ASPR TRACIE Technical Assistance Request

Requestor:
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Request Receipt Date (by ASPR TRACIE): 13 July 2015
Type of TA Request: Standard

Request:

ASPR TRACIE received the following request regarding additional information/ guidance on developing crisis standards of care (CSC). This document provides a general overview and analysis of the current HPP grant requirements, implementation guidance, Healthcare Preparedness Capabilities, and other available resources.

"More federal guidance on crisis standards of care – our region feels more guidance from the feds is needed before we can begin discussion and developing plans. Specifically, we have been told that we, as a region, need to define CSC. That would mean 14 different definitions based on the 14 different regions in my state."

Response:

The response below includes three parts:

1. Part I- comments and recommendations from an ASPR TRACIE Expert Practitioner (further supported by Part Two: Resources)
2. Part II- various resources that support the development of a CSC plan/ guidance
3. Part III- recommendations of how these resources can provide guidance for coalitions and future work planned

If additional assistance is needed, please contact ASPR TRACIE and we will arrange for a meeting with the ASPR Lead for Crisis Standards of Care and/or ASPR TRACIE Subject Matter Expert Cadre members that have specific expertise in this area.

I. ASPR TRACIE Expert Practitioner Comments:

There are good definitions for crisis care in the Crisis Standards of Care document (Institute of Medicine, 2012). See Crisis Standards of Care, Volume 1: Introduction and CSC Framework (pages 1-41 and Figure 2-2) (i.e. 'when demand exceeds healthcare resources in the region to the degree that the care being provided poses a significant risk to patients compared to usual care then a condition of crisis standards of care exists and the following actions will be taken').

One of the actions (as outlined under the Functions for hospitals listed in Crisis Standards of Care Volume 4: Hospitals) should be to notify regional/state authorities of the situation so that appropriate actions can be taken up the chain (see Table 2-2 responsibilities from local to federal). The region should consider what their response will look like in conjunction with Crisis

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Standards of Care Volume 4: Hospitals, page 15 (Box 7-4 shows the response cycle), thinking about their specific situation and resources. This may also drive some good discussion about indicators and triggers – there are some basic tables on this in the various volumes of the Crisis Standards of Care document and a complete document devoted to this topic in the 2013 Crisis Standards of Care Indicators and Triggers report for more advanced planning.

A key point is that the region should seek to distribute the casualty loads within the region or with other regions to get back to contingency or conventional care as rapidly as possible. These clinical actions will have to occur regardless of any legal or other authorities at the state level – so let the driver of the discussions be the clinical demand – the legal and policy issues will have to follow the clinical demand. Address patient distribution and contingency planning for large patient volumes, then staff and supply shortages, deferring facility and regional triage decision-making for last – it will be important if there are triage decisions to be made that these follow recommendations that are consistent between regions, which may be provided by an outside entity (state, CDC, etc. – an example of this might be priority groups for pandemic influenza vaccine).

The role of the region is to provide a decision framework for the implementation of these recommendations. For example, for vaccines, how do PH agencies coordinate their efforts? For clinical care (medications, ventilators, etc.) is there a role for regional vs. institutional-based triage? But again, start with the building blocks – know that the surge capacity spectrum includes crisis care and account for how those situations will be addressed within the region first and foremost to return the regional healthcare system to conventional operations.

II. Resources:

Sections A-C below includes the three primary sources for HHS guidance on CSC for healthcare coalitions.

A. Existing ASPR Resources

ASPR TRACIE has compiled a Crisis Standards of Care Topic Collection: https://asprtracie.hhs.gov/technical-resources/63/Crisis-Standards-of-Care/63, which provides subject matter expert reviewed plans, tools, templates and other resources. Specifically, the following publications by the Institute of Medicine (IOM) of the National Academies serves as CSC foundational documents (as referenced in Part I of this document by the ASPR TRACIE Expert Practitioner). They also provide practical templates and toolkits for the emergency response disciplines and emphasizes the importance of a systems framework.

- Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response
- Crisis Standards of Care: Summary of a Workshop Series
- Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report

In addition, ASPR has an active community of interest of local, state, and regional practitioners where they can share various plans, tools, and templates. This “Communities of Interest: for crisis standards of care and allocation of scarce resources” can be found at

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www.phe.gov/coi/Pages/default.aspx. This site provides a clearinghouse of resources and information; and encourages users to submit their jurisdiction's/ facility's CSC plan. NOTE: per the HPP BP3 Implementation Guidance, awardees are required to post their approved CSC plan on the ASPR COI site (see page 19).

B. Healthcare System Preparedness Capabilities

Capability 10, Function 4 of the HHS Healthcare Preparedness Capabilities (January 2012) is specific to developing CSC guidance. The Healthcare Preparedness Capabilities refers to CSC as a "state led processes to guide healthcare organizations during crisis standards of care when resources are scarce and when requested." See Attachment 1 for the excerpt of Capability 10, Function 4.

C. HPP Cooperative Agreement Measure Manual: Implementation Guidance for the HPP Program Measures

The HPP BP3 Implementation Guidance defines CSC as: "The level of care possible during a crisis or disaster due to limitations in supplies, staff, environment, or other factors….Crisis standards of care will usually follow a formal declaration or recognition by state government during a pervasive (pandemic influenza) or catastrophic (earthquake, hurricane) disaster which recognizes that contingency surge response strategies (resource-sparing strategies) have been exhausted, and crisis medical care must be provided for a sustained period of time…."

a. **Medical Surge, Indicator 1:** Awardee has posted its approved CSC plan on the ASPR Communities of Interest SharePoint Site
b. **Continuity of Healthcare Operations, Indicator 3**: The HCC has a process to enhance its members' situational awareness to support activation of immediate bed availability through continuous monitoring.
    i. This includes developing an operational framework to guide the healthcare member community about actions that warrant transitions across the continuum of care. The framework should include:
        - **Potential indicators** to help members anticipate when it may be needed to make transitions across the continuum of care (i.e., from conventional standards of care to contingency and crisis standards, then back again).
        - **Potential triggers** that identify points at which a decision to transition should be considered.
c. **Healthcare Coalition Developmental Assessment Factors, #16**: The HCC utilizes an operations framework and set of indicators to transition from crisis standards of care, to contingency, and ultimately back to conventional standards of care.
    i. Framework should include the items noted in Continuity of Healthcare Operations, Indicator 3.
        - Indicators should be based on information that is likely to be readily available during an incident, as in most cases in-depth data collection and analysis and the development of new systems will not be feasible.

- Triggers are likely to be context specific, but HCCs can contribute to decision-making processes by identifying triggers for when decisions about these transitions should be explicitly considered by its HCC members and communities.

III. Recommendations and Future Activities

In addition to the resources provided and guidance from an ASPR TRACIE Expert Practitioner (member of the ASPR TRACIE Subject Matter Expert Cadre), below are a few additional recommendations to support regional planning efforts. Additional support can be provided for direct ASPR TRACIE SME Cadre one-on-one consultation if needed.

The Healthcare Preparedness Capability 10, Function 4 specifically directs states to lead a collaborative planning effort to develop a CSC guidance along with healthcare coalitions, healthcare organizations, practitioners, and local and state medical and public health authorities. The HPP Implementation Guidance does not mirror this guidance, but does refer to the capabilities as a primary reference. Therefore, it could be interpreted that HPP will allow the following per the implementation guidance:

- State-level CSC guidance that is clearly a collaborative effort with the partners outlined in Capability 10, Function 4.
- Regional/ jurisdictional CSC plans that meet the requirements of the Implementation Guidance and addresses Capability 10, Function 4. Also, the plan should show collaboration and close ties to the state plan.

Coalitions can use the definition of CSC as outlined in the Implementation Guidance and in the IOM report, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*, but will need to **define their own indicators and triggers** (see Capability 10, Function 4 and *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* for guidance):

- Definition of CSC as provided in the Implementation Guidance, Page 53:
  Crisis Standards of Care: The level of care possible during a crisis or disaster due to limitations in supplies, staff, environment, or other factors. These standards will usually incorporate the following principles: (1) prioritize population health rather than individual outcomes; (2) respect ethical principles of beneficence, stewardship, equity, and trust; (3) modify regulatory requirements to provide liability protection for healthcare providers making resource allocation decisions; and/or (4) designate a crisis triage officer and include provisions for palliative care in triage models for scarce resource allocation (e.g., ventilators) (Chang et al., 2008). Crisis standards of care will usually follow a formal declaration or recognition by state government during a pervasive (pandemic influenza) or catastrophic (earthquake, hurricane) disaster which recognizes that contingency surge response strategies (resource-sparing strategies) have been exhausted, and crisis medical care must be provided for a sustained period of time. Formal recognition of these austere operating conditions enables specific legal or regulatory powers and protections for healthcare provider allocation of scarce medical resources and for alternate care facility operations. Under these conditions, the goal is still to supply the best care possible to each patient. (*Healthcare Preparedness Capabilities*).

- Definition of CSC as provided in *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report:*
  Crisis standards of care: A substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. This change in the level of care delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period. The formal declaration that crisis standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations.

States, regions, and locals should utilize best practices from exiting CSC Plans.

- The ASPR COI site includes a collection of various CSC plans from across the nation. Currently, there are plans and/or relevant guidance documents from 11 states that are publicly available here: http://www.phe.gov/coi/Pages/plandocs.aspx.
- The ASPR TRACIE CSC Topic Collection includes two sample plans from Washington DC Emergency Healthcare Coalition and from Minnesota.
- The Washington DC Emergency Healthcare Coalition's "Modified Delivery of Critical Care Services in Scarce Resource Situations," provides a useful approach to development of CSC guidance from a regional healthcare coalition on behalf of its member organization and in collaboration with the DC Department of Health. They explain how they modified the existing CSC approach as outlined in the Healthcare Preparedness Capabilities and other guidance documents to fit their specific needs.
- See attached the following guidance documents (**not for further distribution** without approval from ASPR TRACIE):
  - Hennepin County Medical Center (HCMC) Crisis Standard of Care Guidelines- Draft September 14, 2009.
  - Summary of Regional Process for Resource Triage Situation
  - Metropolitan Area Hospital Compact

States, regions, and locals should utilize the guidance provided in the IOM reports, specifically *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*, to help develop an operations CSC plan.

- Volume 1, Chapter 2 provides an overview of the CSC framework and planning milestones when developing a plan.
- Volume 1, Chapter 3 provides the legal issues in emergencies that would impact allocation of resources and establishment of CSC.
- Volume 2 includes the roles/responsibilities of local and state government, operational considerations, and core functions for writing and implementing the plan.
- Volume 4 includes roles/responsibilities of healthcare facilities, operational considerations, and core functions for writing and implementing the plan.

Other/Future activities:

- A new guidance document is currently under development from subject matter experts that will discuss the step by step process of developing and implementing a CSC plan. The timeline for the completed product is unknown; however, ASPR TRACIE will share it as soon as it becomes available.
- As part of the HPP cooperative agreement requirements, more awardees will be posting their plan on the ASPR COI site to share. These plans, templates, and guidance documents can be used by other jurisdictions to help develop their plans. In the meantime, consider posting questions and requests through the ASPR TRACIE Information Exchange for colleagues to provide peer-to-peer assistance.
- If requested, ASPR TRACIE can provide expert practitioners from our Subject Matter Expert Cadre to provide one-on-one direct assistance to jurisdictions that have specific needs and questions. In addition, we can also work with them to develop useful tip sheets and/or a webinar.

Attachment 1. Healthcare Preparedness Capability 10, Function 4: Develop Crisis Standards of Care Guidance

Below is an excerpt from the Healthcare Preparedness Capabilities specific to developing crisis standards of care guidance.

P1. State crisis standards of care guidance

States should develop collaborative crisis standards of care guidance by actively engaging Healthcare Coalitions, healthcare organizations, healthcare practitioners, and local and state medical and public health authorities. There are five key elements to include in the development the guidance:

- A strong ethical grounding
- Integrated and ongoing community and provider engagement, education, and communication
- Assurances regarding legal authority and environment
- Clear indicators and roles and responsibilities
- Evidenced-based (informed) clinical processes and operations

P2. Indicators for crisis standards of care

The State, in coordination with healthcare organizations, Healthcare Coalitions, and public health and medical authorities, provides guidance to assist healthcare organizations with crisis standards of care plan development to include indicators for crisis standards of care. Components to consider in the guidance include:

- Identification of the progressive indicators that lead to crisis standards of care (these are general and will vary state by state, use Institute of Medicine (IOM) guidance for assistance):
- Recognition of a surge above the normal operating capacity of the healthcare system during a disaster
    - Recognition of a depletion of the healthcare system's resources to a pre-identified critical threshold of resource availability that warns of impending resource exhaustion including but not limited to: Critical Infrastructure (essential services) availability
    - Staffing availability
    - Equipment and supply availability
    - Patient care space availability
- A plan to discontinue specific patient care services or optimize existing services before resources are at critical levels or exhausted (e.g., elective procedures, primary care)
- A plan to implement crisis standards of care operations and begin the discontinuation of critical services when resources are no longer available

P3. Legal protections for healthcare practitioners and institutions

The State, in coordination with healthcare organizations, Healthcare Coalitions, and public health and medical authorities, identifies the legal protections for public health and healthcare practitioners prior to crisis standards of care implementation. These may include the following (dependent on the State government):

- The scope and breadth of emergency declarations and ensuing powers to respond
- Medical and legal standards of care

- Legal authorization to allocate personnel, resources, and supplies
- Licensure reciprocity and scope of practice limitations
- Risks of liability and available liability protections (e.g., Federal PREP Act) for public health and healthcare practitioners and institutions
- Legal issues related to the deployment and use of volunteer health practitioners
- Special waivers (e.g., 1135) of key regulatory requirements pursuant to emergency declarations
- FDA issuance of emergency use authorizations for non-approved drugs or devices

P4. Provide guidance for crisis standards of care implementation processes
Crisis standards of care processes and/or plans should include but are not limited to the following elements:

- Indicators for crisis standards of care
- Implementation criteria for elements such as:
  - Triage operations
  - Clinical care in disasters
  - Disaster mental/behavioral health
  - Palliative care planning
  - Pre-requisite command, control, and coordination elements
  - Decision tools and resource use guidance

P5. Provide guidance for the management of scarce resources
Crisis standards of care resource allocation planning should be coordinated by the State, the Healthcare Coalition, and local medical and public health authorities to develop guidance based on state laws and regulations. This guidance should assist healthcare organizations to develop strategies for resource management during crisis standards of care. Recommended strategies may include but are not limited to processes that:

- Reduce resource demand such as:
  - Cancelling elective surgeries and outpatient appointments
  - Directing public to shelter-in-place locations
- Optimize existing resources such as:
  - Use of non-healthcare providers for certain roles
  - Adjusting triage techniques
  - Balancing and re-distributing patient loads across the different healthcare organizations
  - Re-purposing existing resources
- Augment existing resources such as:
  - Substituting effective alternatives
  - Implementing mutual aid agreements
  - Utilizing alternate care sites
  - Utilizing volunteers
- Provide guidance for palliative care such as:
  - Means to provide pain management and comfort to those dying during a disaster
  - Reassessment protocols for palliative care patients to determine if resources can be made available for their care
- Include strategies to address specific types of resource shortages such as:

- Ventilators and components
    - Oxygen and oxygen delivery devices
    - Vascular access devices
    - Pediatric equipment and supplies
    - Intensive care unit (ICU) beds
    - Healthcare providers, particularly critical care, burn, pediatric, surgical/ anesthesia staff (nurses and physicians), and respiratory therapists
    - Hospitals (due to infrastructure damage or compromise)
    - Specialty medications or intravenous fluids (sedatives/analgesics, specific antibiotics, and antiviral)
    - Vasopressors/inotropes
    - Medical transportation
- Example strategies to address resource shortages include:
    - Substitution (e.g., narcotic substitution) – Conservation (e.g., oxygen flow rates titrated to minimum required)
    - Adaptation (e.g., anesthesia machines used for mechanical ventilation)
    - Reuse of supplies (e.g., reuse nasogastric tubes and ventilator circuits after appropriate disinfection)
    - Reallocation (e.g., relocates oxygen saturation and cardiac monitors for use with multiple patients with critical illness or those patients with borderline conditions to ensure their condition does not worsen; remove patients from ventilators who are unlikely to survive and use the ventilator for patients with the greatest chance of survival)
- Example strategies for EMS agencies to address shortages:
    - Alternate dispatch options (e.g., assign EMS to only life-threatening calls by pre-determined criteria; no response to cardiopulmonary resuscitation-in-progress calls
    - Staffing adjustments (e.g., adjust shift length and the number of individuals who will respond)
    - Response alternatives (e.g., decline service to non-critical, non-vulnerable patients)

S1. Crisis standards of care training

The State, in coordination with healthcare organizations, Healthcare Coalitions, and public health and medical authorities, provide training for crisis standards of care that should include but is not limited to following elements:

- Multi-agency coordination of planning efforts related to crisis standards of care and the allocation of scarce resources
- The legal protections specific to local or state healthcare
- Training aids for Healthcare Coalitions and healthcare organizations related to crisis standards of care