Standards of Care: Providing Health Care During A Prolonged Public Health Emergency

Marianne Horn, Esq.
Co-Chair, Standards of Care Workgroup
Connecticut Department of Public Health
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“The Perfect Storm”

Overwhelming demand for services

Severe scarcity of resources – stuff, staff & space
Definition of standard of care (CGS 52-184c)

“...that level of care, skill and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.”
Standards of care depend on totality of circumstances.
As circumstances change, so does the standard.
Standard of care

Altered standards of care: Common term used to describe changes to standards of care when there is a prolonged public health emergency and resources become scarce.

It is a legal misnomer, since standards of care, by definition, depend on the totality of the circumstances, including scarcities of resources.
Paradigm Shift – Crisis Standards of Care

When the circumstances include scarcities of resources, the standard of care reflects that circumstance, resulting in a paradigm shift from individual-based care to population-based care, triage and rationing.
Standards of Care (SOC) Workgroup

Studying the provision of care during a prolonged public health emergency

Consisting of stakeholders from across various health care organizations (practitioners, ethicists, educators, DPH staff and other public health professionals)

Developing policy paper to guide SOC planning efforts
SOC Workgroup Mission

In prolonged public health emergencies, standards of care are dependent upon the circumstances, so SOC workgroup must:

**Develop** broad guidelines to assist facilities with their planning efforts.

**Develop** procedures for requesting suspensions/modifications of statutes andregs.

**Clarify** existing laws regarding liability.
SOC Workgroup progress

COMPLETED:

*Literature* review and framework created.

*Draft* white paper produced.

SHORT TERM TASKS:

*Seek* electronic comments from practitioners and public via DPH web site.

*Revise* white paper and respond to comments.

*Roll* out during the next year.
Conceptual Framework

Decision-making concerning the allocation of scarce resources during a prolonged public health emergency must be guided by the ethical principles that are the foundation of our society.
Ethical guidelines

The Canadian Model:
Stand on Guard for Thee

Ten substantive values
Five procedural values
Ethical guidelines: Substantive Values

**Individual liberty:**
restrictions must be proportional to risks

**Protect public from harm:** balance protective measures against loss of liberty

**Proportionality:**
minimum necessary restrictions
Ethical guidelines: Substantive Values (cont.)

**Privacy**: least intrusive measures

**Duty to provide care**: balance duty to care for self against duty to care for others

**Reciprocity**: ease burdens of those who bear a disproportionate burden in protecting public good
Ethical guidelines: Substantive Values (cont.)

**Solidarity**: communication between stakeholders

**Stewardship**: protect and develop resources; accountability for public well-being

**Equity**: which services should be maintained? Who will receive care?
Ethical guidelines: Substantive Values (cont.)

**Trust**: ethical and transparent decision-making processes; build trust before emergency declared.
Ethical guidelines: Procedural Values

DECISIONS MUST BE:

**Reasonable**: evidence-based, relevant

**Open and transparent**: to withstand scrutiny

**Inclusive**: to stakeholders and public

**Responsive**: revised when new information; opportunity to address grievances

**Accountable**: decision-makers should be held responsible for their conduct
Ethical guidelines: Making Clinical Decisions

FOR EXAMPLE, ETHICAL GUIDELINES REQUIRE:

**Policies/standards** be fairly & justly applied w/o regard to payer source or demographics.

**Decision-making** be rational, just, and equitable.

**Standards/protocols incrementally altered** – only enough to meet current circumstances and for no longer than necessary.

**Accountability**: document changes and reason why.
Conceptual Framework

Three types of standards

*Institutionalized* practices within facilities that assume availability of resources.

*Clinical* situations that require the exercise of judgment based on the unique circumstances.

*Statutory and regulatory* requirements regarding staffing, physical plant, dietary, reporting, & documentation.
Institutionalized practices

**Suspend** non-urgent procedures to increase surge capacity (fair decision-making process and criteria; be good stewards of resources).

**Adjust** frequency of assessments and routine care (provide care, stewardship; preserve equity between patients suffering from emergency and those needing care for other illnesses).
Institutionalized practices

Minimizing documentation, using checklists to speed recording of critical information, e.g., medication administration; treatments given; critical parameters

Individualizing care with minimal required parameters, e.g., patient with BP problem – monitor BP, not TPR

Ensuring care decisions as based on, proportionality, and stewardship
Institutionalized practices

Use standardized methodology for decision-making about life-saving care/technology when these are inadequate for the number of patients presenting (e.g., SOFA scale).

Separate triage and treatment functions.
Institutionalized practices

If staff roles expand, do so incrementally and only for as long as necessary.

Expanded roles should be under supervision of experienced, licensed person delegating to and directing a team of healthcare workers and oversees patient caseload.
Institutionalized practices: EMS

Is the practice required by statute or regulation?
Need Title 28 declaration and modification or waiver.

Is the practice established by medical direction?
Need new medical directive
Making clinical judgments

*Many* situations require the exercise of clinical judgment based on the unique circumstances.

*Not* possible to predict every circumstance so providers must give the best level of care skill and treatment in light of the circumstance to comply with the standard of care.
Suspensions and Modifications of Statutes and Regulations

Suspensions/modifications of state laws

Any time after the Governor has declared an emergency, the Governor is empowered to:
Suspensions and Modifications of Statutes and Regulations

Sec. 28-9(a) of General Statutes provides

“... modify or suspend in whole or in part, any statute, regulation or requirement or part thereof whenever in his opinion it is in conflict with the efficient and expeditious execution of civil preparedness functions. ...”
Suspensions/Modifications of Statutes/Regulations

Statutes and regulations mandate, e.g.:

Scopes of practice

Staffing and dietary requirements

Documentation and record-keeping

Physical plant requirements
Suspensions/Modifications of Statutes/Regulations

**Suspensions**: The suspended provision has no force and effect; regulatory agencies cannot penalize persons or facilities for violating the provision; failure to comply will not provide a basis for finding negligence as a matter of law; may eliminate barriers to act swiftly to respond to an emergency.

**Modifications**: result in an immediate change to a statute or regulation.
Suspensions/Modifications of Statutes/Regulations

**COOP** Planning must include identification of state statutes & regulations that could be subject to gubernatorial suspension or modification.

**Statutes & regulations** identified in COOP planning must include a statement supporting rational behind the request.

**Some** lists of statutes and regulations are included in appendix of white paper.
Suspensions/Modifications of Statutes/Regulations

Executive order requests are submitted to DPH for review and possible recommendation Governor.

If recommended, DPH forwards Executive Order to the Governor’s Office for signature.

Order valid when filed with Secretary of the State.

DPH faxes & posts order after SOC filing.

DPH may make preemptive requests.
Ethical responsibility to care for workers

Expect 30-40% absenteeism due to:

worker illness
illness of family or friends
fears safety of self & family
child, elder or pet care needs
need to grieve

worry that they may not be able to perform “up to usual standards”
liability concerns
fear of working outside scope of practice or license
Ethical responsibility to care for workers

Are there ethical obligations of health care workers’ to provide care?

What are the consequences for failure to provide care?

Connecticut has no statute that specifically requires professional staff to provide care.
Could be employment issue.

**DPH** has no standard policy in the event of a complaint.

**DPH** will consider the totality of the circumstances in each individual case.
Ethical responsibility to care for workers

**Core** ethical value of reciprocity requires: easing burdens of those who bear a disproportionate burden in protecting public good, *i.e.*, facilities have ethical obligation to care for their staff.

**This** encourages workers to solve their ethical dilemma in favor of coming to work.

**Work with staff in advance** to create policies and procedures that address their fears, worries and concerns.
Ethical responsibility to care for workers

Develop policies & procedures regarding:

**Physical** safety of staff and their families (e.g., PPE, anti-virals, vaccinations, training, workplace absences, fever stations, telecommuting, uniform infection prevention/control precautions).

**Educating** staff about legal consequences of declaration of emergency (e.g., liability protections, suspensions/modifications of statutes and regulations, etc.).
Liability Laws

Title 28:
Immunity when civil preparedness activity unless willful misconduct. Includes:
• Emergency medical service personnel
• DMAT, MRCs, Urban Search & Rescue, CERTs
• CT Behavioral Health Regional Crisis Response Teams
Does not include persons employed in facilities or facilities
Liability Laws

**PHERA (19a-131 et seq.)**

- Immunity for persons acting on behalf of the state within the scope of practice and pursuant to section 19a-131 – 131h so long as not wanton, reckless or malicious, and written consent is obtained for vaccinations.

Does *not* include providers employed in facilities or facilities unless acting on behalf of the state per PHERA.
Liability Laws

*CT Good Samaritan Law (CGS sec. 52-557b)*

- Protects certain licensee providing emergency medical assistance voluntarily and without compensation, not in the ordinary course of employment, except for willful or wanton acts.

Does *not* include providers employed in facilities or facilities
Liability Laws

**PREP Act (42 USC 247d-6d):**

Immunity from liability under federal and state law for manufacture, testing, development, distribution or use of “covered countermeasure” (*e.g.*, H1N1 vaccine) unless willful misconduct. Includes:

- Licensed providers dispensing, prescribing, administering medication, *e.g.*, physicians, first responders and other health care professionals
- Need federal declaration of emergency
Liability Laws

*Volunteer Protection Act (42 USC 14501):*

- Only protects volunteers (uncompensated except for costs) acting within scope unless willful, reckless or criminal conduct, gross negligence, or gross indifference. Does *not* include providers employed in facilities or facilities
Liability Laws

Federal Tort Claims Act (FTCA) (28 USC 1346(b), 2401(b), 2671-80):

• Only protects health care professionals who *volunteer* during federally declared Homeland Security disaster if they are considered to be a federal employee (*e.g.*, registered with EMAC or National Disaster Medical System)

Does *not* include providers employed in facilities or facilities unless meet above definition
Time Table

*Fall 2009:*
Final whitepaper draft

*Spring 2010:*
Regional Forums/Comments

*Fall – Winter 2010:*
Revisions
Submit comments on the white paper by April 30, 2010, at:

www.ct.gov/dph/standardsofcare

There you’ll find the draft white paper, easy to use comment tools; a recording of this presentation and other related materials.
Contact information

Donna Brewer:  donna.brewer@ct.gov
(860) 509-7648

Marianne Horn:  marianne.horn@ct.gov
(860) 509-7405