Allocation of Scarce Medical Resources in Pandemics

Department of Internal Medicine

Medical Grand Rounds

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Introductions

Pastoral Care & Ethics Committee

- Generally, in medicine, there is an underlying ethic to maximize the benefit for individual patients. When a public health emergency has been declared, the ethic changes to maximize the benefit for the most people.
- Autonomy of a patient gives way to the wellbeing of public health in a pandemic – but it does not give way to what a patient values most in life, especially their religious beliefs and/or spiritual practices.
- Ethics Committee is a stakeholder – Participate and facilitate gathering other stakeholders to create guidelines and policy to address the practical, moral, ethical issues.

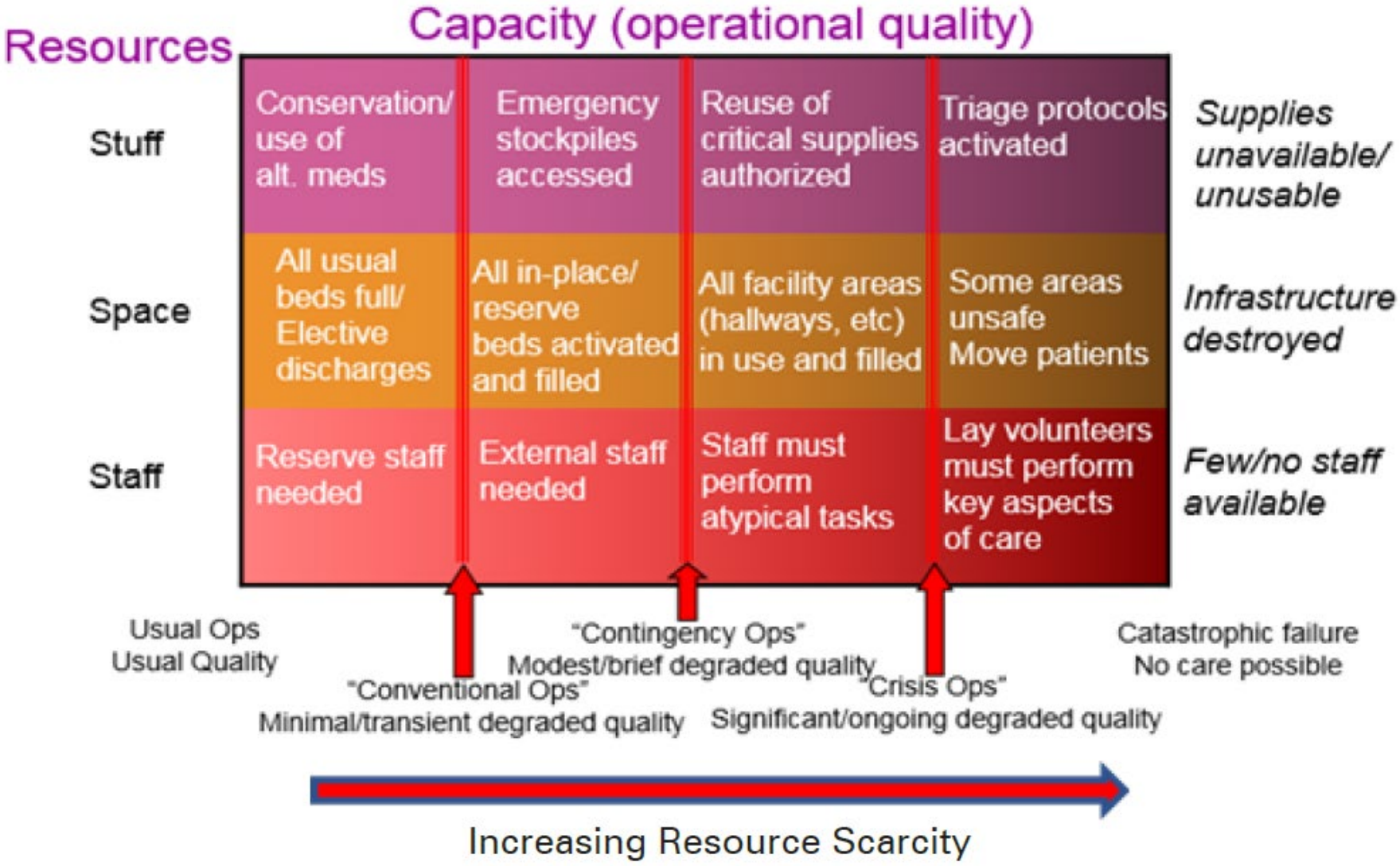

Figure 1: The Gradual Degradation of Quality as Resource Scarcity Worsens

Berlinger Hastings Center March 2020

General Principles

- Public Health Emergency … prioritizes public health over individual …this is an exceptional situation
- Rationing justifiable only after all other available options exhausted
- Public input into guidelines
- Transparency
- Multidisciplinary group development & application
- Flexibility - resources, developing knowledge base
- Consistency .. Within institution & regionally

- Gather existing advance directives

- Engage at risk individuals in COVID specific ACP
  - Respecting Choices – available until June 30
    https://respectingchoices.org/covid-19-resources/
  - Vital Talk – clinician communication guides https://www.vitaltalk.org/guides/covid-19-communication-skills/
  - COVID goals of care videos https://vimeo.com/401465080
  - Life Support During Covid Pandemic .. Univ of Colorado

General Principles (cont'd)

- Obligation to treat even if no vent
  - Alternative modes of oxygenation, Antivirals
  - Comfort meds & basic care
  - We NEVER "withdraw care"
- Treating clinicians are NOT placed in the role of deciding vent allocation
  - Clinician stress
  - Equitable distribution for patients
- **"TRIAL"** of ICU care or ventilation

Berlinger Hastings Center March 2020
SIAARTI (the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care March 2020
Emmanuel NEJM March 2020

Maryland Approach

"Because there are multiple ethically permissible approaches to allocating scarce life sustaining resources and because the public will bear the consequences of these decisions, knowledge of public perspectives and moral points of reference on these issues is critical."

Engaged general public, local health care and disaster professionals 2012-2014

15 forums, 324 participants.

Chest April 2019

Maryland Approach cont'd

1. likelihood of short term survival (with the support of the scarce resource)
2. likelihood of long-term survival (based on presence of comorbid conditions).
3. In the of a tie, life stage … children and adults to 49… as a secondary criterion.
4. Triage officer share information about these decisions with the clinical team and then inform affected patients and family members
5. Implementation mandatory
6. Limited appeal process

Chest April 2019

Justice in Triage

Presumptions:

1. Everyone knows the guiding principle of justice
2. The principle has the solid endorsement of a broad majority of the population

Ethical Principles that Guide Us in a Health Crisis

- **Fairness** – Standards that are, to the highest degree possible, recognized as fair by those affected by them – including the members of affected communities, practitioners, and provider organizations, evidence based and responsive to specific needs of individuals and the population.
- **Duty to care** – Standards are focused on the duty of healthcare professionals to care for patients in need of medical care.
- **Duty to steward resources** – healthcare institutions and public health officials have a duty to steward scarce resources, reflecting the utilitarian goal of saving the greatest possible number of lives.
- **Transparency** – in design decision making, and information sharing.
- **Consistency** – in application across populations and among individuals regardless of their human condition (e.g. race, age disability, ethnicity, ability to pay, socioeconomic status, preexisting health conditions, social worth, perceived obstacles to treatment, past use of resources).
- **Proportionality** – public and individual requirements must be commensurate with the scale of the emergency and degree of scarce resources.
- **Accountability** – of individual decisions and implementation standards, and of governments for ensuring appropriate protections and just allocation of available resources.[2]

National Academy of Medicine, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situation: A Letter Report*, 2009

Ethical Priorities

Usual standards of care	Public Health Crisis/ Crisis Standards of Care
Respect for pt autonomy	Respect for common good, not individual autonomy
Maximize benefit to each of your patients	Less autonomy for practitioners
Fidelity/allegiance to each patient	Maximize benefit to the greatest number of people
Not all who could benefit receive treatment (lack of access/insurance)	Allocate scarce resources responsibly
	Not all who could benefit receive treatment (due to scarcity)
	Fair chance

Ethical Values to Guide Rationing of Absolutely Scarce Health Care Resources in a COVID-19 Pandemic

Ethical Values	Guiding Principles	Application to COVID-19 Pandemic
Maximize Benefits	Save the most lives	Receives the highest priority
	Save themost life-years; maximize prognosis	Receives the highest priority
Treat People Equally	First-come, first-served	Should not be used
	Random selection	Used for selecting among patients with similar prognosis
Promote & Reward Instrumental Value (benefit to others)	Retrospective - priority to those who have made relevant contributions	Gives priority to research participants and health care workers when other factors such as maximizing benefits are equal
	Prospective - priority to those who are likely to make relevant contributions	Gives priority to health care workers
Give Priority to the Worst Off	Sickest first	Used when it aligns with maximizing benefits
	Youngest first	Used when it aligns with maximizing benefits such as preventing spread of the virus

Emanuel, et al., NEJM.org, March 23, 2020.

Justice requires:

…that allocations focus on a specific practical problem…

The Problem

Triage = Avoid the worst outcome

- Efficacy
- Equality
  - Identify those who are least likely to survive regardless of treatment
  - Determine if patient is unlikely to improve sufficiently to:

1) Survive outside the acute care setting
2) Perceive benefits of treatment

The Hard Truth

"There is no way to avoid the hard truth of triage when there are no longer enough resources to provide medically reasonable clinical management to all patients: those patients not treated will get worse, and some of these patients will die."

-Laurence McCullough, Ph.D., Bioethicist

No one is killing anyone in triage protocols. Healthcare professionals try to reduce overall morality levels (= saving lives) and provide palliative care for those who are dying of their serious illnesses, traumas, or this dreadful disease.

Alleviates Physician Burden

"The point of rigorous triage judgment is that we can be confident during triage, and after the need for it ends, that clinical colleagues and healthcare organizations acted with professional integrity."

- McCullough

Triage guidelines ensure individual doctors are never tasked with deciding unaided which patients receive life-saving care and which do not.

-Emanuel, et al

VENTILATOR ALLOCATION GUIDELINES

New York State Task Force on Life and the Law
New York State Department of Health

November 2015

"….provide an **ethical, clinical, and legal framework** to assist health care providers and the general public in the event of a severe influenza pandemic "

"….written to reflect the values of New Yorkers, and **extensive efforts were made to obtain public input during their development.** While these Guidelines are comprehensive, **they are by no means final**"

NYS Framework

- Patients **deemed most likely to survive** with ventilator therapy have the **highest level of access** to this treatment.
- The Adult Guidelines apply to individuals **aged 18 years old and older.**
- Applies to **ALL acute care patients** in need of a ventilator, whether due to influenza or other conditions.
- (Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at an acute care facility)

NYS Guidelines

1) application of exclusion criteria …. patients who have a medical condition that will result in immediate or near-immediate mortality even with aggressive therapy

(2) assessment of mortality risk … patients who have a moderate risk of mortality and for whom ventilator therapy would most likely be lifesaving are prioritized for treatment

(3) periodic clinical assessments **("time trials")**. … assessments at **48 and 120 hours** after ventilator therapy has begun are conducted to determine whether a patient continues with this treatment.

Step 1 - **Exclusion Criteria** for Adult Patients Medical Conditions that Result in Immediate or Near-Immediate Mortality Even with Aggressive Therapy

- **Cardiac arrest**: **unwitnessed** arrest, **recurrent arrest** without hemodynamic stability, **arrest unresponsive** to standard interventions and measures; **trauma**-related arrest
- **Irreversible age-specific hypotension** unresponsive to fluid resuscitation and vasopressor therapy
- **Traumatic brain injury with no motor response to painful stimulus** (i.e., best motor response = 1)
- **Severe burns**: where predicted survival ≤ 10% even with unlimited aggressive therapy
- **Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy**

Step 2 – Mortality Risk Assessment Using SOFA[1]	
Color Code and Level of Access	**Assessment of Mortality Risk/Organ Failure**
Blue No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if ventilators become available.	Exclusion criterion OR SOFA > 11
Red Highest Use ventilators as available	SOFA < 7 OR Single organ failure[2]
Yellow Intermediate Use ventilators as available	SOFA 8 – 11
Green Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No significant organ failure AND/OR No requirement for lifesaving resources

Sequential Organ Failure Assessment (SOFA) Score Scale

Variable	0	1	2	3	4	Score (0-4)
PaO_2/FiO_2 mmHg	> 400	< 400	< 300	< 200	< 100	
Platelets, x $10^3/\mu L$ (x $10^6/L$)	> 150 (> 150)	< 150 (< 150)	< 100 (< 100)	< 50 (< 50)	< 20 (< 20)	
Bilirubin, mg/dL (µmol/L)	< 1.2 (< 20)	1.2 - 1.9 (20 - 32)	2.0 - 5.9 (33 - 100)	6.0 - 11.9 (101 - 203)	> 12 (> 203)	
Hypotension	None	MABP < 70 mmHg	Dop < 5	Dop 6 - 15 or Epi < 0.1 or Norepi < 0.1	Dop > 15 or Epi > 0.1 or Norepi > 0.1	
Glasgow Coma Scale Score (see next page to calculate)	15	13 - 14	10 - 12	6 - 9	< 6	
Creatinine, mg/dL (µmol/L)	< 1.2 (< 106)	1.2 - 1.9 (106 - 168)	2.0 - 3.4 (169 - 300)	3.5 - 4.9 (301 - 433)	> 5 (> 434)	
				TOTAL (0 - 24):		

Step 3 - Ventilator Time Trials (48 Hour Assessment)[1]	
Color Code and Level of Access	**Assessment of Mortality Risk/Organ Failure**
Blue No ventilator provided.[2] Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.	Exclusion criterion OR SOFA > 11 OR SOFA 8 – 11 and No Change in SOFA Score Compared to the Initial Assessment[3]
Red Highest Use lifesaving resources as available.	SOFA < 7 and Decrease in SOFA Score Compared to the Initial Assessment[4] OR SOFA < 11 and Decrease in SOFA Score Compared to the Initial Assessment[5]
Yellow Intermediate Use lifesaving resources as available.	SOFA < 7 and No Change in SOFA Score Compared to the Initial Assessment
Green Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No longer ventilator dependent / Actively weaning from ventilator

Ventilator Removal

- A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.
- **However, if all ventilated patients are in the red category (i.e., have the highest level access), none of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting.**

Scenario 2

A triage officer/committee must select one of many eligible red color code patients to receive (start) ventilator therapy.

A patient's likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient.

If all red code patients all have equal (or near equal) likelihoods of **survival a randomization process, such as a lottery**, **is used each time a ventilator becomes available** because there are no other evidence-based clinical factors available to consider.

Scenario 3 An **incoming red code patient**(s) eligible for ventilator therapy and a triage officer/committee **must remove a ventilator from a patient whose health is not improving.**

1. **Patients in the blue category removed** … then
2. **Patients in the yellow category** are vulnerable for removal from ventilator therapy **if they fail to meet criteria for continued ventilator use.**
3. If the pool of ventilated patients vulnerable for removal consists of only adults or only children, **a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy**
4. A patient may only be removed from **a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list**.
5. **However, if all ventilated patients are in the red category (i.e., have the highest level access), none of the patients are removed from ventilation**

2015 NYS Guidelines

Efforts will be made to inform and gather feedback from the public before a pandemic (a LOST opportunity)

pandemic influenza is potentially fatal

health care providers are **doing our best with the limited resources**

The public must adjust to a different way of providing and receiving health care than is customary.

Patients and families should be informed that ventilator therapy represents a **trial of therapy** that may not improve a patient's condition sufficiently **and that the ventilator will be removed if this approach does not enable the patient to meet specific criteria.**

Ongoing Real-time data collection and analysis to modify the Guidelines based on new information.

Data collection must include **real-time availability of ventilators so that triage decisions are made to allocate resources most effectively**.

Comments