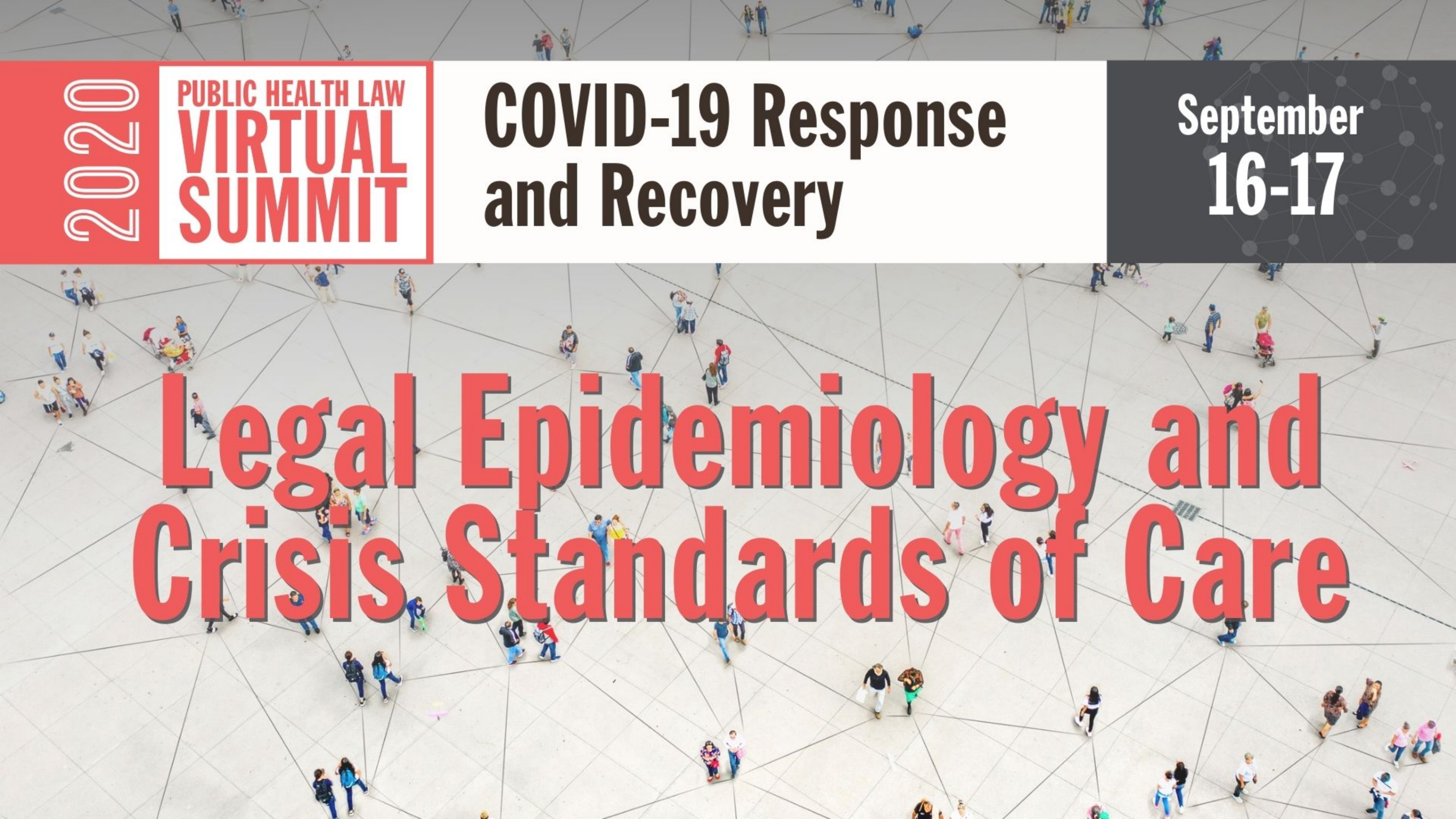
2020 PUBLIC HEALTH LAW VIRTUAL SUMMIT

COVID-19 Response and Recovery

September 16-17



Legal Epidemiology and Crisis Standards of Care

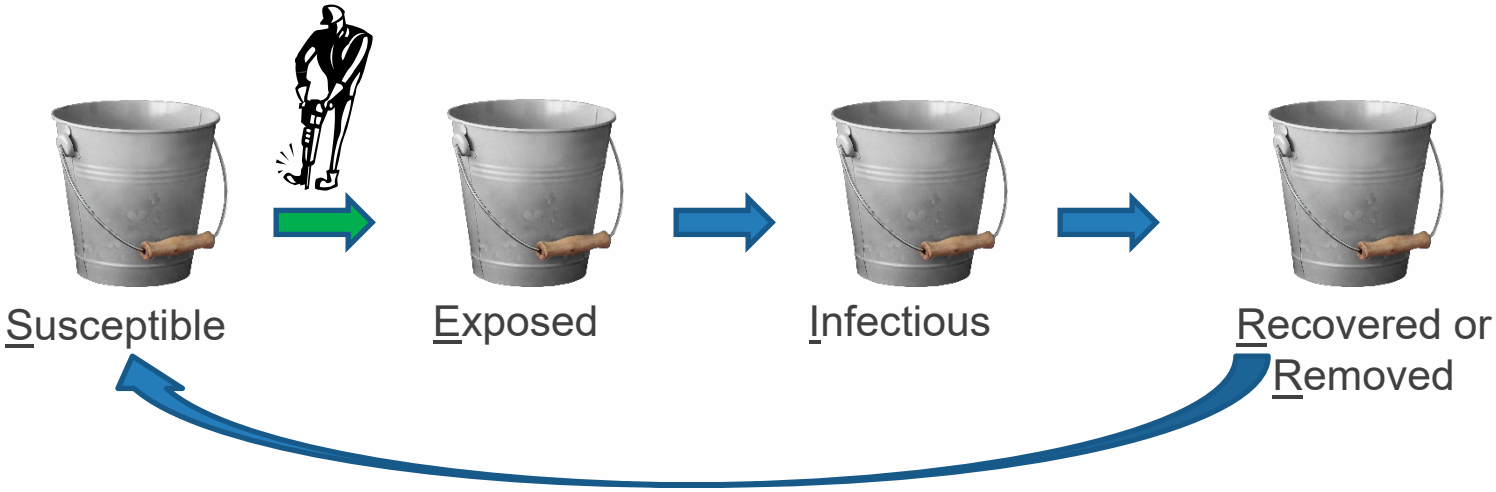
2020
PUBLIC HEALTH LAW VIRTUAL SUMMIT
COVID-19 Response and Recovery
September 16-17

Is Law Working? A Brief Look at the Legal Epidemiology of COVID-19

Evan Anderson
University of Pennsylvania
&
Scott Burris
Temple University Beasley School of Law

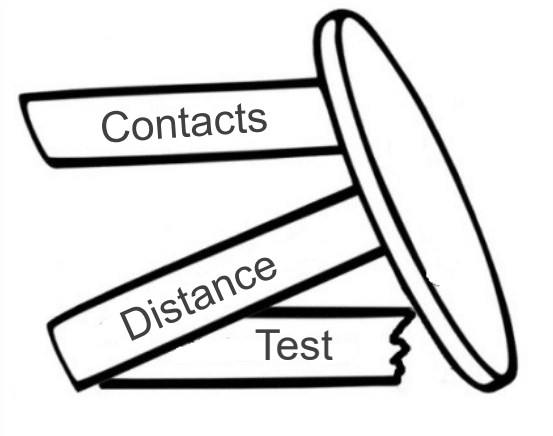
High Level Take-Aways

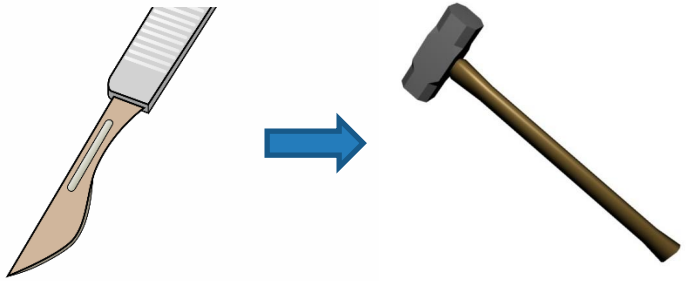
- Lots of legal intervention
- Lots of research
  - Almost no experiments; few quasi-experiments
  - Mostly mechanistic simulations (“helpful but wrong”)



High Level Take-Aways

- So what do we know?
  - Sometimes high face validity w/ simple mechanism (school closures, travel bans)
  - Otherwise, hard to isolate & quantify causal effects; context dependence, contingency, endogeneity





High Level Take-Aways

- Abject failure to address horrifying disparities in infection and death

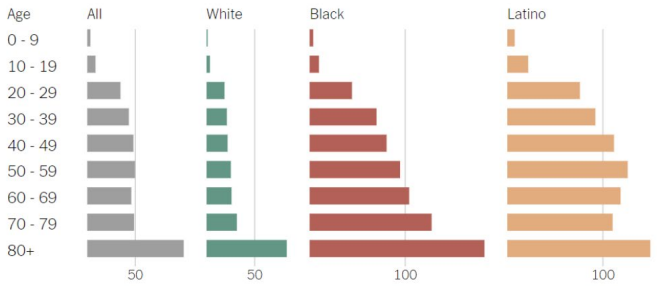
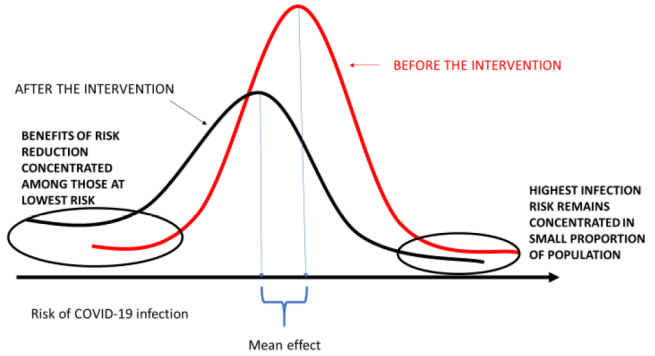


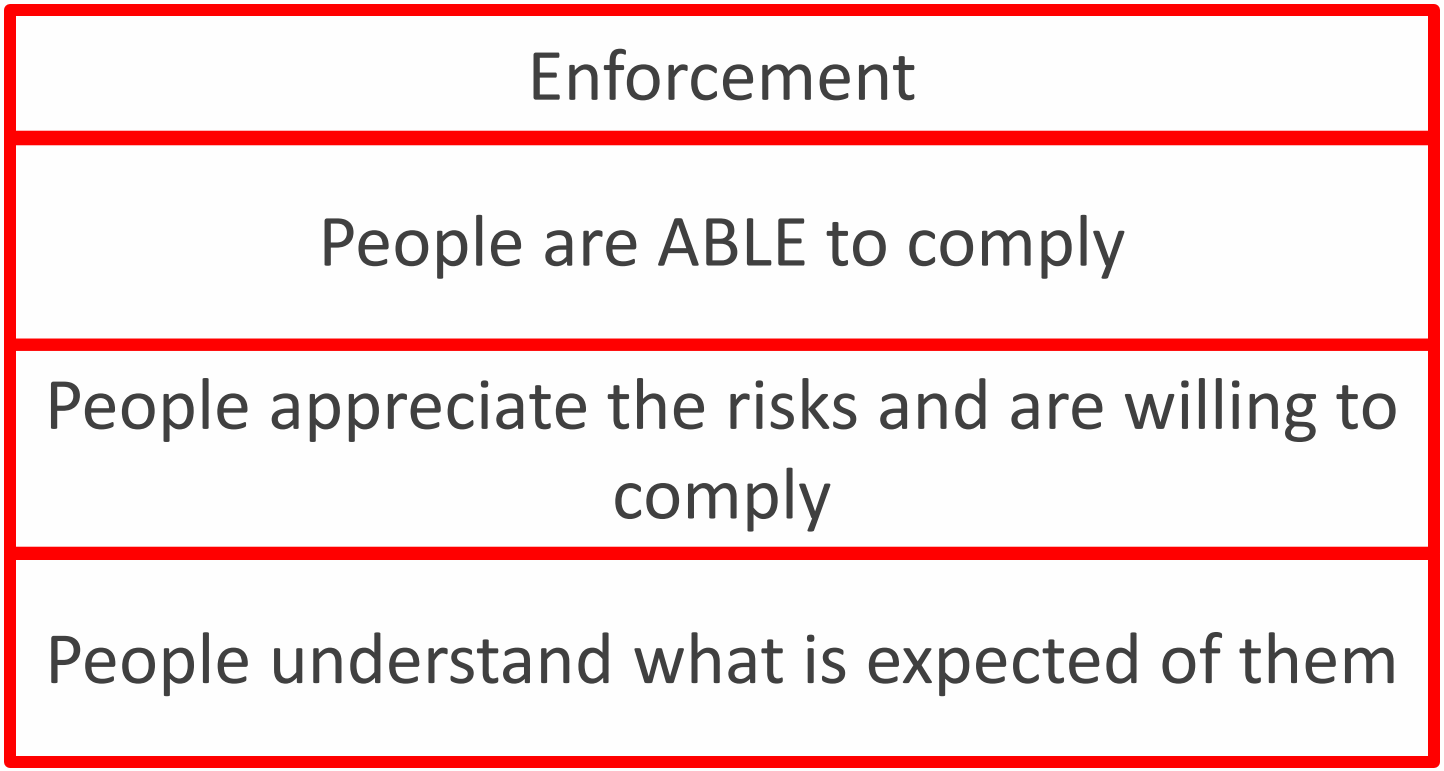
Figure 2.2: Coronavirus Cases Per 10,000 People, by Age and Race. Source: New York Times analysis of CDC data, https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html

- Too few studies explore distributional effects ("it's about mean effects")

Figure 2.1: Potential Disparities in Risks and Benefits of COVID-19 Control Measures. Source: Authors drawing on Frohlich, K. L., & Potvin, L. (2008). Transcending the known in public health practice: the inequality paradox: the population approach and vulnerable populations. *Am J Public Health*, 98(2), 216-221.



Building Blocks of Legal Impact



Tuning the Response

Population compliance and voluntary behavior change to reduce risk

Effective implementation by state and local health departments of traditional case finding and control

Detailed, credible, accurate scientific and practice guidance from CDC

Funding for health and economic needs from Congress

Clear, consistent, accurate messages about pandemic and response from leaders at all levels

at?

losure of
chools,
usinesses,
ffices
hysical
istancing
land hygiene
nd PPE

When?

- Early – timi
  critical
- Until scienc
  based, pre-s
  impact targ
  are met

2020 PUBLIC HEALTH LAW VIRTUAL SUMMIT

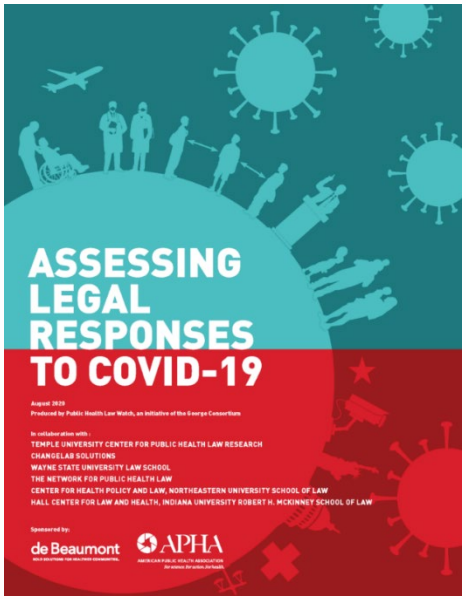
COVID-19 Response and Recovery

September 16-17

2020 PUBLIC HEALTH LAW VIRTUAL SUMMIT

COVID-19 Response and Recovery

September 16-17



If you're tweeting from the Summit, remember to use this hashtag to share your insights with Summit attendees and others:
#COVID19PolicyPlaybook

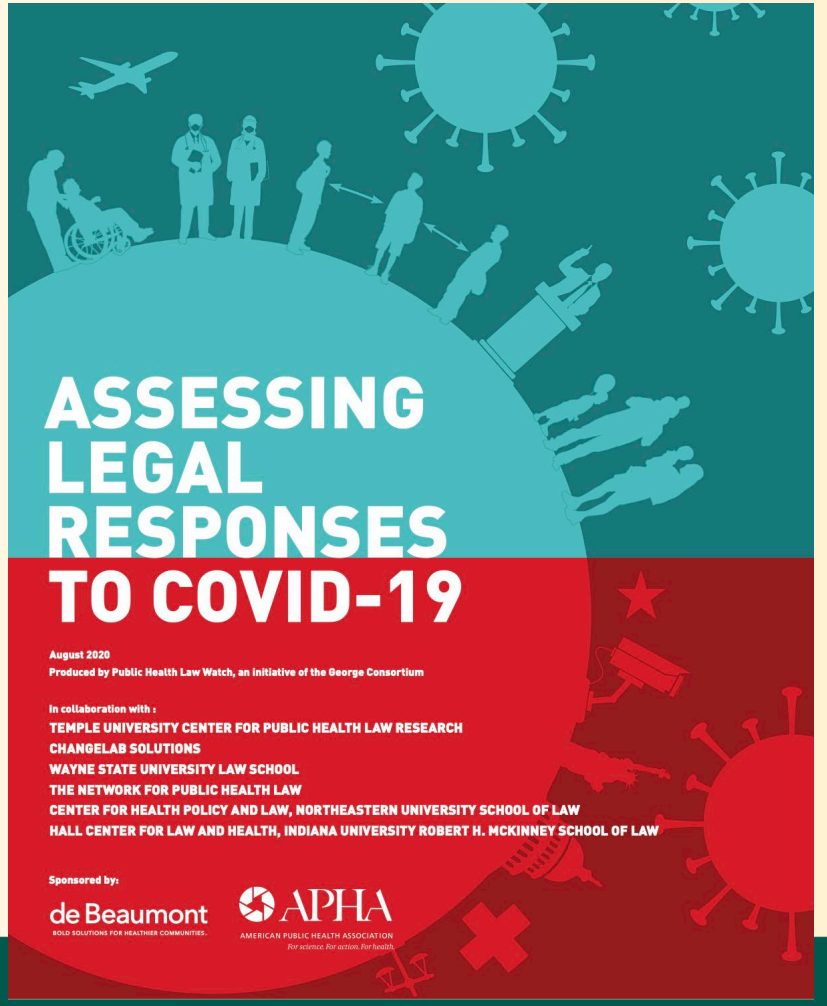
Access the full *Assessing Legal Responses to COVID-19* report or individual chapters at:
COVID19PolicyPlaybook.org

Allocation of Scarce Medical Resources and Crisis Standards of Care

Lance Gable, JD, MPH
Associate Professor of Law
Wayne State University Law School
lancegable@wayne.edu

Overview

- Avoiding scarcity
- Crisis standards of care
- Liability for allocation decisions
- Civil rights protections
- Recommendations



Scarcity during a pandemic

- Causes of resource scarcity during a pandemic
  - Rapid disease spread can overwhelm health care system with an influx of patients
  - Sick and distanced people may be unable or unwilling to work or provide caregiving
  - Many systems are not resilient and don’t have reserves of supplies
- Focus on medical resources and services here but these issues have broader implications

Scarcity during COVID-19

- Medical resource scarcity has occurred during COVID-10
  - Health care systems in New York City, Lombardi, Italy, and elsewhere were stretched beyond capacity
  - Hospitals faced shortages of ventilators, beds, medications, personnel, and PPE
  - Many systems enacted or considered contingency plans to deal with shortages
- Interventions to expand capacity and alter allocation procedures seem to have prevented the worst case scenarios

Avoiding Scarcity

- Planning for scarcity of medical resources and services is not new, but also not sufficient to address the circumstances
- Contingency plans and guidance for allocation of scarce resources exist at the national level and in most states
- Many health care institutions have scarce resource allocation plans
- Avoiding scarcity is preferable to implementing triage and contingency/crisis plans…but public health is significantly underfunded

Conventional, Contingency, and Crisis Care

Conventional Capacity: The spaces, staff, and supplies used are consistent with daily practices within the institution. These spaces and practices are used during a major mass casualty incident that triggers activation of the facility emergency operations plan.

Contingency Capacity: The spaces, staff, and supplies used are not consistent with daily practices but provide care that is *functionally equivalent* to usual patient care. These spaces or practices may be used temporarily during a major mass casualty incident or on a more sustained basis during a disaster (when the demands of the incident exceed community resources).

Crisis capacity: Adaptive spaces, staff, and supplies are not consistent with usual standards of care, but provide sufficiency of care in the context of a catastrophic disaster (i.e., provide the best possible care to patients given the circumstances and resources available). Crisis capacity activation constitutes a *significant* adjustment to standards of care.

SOURCE: Hick et al., 2009.

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 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 acequately 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 re-allocation of life-sustaining resources
Standard of care	Usual care	Functionally equivalent care	Crisis standards of care[a]

Normal operating conditions

Indicator(s): Potential for contingency care[b]

Trigger(s): Decision point for contingency care[c]

Indicator(s): Potential for crisis standards of care[d]

Crisis care trigger(s): Decision point for crisis standardscare[e]

Extreme operating conditions

Scarcity during COVID-19

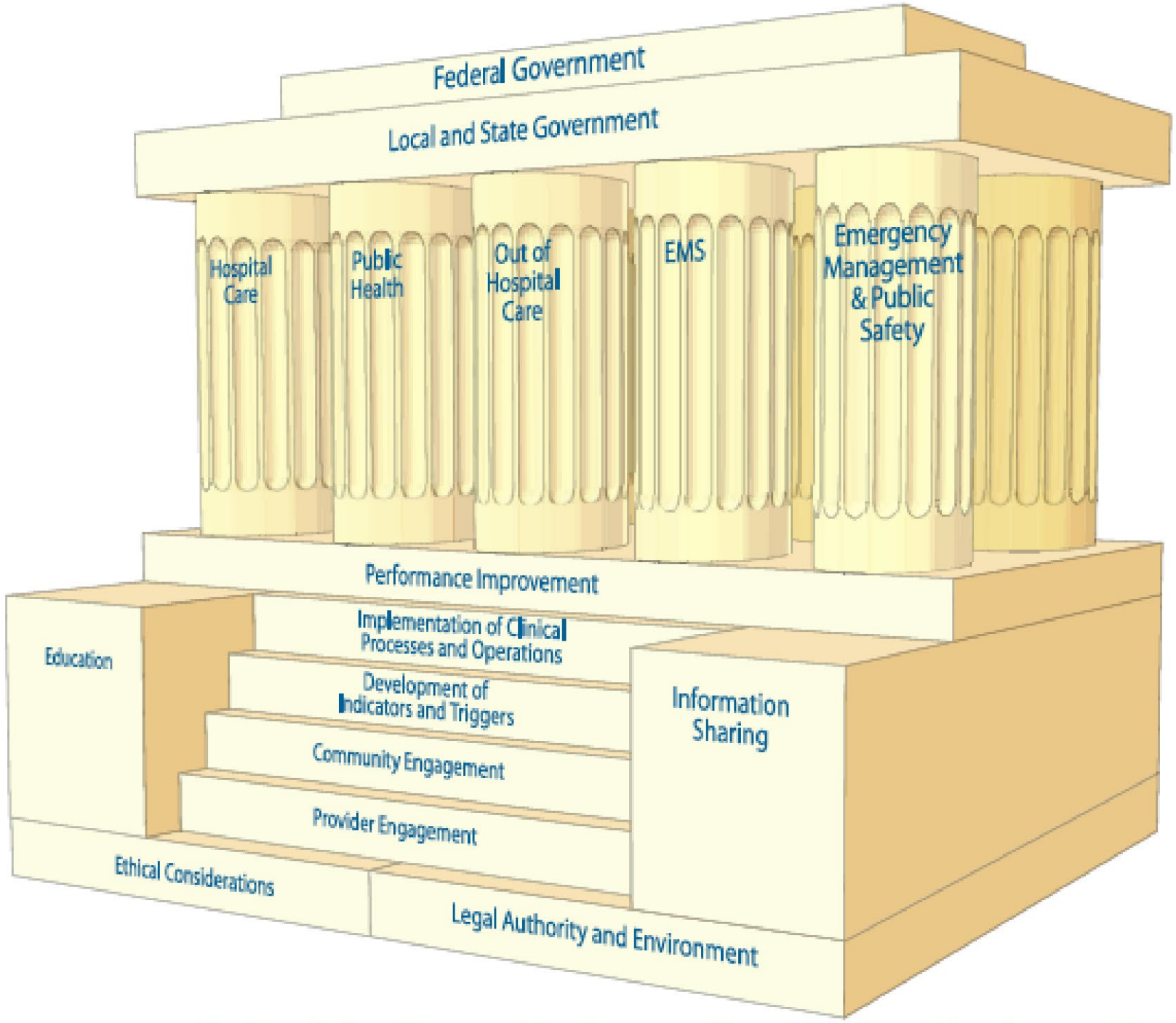
- Shortages
  - Space
  - Staff
  - Stuff
- Legal authorities to expand access to resources
  - Strategic National Stockpile
  - Defense Production Act
  - State Emergency Powers
  - EMAC
  - Coordinated response and resource allocation

Crisis standards of care

- Crisis standards of care are “a substantial change in usual healthcare operations and the level of care it is possible to deliver”
- Most states have adopted guidelines based on federal guidance from the NAS; few have in place clear authority directly authorizing CSC
- CSC raise legal and ethical issues in how resources are allocated and prioritized
- Ethical considerations include fairness, duty to care, duty to steward resources, transparency, consistency, proportionality, and accountability

Crisis standards of care

- Crisis standards of care may include prioritization based on:
  - Saving the most people possible
    - Medical prognosis
  - Preserving society functioning
    - Essential skills and activities
  - Fairness and/or equity in distribution
    - Balancing access across populations or prioritizing greater-impacted populations
  - Reciprocity
    - Prioritizing those who’ve sacrificed for others


Federal Government
Local and State Government
Hospital Care
Public Health
Out of Hospital Care
EMS
Emergency Management & Public Safety
Performance Improvement
Education
Implementation of Clinical Processes and Operations
Development of Indicators and Triggers
Community Engagement
Provider Engagement
Information Sharing
Ethical Considerations
Legal Authority and Environment

Liability for decisions allocating scarce resources

- Tort law allows for the standard of care in a health care setting to adjust to circumstances, including scarcity of resources
- Defendant in malpractice claims based on allocation decisions are likely to be in a strong position, especially if there is a declared emergency in effect. Removal of medical resources (such as a ventilator) would be more likely to lead to a finding of liability.
- Federal liability shields may apply to these decisions
- A few states have implemented stronger, explicit liability shields for triage and allocation decisions in the health care setting

Civil rights protections and scarce resource allocation

- Health inequities pervade health care access and outcomes
- COVID-19 has exacerbated these existing disparities especially for Black, Indigenous, and People of Color and people with disabilities
- Some CSC plans explicitly or implicitly deprioritize people with a lower likelihood of successful treatment
- Antidiscrimination laws and civil rights protections have been invoked to challenge some of these plans

Civil rights protections and scarce resource allocation

- HHS OCR has resolved complaints against at least 3 states which alleged violations of the Rehabilitation Act of 1974, Title II of the Americans with Disabilities Act, and Section 1557 of the ACA
- OCR also issued guidance stating that “no person should be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person’s relative “worth,” including judgments about a person’s worth based on the presence or absence of disabilities or age.”

What's next?

- Additional "waves" of COVID-19 infection may lead to scarcity
- Different resources will be scare at different times in different places
- Legal challenges and retrospective litigation will surely occur if CSC are implemented; liability shields may be expanded
- Development and distribution of treatments and vaccines will present similar allocation problems

Recommendations

Federal government:

- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund, and should expand support for the National Hospital Preparedness Program and the Strategic National Stockpile.

- HHS OCR should develop, expand, and update guidance for the allocation of scarce resource and crisis standards of care consistent with federal antidiscrimination laws.

Recommendations

State government:

- State legislatures or executive agencies should develop and approve protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies and clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19.
- State legislatures or executive agencies should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.
- State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.

Recommendations

State government:

- State legislatures should review their crisis standards of care protocols to clarify necessary protections under federal and state antidiscrimination law.
- States should assess, and if necessary, enact the requisite legal authority for executive branch officials to avoid medical resource and service scarcity through means such as resource stockpiling, alternate care sites, and health care workforce expansion.
- State legislatures should adopt liability shields for health care professionals and institutions related to decisions allocating scarce medical resources and services in the health care setting, provided that health care professionals and institutions follow state-adopted and implemented crisis standards of care protocols in good faith.
- State laws should prohibit medical allocation decision-making based on social stigma or stereotypes regarding age, color, criminal history, disability, ethnicity, familial status, gender identity, height, homelessness, immigration status, incarceration status, marital status, mental illness, national origin, poverty, race, religion, sex, sexual orientation, socioeconomic status, substance abuse disorder, use of government resources, veteran status, or weight.