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Triage protocol for allocation of critical health resources during the COVID-19 health emergency. A review.

Laura Iacorossi[1], Alice J. Fauci[1], Antonello Napoletano[1], Daniela D'Angelo[1], Katia Salomone[1], Roberto Latina [1], Daniela Coclite[1], Primiano Iannone[1]

[1]National Center for Clinical Excellence, Quality and Safety of Care (CNEC), Istituto Superiore di Sanità, Rome, Italy

Summary. *Background and aim of the work.* Triage during the Covid-19 pandemic can impose difficult allocation decisions when demand for mechanical ventilation or intensive care beds greatly exceeds available resources. Triage criteria should be objective, ethical, transparent, applied equitably and publically disclosed. The aim of this review is to describe the triage tools and process for critical care resources in a pandemic health emergency. *Methods.* A narrative review was conducted of the literature on five electronic databases, namely PubMed, CINHAL, Web of Science, Cochrane and Embase, searching for studies published from January 2006 to July 2020. *Results.* The results describe different triage tools. A gold standard of triage does not exist for the adult or paediatric population. Using probability of short-term survival as the sole allocation principle is problematic. In general, each triage protocol should be applied with a specific ethical justification, including transparency, duty to care, duty to steward resources, duty to plan, and distributive justice. *Conclusions.* Clinical triage decisions based on clinical judgment alone are prone to inconsistent application by triage officers in a pandemic. An ethical framework can inform decision-making and improve accountability. It remains difficult to connect clinical criteria and ethical criteria, because of the models on offer for health services. (www.actabiomedica.it)

Key words: Triage, Resource Allocation, Pandemic, COVID-19, Ethics

Introduction

Since 31 December 2019 and as of 01 July 2020**,** 10,446,353 cases of Covid-19 have been reported, including 511,037 deaths (1), and the number of Covid-19 patients and deaths are increasing day by dayin the world (2). The pandemic spread of severe acute respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has placed a massive strain on health-care systems in several countries in the world, including in Europe and in Italy (3,4). Among hospitalized patients, the percentage of patients who required intensive care unit (ICU) care has varied from 5% to 32% (5,6), and in Italy, 1,287 patients (99%) needed respiratory support, including 1,150 (88%) who received mechanical ventilation (7). Without a clear triage protocol to allocate scarce life-saving treatments in a pandemic, heathcare practitioners could be vulnerable to legal actions after the fact, and patients could be vulnerable to the idiosyncratic beliefs, judgments, and morals of individual triage officers making life-and-death decisions (8). Triage also involves allocating scarce resources to "do the greatest good for the greatest number" (9). The Ontario Health Plan for an Influenza Pandemic (10) suggests four key elements of the protocol: a) specific triage processes for different hospital locations, b) definitions of supplementary criteria and guidelines for their use, c) the creation of a triage team model with quality assurance processes and d) worksheets and tools to support practice. The application of a triage

may seem limiting and a danger to the protection of patients and health-care practitioners, with potential ethical, clinical and legal implications, as has happened in other disasters (11,12,13). The most common classification of triage protocols is based on the location and level of care at which the triage takes place: primary (in the community), secondary (in emergency departments), and tertiary triage (14,15). Tertiary triage occurs within the hospital with the aim of prioritizing patients and, if necessary, allocating resources, for definitive care, either in ICU or in palliative care. The choice to set limits on access to treatment is not a discretionary decision, but one in which ethics can offer support and reflection for decision-making activities, balancing ethical principles and duties of care, contextualized to the health emergency (16). The purpose of this document is to describe the tertiary triage tools and process in a pandemic health emergency and in the case of Covid-19.

Methods

A narrative review of the literature was conducted by using five electronic databases, namely PubMed, CINHAL, Web of Science, Cochrane and Embase, from January 2006 to July2020. The search strategy on PubMed was using Mesh-terms and boolean operators: (((((((Allocat* OR manage*) AND ((limit* OR low OR scarc* OR poor OR meagr* OR few) AND (Resource* OR Efficiency)))) OR "Resource Allocation"[Mesh])) AND (((((((“Triage”[Mesh] OR (Triag* OR prioritiz*))) AND (“Clinical Protocols”[Mesh] OR ((Protocol* OR plan*) AND (clinic* OR treatment* OR medic*))))) AND (“Critical Care”[Mesh] OR ((Critic* OR intensiv* OR ICU) AND (care* OR caring OR assistanc* OR treatment*))))) AND (((((Pandemic* OR Epidemic) OR (((health AND (public* OR communit*)) AND (emergenc* OR disaster* OR cris*))))) OR ((“Pandemics”[Mesh] OR “Epidemics”[Mesh]) OR (“Public Health”[Mesh] AND “Emergencies”[Mesh]))))) AND “ethics” [Subheading]. The reference lists of relevant studies were also scanned. The software package EndNote X8 (Clarivate Analytics, PA, USA), was used to manage bibliographies and references.

Inclusion and exclusion criteria

All articles that dealt with triage methods, as clinical protocols, tools, ethical protocols, and frameworks to allocate critical care resources during a pandemic were included, published between January 2006 and July 2020, in English and Italian. All articles written in other languages were excluded.

Study selection

The article titles and then abstracts were initially subjected to a screening process conducted by two independent researchers, aimed at assessing their potential correspondence and relevance to the inclusion criteria. In case of discrepancy, the results were discussed until an acceptable degree of concordance was reached. At the end of the screening of the abstracts, the full text of the relevant publications was retrieved and analyzed. The results of the research process and selection of studies were reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Results

This review describes the triage protocols, tools, criteria, ethical justification, and framework presented in the literature.

1. Triage protocols

The triage process is an effective decision-making strategy for health-care providers (17). The decision to initiate adult and pediatric triage should be developed by an identified regional authority (18). Without a triage plan, patients will receive critical care resources at random or on a first-come, first-served basis (19), which cannot be applicable in a public health emergency, because the response to a pandemic requires provisions on an organizational model employing disaster triage (20). Tertiary triage occurs within the hospital with the objective of prioritizing patients, and if

required allocating resources, for definitive care (14), intensive care, or palliative care. Tertiary triage decisions are generally more complex than earlier triage decisions, and so they are conducted by a senior clinician, such as an anesthetist-intensivist, based on his/her clinical experience among other things (21), and assisted by hospital physicians in deciding whether referral to the Intensive Care Unit (ICU) is appropriate (22). Reverse triage is used to discharge pediatric or adult patients at low risk of adverse events from either the ICU or hospital wards in turn to create ICU capacity (23). In a pandemic, it is unlikely that supplemental resources would be available, so triage of resources would be required to offer the "greatest good to the greatest number" (24). In resource-scarce situations, it is important to keep two key concepts in mind: "under-triage" and "over-triage" as population outcomes. Under-triage results in delayed treatment, impacting the chance of survival for the individual as well as the overall survival rate within the population. Over-triage can cause potentially inappropriate consumption of limited resources, so the overall population outcome is worse (24,14). A fair process is required to establish the legitimacy of all decisions (26). Generally, the triage protocol has 4 main components: 1) inclusion and 2) exclusion criteria: a model set of criteria would define objectively those patients with a high risk for mortality even with ventilator support and would not rely on subjective judgments of quality of life; 3) minimum qualifications for survival: these represent a boundary on the amount of resources that will be expended on anyone patient; 4) prioritization tool(s) used to assist the triage officer in allocating critical care resources (27). The clinical protocol can include an ethically acceptable framework for allocating ventilators in a pandemic (28): a) Pre-triage *requirements*, such as systems for sharing information about equipment availability, staffing shortages. b) *Patient categories* (who require critical care, and not only patients with the pandemic disease). c) *Triage decision-makers* (e.g. triage officers, triage committees). It is most important to separate clinicians providing care from those making triage decisions. These decisions should be reviewed regularly by a centralized state-level monitoring committee to ensure that there are no inappropriate inequities (29). The creation and use of triage committees, informed by experience in the current pandemic (30) and prior written recommendations, can help mitigate the enormous emotional, spiritual, and existential burden to which caregivers may be exposed (31). In all cases, physicians and nurses involved in triage decisions can and should defend egalitarianism in the allocation of health-care resources in a public health crisis and advocate and act against unfair exclusion were it to occur (32). d) *Clinical evaluation*: a variety of tools for triaging exist, each with a specific clinical-criteria justification, and they select or exclude patients on the basis of illness severity, associated medical comorbidities, or predicted mortality (33). Patients with underlying illnesses with high mortality rates are managed outside the ICU and provided with palliative care as needed (17,34). e) *Palliative care***.** Offering and implementing palliative care or end-of-life care to alleviate suffering even in patients suffering from Covid-19/SARS-CoV-2, in a pandemic or public health emergency is good clinical practice (35) as well as an ethical duty, especially in the final stage of life (36), involving a holistic and humane approach (37). Palliative care is based on the ethical principles of beneficence and non-abandonment (38). Protocols for terminal extubation should offer guidance to clinicians where transparency guarantees the adherence to ethical standards (39). The organizations should pay attention to reducing the possible negative effects of transitions to palliative care, such as discontinuity of care (40). f) *Review of triage decisions*. A daily retrospective review of all triage decisions is an alternative to a real-time appeals process (39). The triage algorithm should also be reviewed regularly as knowledge about the disease evolves.

2. Triage tools

Triage should only be initiated when critical care resources are or will be overwhelmed and all efforts to extend available resources or obtain additional resources have been instituted (27). A gold standard of triage tool does not exist, because there is a lack of high-quality studies within the field of disaster medicine (41,42,43). The introduction of multiple evidence-based clinical practice protocols was associated with a decline in severity-adjusted hospital mortality

and improvement in clinical outcomes of critically ill patients (44). The goals of the triage tools are to a) manage patient surge in a variety of healthcare settings during an influenza pandemic; b) sort patients to the appropriate place for appropriate care; and c) provide the greatest good for the most people by treating the maximum possible number of influenza patients in the most appropriate settings (45). Patients who present for tertiary triage are going to fit into one of three categories: a) sick enough to benefit from critical care b) too well to benefit from critical care; (c) too sick to benefit from critical care. It is essential to apply the triage process to all patients presenting with critical illness, not just those infected with SARS-CoV-2 (19). The literature describes several tools applicable to tertiary triage in the event of a pandemic, for adults and pediatric patients. Prior to the emergence of the H1N1 pandemic (2009), Health Protection Agency guidance recommended the use of the CURB65 pneumonia score in adults (46). Another study suggests that CURB65 appeared an unreliable triage tool (47). One study assessed the validity of Sequential (previously Sepsis-related) Organ Failure Assessment (SOFA) scores-based triage in H1N1 critically ill patients during an influenza pandemic (48). The minimum requirement for survival requires a reassessment of SOFA scores at 48 and 120 hours to judge the response to treatment. The scoring is simple, easily reproducible, and based on physiological parameters. SOFA broadly describes the severity of end-stage organ dysfunction, regardless of etiology, from each of six organ systems and the Glasgow Coma Score (GCS) (49). Some authors have previously suggested the use of SOFA scores for triage during pandemic periods, owing to their relative ease of calculation (17). Moreover, Acute Physiology and Chronic Health Evaluation II (APACHE II) scores may help to identify patients at high risk of death (50), and its score demonstrated better discriminative ability than SOFA and CURB65 scores, as an effective clinical tool to predict hospital mortality in patients with Covid-19 compared with the other two tools (51). In a study conducted in ICU, on coronavirus patients, APACHE II and Simplified Acute Physiology Score II (SAPS II) (52) scales had better discrimination, calibration, and power to predict deaths in ICU than SOFA (53). The quick SOFA (qSOFA) was not inferior to SOFA or CURB65 scores in predicting the ICU-admission, ARDS and 28-day mortality of patients presenting in the ED with community-acquired pneumonia (54). Another tool used in a pandemic was the Pandemic Modified Early Warning Score (PMEWS). This score uses physiological variables, age, social factors, chronic disease, and performance status (55), but it is not a particularly good predictor of death in community-acquired pneumonia. In Italy, the Brescia Respiratory COVID Severity Scale (BRCSS) (3) was created and used to describe the clinical improvement or worsening of the disease and to try to create replicable treatments among patients in ICU and admitted to the wards. It offered value in triage and assignment of resources, aspects of care that are foreign to most physicians. Data collection was limited to ICU stays only and can not supply information on non-ICU patients or recovery courses outside the ICU. Although the BRCSS has not been validated for clinical progression of Covid-19, the use of the BRCSS scale may augment communication between non-intensivist physicians and nurses. Periodic reassessment of clinical improvement, deterioration, or any other changes that affect prognosis of patients is a necessary part of any triage algorithm, where Covid-19 illness seems to last longer than influenza, suggesting reassessments at 48 and 120 hours (day 2 and 5) and re-categorization (27). In epidemics, it suggests not using scoring systems alone to determine levels of care or removal from higher levels of care, because they are not accurate in predicting individual mortality (GRADE-Grade 2C) (41). In pediatric settings there are different tools to determine prognostic scores: a) Pediatric Logistic Organ Dysfunction (PELOD) (56); b) Pediatric Risk of Mortality III–Acute Physiology Score (PRISM II) (57), with additional diagnostic categories in PRISM III; c) Pediatric Early Warning System (58); d) SOFA for pediatrics; and e) Pediatric Index of Mortality 2 (59). Although several pediatric prognostic scores are used for research purposes, the lack of a validated global pediatric scoring system requires reliance on disease-specific criteria (34), and their performance characteristics limit their utility in directing resource allocation (60). The ability to operationalize the goals depends on establishing clear goals, and hence it is necessary to develop effective triage protocols (20).

Clinical decisions based on clinical judgment alone are prone to an inconsistent application by triage officers (61), and there are concerns about the inadequate performance of existing scoring systems, based on mathematical modeling and the retrospective application of scoring systems to actual patients (62,63).

3. Triage criteria and ethical justification

Specific clinical criteria for the pandemic influenza triage tools for ICU admission, discharge, and exclusion have been developed (45,64,65), which should be explicitly described (66). Triage criteria should be objective, ethical, transparent, applied equitably, and be publically disclosed (18,27). They must take account of the ethical goals of the allocation framework, and they cannot use categorical exclusion criteria (67). The supplementary criterion of prognosis considers factors that suggest better, or worse outcomes based on clinical judgment and experience (25,39,68). Therefore, flexible systems and processes must be in place to modify existing protocols and guide oversight and research (20). Using the probability of short-term survival as the sole allocation principle is problematic. In public health emergencies a variety of ethical justifications for triaging exists (15):

• ***Save the greatest number of people*****:** When rationing scarce medical resources, it is ethically appropriate to save the most lives (69). It is probably the one principle that serves as a basis for much of any "crisis standards of care" plan.

• ***Maximizing net benefit***: Maximization of benefits can be understood as saving the most individual lives or as saving the most life-years by giving priority to patients likely to survive the longest after treatment (70,71). Removing a patient from a ventilator or an ICU bed to provide it to others in need is also justifiable, and patients should be made aware of this possibility at admission (72).

• ***Protect the most vulnerable:*** This criterion directs us to give priority in allocation decisions to the most vulnerable category or categories of people. Such allocation strategies may be based on a patient's preexisting clinical conditions (e.g., chronic diseases, unable to self-report, pregnancy) and social criteria (e.g., criminal status). If this criterion is chosen, we should give priority for life-saving interventions to members of vulnerable groups.

• ***Equal access:*** If this criterion is chosen, no person should be given priority over another, giving everyone equal access to the benefit of a resource, or at least an equal chance of accessing the benefits. The triage process treats patients equally based on objective, physiological and clinical criteria. In order to ensure procedural justice, any triage operation should be regularly and repeatedly evaluated to guarantee that the process has been followed fairly (68).

• ***Life cycle principle*****:** This means that younger individuals should have a right to the same number of years to live as an older person has already had (childhood, young adulthood, middle age, and old age). Thus, younger individuals receive priority because they have had the least opportunity to live through life's stages. Empirical data suggest that, when individuals are asked to consider situations of absolute scarcity of life-sustaining resources, most believe younger patients should be prioritized over older (73). However, some assessment prognostic tools assign ages as an integrant part of a system that determines the total score, so age is considered as an indirect indicator.

• ***First come, first served*****:** This criterion directs us to give priority in allocation decisions to whoever accesses the resource first, independent of the severity of medical need or the needs of others. This principle violates the duty to steward resources, the duty to plan, and the distributive justice standards (74). It should not be applied in a pandemic public health emergency.

• ***Instrumental value:*** This criterion directs us to allocate resources in such a way as to ensure that the individuals who are most important for society are given priority for access. In a morally pluralistic society, it has not been possible to agree upon a set of criteria to assert that one individual is intrinsically more worthy of saving than another. Thus it is impossible to agree on this "value".

• ***Lottery:*** This criterion means that if equal access cannot be given, the solution is a lottery; it is used for patients with similar prognoses, so equality should be invoked and operationalized through random allocation, rather than a first-come, first-served allocation process (71).

4. Ethical framework

An epidemic of such magnitude as the Covid-19 that is sweeping the world nowadays establishes firstly important ethical issues (75). Discussions of ethics in disaster events generally, but not exclusively, revolve around two classic ethical theories: utilitarianism and egalitarianism. For utilitarianism, the survival of the greatest number is fundamental. Some of the criticisms of the utilitarian approach include the fact that the impartial application of this principle could lead to the rights of the individual being severely trampled as the interests of the majority override those of the minority. The response to the need to save as many lives as possible is closely dependent on the economic resources of each country, the potentiality of the hospitals (number of adults and pediatric, ICU beds available, number of trained health workers), as well as the availability of a programmatic plan as a response to a pandemic emergency. Egalitarianism involves the concept of equality among persons as well as equal distribution of resources (17). During an influenza pandemic, Governments and public health authorities, health-care workers, members of the public and patients, are more likely to accept difficult decisions if the decision-making processes are characterized by:

• ***Transparency.*** This means providing open access to information and decision-making (76). The need for transparency stems in part from the Government's ethical imperative to treat citizens with respect, in particularly vulnerable people, and it is essential to create and maintain trust and responsibility in public health (72,77,78). The components of the decision-making model must be made available to family members in a written document, on or immediately after admission (79). Each state should make public the decision-making process, translate it into different languages, share it also with the representatives of the most disadvantaged citizens (41), and seek public comment (80). Patients and families should receive clear and transparent communication (81,21) about the ethical and procedural triage process (63), ICU admission or ventilator treatment (41), and palliative care (82). The principle of respect for people and their autonomy requires informed consent to be obtained and their informed refusal to be respected (83,17).

• ***Duty to care.*** In a pandemic health emergency (84), by virtue of severe resource scarcity, an ethically sound rationing system must sustain the fundamental obligation of health practitioners to care for patients (85,39). In particular, physicians and nurses must not abandon patients and they should not fear abandonment, in a just system of allocation, as emphasized by physicians' and nurses' Ethical Codes (86,87). The duty to provide care, however, is not limited to patients infected by the pandemic, but includes emergency teams, families, community, colleagues, and non-infected patients (88). Duty of care is possible if hospitals protect their staff and families of staff (84).

• ***Reciprocity.*** Reciprocity requires that society supports those who face disproportionate burdens in protecting the public good and takes steps to minimize their impact as far as possible (26,84). Issues of reciprocity mean that society may have obligations to clinicians during disasters. These obligations may include priority access to scarce resources, liability protection, a duty to plan, and more (85).

• ***Duty to steward resources.*** During a period of true scarcity, all health-care providers need to save the greatest possible number of lives (39). For this purpose, each member of the team should be educated about the disease, its prevention, treatment (18), and on ethical issues in case of pandemics.

• ***Duty to plan.*** Unlike in traumatic disasters, victims of epidemics do not die instantly, and deaths usually occur following hospitalization and critical care interventions, so may require a large surge in the need for critical care capacity (22). Good pandemic planning requires reflection on values because scientific information alone cannot drive decision-making (26). Surge capacity planning identifies the need for each Government to have a plan for crisis standards of care based on objective triage systems, with a reproducible and transparent process born of the need to ration critical care resources.

• ***Distributive Justice.*** Distributive justice refers to the fair and appropriate distribution of benefits, risks, and costs within a society. All patients must have equal access to care. The decrease of disparities in access to care and resources is generally thought to be difficult. Egalitarianism is one example of a distributive justice principle (39).

Conclusions

This review argues for specific priorities on the basis of maximizing health benefits, where triage can saving most lives and equity, but also acknowledges that basic ethics and principles allow consideration of certain other priorities (89). This descriptive review highlighted three aspects: 1) a gold standard of triage does not exist for the adult or pediatric population; 2) triage tools alone, without ethical support, do not guarantee protective standards for all those involved in a pandemic; 3) applying a multi-principle allocation strategy can be a good guide for decision-making during a pandemic, but it is not simple, and the boundary between ethics and clinic is not always clear. It suggests setting up clinical Ethics Committees in hospitals, where not foreseen a support of doctors and nurses, where the intervention of an Ethics Committee ensures that the decision is not left to the sole judgment of health practitioners. Unresolved ethical and practical dilemmas about critical care resources could threaten the success of the response to a public health emergency. These dilemmas should be discussed in advance within the academic curricula of physicians, nurses, psychologists, ethicists, and legal practitioners, and in particular by healthcare workers trained with advanced skills in public health emergencies, to prevent stress and legal impact on practitioners, patients, and family members involved. Future reflection should also be directed to research on triage tools among the population of adults and children so that the multi-principle allocation strategy is integrated as much as possible, and the support of palliative care is strengthened.

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Correspondence:
Dr. Roberto Latina
National Center for Clinical Excellence, Quality and Safety of Care (CNEC), Istituto Superiore di Sanità
Via Giano della Bella, 34, 00162 Rome, Italy
Tel. +390649904385
Email roberto.latina@uniroma1.it