Addressing Challenges Associated with Operationalizing a Crisis Standards of Care Protocol for the Covid-19 Pandemic

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The imminent threat of a Covid-19 surge overwhelming available resources for critically ill patients prompted many state-level public health officials to rapidly develop triage protocols for scarce resources, known as Crisis Standards of Care (CSC). It is important, however, for health care organizations to develop their own local CSC plans to address unique staff and community factors. In Massachusetts, a working group of experts at Brigham and Women's Hospital (BWH) developed a CSC implementation plan by engaging the hospital community, providing support to staff, and responding to changes in state-issued guidance and feedback from the hospital and broader Boston community. This process decreased clinician anxiety and increased hospital-wide understanding of the CSC process. While challenges remain in both the conceptualization and operationalization of these guidelines, health care organizations may adopt elements of the BWH process and incorporate key lessons learned.

The Covid-19 pandemic led to a renewal of the discussion and development of Crisis Standards of Care (CSC) protocols throughout the U.S.[1] CSCs are implemented when a crisis results in a substantial change in the level of care that can be delivered.[2] As resource scarcity increases, the typical availability of "space, stuff, and staff" becomes limited, necessitating a transition of focus from individual patient-centered care to public health–based obligations to the community.[3] CSC guidelines aim to provide direction for navigating this conflict, typically through a focus on maximizing lives saved and/or life years saved. CSC policies provide concrete guidance for clinicians and institutions facing difficult decisions about who should receive scarce resources.[3]

In response to the [2009 H1N1 pandemic](#), the National Academies of Medicine (formerly the Institute of Medicine) released guidance for establishing CSC protocols for implementation during disaster events.[2] These recommendations are based on the ethical principles of fairness, duty to care, duty to steward resources, transparency, consistency, proportionality, and accountability.[2] In the intervening decade, several states established CSC guidelines, though there is variation in the manner in which these guidelines have been operationalized.[4]

By March of 2020, the state of Massachusetts had not yet issued CSC guidelines. As Covid-19 infections grew in Italy and in New York City, hospitals in Massachusetts, including Brigham and Women's Hospital (BWH) in Boston, began working on CSC protocols, anticipating a massive surge in cases.[5,6] There was widespread anxiety that the number of cases might outpace hospital capacity, particularly for critical care resources.

CSC Development Process

In the initial absence of state-based guidelines, individual hospitals in Massachusetts sought to develop their own CSC protocols. BWH worked in conjunction with the broader Mass General Brigham (MGB) health care system to establish a preliminary CSC protocol. Beginning in mid-March of 2020, this work was initiated by an interdisciplinary group, at the request of health care system leadership, with representation from leadership at the hospital and health care system levels. Drafting this protocol involved an iterative process that moved forward quickly, meeting daily and sometimes multiple times per day, in order to ensure that the MGB system and its constituent hospitals were prepared for the potential surge.

Formation of a CSC Working Group

As protocol drafting began, BWH immediately assembled an ad hoc CSC Working Group to help draft the system-wide protocol and subsequently strategize about a BWH-specific operationalization plan that the hospital could implement quickly should the need arise. Our hospital found an interdisciplinary working group to be an effective method for rapidly formulating and reviewing the CSC protocol, and for synthesizing existing literature in ethics, CSC, and disaster medicine.

The CSC Working Group was initially composed of members of the hospital's Ethics Service and Hospital Incident Command System and was expanded within a week to include broader representation from the organization. Ultimately, key members of the core CSC working group at BWH included: the Medical Director of Emergency Preparedness; the Executive Director of the Ethics Service; the Co-Chairs of the Ethics Committee; a Clinical Ethicist/Nurse Scientist; a Pulmonary and Critical Care Fellow with ethics expertise; the Chief of Medical Psychiatry; two project managers; and the Chief Medical Officer as needed.

CSC Approval

After three weeks and multiple revisions, an initial protocol was approved in early April 2020 at the system level by MGB leadership and then at the local level by BWH leadership, including the

Chief Medical Officer and Chief Nursing Officer. The initial MGB protocol was informed by the University of Pittsburgh's CSC policy (originally published March 23, 2020), including its algorithm for assigning *priority scores* in triage decisions.[7] The essential components of the initial MGB protocol were as follows:

- A scoring process for allocating scarce resources that incorporated both the patients' Sequential Organ Failure Assessment (SOFA) score (representing acute illness burden) and an assessment of their major and severe comorbidities (representing the chronic illness burden)

- The designation of a Triage Officer charged with making triage decisions based on priority scores

- The formation of a Triage Team to support the Triage Officer in making these decisions

- The formation of a Triage Review and Oversight Committee (TROC) to ensure that decisions were made in accordance with CSC principles

The HCEC supported the team-based model of triage that avoided ad hoc, individual decision-making by bedside clinicians and the principles of transparency and accountability.

Community Engagement

After MGB approval, and subsequent BWH approval in early April 2020, the initial protocol was shared with the Harvard Community Ethics Committee (HCEC) for their review, which they were able to provide within 24 hours. The HCEC is a group of individuals with diverse backgrounds who "meet regularly to provide public input on the ethical aspects of health care." While the HCEC recognized the ethical challenges inherent to CSC decision-making, it endorsed the ethical framework underpinning the document. In particular, it supported the team-based model of triage that avoided ad hoc, individual decision-making by bedside clinicians and the principles of transparency and accountability. In addition, we solicited feedback from our Brigham Health Covid-19 Equity, Diversity, and Community Health Response Team, which was embedded within our Hospital Incident Command System.[8] This multidisciplinary team's perspectives were critical and several designees became members of our core working group to voice the perspectives of various vulnerable populations.
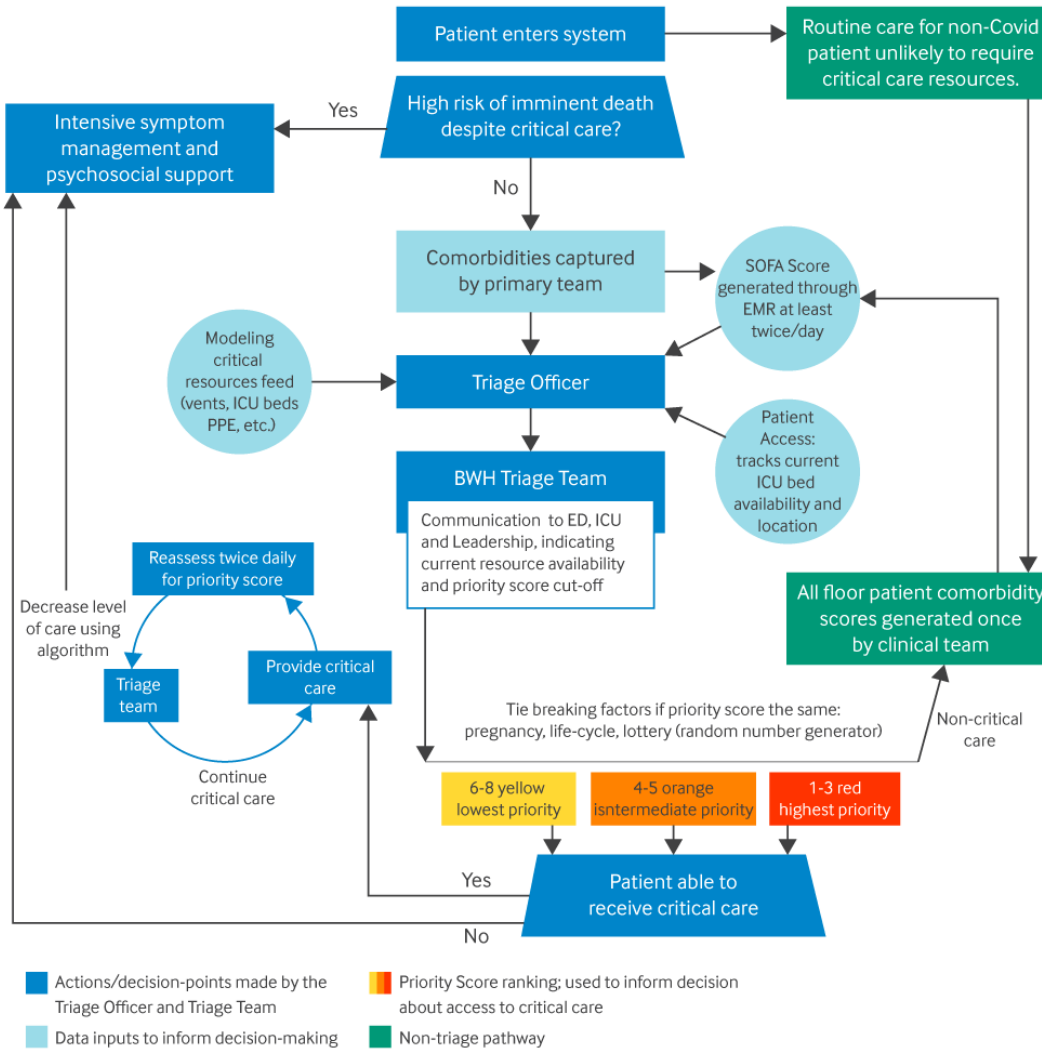
Engagement of the Hospital Community

Dissemination of the protocol and engagement of the local hospital community began as soon as a CSC document was approved by hospital leadership in early April. At BWH, a series of live webinars, outlining key principles, roles, responsibilities, and the process schematic (Figure 1) proved to be an effective method of rapid dissemination.

FIGURE 1

Schematic for Crisis Standards of Care Protocol

The protocol is activated at 70% threshold of ICU bed occupancy. The schematic begins upon patient entry to the system. An initial assessment is made regarding: a) need for critical care resources and b) whether death is expected imminently despite access to critical care. If patient requires critical care and is not expected to die imminently, the patient enters the Triage process and is assigned a Priority Score.

Patient enters system

Routine care for non-Covid patient unlikely to require critical care resources.

High risk of imminent death despite critical care?

Yes → Intensive symptom management and psychosocial support

No

Comorbidities captured by primary team

SOFA Score generated through EMR at least twice/day

Modeling critical resources feed (vents, ICU beds PPE, etc.)

Triage Officer

Patient Access: tracks current ICU bed availability and location

BWH Triage Team

Communication to ED, ICU and Leadership, indicating current resource availability and priority score cut-off

Reassess twice daily for priority score

Decrease level of care using algorithm

Triage team

Provide critical care

Continue critical care

All floor patient comorbidity scores generated once by clinical team

Non-critical care

Tie breaking factors if priority score the same: pregnancy, life-cycle, lottery (random number generator)

6-8 yellow lowest priority

4-5 orange isntermediate priority

1-3 red highest priority

Yes

Patient able to receive critical care

No

Legend:
- Actions/decision-points made by the Triage Officer and Triage Team
- Data inputs to inform decision-making
- Priority Score ranking; used to inform decision about access to critical care
- Non-triage pathway

Source: The Authors

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Webinars were presented by hospital leadership, including the Chief Medical Officer, the Medical Director of Emergency Preparedness, leadership from the Psychological Support Services team, and leadership from the Ethics Service. These webinars also provided an opportunity for clinicians to submit questions about the protocol and receive answers in real time by CSC leaders. Feedback from these sessions was helpful in improving the protocol's procedures, and communication and operationalization strategies.

Operationalization Plan and Execution

Once a draft protocol was approved in early April, the BWH CSC Working Group spearheaded an operationalization plan to rapidly implement the protocol in the event of a Covid-19 surge at BWH that necessitated CSC activation. Ultimately, as of August 1, 2020, BWH has not experienced a surge that would have triggered activation of the CSC.

Identification of Triage Officers and Triage Team Members

The CSC guidelines required identifying a group of physicians with critical care knowledge who would serve as Triage Officers and work in conjunction with a Triage Team. The Triage Team, which would help calculate triage priority scores and provide other needed support to the Triage Officer, would consist of an attending physician, a nurse, and an individual to provide administrative support. The CSC Working Group outlined descriptions for each role that included responsibilities and authority. A call schedule was also developed. Academic Chairs were asked to identify Triage Officers and the Chief Nursing Officer was asked to identify nursing leaders to serve on the team. Triage Officers and members of the Triage Team were quickly identified so that they could become familiar with the CSC protocol and the roles that they would fill should the protocol be activated.

Creation of a Triage Review and Oversight Committee (TROC)

A working group was convened, including representatives from the Ethics Committee, the Chief Medical Officer (CMO), Chief Nursing Officer (CNO), the Office of the General Counsel, Risk Management, the pool of Triage Officers, Safety and Quality, and Diversity, Equity and Inclusion (DEI). This working group considered several possible iterations of the TROC and arrived at the following composition: CMO or designee, CNO or designee, off-duty Triage Officer, Ethics representative, Legal Officer, and DEI representative. The TROC's roles included 1) evaluating priority scores and hearing appeals of individual decisions to withhold or withdraw life-sustaining treatment, 2) reviewing the triage process to determine whether the triage and appeals processes are being conducted in a fair, effective, and timely manner, and 3) adjudicating disputes. The on-call schedule required TROC members to be available for a 24-hour period with Internet accessibility for rapid activation and support.
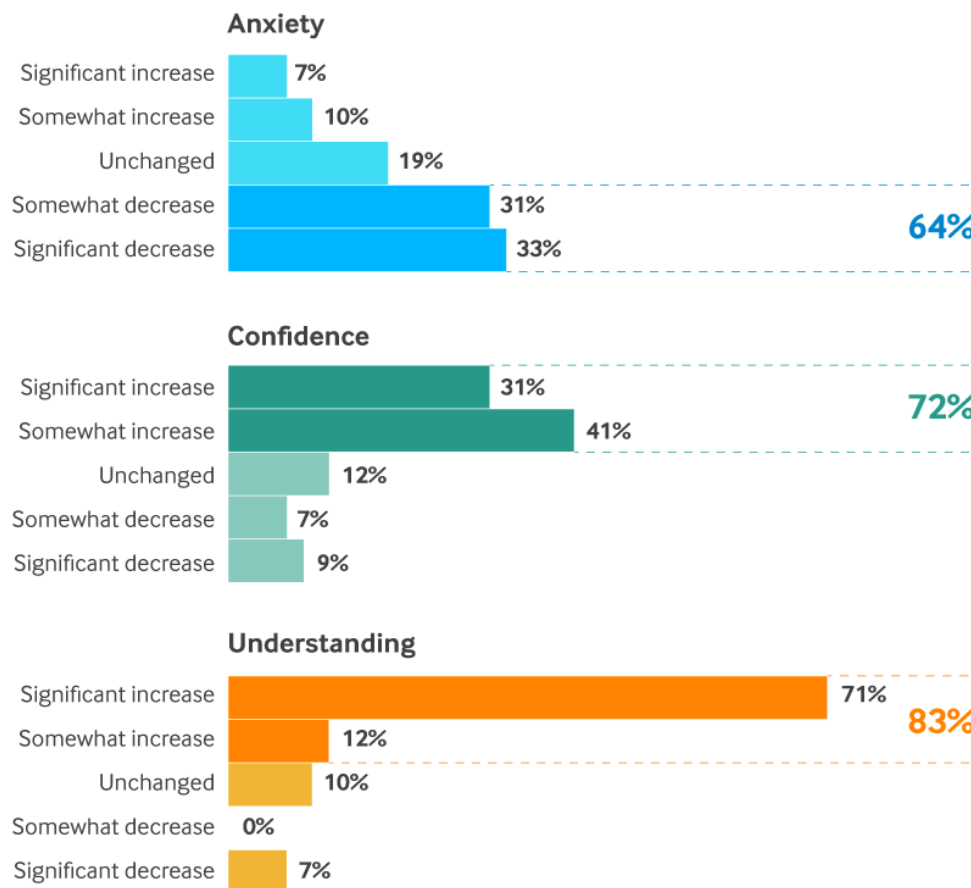
Tabletop exercises

In order to test the scoring and triage process, the BWH CSC Working Group organized a series of tabletop exercises with Triage Officers and Triage Teams using real patient data to practice progressing through the steps outlined in the CSC document, including calculating priority scores. These were begun early in the process (even prior to system-wide approval) but were expanded and intensified after system-wide approval. Tabletop exercises also provided participants with the opportunity to role-play difficult conversations, prompting conversations and reflections about the challenges that triage would create. The tabletop exercises proved to be essential in identifying and ameliorating difficulties in operationalizing the CSC process. These groups also helped members of the Triage Team gain familiarity and comfort with the protocol.

Individuals selected for the Triage Team (n=42) were surveyed following their participation in tabletop exercises in order to garner feedback about the tabletop exercises and to assess their effectiveness (Figure 2).

FIGURE 2

Triage Team Member Rating of Anxiety, Confidence, and Understanding of CSC Facilitated Tabletop Exercises and Practice Sessions (n=42)

Overall, 64% of Triage Team Members reported a decrease in anxiety regarding the Crisis Standards of Care process, 72% reported an increase in confidence, and 83% reported an increase in understanding of the CSC process.

Anxiety

Significant increase	7%
Somewhat increase	10%
Unchanged	19%
Somewhat decrease	31%
Significant decrease	33%

64%

Confidence

Significant increase	31%
Somewhat increase	41%
Unchanged	12%
Somewhat decrease	7%
Significant decrease	9%

72%

Understanding

Significant increase	71%
Somewhat increase	12%
Unchanged	10%
Somewhat decrease	0%
Significant decrease	7%

83%

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The results were encouraging: 64% reported a decrease in anxiety related to the CSC process; 72% reported an increase in their confidence with the CSC process; and 83% reported an increased understanding of the CSC process. Overall, these survey data suggest that the tabletop exercises were an effective way to orient members of the Triage Team to the CSC protocol.

Timely and accurate calculation of triage priority scores was critical for the success of the CSC framework. Manual calculation of these scores would require mining data from each patient's EMR, which could be challenging when faced with the need for rapid triage decisions. Thus, a SOFA calculator was created that would pull patient-specific data from the EMR. The Triage Team could then use this information to validate the SOFA Score, review comorbidities with the primary team, and calculate the priority score. This priority score would then be used to inform triage decisions, should the CSC be activated. A CSC dashboard was then created to display each element needed for decision-making, including: 1) individual priority scores 2) current ventilator/ICU bed availability and 3) a 48-hour projection of ventilator/ICU bed availability. This dashboard was refined over the course of our tabletop exercises based on feedback from participants (Figure 3).

FIGURE 3

Crisis Standards of Care Dashboard

The CSC Dashboard provides information about current and available ICU and Acute (Medical/Surgical) beds and ventilators. Users can also see details by unit, including the number of patients, number of beds, and the patient with the highest triage priority score and corresponding triage color category of the average score in the unit (red, orange, yellow). The right pane reflects volume projections based on modeling data to help understand future supply and demand challenges.
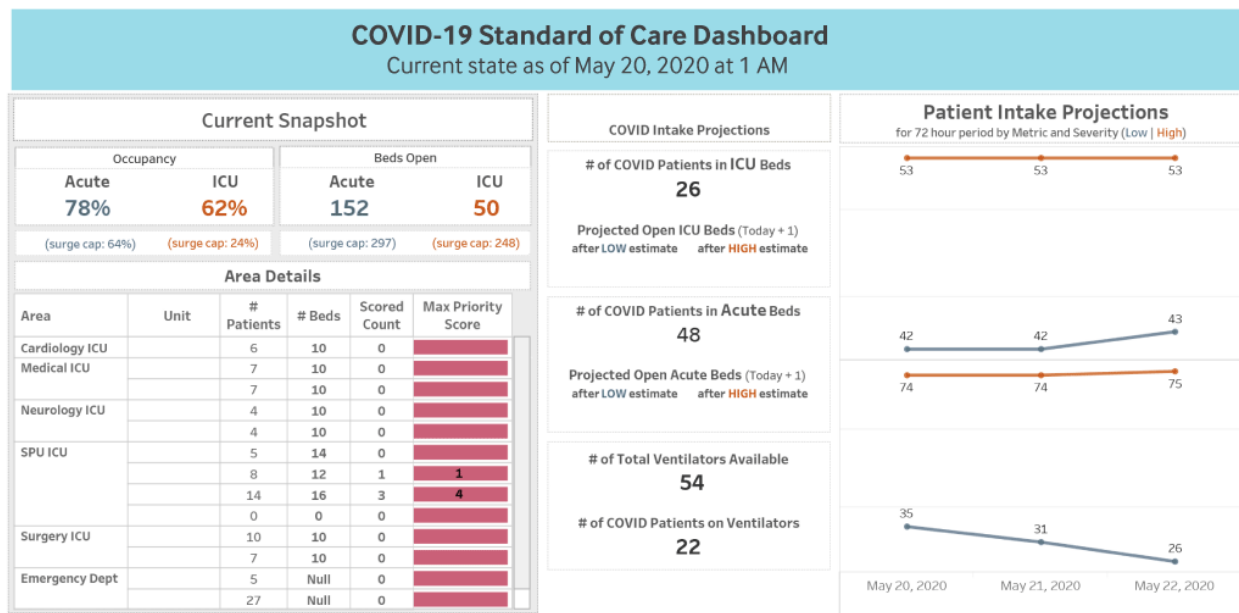
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Psychological Support Team

In recognizing the profound psychological distress that implementation of CSC guidelines might cause, a Psychological Support Service (PSP) was developed at BWH. This interdisciplinary service included members from Psychiatry, Social Work, Patient and Family Relations, Spiritual Care Services, Palliative Care, and the Employee Assistance Program. The service was designed to provide support at all levels of the hospital system. In particular, the team focused on supporting three populations: patients and families, the Triage Officer and Triage Team, and health care workers providing care to patients involved in triage. Plans included proactive check-ins with team members by the PSP and delineation of communication strategies for Triage Team members who would be relaying decisions to patients. These skills were practiced during several of our tabletop exercise sessions. As literature emerges about the lasting psychological impact of the Covid-19 pandemic on health care providers, we believe that this support system is a critically important component of our process.[9]

CSC Command Center

In a desire to support the Triage Team, a CSC command center was created to provide the team with a dedicated work area. Through guidance of PSP leadership, a pre-existing family waiting room was repurposed with adequate space for social distancing and relaxation when needed, including a lounge area. The area included telemonitoring capabilities for all patients in the hospital and several workstations for access to our EMR and dashboard.

Discussion

Here we consider the various challenges that we faced during the process and review major lessons learned.

Hurdles

Despite certain successes, the urgent need to develop a functioning process created many obstacles, including the limited opportunity for community engagement. As such, the voices of important stakeholders were not sufficiently incorporated in early CSC documents, resulting in operationalization challenges. A critical missing piece of early CSC documents was the additional perspectives of the diversity, equity, inclusion, and disability communities.

As described, in early April 2020, the Massachusetts DPH released state CSC guidelines.[10,11] These guidelines were subsequently revised in response to feedback from the public, primarily surrounding concerns that the guidelines, as written, would disproportionately and unfavorably impact communities of color, persons with disabilities, and others who are already vulnerable to

health inequities.[12] Major changes to the DPH guidelines included reframing the ethical goal of the document to focus solely on *lives saved* rather than *life-years saved*. Additional language was incorporated to address the concerns about vulnerable populations. Many other states are also rethinking guidelines in response to robust public feedback and, in some cases, litigation.[12]

The MGB protocol is currently undergoing revision to be consistent with the state-issued guidance and to incorporate additional community feedback. Ongoing engagement with stakeholders has revealed further challenges to creating an implementable process.[13]

Ethical Challenges

Several ethical questions remain unanswered. First is the debate over the focus on lives saved versus life-years saved. Concerns have been raised that a focus on life-years saved, by deprioritizing those with pre-existing conditions, may be subject to both implicit and overt biases in clinician assessments.[12,14,15] This concern underpins the Massachusetts DPH revising its initial focus on *life years*.

A related issue is whether, and how, to incorporate considerations of comorbid conditions and long-term prognosis into scoring schemes. Though there is general consensus that short-term prognosis (i.e., expected survival <1 year) is an acceptable consideration, considerations of long-term prognosis (i.e., 5-year life expectancy) raise concern. For example, how are such assessments to be made objectively and in a way that minimizes variability in judgment across clinicians? Can an exhaustive list of conditions be developed? How should scoring mechanisms account for conditions, such as chronic kidney disease and hypertension, that disproportionally impact communities of color? If CSC guidelines do not incorporate co-morbidities and instead rely on short-term measures alone such as SOFA score, patients will often end up with the same scores. Depending upon how algorithms are designed to break ties, prioritization scoring may default to considerations of age, lottery, or *first-come, first-served* principles, each of which has its own ethical challenges.[16] The most recent Massachusetts guidelines incorporate scoring deprioritization for both 1-year and 5-year prognosis. Whether such co-morbidities will remain in these guidelines is an area of ongoing debate.

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A second challenge concerns the role of prioritizing health care workers. While arguments have been made in favor of their prioritization on the basis of *quid pro quo* considerations, meaning they have earned a right to care as a result of their service, and *instrumental value* considerations, meaning the person, if treated, could return to work and aid in the public health response, others

have raised concerns that *only* prioritizing health care workers may, again, worsen existing health inequities and further disadvantage vulnerable populations.[4,17] The revised Massachusetts DPH document prioritizes individuals who "are vital to the public health response, including all those whose work supports the provision of care to others."[11] Nevertheless, questions remain about how decisions of prioritization are to be made. Who counts as "vital to the public health response?" Should this consideration be incorporated into the calculation of the initial priority scores, used only as a tie breaker, or eliminated entirely?

As a result of these challenges, the BWH CSC Working Group expanded to include broader representation from experts in diversity, equity and inclusion, and disability. Ongoing work with these groups is underway in an effort to develop a document that can be implemented if CSC is activated but that takes into account and compensates for existing inequities.

Practical Challenges

Additionally, there are practical challenges to consider. Though webinars proved to be an effective method for timely dissemination of information, the crisis evolved rapidly during March and April, necessitating changes to the CSC protocol in real time. This meant that information given to the hospital community changed over time. For example, the Massachusetts DPH guidelines were released shortly after the webinar series. Though the MGB protocol and DPH guidelines were closely aligned, there were subtle differences, including the scoring of health care workers and considerations around comorbidities, which required clarification and dissemination of updated information.

Facilitating tabletop exercises in the midst of a pandemic also proved challenging, as social distancing requirements prevented large groups from gathering in one room. A hybrid approach using in-person and video calling was attempted, though ultimately the group found serial meetings in small groups to be the more effective method.

Lessons Learned

One of the major lessons learned in this crisis was the importance of preparedness. BWH did not reach the point of needing activate the CSC, in large part due to extensive work to increase capacity during the "contingency phase" of the crisis. Of note, on June 19, 2020, the Massachusetts Covid-19 CSC guidelines were rescinded[18] after the state's first Covid-19 surge, and to date no hospitals in Massachusetts have activated Crisis Standards of Care.

Because the future course of the Covid-19 pandemic remains uncertain, we recommend that hospitals begin by developing a CSC framework or adapting their state's CSC framework, if in place, into a workable policy. State-based guidelines help minimize variation across hospitals to ensure that patients have access to similar care, regardless of location.3 This process should be undertaken by hospital leadership and community stakeholders and founded on work carried out by states, national organizations, and other hospitals.

We recommend the early formation of a small interdisciplinary working group. The BWH CSC Working Group helped move the process forward by developing and modifying the CSC protocol based on feedback. Additionally, we recommend the early use of tabletop exercises to familiarize those who would be participating in the process with the process and identify challenges for operationalization. As described, these exercises decreased clinician anxiety and increased confidence and understanding in the CSC protocol at BWH.

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Though BWH has not, as of August 1, 2020, activated the CSC protocol during the Covid-19 pandemic, the hospital continues to work on CSC guidelines. Many questions remain and will require engagement with members of the public to ensure that standards are responsive to the concerns of our communities, implementable if needed, and grounded in sound ethical principles.

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