Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in VHA

FAQ: Ethical Challenges Preparing for and Managing COVID-19

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Overview

- Public health principles and values
- Ethical decision-making processes
- VA protocols for Scarce Resource Allocation (SRA)

Bottom Line Up Front

- The “Meeting the Challenges…” document is VHA authoritative guidance (not local or state plans)
- Facilities in hot spots should be standing up SRA Teams and Triage Teams now (and others close behind)
- Crisis standards of care should be authorized by Facility and/or VISN leadership before any change from usual or contingency standards of care

Values in a Pandemic

Duty to Care:

- Obligation of the health professions
- Central to VA's public service mission
- Take proportional risk to care for patients and not abandon them

Organizational Reciprocity:

- Responsibility to support staff to meet duty and their other obligations
  - Provide PPE, security, basic needs, indemnification

Tension Between Clinical and Public Health Ethics

Clinical Ethics

- Individual patient
- Patient-centered care
- Primary of patient preferences/values
- Advocacy and fidelity to patient

Public Health Ethics

- Community
- Common good
- Moral equality of all people
- Fairness in distribution
- Follow scarce resource allocation protocols to ensure maximal survival for greatest #

Ethical Leadership Decision-Making

Informed and participatory: gather all the facts and stakeholder views

Values-based: weigh options in relation to organizational values

Beneficial: weigh short/long term consequences so benefits outweigh harms

Systems-focused: ensure precedents can be applied to similar cases

Transparent: communicate how decisions made and reasoning behind it

VA's Ethics Framework and Structure for Pandemic Response

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- Establishing a Scarce Resource Allocation (SRA) Team
- Protocol for triage of scarce resources, including ventilators

Ethical Framework for Allocation of Scarce Resources

- Consistent allocation decisions are necessary to ensure the greatest good for the greatest number (**justice**)
- Allocation must be fair and applied consistently across groups of people according to specified criteria (**fairness**)
- Allocation criteria must be **transparent**, reasonable, legal, **feasible**, and **practical**

Benefits of the Scarce Resource Allocation (SRA) Process

- Practicing in accordance with institutional crisis standards of care policy or guidance may:
  - Reduce liability
  - Promote accountability
  - Minimize moral distress
  - Enhance ethical quality of care
- Brings order to chaos early in an event
- Provides mechanisms to evaluate outcomes and adjust

Scarce Resource Allocation Structure (p. 26)

- SRA Team
  - Assists in the shift to crisis standard of care and guides implementation of triage protocol
- Triage Team
  - Implements the triage protocol
- Providers
  - Follow direction of the Triage Team

Team-Based Structure for Allocation Decisions

SRA Team - Facility specific

- Works within the incident command structure
- Assists facility leadership in determining shift to crisis standards of care
- Formally oversees SRA operations within resource availability
  - Assures situational awareness
  - Provides facility and regional context
- Implements tertiary triage based on conditions and SRA protocols

Triage Team - Patient specific

- Functions under and reports back to SRA team
- Responsible for gathering clinical data and assigning pts. to categories
- Makes/documents triage decisions based on protocol and resources
- Directs bedside providers on triage decisions

Ideal Membership* (p.28)

SRA Team:

- Team Leader
- Logistics/Management
- Critical Care Medicine
- Nursing
- Emergency Department
- Ethics
- Other
  - Infectious Diseases
  - Palliative Care
  - Social Work
  - Chaplain
  - Patient/Veteran/VSO

Triage Team:

- Team Leader
- Critical Care Medicine
- Nursing representative
- Logistics/Management
- Other

*Facilities should try to ensure full and separate representation on these teams. There may be some members with dual roles on a single team.

Current and Anticipated Conditions

- Regional COVID-19 conditions vary and are evolving across VA
- Facilities with COVID-19 surges should set up SRA and triage structures
- Authorization to shift to crisis standards of care should be considered with Facility and VISN leadership when appropriate
  - Once authorized, will be temporary and should be used only when absolutely needed

Tertiary Triage Protocol

Conceptually based on 2 rank-ordered criteria:

1. **Survivability:** Priority is given to those for whom treatment has the highest probability of medical success/survival

   - Then, if there is still resource scarcity

2. **Tie-Breaker:** For those who have similar survivability, resources will be made available by suitable tie-breaker (e.g., first-come, first-served OR lottery, NOT age or disability)

Application of Triage Protocols to Everyone

- Triage protocols apply to all patients receiving care in acute care facilities, regardless of their diagnosis or their current treatment modalities
- Triage protocols will not apply to VHA patients in VA long-term care facilities or at home unless these patients are admitted to an acute care facility.

Tracking Patient Data

- Situational awareness is a challenge in any disaster, knowing every patient's score in the ICU every time a decision has to be made is impractical
- Regular assessment, color coding, and the use of triage categories with pre-defined guides for actions are components of triage protocols
- Tools in development

Tertiary Triage - Color-Coded Levels

- Blue – Patients with very poor expected outcomes even with life-saving resources
- Red – Patients who require life-saving resources and are most likely to recover by receiving those resources
- Yellow – Patients who require life-saving resources with intermediate likelihood to recover by receiving those resources
- Green – Patients who do not require life-saving resources to recover

Prioritization

Initial Criteria	Priority	Action
Blue	Excluded	Do not use life-saving resources Use other resources including palliative measures
Red	Highest	Use life-saving resources, as available, per the direction of the SRA through the Triage team
Yellow	Inter-mediate	Use life-saving resources, as available, per the direction of the SRA through the Triage team
Green	None	Use other medical management Reassess as needed

Summary of Exclusion Criteria (p.33)

1. Confirmed presence of any advanced disease with a life expectancy of 6 months or less
2. Recent history of cardiac arrest
   - i.e., “Unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures, or trauma-related arrest.”
3. Confirmed severe, irreversible cognitive impairment

Resuscitation Status for Patients with Exclusion Criteria

- Normal decision making about resuscitation status is suspended (i.e., notification not consent)
  - A DNR order should be entered and the patient/surrogate notified
- Other life-saving resources may be withdrawn
- Other appropriate non-life saving, non-scarce resources should be provided (e.g., antibiotics, oxygen, clinical care, palliative care, etc.)

Initial Assessment (p.33)

Life-Saving Resources Triage Tool for Initial Assessment			
	Initial Criteria	Priority	Action
B	Exclusion Criteria or SOFA > 11	Excluded	Do not use life-saving resources Use other resources including palliative measures
R	SOFA ≤ 7 or Single Organ Failure	Highest	Use life-saving resources, as available, per the direction of the Triage Review team
Y	SOFA 8 - 11	Intermediate	Use life-saving resources, as available, per the direction of the Triage Review team
G	No requirement for life-saving resources	None	Use other medical management Reassess as needed

48-Hour Assessment (p. 38)

Life-Saving Resources Triage Tool for 48-HOUR REASSESSMENT			
Category	48-Hour Criteria	Priority	Action
Blue	Exclusion Criteria or SOFA > 11 or SOFA 8 – 11 and increasing since last assessment	None	Discontinue life-saving resources Use other resources including palliative measures
Red	SOFA 8 – 11 and decreasing since last assessment or SOFA < 8	Highest	Continue life-saving resources, as available
Yellow	SOFA 8 – 11 and no change since last assessment	Intermediate	Continue life-saving resources, as available
Green	No longer requiring life-saving resources	None	Discontinue life-saving resources. Reassess as needed

Triage Team

- Meets at least daily to review triage assessments, bed status, and other contextual information from the SRA Team.
  - Available 24/7 for urgent decisions
- Responsible for gathering clinical data for tertiary triage scoring
- Makes triage decisions based on protocol and resources
- Directs bedside providers on triage decisions
- Reports back to SRA Team

Due Process: Appealing Triage Decisions (p.39)

- Real-time appeals process to consider only:
  - Whether applicable standards are being followed fairly, consistently, and correctly
  - NOT an appeal of the standards
  - Ensure accountability for triage processes
- Avoid conflict of obligations
- Other dispute resolutions methods suspended

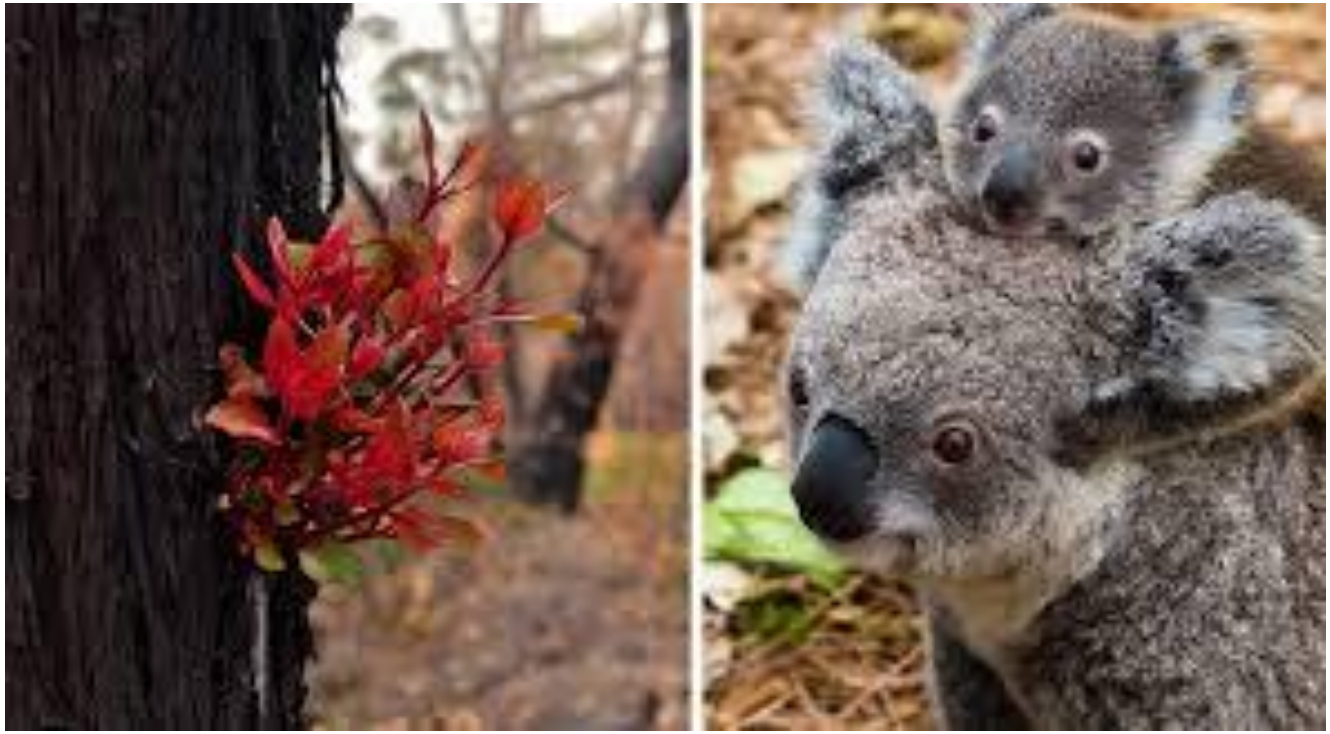
Non-SRA Ethical Practices What is the Same/Different?

- Informed consent is still required
  - Can group treatments by a single specialty into one a 'bundled' consent form for signature by the patient
  - If obtaining signature impractical follow policy for documenting consent when patient cannot sign
  - Using social distancing practices to document witnesses is permitted
- Other modifications evolving
  - Disclosure of adverse events

Hope

"When you're going through hell, keep going"

Winston Churchill, and others



Standards of Care

- Usual or conventional standards
- Contingency standards
- Crisis standards

Standards of Care

- **Usual or conventional standards**
  - Based on VA standards (e.g., policy, regulation, SOP)
  - Care in accord with accepted standards of medical practice
  - Patient-centered
- Contingency standards
- Crisis standards

Standards of Care

- Usual or conventional standards
- Contingency standards
- **Crisis standards**
  - A substantial change in usual health care operations and the level of care it is possible to deliver made necessary by a pervasive or catastrophic disaster.

Standards of Care

- Usual or conventional standards
- Contingency standards
- **Crisis standards**
  - After all attempts at augmentation have been exhausted and the demand for life-saving health care resources outstrips supply, a necessary shift from patient-centered decision-making to community-centered decision-making.

Standards of Care

- Usual or conventional standards
- **Contingency standards**
  - Efforts to maintain quality while adapting to the rapidly changing clinical conditions when some health care resources (i.e., space, staff, or supplies) are scarce or when providing them exposes staff to disproportionate risk of harm.
  - *Functionally equivalent* to conventional standards
- Crisis standards

Continuum of Care

Incident demand/resource imbalance increases →
Risk of morbidity/mortality to patient increases →
← Recovery

	Conventional	Contingency	Crisis
Space	Usual patient care space fully utilized	Patient care areas repurposed (PACU, monitored units for ICU-level care)	Facility damaged/unsafe or non-patient care areas (classrooms, etc.) used for patient care
Staff	Usual staff called in and utilized	Staff extension (brief deferrals of non-emergent service, supervision of broader group of patients, change in responsibilities, documentation, etc.)	Trained staff unavailable or unable to adequately care for volume of patients even with extension techniques
Supplies	Cached and usual supplies used	Conservation, adaptation, and substitution of supplies with occasional reuse of select supplies	Critical supplies lacking, possible reallocation of life-sustaining resources
Standard of care	Usual care	Functionally equivalent care	Crisis standards of care[a]

Usual operating conditions

Indicator: potential for crisis standards[b]

Trigger: crisis standards of care[c]

Austere operating conditions

Institute of Medicine (US). Barriers to Integrating Crisis Standards of Care Principles into International Disaster Response Plans. 2012.

Why discuss contingency standards now?

- Duty to plan
- VA's 4th Mission
- Fairness
- Consistency
- Transparency
- Accountability
- Proportionality
- Stakeholder engagement
- Reduce moral distress

Example of Contingency Standard - **Staff**

- Modifying scope of clinical practice:
  - Reassigning ENT residents as medical interns
  - Primary care physicians serving as ward attendings
  - Assigning an operating room nurse to ICU
- Maintaining adequate supervision

Example of Contingency Standard - **Supplies**

- Reduce transmission risk without diminishing quality.
  - Substituting nebulized inhaled treatments with metered dose inhalers
  - Modifying requirements for patient signature on informed consent forms
- Augment capacity through adaptation or substitution
  - Using peritoneal dialysis when there is scarcity of hemodialysis machines
  - Face shields created by medical students

Example of Contingency Standard - **Space**

- Telehealth in place of in-person care
- Opening additional inpatient wards and ICU beds
- Drive-thru COVID-19 swab testing

Ethically Problematic Implementation of Contingency Standards

- Practices that harm patients by denying them access to otherwise medically appropriate care
  - Withholding CPR to *all* patients with COVID-19
  - Rationing care based on *potential* resource scarcity
  - Providing ICU-level care on a regular ward without adequate staffing or space
  - Banning all visitors with *no* consideration for compassionate visitation with dying patients

Maintaining Conventional Standards of Care

- Using existing ethical and clinical decision-making frameworks
  - CPR
  - Informed consent

Deciding on Contingency Standards

- **Involve subject matter experts and local leadership**
  - Team-based decision, not an individual one
- Is it necessary? Can staff operate under existing standards? When and how will we return to existing standards?
- Is it effective?
  - Will it address the scarcity or the transmission risk?
- Is it functionally equivalent to usual care?
- Is it proportional to the need?
- Can it be applied consistently and transparently?