ASPR TRACIE Technical Assistance

On December 3, 2020, ASPR TRACIE hosted the webinar, *Crisis Standards of Care and COVID-19: What's Working and What Isn't*. During this webinar, presenters discussed clinical consultation versus triage support, systems-level information sharing, coalition-level coordination activities, and recent publications/resources to help with planning efforts. For additional resources, go to ASPR TRACIE COVID-19 Patient Surge and Scarce Resource Allocation page.

The questions below include both those that were not able to be answered during the webinar due to the large number of questions received and a summary of the Q&A during the webinar. Questions that were not able to be asked during the webinar were sent to panelists and their answers are provided in this document. Please note: These are direct quotes or paraphrased comments provided by the webinar panelists in response to these specific questions. They do not necessarily express the views of ASPR or ASPR TRACIE.

These supplemental resources on crisis standards of care (CSC) considerations for COVID-19 also contain related information:

- Principles
- Planners
- Public Messaging
- Healthcare Providers
- Roles and Responsibilities
- Support for Clinical Allocation Decisions

Quick Links to Response Categories

- Clinical Allocation Decisions
- Planning and Training
- Communications
- Support for Healthcare Professionals
- Legal Considerations

Clinical Allocation Decisions

1. Can you clarify the roles of the Triage Officers and Consultants?
    - A triage team may be used for major life support allocation decisions. Consultation should be obtained for any situation in which the provider feels they are making a care decision that puts a patient at risk that is outside their usual scope/practice and for which they do not have good facility policy.
    - Access the Support for Clinical Allocation Decisions document for additional information.
    - Please note that this presentation was referring to the structured triage team concept for allocation of life-saving resources described in many CSC plans and not the triage officer position used during response to a mass casualty incident.

2. What would be the best way for hospitals to transition from the triage team model to the clinician consultant model or at least to lower that threshold for activating their triage team to get the bedside support that these providers need to help with decision making?
    - We must clearly communicate to providers that they should not be making decisions about true rationing or restriction or resources where the care provided is "not good enough" without engaging a consultant/on-call. Or if you're making decisions about futility of care that you normally wouldn't be making, then you need to call whoever the designee is for that hospital, system, or coalition. There needs to be a pretty clear expectation that providers get in touch with the consultant and that may be as simple as the on-call critical care, a critical telemedicine provider, or a Chief Medical Officer.
    - It is equally important to ensure that incident command is integrating realistic clinical information into their assessments, anticipating conditions, and making sure that the written plan—especially for staffing—is well communicated. Also ensure that there is good, open communication between the different hospitals within a healthcare coalition and/or within a region. This also provides the opportunity to share objective content like data on beds available and related information. Making sure that clinicians consult when they face a resource constraint provides a gateway for that consultant to link with incident command – elevating a provider issue to a systems solution level.

3. We have a policy for "scarce resources" situations using a triage team and Sequential Organ Failure Assessment (SOFA) Score, etc. There has never been a reason to use it. How do we move away from that and towards the "reach up" or "consultation" model?
    - Access the Support for Clinical Allocation Decisions document for additional information. The triage team framework has been to "high a bar" during COVID-19 because few decisions are about overt triage of life-saving resources but many decisions have required compromises in care that would benefit from additional engagement and a systems approach.
    - Emphasize less-formal reach-outs to critical care consultants that do not rise to a level of needing a "triage team" but are still resource utilization / allocation decisions.

4. Given scoring should help unconscious bias, why would scoring systems not be utilized in combination with clinical input?
    - Based on H1N1 and COVID-19 data, very few COVID-19 patients fall into the higher scores in the SOFA framework. Those that do often have pre-existing end-stage renal disease and are therefore "over-scored." Whenever possible, other predictors that are disease/process specific for estimating outcomes should be used to assess patients (e.g., scoring systems for CNS hemorrhage, burns) as these are likely more beneficial than SOFA. SOFA may still have value to look at comparing relative degree of organ involvement between patients or across units in a hospital or between hospitals but should not be used on its own as a basis for resource restriction.
    - The SOFA Score: What it is and how to use it in Triage Tip Sheet includes information on why SOFA scores are not ideal for resource allocation decisions.

5. Do you need an emergency declaration from the president, the governor, or some other elected official to "declare crisis standards of care?"

- Crisis standards exist at the bedside and must be addressed whether or not they are "declared." In some cases, declarations are tied to liability protections and other regulatory relief and may therefore be needed. Otherwise, the state should seek to support necessary decision-making and surge strategies through appropriate guidance documents, policy, resources, patient movement, legal protections, and suspension or modification of regulations that might restrict the response.
- Too much emphasis has been placed on "declaring" crisis standards of care. *Recognizing* crisis conditions, mitigating them through cooperative effort, and *coordinating* to promote consistency when the situation cannot be easily addressed should be the key focus.

Planning and Training

6. What two things can hospitals do now to plan for or respond to patient surge?
    - Implement your plan. And if you do not have a plan, write one quickly; and there are plenty of references and resources to help you do that. This should be a surge plan that stretches from conventional to crisis in a step-wise fashion and addresses both space and staff issues ("stuff" issues can be addressed as limits are anticipated to items such as high-flow nasal cannulas, etc. for prioritization).
    - Next, communicate your plan to your doctors, advanced practice providers, and nurses so that they know what is expected of them and what resources and support they have.
    - Ensure that there is good information flow up and down from bedside to boardroom, so that the incident commanders understand this situation at the bedside and the people at the bedside know what resources are running short before they run out.

7. Training and exercise are always big issues, yet many facilities lack resources in terms of HICS teams, crisis teams, and even funding for training and exercises. Moreover, it is very difficult to train and exercise in a hospital that is actively open for business. What are the thoughts on how to do so?
    - ASPR TRACIE has many resources available on how to effectively conduct exercises and how to establish an emergency management program, including an incident command structure within your hospital. In addition, the Centers for Medicare and Medicaid Services Emergency Preparedness Final Rule has established the minimum requirements for emergency management programs, plans, testing, and training for all hospitals.
    - At this point in time, newly developed processes for clinical consultation, staffing, etc. may not be able to be tested through usual exercise frameworks, but should be "workshopped" with key stakeholders and re-examined as they are used to assure efficacy and improve quality.

8. How should facility bioethics committees be engaged in allocation of scarce resources and specifically the bedside clinical advisory roles being recommended?
    - Ethicists and bioethics committees should be engaged in helping to craft facility specific CSC plans and supporting the overarching decision making in the facility. Members of the committee should be available to address real time consultation requests from frontline clinicians, however, formal ethics consultations in their usual

form are often not appropriate to the timeframe (e.g., individual patient consultations). Anticipating and providing proactive guidance for common scenarios and situations will be a much more effective use of the ethics committees.
- Having a committee member on-call for unusual or difficult situations is advantageous.
- The ethics committee may be a valuable source of information that can be circulated to providers and patients explaining the ethical foundations and what is being done to assure the best care and decisions possible for each patient.

9. Concepts such as "care traffic control" have been around for a while. Why have they not been widely adopted? What are the barriers to adoption?
   - These are efforts that require systems-level coordination, cooperation, and collaboration. Many such efforts have largely been hampered by limitations in the embrace of operational responsibilities for health care coalitions. In some cases, this has been due to the absence of interoperability of information sharing platforms. By and large, the barriers to adoption are policy driven, not technological.

10. Since we are relying on our administrators so heavily, how can we improve the readiness of our "c-suite" administrators to address this crisis?
    - C-suite administrators need to become familiar with the principles and practical implementation strategies of CSC. This requires their education and ongoing briefing on a regular basis from clinician leaders and engagement with their operations and clinical leads to assure relevant policies are developed and actions are taken. The administrators need to understand the regional communication / coalition / resource situation and mechanisms.

11. To facilitate patient load balancing, how do emergency medical services (EMS) systems play a role, especially in moving patients from smaller, rural facilities to larger facilities?
    - Ensuring that EMS is partnered with the Medical Operations Coordination Cell (MOCC) or other construct that is determining what the current patient loads are and where opportunities are for level-loading is critical for matching appropriate transport resources to the needs.
    - In many cases, EMS resources from outside the impacted area may be needed to facilitate transfers including supporting rural communities so that they can maintain 911 services or doing “reverse transfers” of more stable patients from the tertiary centers to smaller hospitals.

12. Who is best positioned to lead this sort of patient load balancing process? At what level do you think it works most effectively—the coalition or substate regional level, the state or interstate level, or is it necessary to have some combination of all three?
    - A combination is ideal. At the very least, the C-Suite leadership (e.g., the Chief Medical Officer and Chief Nursing Officer) at each hospital should collaborate with the head of public health. And maybe a senior government official, whether from emergency management or the Mayor's office to ensure real-time information sharing with regards to availability and needs. Run that meeting every day and share that information with clinicians at the bedside so they understand that their facility is not an island, that they

are connected above and beyond just what is happening at the facility level. If there are not local healthcare coalitions, then have a direct connection with leadership at the state EOC and state health department. A lot of it depends on the geography, population, and healthcare referral patterns in the area as well as what agencies/entities are best equipped or engaged to provide this service.

13. Did New York have any organized layperson community involvement or vetting of the hospital CSC plans?
    - Most hospital plans for CSC did not anticipate the "soft" triage decisions and staffing adaptations that were required by COVID-19. Because ventilator triage was not required, the state plan was not invoked even though crisis conditions for staffing and many other resources existed.

14. Can you please expand on the concept of the Learning Health System you mentioned?
    - The Agency for Healthcare Research and Quality (AHRQ) defines a learning health system as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.
    - Also access this short presentation by Dr. Andrew Masica, Senior Vice President and Chief Medical Officer for Reliable Health at Texas Health Resources, as part of the ASPR TRACIE Maintaining Healthcare Safety during COVID-19 Speaker Series. In this presentation, Dr. Masica discusses application of learning health system concepts to their COVID-19 response. He specifically highlights how they developed dashboards for real-time use of internal data, synthesized external information, and participated in generation of new evidence to support their workforce and promote safety

Communications

15. Can you comment on a few mechanisms to improve situational awareness across multiple systems? The Incident Commands tend to be "stovepipes" and thinking across the larger region is always a challenge.
    - This can be facilitated by healthcare coalitions, where healthcare system leaders, public health authorities, EMS Chiefs, and emergency management authorities representing local jurisdictions can all come together to support an "emergency response system."
    - Mechanisms should involve both essential elements of information (beds available, occupancy rates vs. baseline, elective procedure status) that can be shared on an electronic system and means for sharing more subjective data (staff adaptations, critical care practices) between critical care or patient placement provider groups. Both types of information can help systems learn from each other as well as have situational awareness and guide resource-balancing.

Support for Healthcare Professionals

16. How can you prepare your staff mentally to enter resource allocation decision making or CSC mode? What are some ways leaders can help alleviate pressure on staff when operating

in a scarce resource environment? Healthcare worker wellbeing and behavioral health is critical during this response.

- Provide education on the strategies so there are no surprises.
- Help providers understand the resources available for consultation.
- Provide training and mentoring on new roles.
- Support staff with adequate PPE, "buddy systems," family care and other support, adequate rest and nutrition and the like.
- Check out ASPR TRACIE Exchange Issue 12, COVID-19 and Healthcare Professional Stress and Resilience for related resources .

Legal Considerations

To assist with answering questions related to legal considerations and CSC during COVID-19, ASPR TRACIE hosted a short presentation by James G. Hodge Jr., JD, LLM (Peter Kiewit Foundation Professor of Law; Director, Center for Public Health Law and Policy; Director, Western Region Office - Network for Public Health Law, Sandra Day O'Connor College of Law, Arizona State University). During the presentation, Prof. Hodge shares legal information specific to COVID-19 and emergency declarations, emergency powers and limitations, crisis standards of care, and liability protections. Questions posed during the CSC and COVID-19 Webinar were asked during this presentation. The summary of the Q&A is below. View the presentation recording here.

17. What is the Reasonable Provider Standard and how can it be used to protect healthcare providers?
    - Every licensed doctor or other health care provider with sufficient training in the U.S. is expected to meet specific, national objectives.
    - The expectations on a "reasonable provider" shifts in real-time, particularly during a pandemic. The standard of care centers on whether a provider acted in the same reasonable, consistent manner as like providers in similar situations. Meeting a standard of care insulates providers from liability even if a medical outcome is not particularly favorable for a patient. Documentation of the circumstances and the decision process as well as any consultation or use of existing guidelines or plans is important evidence that helps establish the standard of care was reasonable.
    - Any reasonable provider in a COVID-related event as patients surge may shift into "crisis standard of care," (CSC) practices if needed - though they must assure that they are trying to obtain necessary resources to the degree possible and exhaust other options prior to making any triage decisions.

18. How can we ensure legally robust documentation during CSC events?
    - Documentation of specific practices and alterations (e.g., screening, stabilizing, or treating patients) pursuant to shifts to CSC can be critical but difficult to do. Documenting altered practices or efforts can be especially helpful when they reveal a consistent pattern of provider changes in practice grounded in the exigencies and backed by efficacious interventions.
    - While the dynamic nature of triage decisions pursuant to CSC inhibits full documentation during routine health care practice, adherence to existing hospital or

public sector CSC plans and protocols greatly supports the decisions of specific providers especially against the backdrop of alleged liability claims.

19. Because liability protection varies by state and disaster/emergency declaration, what does the official declaration of CSC mean? How can states clarify this?
    - "Declarations" of CSC create a lot of confusion. What it means to declare a CSC really entails invoking CSC plans or shifts to altered standards through a variety of different routes. The routes, or "triggers" for invoking CSC vary significantly by state, and even within jurisdictions (i.e., some healthcare enterprises or entities within specific states may be in CSC mode even as other entities in state are not).
    - While the U.S. remains under national, state, and regional public health emergencies, not every state must or should invoke CSC. Rather, invocation is tied to observed and documented patterns of scarcity among key resources – e.g., ICU beds, vents, personnel, PPE.
    - Since CSC may be experienced distinctly even among hospitals in single large city, they may invoke their own CSC plans even if a Governor, state health commissioner, or local official has not. Many public sector CSC plans effectively allow entity-specific invocations in recognition of differing needs in emergencies.

20. What are some of the pitfalls regarding civil rights protections and CSC?
    - Any implementation of CSC can have deleterious impacts on specific populations, mostly unintended, that would still not survive legal muster. For example, if a provider engages in an intervention that directly and negatively targets or impacts people of a specific race, ethnicity, disability, or age, or in an intervention with no scientific support, constitutional or other legal claims may quickly follow.
    - CSC plans that have survived scrutiny or been approved by HHS's Office of Civil Rights typically are based on the best known science and epidemiologic data that (i) allow predictive determinations untethered from suspect factors like ethnicity, disability, or age as social factors, and (ii) avoid simplistic or obtuse scoring mechanisms that negate persons from specific interventions based on unwarranted factors, particularly when such systems exclude patients from care based on a specific "score" and do not look at the patient as an individual and at the disease-specific factors.

21. Many people think about CSC as "all or nothing" determinations. In reality, CSC involves upward and downward shifts into practices based on new data, available resources (e.g., N-95 masks), and ethical allocations (e.g., COVID-19 vaccines). How do legal provisions change at the same time?
    - CSC is dominated by underlying scarcity of resources – e.g., beds, personnel, PPE, vaccines, funds. Just as medical practitioners must triage decisions related to patients, lawyers and ethicists providing guidance must triage critical real-time issues based on changing circumstances. What I call "legal or ethical triage" necessitates regular, repeated, and reassessed determinations of legality and ethicality of critical decisions based on available data and public health needs. As factors shift daily, so must legal and ethical assessments.

22. What is the legal role of the PREP Act related to CSC?
    - The federal PREP Act applies to HHS' approved or authorized medical countermeasures during COVID-19 (e.g., tests, treatments, vaccines, or interventions) and protects from liability claims those persons or entities involved in their manufacture, distribution, or use of those specific measures or resources. While PREP Act liability protections pursuant to HHS' declarations are extensive, they do not apply to willful acts intended to bring direct harm to individuals.

23. What suggestions do you have for legal counsel representing or working healthcare entities seeking to engage in CSC planning and response efforts with others?
    - Understand and assess the legal environment that you are in currently, including associated liability risks and protections. Interventions are authorized and undertaken quickly in real-time in efforts to save lives in health care settings. Know your role as a facilitator, not inhibitor, of warranted medical or public health efforts intended to improve health outcomes. Creating legal barriers to thwart efficacious interventions may cost lives. Reach out to colleagues across your locality or state to improve collaboration and interjurisdictional assistance that can alleviate CSC pressures on your healthcare entities, staving the need to invoke CSC overall.

24. For healthcare providers at the bedside, CSC involves difficult, uncomfortable, and emotionally-challenging decisions – how can one adjust to all the unknowns?
    - Health care providers thrust into CSC during this pandemic represent the most laudable of our national responders. They have to make critical choices for their patients and others that exceed their training, experiences, and ethical norms. Implementation CSC involves decisions that feel wrong – and absent exigencies would not have to be made.
    - Note, however, that as medical environments changed in response to COVID-19 so have our legal and ethical norms. These shifts are designed in lock-step to support those critical choices centered on a population of patients within your hospital, and not just a specific patient. Keeping sight of the goal to save the most lives and prevent the greatest amount of morbidity possible in the throes of the pandemic is key.
    - Follow consistently those policies and interventions within one's own institution guided by CSC plans and the very best knowledge and "best practices" to assure one's individual choices and actions are grounded in emergency medicine, law, and ethics.