is that the stress that clinicians in high-profile and high-income settings have experienced acutely and for weeks to months is the life-and-death (dis)stress that clinicians in many low- and low-middle income settings face every day under routine circumstances. In these countries, even masks, water and soap are hard to come by in clinics and hospitals, and therefore detailed triage strategies for admission to a handful of ICU beds in the pandemic seem out of context. The true maximization of benefit in such circumstances would be the prevention of community spread, testing and contact-tracing, strict referral protocols, hotlines for suspected cases, provision of appropriate PPE to hospital staff, support for the poor to survive lockdowns, and the continuing provision of basic medical care, such as vaccinations, malaria control, TB and HIV treatment, and the treatment of other conditions such as hypertension and diabetes to minimize additional deaths. Ironically, countries such

⁵⁰White, D. B., & Lo, B. (2020). A framework for rationing ventilators and critical care beds during the COVID-19 pandemic. *JAMA*, <https://doi.org/10.1001/jama.2020.5046>, <https://www.ncbi.nlm.nih.gov/pubmed/32219367>.

⁵¹*Ethics and COVID-19: resource allocation and priority-setting*. Retrieved from <https://www.who.int/blueprint/priority-diseases/key-action/EthicsCOVID-19resourceallocation.pdf> [accessed May 12, 2020].

⁵²Satomi, E. P., Souza, M. R., Thome, B. D. C., Reingenheim, C., Werebe, E., Troster, E. J., ... de Mello Borges, P. C. (2020). Fair allocation of scarce medical resources during COVID-19 pandemic: ethical considerations. *Einstein (Sao Paulo)*, *18*, https://doi.org/10.31744/einstein_journal/2020AE5775.

⁵³Peterson, A., Largent, E. A., & Karlawish, J. (2020). Ethics of reallocating ventilators in the covid-19 pandemic. *BMJ*, *369*, <https://doi.org/10.1136/bmj.m1828>.

⁵⁴Phua, J., Faruq, M. O., Kulkarni, A. P., Redjeki, I. S., Detleuxay, K., Mendsaikhan, N., ... Fang, W. F. (2020). Critical Care bed capacity in Asian countries and regions. *Crit. Care Med.*, *48*(5), <https://doi.org/10.1097/ccm.0000000000004222>.

as South Africa and India have experienced fewer deaths overall during lockdowns for COVID-19 than at baseline, as homicides and road-traffic accidents declined. There has been a massive mobilization of resources to increase treatment capacity in high-income settings: such efforts are urgently required to develop a long-term and sustainable approach in lower-income settings, and to begin to address the social and structural inequities that underlie health inequities.⁵⁵ Attention is required to address much beyond COVID-19 worldwide.⁵⁶

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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⁵⁵Marmot, M. (2018). Just societies, health equity, and dignified lives: the PAHO Equity Commission. *Lancet*, 392(10161), [https://doi.org/10.1016/s0140-6736\(18\)32349-3](https://doi.org/10.1016/s0140-6736(18)32349-3).

⁵⁶Chiriboga, D., Garay, J., Buss, P., Madrigal, R. S., & Rispel, L. C. (2020). Health inequity during the COVID-19 pandemic: a cry for ethical global leadership. *Lancet*, 395(10238), 1690–1691. [https://doi.org/10.1016/s0140-6736\(20\)31145-4](https://doi.org/10.1016/s0140-6736(20)31145-4).