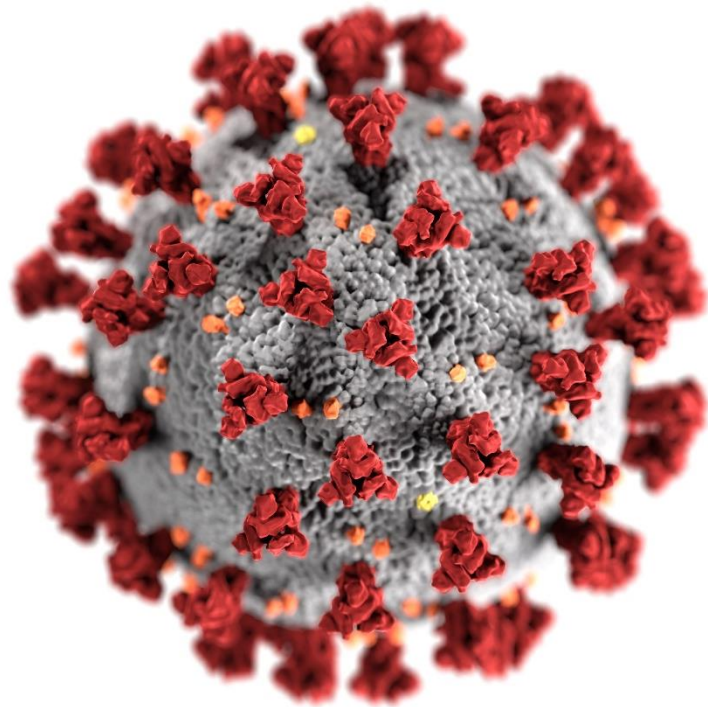


Altered Standards of Care in Response to COVID-19: Background, Tools and Experiences

March 19, 2020



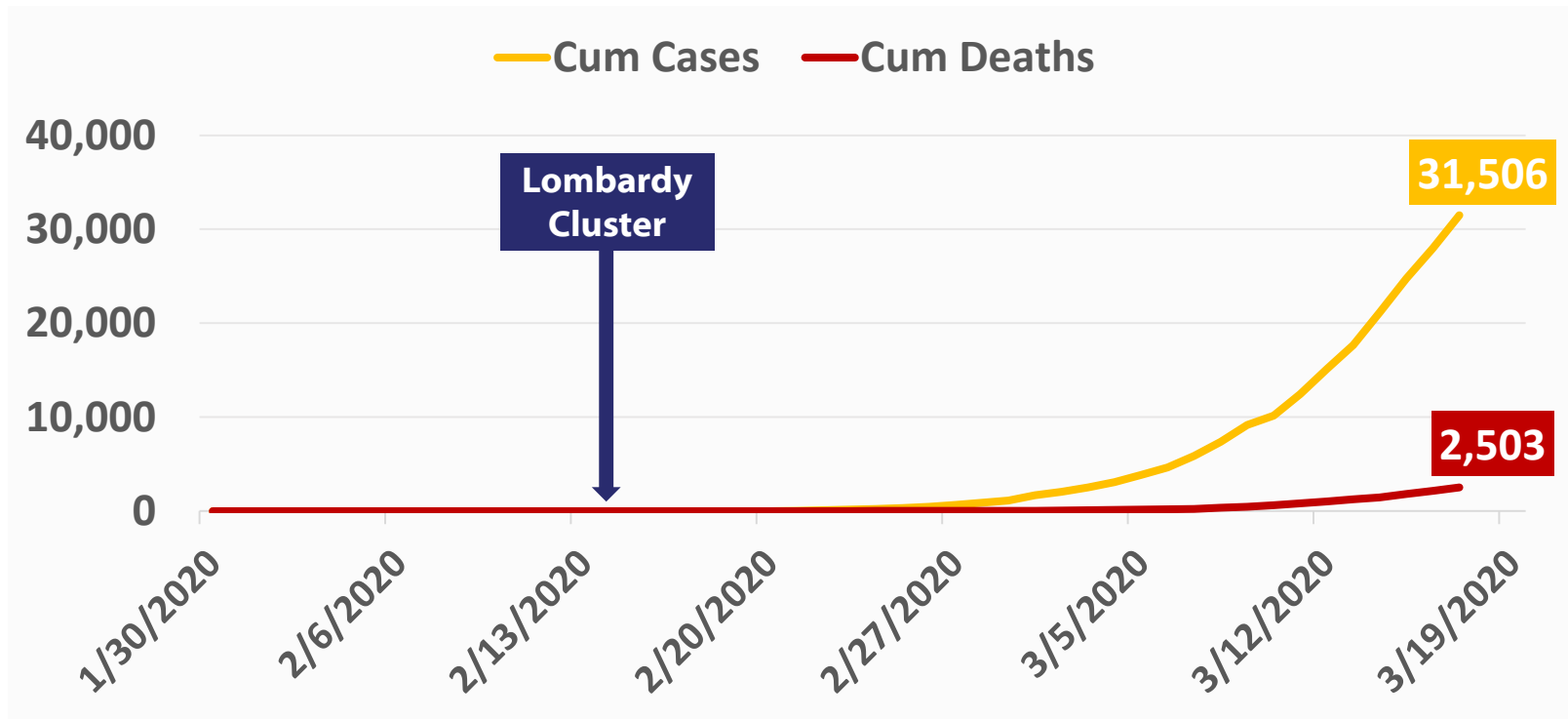
For more information: www.cdc.gov/COVID19

Outline

- Example from Italy
- Fundamentals of a Response: Space, Staff, Stuff
- Crisis Standards of Care (CSCs)
- Examples of Elements of CSCs
- Applying CSCs to COVID-19
- Legal considerations

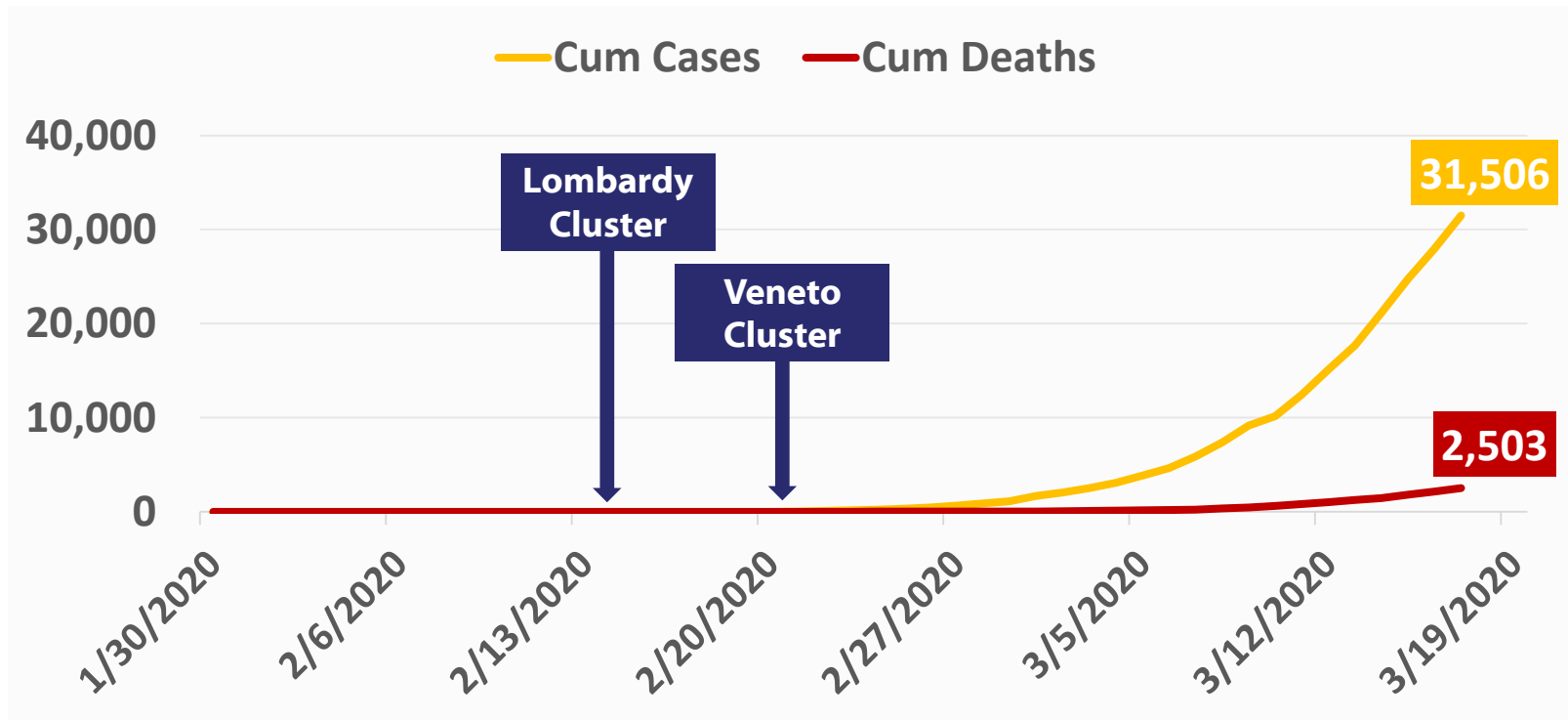


The outbreak in Italy started with a cluster of cases in the Lombardy region of Italy in mid-February



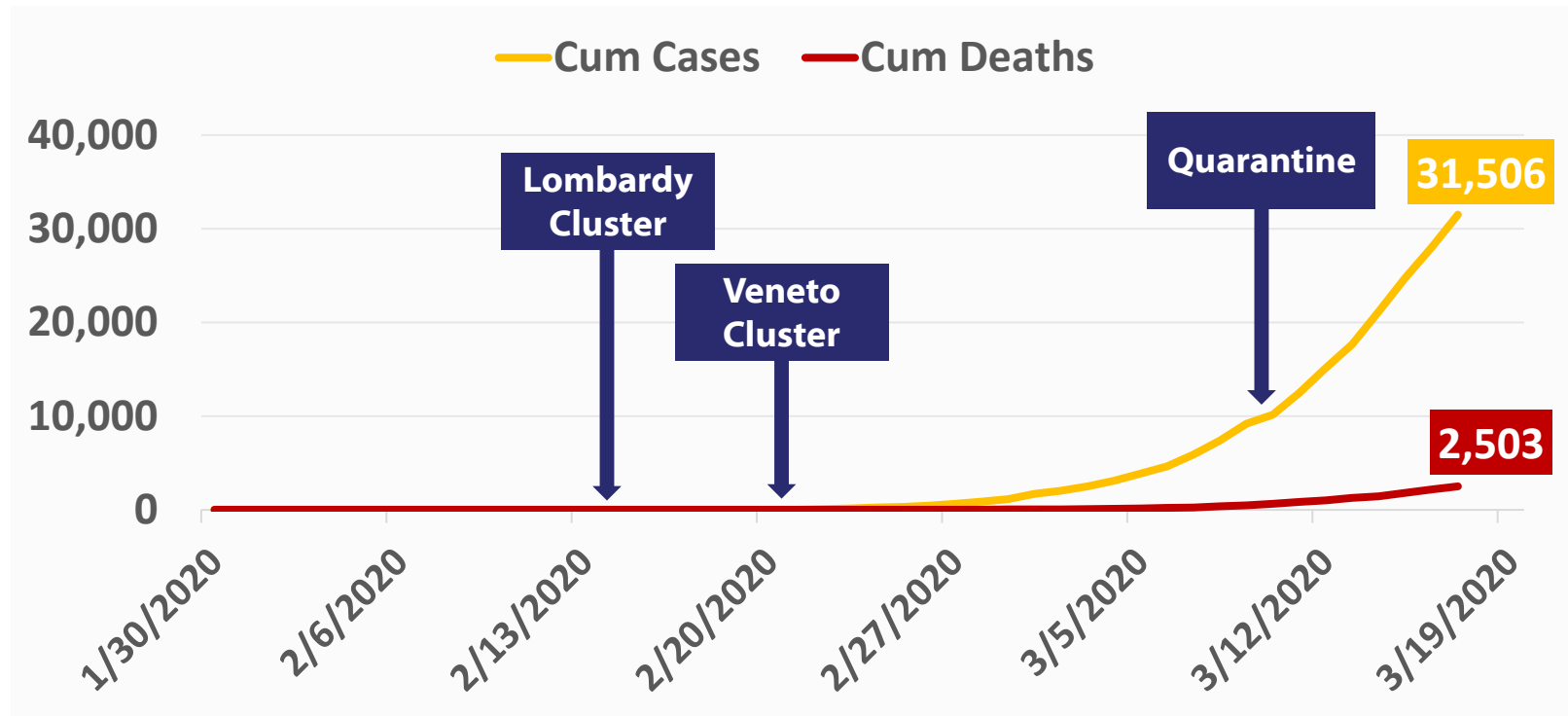
Data: [Italy Protezione Civile](#)

One week after the Lombardy Cluster, a smaller cluster of cases appeared in the Veneto region



Data: [Italy Protezione Civile](#)

Cases in Italy continued to rise exponentially and exceed healthcare system capacity



Data: [Italy Protezione Civile](#)

Lombardi region: Large influx of critically ill patients

- **Pre-Crisis ICU capacity**

- 720 beds (representing 2.9% of total hospital beds at 74 hospitals)
- Routinely operated at 85-90% capacity in the winter

- **Between 20 February and 7 March:**

- 3,420 COVID-19 admissions of which 556 (16%) required ICU level care
- Related to the older population with more medical co-morbidities

- **Adjusted to form cohorted COVID-19 ICU beds**

- Increased capacity to 482 dedicated COVID-19 ICU beds for in 14 days



Francesca Mangiatordi

il y a environ une semaine

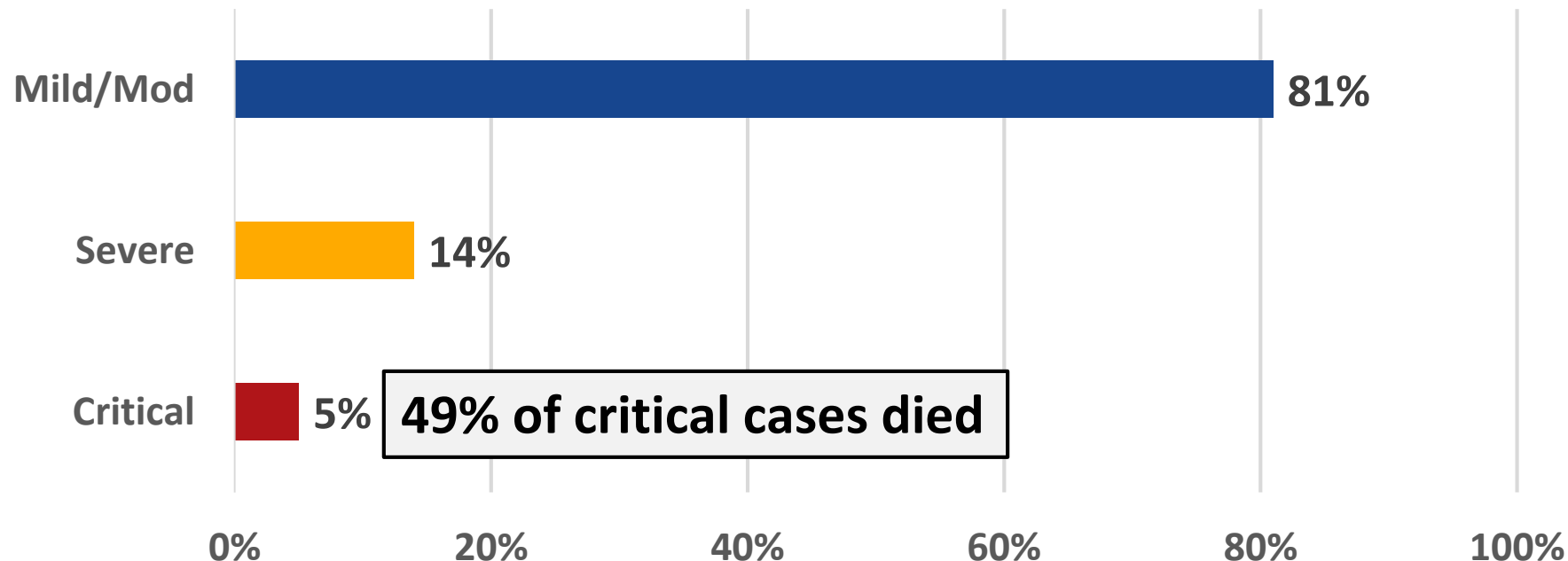


Images: <https://www.nytimes.com/2020/03/12/world/europe/12italy-coronavirus-health-care.html>

57

632

COVID-19 – China: most patients had mild illness, but a fifth had severe or critical disease (through 11-Feb-2020 (N=44,415))



Three Foundational Elements of a Response



Space



Staff



Supply

Images: <https://thenounproject.com/search/?q=doctor&i=1030175>

COVID-19 Concerns for the health system

- Current concerns as transmission accelerates:
 - **Space:** Maintaining capacity for inpatient, emergency, and critical care
 - **Staff:** Sufficient staff for patient triage and appropriate level of care
 - **Supply:** Increasing stress on PPE supply
- Clear communications to the public

What are Crisis Standards of Care (CSC)?

- Crisis Standards of Care (CSC) guidelines help public health and healthcare personnel determine how to utilize resources during a public health emergency.
- Guides action by the state, county, and healthcare facilities
- Why is it necessary?
 - During catastrophic events, there may not be enough resources to give all patients the level of care they would normally receive.
 - A substantial change in usual healthcare operations and level of care it is possible to deliver due to a catastrophic disaster (e.g., pandemic influenza, earthquake, hurricane) (IOM 2012).

COVID-19 health system elements to be accounted for as demand exceeds capacity

- **Process**

- How are crisis care decisions integrated into hospital incident command?
- What is the process for resource triage or allocation?

- **Criteria**

- What is the basis for the allocation decisions (i.e. best practices/best evidence)?

- **Coordination**

- How is this standard of care equalized across the region to assure consistency?

- **Policy**

- How do regulatory and state actions support these non-traditional approaches to care?

Continuum of Care

Conventional

	Conventional
Space	Usual patient care space fully utilized
Staff	Usual staff called in and utilized
Supplies	Cached and usual supplies used
Standard of care	Usual care

Normal operating conditions

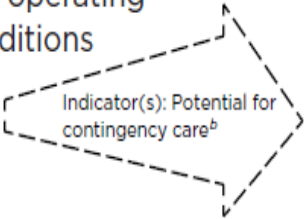


Continuum of Care

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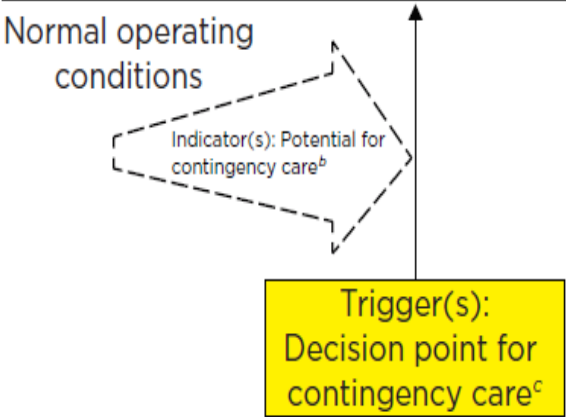
Trigger(s):
Decision point for contingency care^c

Continuum of Care

Conventional

Contingency

	Conventional	Contingency
Space	Usual patient care space fully utilized	Patient care areas re-purposed (PACU, monitored units for ICU-level 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.)
Supplies	Cached and usual supplies used	Conservation, adaptation, and substitution of supplies with occasional re-use of select supplies
Standard of care	Usual care	Functionally equivalent care



Continuum of Care

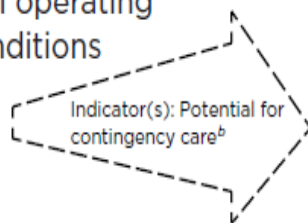
Conventional

Contingency

Crisis

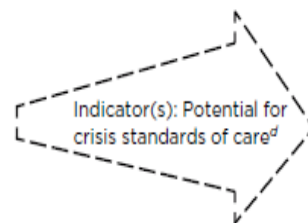
	Conventional	Contingency	Crisis
Space	Usual patient care space fully utilized	Patient care areas re-purposed (PACU, monitored units for ICU-level care)	Facility damaged/unsafe or non-patient care areas (classrooms, etc.) used for patient care
Staff	Usual staff called in and utilized	Staff extension (brief 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 re-use 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

Normal operating conditions



Trigger(s):
Decision point for
contingency care^c

Extreme operating conditions



Crisis care trigger(s):
Decision point for
crisis standards of care^e

Examples of triggers for shifting along this continuum of care standards

- Sustained community wide transmission
- Supply/medication shortage
- Unable to maintain normal staffing levels
- No available ICU beds
- Significant delays in access to care due to demand
- Duty to Plan: Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2 (<https://nam.edu/duty-to-plan-health-care-crisis-standards-of-care-and-novel-coronavirus-sars-cov-2/>)

Crisis Standards of Care Considerations: Stuff

PPE	Current recommended actions	Planning for next 2 weeks
N95s	Reference CDC optimizing guidance OSHA fit testing waiver FDA EUA	Optimizing guidance incorporated for all products as part of larger IPC program <ul style="list-style-type: none">• Extended use• Re-use• Alternative strategies• Disinfection
Face masks	CDC optimizing guidance posted 3/18/2020	
Face shields		
Gowns		
Gloves	Single use	Single use
Vents	<ul style="list-style-type: none">• Understand stockpiled resources and how to request• Review CDC technical recommendations• Account for available ventilators and ancillary equipment	Identify alternative ventilator options Develop, socialize and coordinate triage and care protocols for life saving supplies across healthcare coalition

Crisis Standards of Care Considerations: Space

Current Recommended Actions	Planning for next 2 weeks
Monitor daily bed use	<p>Identify options for non-ED triage/evaluation and other locations for hospital-level care</p> <ul style="list-style-type: none">• Tents or off-site locations, understanding the minimum requirements for clinical care• Remote telehealth• Bots• Outpatient outreach and tools
Timely discharge of patients not requiring acute, inpatient management	<p>Identify non-medical floor beds to accommodate overflow patients (e.g. surgical floors)</p> <p>Identify referral facilities within coalition if capacity exceeded</p>
Timely transition of ICU patients to regular medical floor when appropriate	<p>Identify non-ICU locations to provide advanced level care (e.g. post-anesthesia care units, telemetry floors)</p> <p>Identify referral facilities within coalition if capacity exceeded</p> <p>Review triage algorithms for ICU admission</p>

Crisis Standards of Care Considerations: Staff

Current recommended actions	Planning for next two weeks
<p>Review hospital incident command system plans at the hospital and healthcare coalition level</p> <p>Plan for continuity of operations due to absenteeism</p> <p>Review facility telemedicine services</p> <p>Understand authorities around expanding scope of practice policies and establish t trigger decisions</p> <p>Create crisis standards of care teams to assist with hospital specific triage and coordination</p> <p>Evaluate potential federal staffing option</p>	<p>Curtail non-essential staff</p> <p>Reassignment of staff from other duties (shift elective surgery staff to other emergent/inpatient/critical care locations)</p> <p>Change staff hours, staffing patterns</p> <p>Modify staff – to – patient ratios</p> <p>Obtain equivalent staff through hiring, expanded practice scope</p> <p>Coordinate and allocate staffing resources between hospitals and facilities within and outside jurisdiction</p> <p>Track triggers to expand scope of practice for provider</p>

Actions for Hospital Incident Command

Prepare for patient surge while facing staff and supply shortages

- Be in regular communication with healthcare coalition or health department to understand regional resources
- Understand current hospital resources (vents, bed counts, etc.)
- Determine allocation strategies and triggers for when/how they need to be implemented
 - Decision process needs to be clear and made only when no other resources are available
 - Determine a triage process and team to include two clinicians that are not the caregivers for the patient(s) for clinical decision making
 - Ensure strategies/decision making processes are reviewed by health facility leadership

Actions for Outpatient Services

- Review future appointments for the next three months
 - Strive to move visits to virtual appointments (telehealth, telemedicine, phone based appointments)
 - Cancel or postpone elective or non-urgent appointments and procedures
 - Provide good communication to patients about COVID-19
 - Encourage home care and over the counter medication unless they have severe symptoms
 - Offer to write “prescriptions” for home quarantine and self isolation as needed

Actions for Emergency Departments

Prevent transmission from suspect COVID patients, reduce burden in ED, and divert non-critical suspect COVID-19 patients

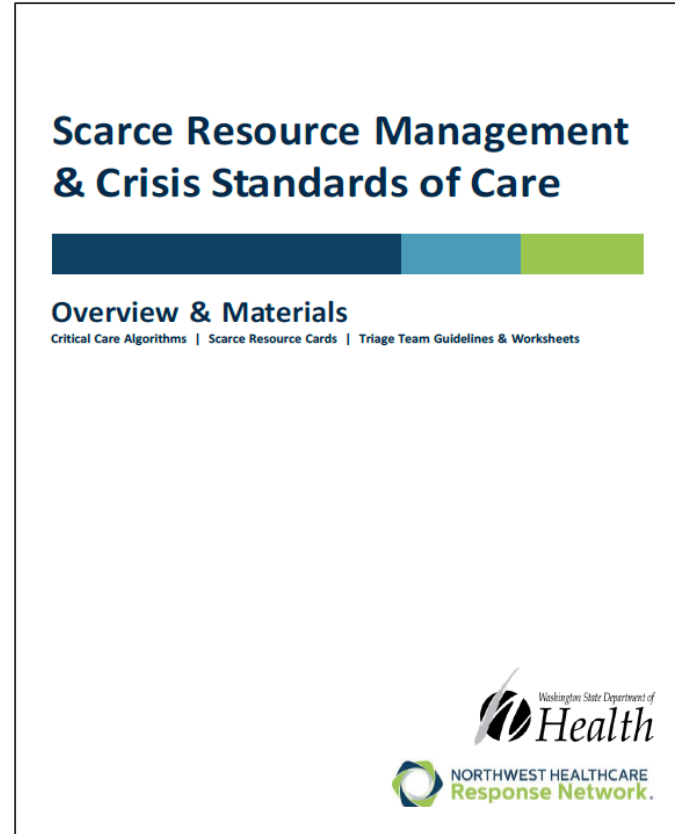
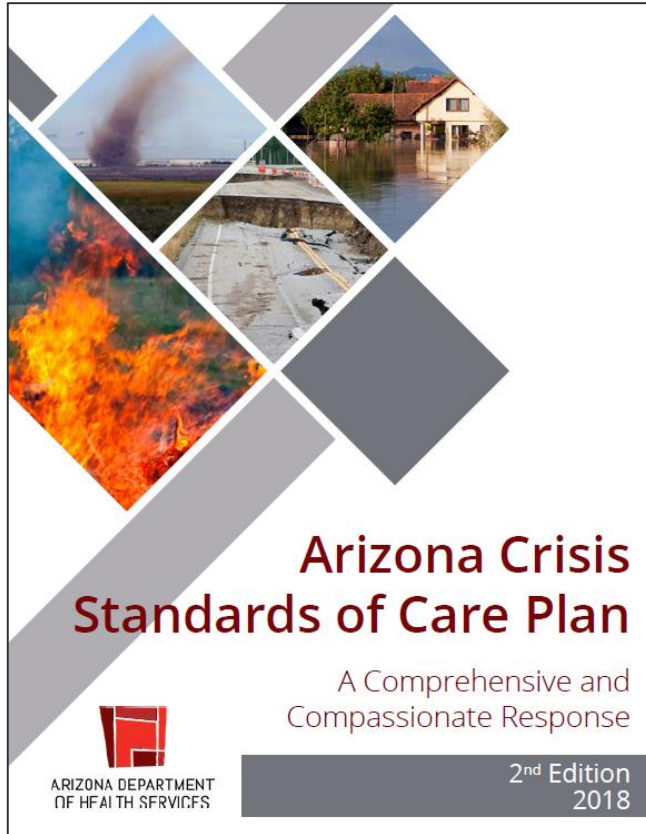
- Identify and establish outside triage point for non-critical COVID-19 patients (triage tents, parking lot triage)
- Coordinate with EMS (e.g. telephone triage) to avoid ED visits that can be treated as outpatient
- Identify potential changes in patient flow that can expedite non-emergency visits, when necessary
 - Specific times of day that individuals with respiratory illness to present
 - Specific entrance and triage route for those with respiratory illnesses

Actions for Inpatient Care

Optimize personal protective equipment, protect staff, and prevent hospital transmission of COVID-19

- Cohort patients and staff by unit or floor as numbers of cases increase
- Designate a specific room/floor for non-infectious hospitalized patients
- Cancel elective procedures
- Assess spaces such as pre-, post- anesthesia care, same day surgery, gastroenterology labs, intermediate care, and step-down units for critical care expansion
- Restrict visitors and promote electronic visiting instead of in-person visits

Examples and tools of CSC plans from two states



CSCs can help decide whether escalation of care is appropriate

ADULT Critical Care Triage Worksheet Critical Care Guidelines During Crisis Capacity¹



This Worksheet, along with the corresponding Adult Critical Care Algorithm, are to be used by “Triage Teams” during a declared emergency event whereby an appropriate healthcare official has implemented crisis standards of care. It is recommended that a “Triage Team” be comprised of senior medical personnel, preferably not those primarily taking care of the individual patient under consideration. Please see “Scarce Resource Triage Team Guidelines” for further information.

STEP 1: Screen adult patients for ICU care during scarce resources

Proceed to following after reviewing patient’s end of life directives/POLST or similar living will documents. For the following conditions consider available staffing and resources. If resources are inadequate, **consider** transferring the following patients to out-patient or palliative care with appropriate resources and support as can be provided.

- ☐ 1. Pre-existing or Persistent coma or vegetative state
- ☐ 2. Severe acute trauma (e.g. non-survivable head injury)
- ☐ 3. Severe burns with Low Survival burn scores based on the Triage Decision for Burn Victims table (See Table A below). See Burn Scarce Resource Card for management of critical burn patient outside of a Burn Center.
- ☐ 4. Significant underlying disease process that predict poor short term survival*
**Examples of underlying diseases that predict poor short-term survival, despite standard treatment, include but are not limited to:*
 - Severe congestive heart failure
 - Severe chronic lung disease
 - Central nervous system, solid organ or hematopoietic malignancy with poor prognosis for recovery
 - Severe cirrhotic liver disease with multi-organ dysfunction
- ☐ 5. Baseline functional status (consider loss of reserves in energy, physical ability, cognition and general health)

Legal considerations

- Space
 - Waiving facility licensure rules to allow alternate triage, testing, and care sites
- Staff
 - Waiving or suspending healthcare provider licensing statutes and regulations to expanding scopes of practice, ease continuing education requirements, or allow retired practitioners to respond
 - Providing licensure reciprocity, liability protections, and workers compensation
- Equipment
 - Waiving procurement rules
 - Seizing private property for public use

Legal considerations (cont.)

Tools for state law examples:

- Gubernatorial emergency suspension powers:
<http://lawatlas.org/datasets/emergency-powers>
- Collection of state laws on liability protections and expanding scopes of practice:
<https://emergencylawinventory.pitt.edu/display-laws>
- ASTHO Scope of Practice Toolkit: <https://www.astho.org/ScopeofPracticeToolkit/>
- Public Health Emergency Law Unit 3 (see slide “Commandeering or Utilizing Property Laws”): <https://www.cdc.gov/phlp/phel-training/PHEL-Unit-03/>

CMS Waivers to support CSC: WA State experience

- Washington is implementing all of the blanket waivers announced by CMS on March 13 in Medicaid and CHIP, to the extent applicable
- Washington state is seeking additional blanket waivers under which “all CMS licensed providers will operate upon CMS approval”

CMS Waivers to support CSC: WA State experience (cont.)

- Washington is implementing all of the blanket waivers announced by CMS on March 13 in Medicaid and CHIP, to the extent applicable
- Washington state is seeking additional blanket waivers under which “all CMS licensed providers will operate upon CMS approval”
 - Emergency Medical Treatment and Active Labor Act
 - Institutions of Mental Disease (IMD)
 - Medicaid and Medicare Hospital Conditions of Participation (CoPs) and similar requirements

Additional Resources

- Duty to Plan: Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2 (guidance on triggers, strategies for scarce resources, and actions for hospitals)
 - <https://nam.edu/duty-to-plan-health-care-crisis-standards-of-care-and-novel-coronavirus-sars-cov-2/>
- How Should U.S. Hospitals Prepare for Coronavirus Disease 2019 (COVID-19)?
 - <https://annals.org/article.aspx?articleId=2763037&guestAccessKey=8ba4f05e-efd2-4967-bd82-764ba23301f7>
- CMS Emergency Waivers (includes state-specific waivers)
 - <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>

Background



Guiding Ethical Principles of Crisis Standards of Care

Save the largest number of lives among those who have the longest to live

- Duty to Plan
- Distributive Justice
- Duty to Steward Resources
- Duty to Care
- Proportionality
- Consistency and Fairness
- Transparency and Public Accountability

CMS Waivers to support CSC: WA State experience (cont.)

- **Discharge Planning** 42 C.F.R. §482.43(a)(8), 485.642(a)(8): Allowing for discharges in an efficient manner will free beds for acutely ill patients.
- **Facilities and Make-shift clinic and Physical Environment** 42 C.F.R. §482.41; A-0700 et seq: Non-hospital buildings/space can be used for patient care, provided sufficient safety and comfort is provided for patients and staff.
- **Medical Staff** 42 C.F.R. §482.22(a); A-0341: Physicians whose privileges will expire and new physicians can practice before full medical staff/governing body review and approval, keeping clinicians on the front lines during the emergency.

CMS Waivers to support CSC: WA State experience (cont.)

- **Delivery of Services in Alternate Clinic Locations:** Waiver/flexibility to allow Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) providers to bill for their Prospective Payment System (PPS) rate, or other permissible reimbursement, when providing services from alternative physical settings, such as a mobile clinic or temporary location.
- **Flexibility for Teaching Hospitals.** Allow flexibility in how the teaching physician is present with the patient and resident.

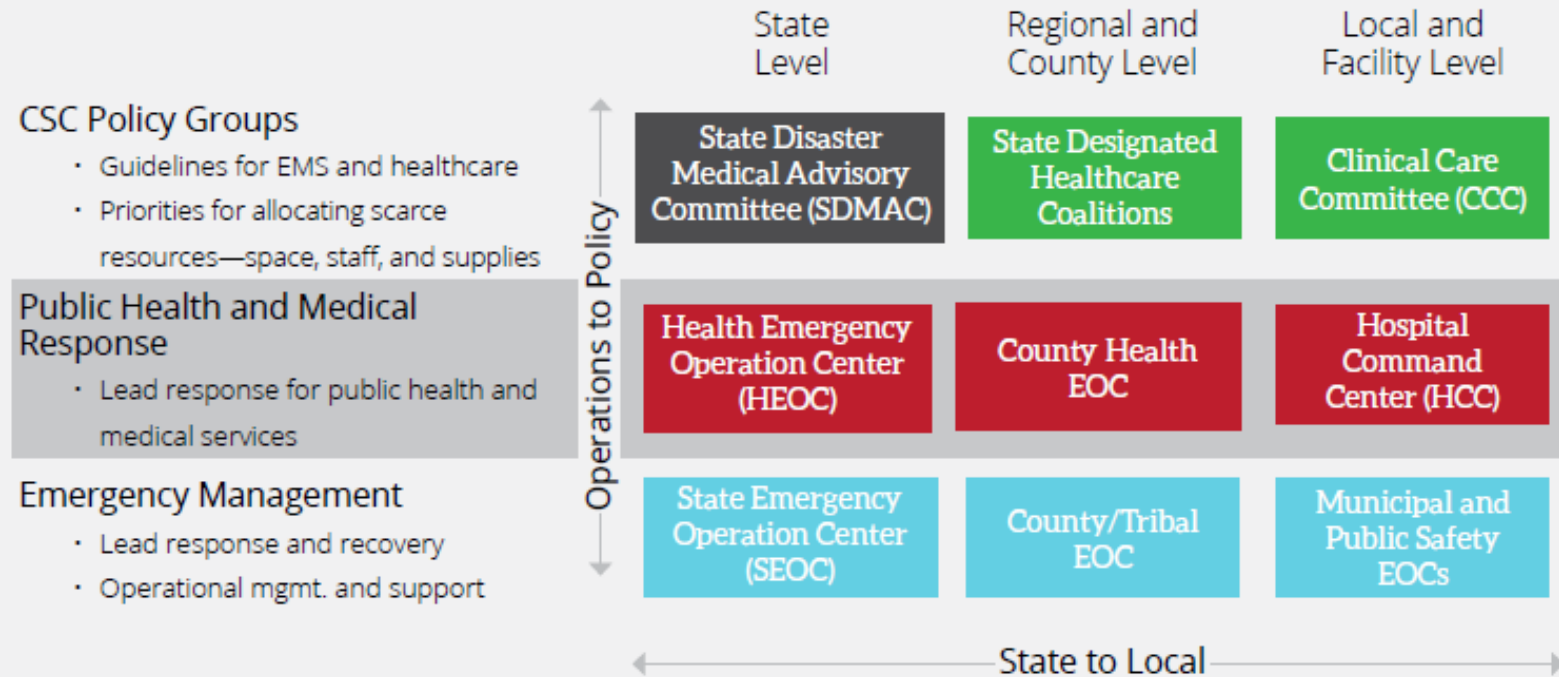
CMS Waivers to support CSC: WA State experience (cont.)

- **Skilled Nursing Facility/Nursing Facility (SNF/NF) Conditions of Participation (CoP):**
 - Waiver to allow receiving facilities or alternate settings to receive SNF/NF or ICF/IID payment if a client is moved to a specialty facility to receive care and recover from COVID-19 during the COVID-19 crisis.
 - Non-SNF/NF buildings/space can be certified for use as a temporary SNF/NF... allows state to open a temporary COVID 19 nursing facility to assist COVID 19 positive SNF/NF residents
 - Waiver of certain conditions of participation and certification requirements for opening a nursing facility if the state determines there is a need to quickly stand up a temporary COVID-19 facility

CSCs establish direction, control, and coordination across different levels of the response.

Ref: [AZ CSC](#)

Figure 4—Arizona CSC: Direction, Control, and Coordination



CSCs can suggest standard protocols to continually evaluate whether medical care should be continued.

ADULT Critical Care Triage Algorithm
Crisis Standards of Care
Updated Version: Mar 2020

