



PRELIMINARY GUIDANCE FOR HEALTH CARE FACILITIES

Ethical Considerations, Implementation Processes, and Clinical Evaluation Tools for Crisis Standards of Care for Pandemic or Disaster Planning and Response

ADOPTED _____, 2020

INTRODUCTION

In the event of a disaster, the medical needs of the public can usually be met by the existing health care system operating under a coordinated response effort among local, state, and federal resources, without major alterations in the standard of care. However, some large-scale disasters or catastrophic public health emergencies, such as a pandemic, can threaten to overwhelm capacity of available critical resources within a community or region for a period of time. In such catastrophic events, there may not be enough critical resources for all who need them or there may be disruptions in how those resources are accessed, despite advance planning and all reasonable efforts to mitigate shortages, coordinate resources across the state, and augment medical surge capabilities. Accordingly, changes in the usual approaches to care and practice may be necessary forcing the health care systems to transition from conventional or usual care, to contingency-level care that supports the provision of functionally equivalent care, and, if necessary, to crisis-level care when available resources are inadequate to meet all important patient care needs.

Proper disaster preparedness and response strategies indicate that it is appropriate to establish formal guidance regarding how critical resources should be allocated under crisis standards of care and where there is a scarcity. Such guidance has been developed in the Commonwealth of Virginia in the past, but now must be updated and refined to ensure that it is equitable and reflects principles of ethical decision-making that take into account the values of its people and communities.

PURPOSE

The purpose of this guidance document is to set forth a framework through which all hospitals and other health care institutions in the Commonwealth involved in allocation of critical resources should establish and implement an equitable and ethical policy for allocating such

scarce resources under crisis standards of care should capacity be strained as a result of a pandemic or other disaster. This framework includes ethical considerations that should guide development and implementation of such policies and procedures, as well as, recommendations for the development of clinical decision-making processes and algorithms for triaging patients under crisis standards of care. The primary focus is acute care hospitals and the policies and triage protocols contained herein are directed towards possible shortages of acute care resources such as intensive care unit beds, critical care services, ventilators, and other resources deployed in inpatient hospital care. However, any facility involved in allocation of critical resources should recognize and adhere to the ethical considerations and non-discrimination principles contained in the policy in decision-making around critical resources and in their disaster planning and response activities. Also, with respect to hospitals, while this guidance document prescribes certain actions that all hospitals should take, it recognizes that there will be variability in hospitals' capacity to allocate resources based on the real-time situation in their communities and in the specific clinical decision-making tools and algorithms used to evaluate patients.

Implementation of allocation policies will occur when adherence to conventional standards of care is no longer possible due to resource constraints, capacity demands, and other factors. Furthermore, allocation policies are not a substitute for, and are only implemented after, mitigation strategies are no longer sufficient to allow conventional use of resources and when coordination efforts within and among facilities, in a region, and across the state, are no longer possible because the system is overwhelmed. As an overarching principle, every effort will be made to avoid the need to implement allocation policies through advance planning, mitigation, and coordination of resources across the state. Consistent with the principles embodied in this guidance document, these mitigation strategies, and the sharing of resources and coordination efforts among facilities, in a region, and across the state, should be undertaken in a manner that is equitable and reflects principles of ethical decision-making that take into account the values of the people of the Commonwealth.

To address these needs, it is therefore essential that all hospitals develop an ethical, evidence-based process for the allocation of critical resources. This guidance is intended to provide a unified, transparent framework that supports consistent hospital and health care provider decision-making aimed at maximizing the benefit from allocation of critical resources. Each hospital or other institution has the flexibility to develop its specific allocation policy and triage protocols based upon its particular resources and circumstances and the needs of the communities it serves, but each institution's policy and protocols should be consistent with this overall framework.

To assure providers, patients, their families, and the community that crisis standards of care will be applied fairly, it is essential that the ethical grounding of this guidance be clearly and

specifically stated. The overwhelming need for care created by a disaster would necessitate a shift of focus from the absolute care of the individual to promoting the conscientious stewardship of limited critical resources intended to result in the best possible health outcomes for the population as a whole. The delivery of health care under crisis standards of care is ultimately about maximizing the care delivered to the population as a whole under austere circumstances that may limit treatment choices for both health care providers and patients. Health equity for all persons is a key foundation for compliance, and advance planning is critical to providing the best quality of care to every person.

To ensure no person with a disability will be discriminated against in the implementation of allocation policies or triage protocols, or in communication access related to same, any such policies or protocols and any criteria used in making decisions about treatment during a health care emergency must include measures to address compliance with the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act, the Age Discrimination Act, and Section 1557 of the Affordable Care Act, which prohibit discrimination in HHS-funded health programs or activities, and corresponding state laws, including the Virginians with Disabilities Act.

This guidance document should be routinely reviewed and updated as necessary to take into account new information and developments, such as clinical information or data on treatment effectiveness, and to reflect changes in best practices for allocation of critical resources during a scarcity, such as development or adoption of new methodologies for objectively assessing and triaging patients for critical resource allocation.

DEFINITIONS

Provided below are definitions and additional information on various terms used throughout this guidance document.

Activate or Activation – Initiation of a triage protocol for all facility patients in need of critical resources.

Allocation Policy – a policy for distribution of critical resources to facility patients for activation during a scarcity using a triage protocol consistent with this guidance document.

Triage Protocol – the specific procedures consistent with this guidance that, when an allocation policy is activated, are implemented to analyze how critical resources are to be distributed among patients during a scarcity.

Critical Resources - may include, but are not limited to: medications; tests and testing supplies; space; personnel; mechanical ventilators; extracorporeal membrane oxygenation; beds; medical gases; antibiotics; vaccines; antivirals; vasopressors; personal protective equipment; hemodialysis equipment; blood products; crystalloid; operating room equipment; pharmacological treatments; palliative care resources; persons trained in critical care or other specialty-trained and qualified staff; and other resources and related infrastructure that authorized facility representatives deem medically necessary for appropriate patient care.

Scarcity – circumstances under which critical patient care needs at a facility exceed that facility’s supply of critical resources that cannot be mitigated through coordination of resources or augmented medical surge capabilities.

Health Equity – Health equity is achieving the highest level of health for all people. Health equity entails focused societal efforts to address avoidable inequalities by equalizing the conditions for health for all groups, especially for those who have experienced socioeconomic disadvantage or historical injustices.

Facility – an acute care hospital, emergency department, or other location providing acute health care.

Critical Resource Allocation Group (CRAG) or Resource Planning and Allocation Team (RPAT) – a multi-disciplinary group responsible for developing and overseeing a system-wide allocation policy for a facility or group of facilities.

Triage Team – group comprised of professionals with the relevant skill sets, including: medical, nursing, or other specialized clinical experience responsible for implementing triage protocols at the facility level and make decisions related to distribution of patient care resources based upon the allocation policy and triage protocols.

Treating Provider – an appropriately licensed physician or licensed independent practitioner (LIP) involved in direct patient care at a facility.

Health Care Team – the group of health professionals (treating providers, registered nurses, physician assistants, clinical pharmacists, respiratory therapists, and other healthcare professionals) and administrative and support staff responsible for coordinating care specific to a patient’s clinical needs and circumstances.

Regional Health Care Coalition – a collaborative network of health care organizations and their respective public and private sector response partners established by Virginia

Healthcare Emergency Management Program (VHEMP) that serve as a multiagency coordinating group to assist with preparedness, response, recovery, and mitigation activities related to health care organization disaster operations. The purpose of the Regional Health Care Coalition is a health care system-wide approach for preparing for, responding to, and recovering from incidents that have a public health and medical impact in the short and long-term. Regional Health Care Coalitions are responsible for coordinating across diverse and otherwise competitive health care organizations and emergency response partners to ensure that the region and its health care providers have the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to disasters, including pandemics.

BACKGROUND ON CSC PLAN AND IMPLEMENTATION

The Commonwealth's Crisis Standards of Care (CSC) Plan establishes a process for, among other things, developing incident-specific priorities and guidance for the delivery of health care and the use of scarce medical resources on topics such as:

- Triage and transportation determination for emergency medical services (EMS);
- Primary, secondary, and tertiary triage for health care facilities;
- Expanded scopes of practice, as approved by regulatory authorities;
- Priorities for medical resources including space, staff, and supplies; and
- Considerations for health care access points, including hospitals, long-term care facilities, outpatient care centers, and alternate care sites.

This process involves coordination among the State Commissioner of Health, Secretary of Health and Human Resources, the Unified Command, the Virginia Disaster Medical Advisory Committee (VDMAC), and the Virginia Healthcare Emergency Management Program (VHEMP).

The VDMAC is activated by the State Commissioner of Health to serve as the statewide policy group for the Virginia Healthcare Emergency Management Program (VHEMP).

VHEMP is a statewide hospital preparedness and response program funded by the Virginia Department of Health through a federal grant from the U.S. Department of Health and Human Services, Assistant Secretary of Preparedness and Response. VHEMP oversees and coordinates across the six Regional Health Care Coalitions to prevent the need for critical resource allocation within hospital or other institutions allowing for critical resources, such as ventilators to be

moved to facilities where there is a capacity shortage or to transfer patients where intensive care units are overwhelmed. Nevertheless, prudent planning calls for hospitals and other institutions to have allocation policies in place and that can be quickly activated should they be needed.

ACTIVATION OF ALLOCATION POLICIES

The primary objective for comprehensive critical resource management is to maintain the usual or functionally equivalent standard of patient care during a medical surge event. The cornerstone of these planning efforts is the ability of facilities to anticipate, mitigate, and respond to imbalances between resource availability and demand for services as necessary to avoid a scarcity of critical resources. This requires a system-wide approach to disaster planning and response.

Although this guidance document focuses on acute care hospitals, it is important to note that responsibility for disaster planning and response and appropriate use of medical resources does not rest solely with hospitals, rather it is shared across the continuum of care. Long term care facilities, emergency first responders, freestanding emergency departments, community-based health clinics, home health, hospice agencies, outpatient medical and surgical facilities, and primary care physicians also play a role in preparing for staff shortages, adaption of space for surge response or mitigation, conservation of resources, and continuity of operations during a scarcity in their facility or the community.

Recognizing that, despite extensive disaster planning and response efforts, mitigation strategies, and conservation of resources across the continuum, shortages of medical resources is probable, crisis standards of care planning efforts should include identifying specific indicators and triggers for when a crisis-level standards of care is approaching and implementation of allocation policies may be required. These indicators and triggers will guide transitions along the continuum of care, from conventional, to contingency, to crisis, and in the return to conventional care. Use of allocation policies will be implemented only when there is no acceptable alternative, and their use will be discontinued as soon as possible.

Indicators are measures or predictors of changes in demand and/or resource availability in the health care system that may be based on situational awareness or factors specific to an event. The presence of indicators is detected through monitoring events and data that may affect the health care system and observing changes in the usual resources and usage patterns at the local regional and state levels.

Examples of indicators for health care facilities included in the Commonwealth Crisis Standard of Care Plan include:

CONVENTIONAL	CONTINGENCY	CRISIS
<ul style="list-style-type: none"> • Usual patient care space fully occupied • Usual staff called in and utilized • Cached and usual supplies being used 	<ul style="list-style-type: none"> • Patient care areas re-purposed (e.g., PACU or monitored unit used for ICU-level care) • Staff extension in place (brief deferrals of non-emergency patient-care services, supervising broader groups of patients, changes in responsibilities and documentation, etc.) • Conservation, adaptation, and substitution of supplies • Hospital on diversion 	<ul style="list-style-type: none"> • Health care facility unsafe or closed • Non-patient care areas used for patient care • Trained staff unavailable or unable to care for the volume of patients • Critical supplies lacking • Re-allocation of life-sustaining resources • Patient transfer not possible or sufficient

Triggers are decision points to activation of crisis standards of care based on changes in the resource availability that require adaptations to health care services delivery along the continuum. These triggers occur at the point where strategies implemented for conventional or contingency care are no longer sufficient to provide functionally equivalent care. Applying this to the indicators listed above at the individual facility level, should the indicators suggest that elevation to contingency or crisis-level standards of care is occurring or can be anticipated, despite mitigation strategies and conservation of resources, the facility would coordinate with state partners and other facilities as part of the larger disaster response efforts to assess whether there are other available resources (*e.g.*, supplies, staff, or space) through which such contingency or crisis standards of care activation could be averted. It is possible that an individual facility could elevate to crisis-level standards of care for a brief period until reallocation of critical resources is possible as part of larger facility coordination and response efforts. To the greatest extent possible, activation of allocation policies and use of triage protocols should be avoided; it is only when critical resource capacity for facilities in a region or across the state becomes overwhelmed that the need for more continual or widespread use of allocation policies is required.

DEACTIVATION OF ALLOCATION POLICIES

As the severity of the disaster subsides or stabilizes, the scarcity of certain critical resources may be resolved at different times (*e.g.*, intensive care units may become available, but ventilators may remain scarce) and in different areas or regions of the state. When there is no longer a scarcity of critical resources, termination of crisis-level standards of care should occur and health care facilities should strive to return to contingency or conventional standards of care as quickly as possible. This deactivation will occur when all impacted facilities are able to meet patient demand using contingency-level standards, or when patient transfer or evacuation becomes a feasible tactic to alleviate crisis-level surge at affected facilities. In the case of a severe resource shortage prompting crisis-level standards of care, deactivation may occur when supply levels become sufficient to meet health care system demands.

It is important to note that the deactivation does not stop emergency operations at the state, local, or facility level. Emergency operations and emergency declarations may still be in place, despite the fact that crisis-level standards of care has been deactivated.

STATEWIDE APPLICATION OF ALLOCATION POLICIES

There is no national or universally accepted standard for allocation policies in response to a pandemic or other disaster. Professional organizations, states, regions, and localities have adopted different approaches to allocation of critical resources during a scarcity. One reason for the lack of a single accepted allocation method is the lack of an empirical basis establishing reliability and validity. In addition, Virginia hospitals and other institutions vary in capabilities and populations served: organizational mission, culture, and values; and corporate structure and obligations that may cross state boundaries.

Despite the absence of a national standard, resource allocation policies generally contain similar core ethical values and assumptions and use similar core methodologies that:

1. Reflect core ethical values and include a commitment to respect for persons, fidelity, fairness, equity, justice, accountability, and transparency;
2. Are designed with the goal of maximizing benefits based on an objective assessment of patients' chances of survival;
3. Use objective indices of organ failure to make clinical assessments;
4. Will not allow decisions to be negatively influenced by, or disadvantage individuals based upon, race, culture, color, national origin, religion, marital status, age, sex, sexual orientation, gender identity, disability, socio-economic or insurance status, geography,

perceived social worth, perceived quality of life, citizenship, immigration status, incarceration status, homelessness, or other discriminatory characteristic;

5. Are supported by teams of expert health care professionals who, to the extent possible, are not directly involved in the care of patients affected by triage decisions;
6. Include an appeal mechanism provided to address errors in application of the allocation criteria.

In an effort to establish a consistent and equitable process across the Commonwealth that reflects these core ethical values this guidance document sets forth a framework through which all facilities in the Commonwealth involved in allocation of critical resources should establish and implement an ethical and equitable policy for allocating such critical resources under crisis standards of care should capacity be strained as a result of the pandemic or other disaster.

ETHICAL CONSIDERATIONS FOR CSC AND ALLOCATION POLICIES FOR PATIENT CARE RESOURCE IN SCARCITY

Ethical considerations for allocation policies for critical resources during a scarcity under crisis standards of care balance the goal of maximizing the benefits produced by critical resources in a population-oriented approach with the goals of individual patient-focused care under normal conditions, and additionally incorporate important societal values, such as equity and protecting vulnerable populations.

A commitment to health equity in the Commonwealth requires that we make every effort to eliminate disparities in the design or implementation of allocation policies, including disparities based on race, culture, color, national origin, religion, marital status, age, sex, sexual orientation, gender identity, disability, socio-economic or insurance status, geography, perceived social worth, perceived quality of life, citizenship, immigration status, incarceration status, homelessness, or other discriminatory characteristic.

The following ethical considerations are proposed as an Ethics Framework in *Crisis Standards of Care: A systems Framework for Catastrophic Disaster Response* (developed by the Institute of Medicine) and have been incorporated into similar documents in many other states. They are grounded in a solid ethical and legal foundation and rely on widely shared social values. Thus, they can be expected both to receive general support from the public and health care professionals and to sustain public trust.

The ethical considerations include:

- Fairness;
- The duty to care;
- The duty to steward resources;
- Transparency;
- Consistency;
- Proportionality; and
- Accountability

Facilities can operationalize each of these broad ethical considerations with more specific guidance for decision-making within their context and based upon the needs of the communities they serve.

STATEMENT ON HEALTH DISPARITY AND HEALTH EQUITY

There is growing recognition and mounting clinical evidence that structural racism, economic injustice or poverty, or the resultant major health disparities in rates of chronic conditions such as asthma, hypertension, diabetes, and obesity disproportionately harm and effect Black, Latino, indigenous and other historically disadvantaged communities. These factors suggest that people from these communities may be less likely to be allocated critical resources during a scarcity when facilities depend upon more traditional triage protocols and scoring systems.

In addition, epidemiologic data on the recent experience with COVID-19 pandemic highlights the inequities in our health care system that result from the intersection of race, ethnicity, and other socio-economic factors that are often referred to collectively as “social determinants of health”. Accordingly, it is essential that allocation policies acknowledge and support the intentional inclusion of the needs of all individuals and communities so that preparedness, mitigation, response, and recovery efforts are more effective in promoting health equity and do not perpetuate or exacerbate health disparities.

Virginia Department of Health, Office of Health Equity, has created a Health Equity Guidebook¹ in response to COVID-19.

The Guidebook identifies several populations at elevated risk:

- **Communities of Color:** Communities of color are identity-based communities that hold a primary identity that describes shared racial characteristics among community members. The term aims to define a characteristic of the community that its members share (such

¹ Available online at <https://www.vdh.virginia.gov/health-equity/>.

as being African American) that supports self-definition by community members, and that typically denotes a shared history and current/historic experiences of racism.

- **Older Adults:** Adults who are 65 years and older.
- **People with Limited English Proficiency (LEP):** People who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English can have limited English proficiency.
- **People Adversely Impacted by Social Determinants of Health:** Those who may experience disproportionately high impacts of housing, food, transportation, and employment insecurity. These individuals may also have higher rates of un-insurance and underinsurance and lack access to nutritious food and recreation areas.
- **Medically Underserved Individuals:** Areas/Populations designated by the Health Resources and Services Administration as having too few primary care providers, high infant mortality, high poverty, or a high elderly population.
- **Individuals with Physical or Mental Disabilities:** Disability is defined by the ADA as a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment.
- **LGBTQ+ Communities:** Those who identify as Lesbian, Gay, Bisexual, Pansexual, Transgender, Genderqueer, or Queer.

The Guidebook also identifies several barriers often faced by these elevated-risk populations:

- **Health Literacy Barriers:** Health literacy is a cognitive and social skill that determines the motivation and ability of individuals to gain access to, understand, and use health-related information.
- **Access and Functional Barriers:** Several types of obstacles can increase the burden of receiving proper care for some individuals. For more information regarding identifying at-risk individuals with access and functional needs visit the U.S. Department of Health & Human Services at:
<https://www.phe.gov/Preparedness/planning/abc/Pages/atrisk.aspx>.
- **Communication Barriers:** Differences in the language spoken and understood are often another barrier experienced by underserved communities. They can also limit access to

information and services for people who are hard of hearing, deafblind, blind, or have low vision, people with LEP, as well as those with limited access to communications channels, such as the Internet. Communication must be effective, and also accessible, in accordance with the ADA, Sections 504 and 508 of the Rehabilitation Act, and other applicable federal and state laws. For more information regarding communications accessibility and accommodations, visit the U.S. Department of Justice at:

<https://www.justice.gov/crt/page/file/1104281/download>. Communication must also be culturally and linguistically appropriate. For more information on Culturally and Linguistically Appropriate Service (CLAS) initiatives, visit the Virginia Department of Health at: <https://www.vdh.virginia.gov/health-equity/division-of-multicultural-health-and-community-engagement/culturally-and-linguistically-appropriate-service-clas-initiatives/> or National CLAS Standards at <https://thinkculturalhealth.hhs.gov/clas>.

- **Socioeconomic Barriers:** Socioeconomic barriers can pose serious challenges to providing equitable access to care.
- **Cultural Barriers:** Community members may have varying levels of comfort with our health care system due to cultural sensitivities. For example, some may feel uncomfortable discussing health status with a health professional or sharing personal information, or may prefer to receive services from a person of the same or different gender.
- **Social Barriers:** Beliefs about our health care delivery system and its implications are wide-ranging and heavily impacted by media portrayals, news sources, and an individual's social network and community.

Identification of these and other barriers highlights the importance of designing procedures, operations, and communications to actively and systematically address the needs of populations at elevated risk and intentionally seek to avoid inequitable access and outcomes. Accordingly, in developing and implementing allocation policies and triage protocols, consideration must be given to possible approaches for mitigating these disparities in outcomes within and across communities and measures that can be taken to proactively address known barriers faced by these populations. Allocation policies that use traditional triage protocols and scoring mechanisms should state features of their policies that address social, structural, and historical determinants of health.

STATEMENT ON NON-DISCRIMINATION

Any policy for allocating critical resources and any criteria used in making decisions about treatment during a health care emergency must reflect the values, wishes, and interests of all patients, especially the most vulnerable. No person may unlawfully discriminate against people with disabilities when making decisions about their treatment during a health care emergency. Discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion is strictly prohibited by the ADA, Section 504 of the Rehabilitation Act, the Age Discrimination Act, and Section 1557 of the Affordable Care Act, which prohibit discrimination in HHS funded health programs or activities, and corresponding state laws, including the Virginians with Disabilities Act.

Accordingly, any policy for allocating critical resources and any criteria used in making decisions about treatment must not deny medical care, for example, on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative "worth" based on the presence or absence of disabilities or age. Any such policies should ensure that implementation and decision-making is based on an individualized assessment of the patient, based on the best available objective medical evidence and as the circumstances of the emergency response allow.

The U.S. Department of Health and Human Services has recently issued a bulletin entitled "Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)" that provides broad guidance on the obligations of states and health care providers to comply with federal disability rights laws in developing allocation policies and triage protocols during a scarcity of critical resources.² The bulletin conveys that the lives of people with disabilities are equally worthy and valuable as those of people without disabilities and instructs that people with disabilities have an equal opportunity to receive critical resources during a scarcity.

This serves as a stark reminder that a disaster or pandemic does not excuse states and health care providers from compliance with the ADA and other laws prohibiting discrimination on the basis of disability or other discriminatory characteristic. Given the reality that people with disabilities have historically experienced discrimination in receiving medical care, treating providers must not assume themselves to be free from conscious or unconscious bias in decision-making. To avoid discrimination, allocation policies and triage protocols must involve a thorough individualized review based upon objective evidence. Allocation policies should include requirements for training treating providers and triage teams on non-discrimination. Allocation policies should also be made publicly available and widely distributed to stakeholders in the community, including state and local disability organizations.

² Available online at <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>

States and health care providers are also reminded that they must not overlook their obligations under applicable laws to help ensure all segments of the community are served by providing effective communication, especially to those who are hard of hearing, deafblind, blind, have low vision, or have speech disabilities, and by providing meaningful access to individuals with LEP through the use of qualified interpreters and through other means and making messaging available in plain language. Reasonable modifications must be made when needed by a person with a disability to have equal opportunity to benefit from treatment. Providing effective and accessible communication to individuals with disabilities extends to family members as well. There are various resources to help facilitate effective communication with patients and their family members with disabilities:

- U.S. Department of Justice: Communicating with People Who Are Deaf or Hard of Hearing in Hospital Settings
- U.S. Department of Justice: Access to Medical Care for People with Mobility Disabilities
- U.S. Department of Justice: Effective Communication Requirements

The U.S. Department of Health and Human Services, Office of Civil Rights (OCR), has settled a number of recent complaints relating to various crisis standard of care guidelines issued by states. To help ensure that this guidance and any resulting allocation policies adopted by facilities do not discriminate on the basis of age or disability, allocation policies maintained by facilities should be specifically reviewed with an aim towards compliance with OCR orders.

This would include, among other things:

- Removing any language permitting the use of a patient's long-term life expectancy as a factor in the allocation of critical resources, and removing such factors from crisis standard of care plans;
- Removing categorical exclusion criteria on the basis of age, disability, and functional impairment, and instead requiring an individualized assessment based on the best available objective medical evidence;
- Removing resource-intensity and duration of need as criteria for the allocation or re-allocation of critical resources and removing such factors from crisis standard of care plans to protect patients who require additional treatment resources due to their age or disability from being given a lower priority score;

- Including language stating that reasonable modifications to the use of triage protocols should be made when necessary for patients having underlying disabilities to ensure that people with disabilities are accurately evaluated based on their actual mortality risk, not disability-related characteristics unrelated to likelihood of survival;
- Including protections against “steering” patients into agreeing to the withdrawal or withholding of life-sustaining treatment, clarifying that patients may not be subject to pressure to make particular advance care planning decisions, providing information on the full scope of available alternatives, and prohibiting blanket “do not resuscitate” policies for reasons of resource constraint, or requiring patients to consent to advance care planning decisions in order to continue to receive services from a facility;
- Including language stating that facilities should not re-allocate personal ventilators or other critical resources brought by a patient to a facility to continue pre-existing personal use with respect to a disability. Under this language, long-term ventilator use will be protected from having a ventilator removed and given to another person.

PROCESS FOR DEVELOPING POLICIES FOR PATIENT CARE RESOURCE ALLOCATION IN SCARCITY

Any allocation policy must be implemented in an objective and fair manner. It must be administered consistently and in a way that engenders trust among patients, families, and the general public. Those responsible for implementing the allocation policy must have a high level of awareness regarding the negative impacts of bias and conflicts of interest. The following is a suggested approach for developing a process to allocate critical resources during a scarcity. The key to developing these policies is to make them efficient and easy to operate. When operating under crisis-level standards of care, decisions need to be made efficiently, accurately, and consistently to ensure timely and appropriate use of resources.

STEP ONE – ESTABLISH A SPECIFIC COMMITTEE FOR RESOURCE ALLOCATION DECISIONS

Every facility engaged in allocation of critical resources should establish a committee (sometimes referred to as the Critical Resource Allocation Group (CRAG) or Resource Planning and Allocation Team (RPAT)) comprised of at least three members to develop and oversee a policy for the allocation of critical resources during a scarcity. For facilities affiliated with a health system, these committees may be organized at a system-wide level. Representatives on the committee may include a health professional(s), a board member, a spiritual care team member,

or an independent community member (*e.g.*, retired physician or other licensed independent practitioner (LIP)).

Responsibilities of the committee may include, but not necessarily be limited to:

- Providing support, as needed, to triage teams;
- Consulting, as needed, with clinical and ethics leadership concerning allocation of patient care resources during a scarcity;
- Identifying resources that may require allocation;
- Acquiring the information necessary to facilitate and oversee informed and ethical triage protocols;
- Supporting and establishing communications with triage team;
- Advising and assisting with resolution of uncertainties and disputes over a hospital's capacity;
- Maintaining a record of, and undertaking retrospective review of all triage decisions and serving as a routine quality review process of decision-making;
- Assisting with development and execution of plans to support staff with emotional and moral distress;
- Supporting and working with pastoral care providers and clinicians to assist and support patients, families, and caregivers who are affected by decisions regarding allocation of critical resources during a scarcity;
- Coordinating deployment of palliative care, spiritual care, counseling, and care coordination providers to hospitals;
- Facilitating effective communications between and among the facility, the CRAG/RPAT, triage teams, and Regional Health Care Coalitions established under VHEMP;
- Coordinating with hospital or institutional leadership to maximize access to resources; and
- Regularly assessing compliance with resource allocation policies and re-evaluating the effectiveness and appropriateness of critical resource allocation policies.

These committees are focused on availability and allocation of resources within a facility or within a system of facilities. As discussed above, allocation of critical resources among

unaffiliated hospitals or other institutions during a scarcity should be done in coordination with the Regional Health Care Coalitions established by VHEMP. Such regional coordination needs to occur on this regional level to avoid to the greatest extent possible a scarcity of critical resources in any given facility.

STEP TWO – DEVELOP A SYSTEM-WIDE ALLOCATION POLICY

Each hospital or other institution should develop a policy for the allocation of critical resources during a scarcity that relies on the ethical considerations discussed above and includes an objective, evidence-based clinical decision-making process and algorithm that is used consistently across all patients Front desk security . The processes and algorithms are discussed further below in the section titled **CLINICAL DECISION-MAKING TOOLS AND TRIAGE PROTOCOLS**. To avoid discriminatory impacts, it is fundamental that system-wide resource allocation policies:

- Omit criteria that automatically or by implication or application deprioritize persons on the basis of particular disabilities or categorically exclude people with disabilities from receiving care on the basis of their diagnosis or disability.
- Require *individualized assessments* based on the best available, relevant, and objective medical evidence to support triaging decisions.
- Ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person’s “worth” based on the presence or absence of disabilities.
- Are clear that resource-intensity and duration of need on the basis of age or disability should not be used as criteria for the allocation or re-allocation of critical resources. This protects patients who require additional treatment resources due to their age or disability from automatically being given a lower priority to receive life-saving care.
- Include language stating that reasonable modifications to the use of the state’s primary instrument for assessing likelihood of short-term survival should be made when necessary for accurate use with patients with underlying disabilities. Such reasonable modifications ensure that people with disabilities are evaluated based on their actual mortality risk, not disability-related characteristics unrelated to their likelihood of survival.
- Expressly prohibit facilities from re-allocating personal ventilators or other critical resources brought by a patient.
- Refrain from including any language permitting the use of a patient’s long-term life expectancy as a factor in the allocation and re-allocation of critical resources, instead indicating that providers should consider short-term life expectancy.

STEP THREE – ESTABLISH FACILITY-SPECIFIC TRIAGE TEAMS

Each facility should designate a triage team to implement the allocation policy at the facility level and make decisions related to allocation of critical resources during a scarcity. The purpose of the triage team is, to the greatest extent practical, to relieve the treating providers, who have a duty to advocate for patients, from moral distress and to promote greater objectivity. The triage team acts as an impartial team. It should have a limited number of members comprised of professionals with the relevant skill sets, including: medical, nursing, or other specialized clinical experience related to the critical resource in question and if possible, experience in tertiary triage. However, consideration should be given to the need for rotation of participation on triage teams where procedures are in place for a prolonged period of time as necessary to prevent fatigue or “burnout” of triage teams.

Responsibilities of the triage teams may include, but not necessarily be limited to:

- Working in close cooperation with and taking direction from the CRAG/RPAT for resource allocation decisions (see Step 1) concerning allocation of resources and triage decisions;
- Arranging a schedule among triage teams to meet daily to assess all patients who have clinical indications for need of critical resources and evaluating such patients in terms of ethical and evidence-based clinical criteria to determine the appropriateness of initiation and/or continued use of critical resources;
- Making triage decisions based on the allocation policy;
- Providing patient scores and priority categories to treating clinicians who will implement triage decisions;
- Reassessing, as frequently as circumstances indicate is appropriate, patient priority scores for all patients receiving or being considered for allocation of critical resources;
- Applying ethical and evidence-based criteria to determine allocation of resources in instances where similar patients have the same scores;
- Maintaining records of triage decisions and the data supporting them; and
- Reporting triage decisions to the CRAG/RPAT for oversight and reporting to incident command.

STEP FOUR – COMMUNICATE ALLOCATION POLICY

Once the allocation policy is developed and being implemented, clinicians will communicate in transparent language with patients, families and legal surrogate decision-makers about the public health emergency and the need to allocate resources differently under crisis standards of care. Any public or direct communications should be consistent and timely; be effective and accessible to ensure that information reaches individuals who are hard of hearing, deafblind, blind, or have low vision with accommodations as appropriate to overcome communication barriers among the health care team, patients, families, and legal surrogate decision-makers; and be culturally and linguistically appropriate to ensure that information reaches individuals who have LEP or limited health literacy.

When operating under crisis standards of care, clear and frequent internal and external communication is essential to convey information and maintain situational awareness with hospitals, emergency medical services, alternate care facilities, health care personnel and the public about crisis standards of care concepts such as triage of critical resources.

STEP FIVE – RE-EVALUATE ALLOCATION POLICIES

As the pandemic unfolds, it will be critical to periodically re-evaluate allocation policies to ensure they address and are applicable to the current situation on the ground. A pandemic or other disaster will impact each community and each facility's resource capacity differently and will change over time. The allocation policy and its application to patient care should match the current real-time situation in the community.

Accordingly, the allocation policy should include a mechanism for retrospective review of triage decisions and triage protocols and establishment of compliance “checkpoints” to ensure that the allocation policy and triage protocols are being complied with (*e.g.*, that scores are being updated and rankings are being re-assessed at established intervals) and that the purpose of the allocation policy is being achieved, specifically as it relates to ensuring that processes are objective and are effective in avoiding or eliminating any practices that produce inequitable results or produce a discriminatory effect. Such review should be conducted at pre-determined intervals (*e.g.*, weekly, subject to time and resource constraints, and annually).

CLINICAL DECISION-MAKING TOOLS AND TRIAGE PROTOCOLS

As discussed above, decisions about allocation of critical resources during a scarcity should be based on an objective, evidence-based clinical decision-making process and algorithm that is used consistently across all patients. This section includes recommendations for such a process and the use of clinical decision-making tools and protocols or algorithms that should be used to make initial triage decisions for patients who present with illnesses that typically require critical resources. Any evidence-based clinical decision-making tools and protocols or algorithms adopted for use by any facility should be consistent with these recommendations.

Flexibility and Limitations

This guidance document provides a framework and guidelines for decision-making regarding allocation of critical resources during the pandemic or other disaster in the event that demand outstrips capacity. Institutions with limited access to individuals having expertise in critical care management, ethics, or other resources may not be able to follow the precise processes outlined in this guidance document. However, they should follow them to the extent possible given local constraints, modifying them as necessary to adhere to the guidance document's ethical foundations and equitable principles. Triage protocols should be updated as understanding of the spread, pathophysiology, treatment and outcomes of a pandemic evolves.

Use and Implementation

Critical resource allocation clinical decision-making tools and protocols or algorithms are to be instituted when there is a scarcity of a critical resource and it becomes necessary to make clinical decisions to ensure that the facility is able to deliver the most good for the most persons with the limited resources available. Critical resource allocation clinical decision-making tools and protocols or algorithms should be designed to include:

- Clinical criteria for the application of the critical resource to new patients to ensure that the resource is applied to patients most likely to benefit. Depending on the time-sensitive nature of the decision to apply a resource, clinical criteria may need to be applied by the triage team.
- Assessment of all patients currently using the critical resource and ranking or prioritizing of patients to determine those least likely to benefit from continued use of that resource.

As stated above, it is fundamental that critical resource allocation clinical decision-making tools and protocols or algorithms or their implementation:

- Omit criteria or do not have the effect of automatically deprioritizing persons on the basis of particular disabilities, and require individualized assessments based on the best available, relevant, and objective medical evidence to support triaging decisions; and
- Ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person’s “worth” based on the presence or absence of disabilities.

Triage Process Using a Multiple-Principle Allocation Framework

Critical resource allocation clinical decision-making tools and protocols or algorithms incorporate the use of scoring systems that apply to the individualized assessment of *all* patients presenting with critical illness, not simply those with the disease or disorders that arise from a pandemic or other disaster. The results of these scoring systems are then used to prioritize or triage patients.

These triage protocols involve several steps, detailed below:

1. Calculating each patient’s priority score based on the multi-principle allocation framework;
2. Assigning each patient to a priority group; and
3. Determining on a frequent basis how many priority groups will receive access to critical care interventions.

STEP ONE - CALCULATION OF PATIENT-SPECIFIC SCORE USING A MULTI-PRINCIPLE ALLOCATION FRAMEWORK

Under this triage protocol framework, patients are individually assessed to determine a score indicating probability of survival from the critical resource in question. Patients who are more likely to survive with access to critical resources are prioritized over patients who are less likely to survive with such resources.

As summarized in **Table 1**, the Sequential Organ Failure Assessment (SOFA) score³ (or an alternate, validated, objective measure of probability of survival to discharge from the facility) is uniformly used to determine patients’ prognoses for surviving hospitalization. The presence of medical conditions in such an advanced state that they limit near-term duration of benefit (defined below) is used to characterize patients’ prognosis for near-term survival.

³ The SOFA score combines a clinical assessment of the cardiovascular and central nervous systems, with laboratory measurements for evaluation of the remaining organ systems: respiratory, hematologic, liver, and renal. The requirement for arterial and venous blood specimens from each patient in order to calculate a SOFA score may prove impractical with a large number of patients and constrained resources.

These judgments should be made in the context of individualized assessments by clinicians, based on the best available objective medical evidence.

Table 1. Multi-principle Strategy to Allocate Critical Resources During a Scarcity

Principle	Specification	Point System*			
		1	2	3	4
Save lives	Prognosis for surviving hospitalization (SOFA score or other severity of illness score#)	SOFA score < 6	SOFA score 6-8	SOFA score 9-11	SOFA score ≥12
	Prognosis for near-term survival (medical assessment of near-term prognosis)	Death expected within 6 months despite successful treatment of acute illness

#SOFA= Sequential Organ Failure Assessment; note that another measure of acute physiology that predicts in-hospital mortality, such as LAPS2 score, could be used in place of SOFA, and should similarly be divided into 4 ranges.

Scores range from 1-8, and persons with the lowest score would be given the highest priority to receive critical resources.

Between one and four points are assigned according to the patient’s prognosis for surviving hospitalization using an acute severity of illness score (e.g., SOFA score). Table 1 provides an example using the SOFA score. More points are assigned the higher the risk of death during the hospitalization.

As illustrated in **Table 1**, between 1 and 4 points are assigned according to the patient’s prognosis for surviving hospitalization. Four points are assigned if the patient is expected to die from underlying medical conditions within six months despite successful treatment of the acute illness. Zero points are assigned if the patient is expected to live more than six months if s/he survives the acute illness.

These points are then added together to produce a total priority score, which ranges from 1 to 8. Lower scores indicate higher predicted benefit from critical care, and priority will be given to

those with lower scores. Scores should be re-calculated at frequent intervals (*e.g.*, no less frequently than every 48 hours) to allow for ongoing reassessment under Step 4 below.

Reasonable Modification to Scoring

Scores may need reasonable modifications to ensure that disability-related characteristics unrelated to short-term mortality risk do not worsen a patient's score. For example, the Glasgow Coma Scale, a tool for measuring acute brain injury severity, adds points to the score when a patient cannot articulate intelligible words or has difficulty with purposeful movement. For patients with pre-existing speech disabilities or disabilities that effect motor movement, this may result in a higher score even in instances where the patient's disability is not relevant to short-term mortality risk.

Application to Pediatric Patients (< 18 years of age)

Scoring systems that are meaningful for adult critical care patients do not apply to pediatric patients or newborns. While there are similar scoring systems for pediatric and neonatal patients, they are less reliable as the basis for determining priority for several reasons. During normal, non-crisis standards of care periods, most children requiring critical care and mechanical ventilation have a much higher likelihood of survival to facility discharge than adults who require these interventions and therefore most will have favorable scores. Moreover, many children who require neonatal or pediatric critical care have chronic medical and surgical conditions, some congenital and some acquired. Many of these are rare conditions that require multi-specialist expertise, and the interplay between the underlying disease and the current illness is not captured by any scoring system. Finally, within the small range of ages included under the umbrella of pediatrics, patient age is not a meaningful factor to distinguish priority for some critical resources such as ventilators or critical care.

For these reasons, experienced pediatric intensivists and neonatologists may serve on triage teams to assist in the exercise of clinical judgment in assigning priority scores for children. The triage team should focus on the likelihood of surviving hospitalization and should also take into account conditions that are expected to severely limit survival in the near-term regardless of whether the patient recovers from the episode of critical illness. Triage should be guided by the acute severity of the patient's current medical condition, the epidemiology of the disease, and the current status of any underlying medical diseases that may hinder recovery. The use of validated scoring systems (*e.g.*, Pediatric Logistic Organ Dysfunction Score-2 (PELOD-2), modified pediatric SOFA, or Score for Neonatal Acute Physiology II (SNAPPE-II)) may also aid in their assigning of priority scores. Triage teams should not factor a patient's pre-hospitalization quality-of-life or predictions of future quality-of-life into the assignment of priority scores.

Limitations of Scoring Systems

Ongoing research on the use of scoring systems and their use in particular patients with communicable disease in a pandemic, such as COVID-19, highlight the need for a multi-principle approach that does not rely solely on scoring results in making triage decisions; however, no single approach has emerged. Triage protocols need to be actionable and complex enough to provide prognostic information that is objective and accurate, but algorithms can be supplemented with other predictors of mortality, such as disease-specific indicators for non-disaster conditions, frailty scores, comorbidity indices, and clinician judgment as best possible.

STEP TWO - ASSIGN PATIENTS TO PRIORITY GROUPS

Critical resource allocation clinical decision-making tools and protocols or algorithms may include a system for prioritizing patients into groups based upon the results of individualized assessment using the scoring methodology. Each priority group organizes patients in priority based upon the likelihood of survival. Patients who are more likely to survive with intensive care or ventilator care are prioritized over patients who are less likely to survive with intensive care or ventilator care. Patients who do not have serious comorbid illness may be given priority over those who have illnesses that severely and immediately limit their life expectancy.

For example, individuals in the highest priority group have the best chance to benefit from critical care interventions and should therefore receive priority over all other groups in the event of scarcity. The medium priority group has intermediate priority and should receive critical resources if there are available resources after all patients in the high priority group have been allocated critical resources. The low priority group has lowest priority and should receive critical resources if there are available resources after all patients in the high and medium groups have been allocated critical resources. The priority scoring process must be consistently applied across all patients within the facility.

All patients other than those who are thought to be imminently dying regardless of critical care interventions will be eligible to receive critical care beds and services regardless of their priority score. The availability of critical resources will determine how many eligible patients will receive critical care. Patients who are not triaged to receive intensive care or ventilator care should receive medical care that includes intensive symptom management and psychosocial support. They should be reassessed daily to determine if changes in resource availability or their clinical status warrant provision of critical care services.

Where available, specialist palliative care teams should be available for consultation. Where palliative care specialists are not available, the treating clinical teams should provide primary palliative care.

STEP THREE - MAKE DAILY DETERMINATIONS OF PATIENT CARE RESOURCE ALLOCATIONS DURING A SCARCITY

Facility leaders and the triage team should make determinations at least two times per day, or more frequently if needed, about what priority groups will have access to intensive care and ventilator care. These determinations should be based on real-time knowledge of the degree of scarcity of the critical resources, as well as, information about the predicted volume of new cases that will be presenting for care over the following several days.

While the use of clinical decision-making tools and protocols or algorithms is necessary when operating under crisis standards of care, clinicians should retain the ability to make clinical judgments about the appropriateness of critical care using the same criteria they use during normal clinical practice. To the extent critical care utilization would be deemed non-beneficial during normal clinical practice, nothing in allocation policies should require such resources to be offered during a public health emergency. The triage team and attending physicians/licensed independent practitioners (LIPs), however, should make clear in communicating with families whether critical care is not being offered based on the existence of a non-survivable medical condition or based on the allocation framework.

STEP FOUR - REASSESSMENT FOR ONGOING PROVISION OF CRITICAL RESOURCES

In a public health emergency, when there are not enough critical resources for all, the goal of maximizing population outcomes would be jeopardized if patients who were determined to be unlikely to survive were allowed indefinite use of critical resources. In addition, periodic reassessments lessen the chance that arbitrary considerations, such as when an individual develops critical illness, unduly affect patients' access to treatment.

The triage team should conduct periodic reassessments of all patients receiving critical resources. These assessments should involve re-calculating scores established under the policy at frequent intervals (e.g., no less frequently than every 48 hours) and consulting with the treating clinical team regarding the patient's clinical trajectory. Patients showing improvement should continue with critical resources until the next assessment. If there are patients in the queue for critical care services, then patients who, upon reassessment, show substantial clinical decline as evidenced by worsening scores or overall clinical judgment, or demonstrate a failure to progress may be considered for de-prioritization for ongoing critical resources. Although patients should generally be given the full duration of a trial, if patients experience a precipitous decline or a highly morbid complication (e.g., massive stroke) that portends a very poor prognosis, the triage team may

make a decision before the completion of the specified trial length that the patient is no longer eligible for critical resources.

Patients who are no longer prioritized for critical resources should receive medical care including intensive symptom management and psychosocial support. If available, specialist palliative care teams should be available for consultation.

This approach to reassessment should apply to all patients receiving critical resources, including those who were already receiving critical resources at the time the allocation framework was activated. The triage team should review all patients receiving critical care at the time of the allocation.

APPEALS

A treating provider or patient family member (or legal surrogate decision-maker, if applicable) may appeal the decision of the triage team for a specific patient. Procedural fairness requires the availability of an appeals mechanism to resolve such disputes. It is also essential to procedural fairness that information about the availability of, and mechanisms for, appeals be effective and accessible to ensure that information reaches individuals who are hard of hearing, deafblind, blind, or have low vision with accommodations as appropriate to overcome communication barriers among the health care team, patients, families, and legal surrogate decision-makers; and be culturally and linguistically appropriate to ensure that information reaches individuals who have LEP or limited health literacy.

Appeal of Initial Triage Decisions

Initial triage decisions are designed to be made uniformly and based upon an objective determination. As such, for initial triage decisions, appropriate bases for appeals would be limited to whether the allocation policy and triage protocols were followed or whether an error was made by the triage team in the calculation of the priority score. An appeal may not be brought based on an objection to the overall allocation policy consistent with this guidance.

For appeals based upon grounds that the allocation policy or triage protocols were not followed, review and inquiry by the Critical Resource Allocation Group (CRAG) or Resource Planning and Allocation Team (RPAT) would be appropriate. For appeals based upon grounds that an error was made by the triage team, recalculation and verification by the triage team and review by the CRAG/RPAT would be appropriate.

Appeal of Decisions to Withdraw or Not Approve Patient Care Resources

Decisions to withdraw critical resources for a patient who is already receiving critical care may cause heightened moral concern and may also depend on more clinical judgment than initial

allocation decisions. Treating providers, patients, and legal surrogate decision-makers will be informed of their right to appeal any such decisions.

If a treating provider, patient, or legal surrogate decision-maker would like to appeal such a decision, the following process would be appropriate:

- The appeal will be promptly brought to the CRAG/RPAT.
- The individuals who are appealing the triage decision should be asked to explain the grounds for their disagreement with the triage decision. An appeal may not be brought based on an objection to the overall allocation policy.
- The triage team should explain the grounds for the triage decision that was made and provide relevant documentation.
- The appeals process must occur quickly enough that the appeals process does not harm patients who could benefit from the critical resource.
- The final decision on appeal should be made by a majority vote of the CRAG/RPAT with a quorum present.
- The decision should be provided to the appellant in writing and documented in sufficient detail to demonstrate that the outcome represents a well-considered decision.