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AJOB Empir Bioeth. Author manuscript; available in PMC 2021 July 01.

Published in final edited form as:

AJOB Empir Bioeth. 2020 ; 11(3): 148–159. doi:10.1080/23294515.2020.1759731.

"We're not ready, but I don't think you're ever ready." Clinician Perspectives on Implementation of Crisis Standards of Care

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Abstract

Background: The COVID-19 pandemic has highlighted health care systems' vulnerabilities. Hospitals face increasing risk of periods of scarcity of life-sustaining resources such as ventilators for mechanical respiratory support, as has been the case in Italy as of March, 2020. The National Academy of Medicine has provided guidance on crisis standards of care, which call for the reallocation of scarce medical resources to those who will benefit most during extreme situations. Given that this will require a departure from the usual fiduciary duty of the bedside clinician, we determined and mapped potential barriers to the implementation of the guidelines from stakeholders using an implementation science framework.

Methods: A protocol was created to operationalize national and state guidelines for triaging ventilators during crisis conditions. Focus groups and key informant interviews were conducted from July-September 2018 with clinicians at three acute care hospitals of an urban academic medical center. Respiratory therapists, intensivists, nursing leadership and the palliative care interdisciplinary team participated in focus groups. Key informant interviews were conducted with emergency management, respiratory therapy and emergency medicine. Subjects were presented the protocol and their reflections were elicited using a semi-structured interview guide. Data from transcripts and notes were categorized using a coding strategy based on the Theoretical Domains Framework.

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AUTHOR CONTRIBUTIONS: Drs. Chuang, Powell, and Gong conceived of and designed the work. Dr. Chuang and Mr. Cuartas collected and analyzed the data. All authors contributed substantially to the interpretation of the data and drafting the manuscript. All authors gave final approval of the version to be published and agree to be accountable for all aspects of the work.

CONFLICTS OF INTEREST: None.

ETHICAL APPROVAL: This study was approved by the institutional review board at the Albert Einstein College of Medicine (IRB # 2018–9179).

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Results: Participants anticipated that implementing this protocol would challenge their roles and identities as clinicians including both their fiduciary duty to the patient and their decision-making autonomy. Despite this, many participants acknowledged the need for such a protocol to standardize care and minimize bias as well as to mitigate potential consequences for individual clinicians. Participants identified the question of considering patient quality of life in triage decisions as an important and unresolved ethical issue in disaster triage.

Conclusion: Clinicians' discomfort with shifting roles and obligations could pose implementation barriers for crisis standards of care.

Keywords

disaster triage; pandemic; COVID-19; qualitative; implementation science

Introduction

Given the projected increase in frequency of extreme weather events (Woodward and Samet 2018), and the ongoing risks of emerging infectious diseases (Zumla et al. 2016), hospitals in the United States face an increasing vulnerability to conditions that may result in periods of scarcity of life-sustaining resources such as ventilators for mechanical respiratory support. The occurrence and duration of these periods of scarcity are hard to predict (Babar and Rinker 2006). The emergence of the novel SARS-CoV-2 virus and attendant COVID-19 disease has made planning for these periods of scarcity imperative and urgent. SARS-CoV-2 has spread rapidly throughout the world and in the United States (Burke et al. 2020). Given the high morbidity and mortality experienced by patients with respiratory failure due to COVID-19 (Yang et al. 2020), shortages of ventilators and critical care beds can be expected and have already been experienced in Italy (Mounk 2020).

In 2012, the National Academy of Medicine provided extensive guidance on crisis standards of care to prepare local governments, emergency medical services, hospitals and other healthcare institutions, and the public for disaster conditions (Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster and Institute of 2012). These guidelines outline coordinated efforts to maximize existing human and physical resources such as building surge capacity, retraining staff, and adapting and reusing equipment. However, if all efforts to expand capabilities are exhausted, the guidelines then call for the *reallocation* of "medications or supplies to those who will derive the greatest benefit and/or make the least demand on resources" (p. 234, table 7–1 of the National Academies of Medicine's Crisis Standards of Care: A Systems Framework For Catastrophic Disaster Response, 2012). This recommendation and accompanying guidance on implementation of triage criteria were created in an effort to ensure equitable delivery of care and minimize adverse outcomes.

According to a 2012 estimate, there are close to 105,000 ventilators in the United States (Corcoran, Niven, and Reese 2012). Other human and physical resources including hospital beds, critical care physicians, and respiratory therapists also limit the number of patients who can be ventilated (Sandelowski 2001). Given the emergence of novel respiratory viruses such as SARS-CoV-2 and nature of seasonal flu, hospitals are particularly vulnerable to

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ventilator shortages (Patel et al. 2010). In an emergency ventilator scarcity scenario, crisis standards of care would call for reallocating some ventilators from patients with a low likelihood of benefit to patients who are most likely to survive. Although the ethical framework that underpins this recommendation is supported by expert consensus and careful weighing of the relevant ethical issues (Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster and Institute of 2012), it runs counter to the bedside clinician's professional duty to the individual patient under usual circumstances (O'Laughlin and Hick 2008). This may be problematic for some bedside clinicians, particularly in the event that withdrawing mechanical ventilation is indicated during crisis standards of care. There are variations in physicians' perceptions of the ethical permissibility and psychological difficulty of withdrawing life support even under normal circumstances when the withdrawal is in-line with the patient's wishes for end of life care (Chung et al. 2016). Unilateral decisions to withdraw life support are likely to be even less acceptable to these clinicians.

Guidelines may ameliorate moral distress by removing some of the decision-making burden from front-line clinicians (O'Laughlin and Hick 2008). Standardized guidelines for triage are particularly important because the emotional stress of a disaster situation is likely to erode decision-making capabilities (Ryus and Baruch 2018). However, guidelines are unlikely to be implemented if they are considered ethically unacceptable by the health care providers at the scene. Implementation may be inadequate or delayed if bedside clinicians experience role conflict. Other implementation barriers may include clinicians' perceptions of the validity of the triage criteria and concerns about legal repercussions (Curiel 2006). Although qualitative work has been done to assess acceptability of guidelines among community members (Biddison et al. 2018), similar work with clinicians has been limited and identified as a gap in the literature regarding knowledge for how best to prepare for disasters. Specifically, evaluation of strategies for resource allocation in disaster scenarios based on multi-disciplinary team input and implementation of findings has been identified as an area of need for further research (Gowing, Walker, and Elmer 2017).

Recently, the field of implementation science has emerged as a field of study focused on methods to promote the adoption and integration of best practices or other interventions into health care. Systematic measurement and mapping of barriers to successful implementation and adoption of protocols is a key aspect of this field. Under the frameworks developed in implementation science, we aim to better understand potential barriers that can arise from ethical conflicts to the implementation of a national guideline for a ventilator allocation in the event of resource scarcity among front-line clinicians.

Materials and Methods:

The Albert Einstein College of Medicine Institutional Review Board approved this protocol (IRB # 2018–9179).

An extensive review of the medical literature and grey literature was conducted to develop a specific protocol for triaging ventilators during a crisis where a shortage of this life-sustaining resource is unavoidable. This protocol was derived from and complies with both

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the National Academies of Medicine Crisis Standards of Care and the New York State Guidelines (2015, Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster and Institute of 2012). This protocol operationalizes the guidelines by specifying key details necessary for implementation in the event of a critical shortage of ventilators. The protocol consists of two phases. During phase I, efforts are made to augment capacity and avoid critical shortages. Phase II is only activated when a state of emergency has been declared at the federal, state, city or hospital level, AND when demand has exceeded available ventilators despite all efforts to augment capacity (Table 1). During phase II, the triage officer uses the protocol to determine which patients should receive priority for intubation, and does not intubate patients that meet exclusion criteria (Figure 1). Intubated patients are re-evaluated at 48 hours, 120 hours and each 48-hour interval afterwards for eligibility to continue mechanical ventilation (Figure 2). These re-evaluations are performed by the triage committee consisting of a senior critical care attending, a member of the bioethics committee, a senior respiratory therapist, a critical care nursing leader, and a specialist appropriate to the emergency or disaster.

Focus groups of clinical staff and key informant interviews were conducted from July-September 2018. Because we aimed to identify barriers and facilitators to implementation of this protocol, we purposefully targeted clinicians who would be involved in implementing such a protocol. We used convenience samples of those clinicians available during regularly scheduled staff meeting times. Because we were able to schedule focus groups during times that staff usually expected to convene, we were able to capture most of the relevant staff excluding those who were off duty at the time of the focus group. Clinicians were included who provide care on adult medical services at three acute care hospitals of an academic medical center. The three hospitals collectively provide 1500 beds to an urban, racially and ethnically diverse population of patients. Focus groups were conducted with respiratory therapists, critical care physicians (including attending physicians and fellows), nursing leadership, and the palliative care interdisciplinary team. We were unable to coordinate focus groups with bedside nurses due to scheduling constraints. Because of the difficulty coordinating focus groups with some staff, key informant interviews were conducted with leadership in emergency management and emergency medicine. After conducting the focus group with the respiratory therapists, a follow up key informant interview was conducted with one of the respiratory therapists for further clarification. A key informant interview was conducted with the medical director to contextualize the project.

The research team consisted of the principle investigator (PI), who is a palliative care physician, bioethicist and qualitative researcher; a critical care physician-researcher; a physician bioethicist with public policy expertise; and a medical student researcher. Focus groups were led by the PI and the student researcher. A loosely structured interview guide was developed using standard iterative processes (Supplemental Appendix). Open-ended questions were used to explore a range of concerns regarding protocol implementation including physical, operational, cognitive, and emotional barriers and facilitators to implementation.

Focus groups ranged from 40 to 60 minutes in length and were audiotaped and transcribed. The triage protocol was presented to participants both in print and in a PowerPoint

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presentation prior to recording data. With the exception of the respiratory therapist, key informant interviews were not audiotaped but research notes from these interviews were included.

The data were examined and categorized using a coding strategy based on the Theoretical Domains Framework (TDF) (Cane, O'Connor, and Michie 2012). The TDF was developed in 2005 by health psychologists and implementation science researchers to provide a comprehensive framework to identify factors which influence behavior, including clinician behavior in the healthcare setting (Michie et al. 2005). The domains included in TDF are knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention, and decision processes; environmental context and resources; social influences; emotion; and behavioral regulation. We chose this framework because it captured the domains related to moral acceptability such as social and professional role and identity, emotion, and beliefs about consequences. It also allowed us to capture other common barriers that might influence implementation of the protocol.

All of the transcripts were read in depth by two of the researchers (E.C. and P.C.) who independently applied the codes. Coding differences were resolved with discussion. The data were coded in the Dedoose™ software program (Hermosa Beach, CA). Once the coding was completed, the immersion/crystallization approach (Crabtree and Miller 1999) was used to identify patterns related to the TDF thematic categories. Immersion/crystallization was alternated with discussion (E.C. and P.C), until all the data had been examined and the meaningful patterns and themes extracted and described. The interviews were then re-read to identify any disconfirming data (E.C.).

Results:

The palliative care focus group consisted of 14 subjects including three social workers and eleven physicians ranging in experience from interns to seasoned attending physicians. The critical care focus group consisted of 25 physicians including fellows, junior attending physicians, senior attending physicians, and intensive care unit leadership. The nursing focus group consisted of four members of senior nursing leadership. The respiratory therapist focus group consisted of approximately 20 therapists. Key informant interviews were conducted with the medical director of one academic hospital, directors of emergency management and emergency medicine, and one respiratory therapist. Quotes included in the manuscript were chosen based on representativeness of the ideas expressed under each theme.

The domains of the TDF that were most salient in the data were grouped into two themes: (1) personal and social factors (including TDF domains of Social/Professional Role and Identity, Beliefs about Consequences, Emotion, and Social influences) and (2) technical factors (including TDF domains of Skills, Ability, Condition/Scientific Rationale, Environmental Context and Resources, Memory, Attention and Decision Processes). During the course of coding and analyzing data, a code of "consideration of expected quality of life in judging benefit" was added to encompass a major theme that arose in the data. The TDF

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domains of reinforcement, optimism, intentions, goals, and behavioral regulation did not emerge as significant themes in this data set.

Personal and Social Factors

Social/Professional Role and Identity—One of the main overarching issues that participants grappled with was the meaning of this protocol in relationship to their roles and identity as health care providers. In some ways, the protocol represented a threat to the participants' sense of self in the professional sphere. One concern was that the protocol threatened the fiduciary duty of health care providers to advocate for their individual patients.

> Once this patient hit the ICU, we wouldn't give up on them within 48 hours.
>
> (Critical Care)

> I don't know, I would have an issue taking [the hypothetical patient] off the vent, personally.
>
> (Critical Care)

Another concern was abdicating the physician's authority as an autonomous decision-maker to a protocol and a committee.

> Most likely in a disaster situation people wouldn't be calculating scores. I think you'd go on your clinical gestalt as a trained doctor.
>
> (Critical Care)

> No matter what, you have to remove the vent. I mean, the decision came from on high…so you're no longer a physician at this point, you are just following orders.
>
> (Critical Care)

Having an appeals process provided clinicians with some increased sense of control, but clinicians were very clear that only the attending physician should be allowed to appeal. It was generally expressed that family appeals would only serve to slow down the process and jeopardize the ability to harness scarce clinical resources.

> I think maybe as long as there's checks and balances, people would feel better.
>
> (Critical Care)

> Opening the appeals process to the family in [a] time when you are in a crisis could overwhelm the committee…What family member would be OK with extubating?… it should be the attending in the critical care unit taking care of that patient that is the one that could appeal…seeing some improvement or…thinking of some other therapy.
>
> (Critical Care)

Despite these concerns and threats to professional identity and role, in general, the clinicians interviewed expressed an agreement that such a protocol may be necessary in an extreme situation to improve outcomes for the population as a whole and would be acceptable to them as healthcare professionals.

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> This is kind of an expedited situation, but if they're deemed that they're not reversing anyways, I think most of us are of the mindset to help the person that we can help.
>
> (Respiratory Therapy)

> We're going to have to pick the patient that's going to do the best. Is everyone going to like it? Is the family going to agree to it? No. My concern is, as long as I can go to bed at night with a clear conscience knowing that I did the right thing, I'm okay with that.
>
> (Nursing Leadership)

Other clinicians recognized that using clear objective criteria and relinquishing decision-making control to the committee would be beneficial due to the extreme circumstance and the danger of subjective and unilateral decision-making, and one participant suggested having a person external to the institution as a member of the triage committee to improve transparency.

> I like the fact that there's a clear guideline for the triage officers to decide who qualifies so that in some ways the pressure of making that decision is away from the … person.
>
> (Critical Care)

> I would follow the protocol and I would remove the treating physician from having to make those decisions independently.
>
> (Critical Care)

Beliefs about Consequences—Many participants recognized the importance of having a protocol to help justify decision-making in the event of questioning by the public after a mass critical care event (MCCE). At the same time, concerns about consequences remained a dominant thread throughout the data. Some participants expressed concern about being penalized or scrutinized after the fact, while others worried about the emotional consequences.

> I think these definitions have to be done and then absolve physicians and each local hospital of any kind of sense that they are going to be brought to criminal justice or whatever else if they disconnect people from the ventilator if they are acting in the best interest of the community.
>
> (Critical Care)

> So once the dust settles…they won't ever go back and say this is an RCA [root cause analysis] because …they should've given the vent to this patient and not that patient…are we then going to go back and throw somebody under the bus?
>
> (Nursing Leadership)

> One participant, on the other hand, worried about giving too much power to the triage committee:

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> I brought up the Milgram experiment during the discussion because I genuinely fear a blind obedience to authority. There must be a careful selection of who is on the triage committee making these decisions. I like the suggestion…that an appeal process be limited to the treating physicians.
>
> (Critical Care)

Several participants discussed the possibility of including a member of the community independent of the hospital administration in the triage committee to improve transparency.

> [I'm suggesting] the idea of having an external judge, you know like somebody outside the [name omitted] system so as to remove the specter of families or patients thinking, "Oh [name of institution omitted] is doing this for secondary gain."
>
> (Critical Care)

Emotion—The major emotions that emerged from coded data were fear and stress. Fear included fear of legal repercussions and facing the anger of family members if a patient was removed from a ventilator according to protocol.

> So it's kind of hard to say that "Hey sorry because of this criteria, your mom or your dad or your son doesn't meet the criteria to remain on life support," and not expect there to be some sort of anger.
>
> (Respiratory Therapy)

> If we know that it's an upset family that might lash out, nobody in my field wants to get attacked because we're essentially the ones pulling the trigger so to speak, because we're taking them off life support.
>
> (Respiratory Therapy)

Participants also feared their own emotional reactions. A particularly well-received idea was implementing debriefing for clinicians post-disaster to mitigate emotional fallout, including risk for PTSD.

> We are not ready, but I don't think you're ever ready.
>
> (Nursing Leadership)

> Before we end I think it is important that if this were to ever occur, that we have a hospital-wide debriefing session after everything is said and done and things cool down, otherwise you may have a significant number of clinicians who may be at risk for hurting themselves or quitting the profession altogether.
>
> (Palliative Care)

Social Influences—Subjects discussed difficult social situations that could cause emotional distress in carrying out the protocol, particularly if there is a relationship between the health care system and a particular patient.

> It's just that sometimes you get squeezed, "Oh don't touch this one because this belongs to so-and-so or this one is a third cousin twice removed from the guy who

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was on the board three years ago." I think as long as we don't feel that that is a pressure then I think the decision would still be the same.

(Critical Care)

Subject 1: No, we have to decide between, you know, God forbid Dr. [Medical Director]'s mother and patient B.

Subject 2: Right, so we decide based on the criteria.

Subject 1: But how do we make a decision like that?

Subject 3: We have to.

(Nursing Leadership)

Positive social influences were also mentioned. Several participants discussed the importance of social cohesion amongst providers in carrying out the protocol.

I think [triage committee members] are going to need a really good rapport with each other and have to be very decisive.

(Critical Care)

I think that when you're in a state of crisis like we'd be at, at that point, everybody understands what's going on; I think that's when people kind of pull together.

(Nursing Leadership)

A final concern was raised about health professionals' social responsibility. One participant noted that while the protocol aims to decrease biased decision-making by focusing on objective data, those who are socially disadvantaged are more likely to have serious illness and therefore are more likely to be excluded from accessing ventilators under the protocol.

God forbid if when we do a chart review we find that the patients that were allocated ventilators… were from privileged patient populations as opposed to vulnerable patient populations like, the people who are more destroyed or more critical are going to be our chronically critically ill. It's not the healthy person is going to get the bad MRSA [methicillin-resistant staphylococcus aureous] pandemic flu pneumonia, it's going to be the COPD'er [patient with chronic obstructive pulmonary disease] who didn't have access to good healthcare who's locked up in some nursing home and that's just like the perfect Petri dish…and it's the more vulnerable people that are going to be said, "No, you don't qualify because you're vulnerable to begin with."

(Palliative Care)

Technical factors

In contrast to the ambivalence voiced regarding roles, beliefs, emotion, and social influences, participants reported high levels of confidence in their procedural and clinical knowledge and skills in implementing a protocol like this. Some participants voiced concern about eroding abilities over time given the cognitive overload and severe time constraints of a disaster situation.

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Skills—Many clinicians emphasized the ability to use creativity to extend available resources as much as possible to avoid or delay the necessity of triage.

> There's also option of using other devices that…can technically ventilate patients. I know some of the BiPAPs can be used as ventilators, some of the trans4 modules can be used as a ventilator.
>
> (Critical Care)

> Another question is that you're putting this option between being on a ventilator or being dead. But there could be other options. You could manually ventilate patients to some degree, to some capacity.
>
> (Critical Care)

Respiratory therapists and palliative care clinicians noted that extubating a patient under the protocol is technically similar to routine palliative extubations. Several participants also pointed out that lower stakes triage decisions, such as allocating ICU beds, are made during usual care situations, making clinicians comfortable with the clinical skills required. One clinician felt that given the clinical readiness to make triage decisions, the protocol may actually include unnecessary delays.

> I really don't think we'd have a problem participating when we do it on a daily basis.
>
> (Respiratory Therapy)

> Could the treating physician have extubated [the hypothetical patient] before the 48 hours if her clinical situation declined before 48 hours? Within 24 hours, if she is worse at that point? Could the treating physician already have decided to extubate without the triage committee?
>
> (Critical Care)

This confidence was not unanimous. One more senior clinician did caution that the type of triage required by the protocol is on a higher-stakes level.

> They would be able to be transferred out of the ICU [during usual circumstances of allocating ICU beds], but I don't think anybody has ever removed a ventilator [as a unilateral physician decision]. We are not making these decisions every day, I don't think anybody has ever removed a ventilator.
>
> (Critical Care)

Ability—Although clinicians reported a high level of confidence in their technical abilities to carry out the protocol, they recognized that cognitive overload and time constraints might be limiting in a disaster situation.

> I think that if you are going to make a protocol it should be very simple and it should be able to go on a piece of paper and be on the wall so that people don't have to use a lot of cognitive energy in a stressful event.
>
> (Critical Care)

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> I would think that it would be probably better to keep it streamlined and simple. If you add too much criteria there's too much opportunity for one little thing…like if they're over 60. If they're 59 and they don't meet that criteria, then that might open the door for there to be an argument about keeping this one instead of that one…If you give them too many options…then who makes the decision like, "well it's close enough." Instead of just saying no.
>
> (Respiratory Therapy)

Scientific Rationale—Several clinicians did not accept the scientific rationale for the protocol. While some voiced an appreciation for the idea of using objective criteria like the SOFA score, others recognized the inherent flaws in any prognostic tool.

> I guess the consensus is more like stick with medical facts and criteria and try to remove emotional response from that to be able to be fair and find patients that can benefit…short term ventilator support will get them through and then you estimate and move on…makes sense to most of us.
>
> (Palliative Care)

> I've seen this published before and I think they just made this because it seems "sciencey" because there's a number…Like if somebody was in DKA and their SOFA was 9, you know, they're in DKA, they'll get better, or if they had a seizure, you know? So, I think they intentionally made this so that there was a number but not thinking this was a good idea or that it makes sense.
>
> (Critical Care)

Barriers and Facilitators—Clinicians expressed a desire to practice using the protocol during drills to make sure the details of the protocol would work. Several technical issues of implementation were brought up, some of which could be addressed with drills and training.

> Who would declare an emergency and notify us? As in how do I as an individual critical care attending know when I need to use this triage tool?
>
> (Critical Care)

Potential lack of specific physical resources including laboratory results and access to the electronic health record in the event of a natural disaster was mentioned by several participants.

> How are patients labeled, based on what category they are? And how are doctors going to keep track of when their reassessment needs to be if there's a chance that the medical record is down or even if the medical record is up. How do people keep track of that?
>
> (Critical Care)

> Just having gone through Ebola…the personal protective equipment that we were supposed to have as a facility that was designated as an Ebola treatment unit was not available to us…we didn't have enough equipment to train and learn how to use.

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(Critical Care)

Human resources were also noted frequently as both a potentially limited resource and an asset or facilitator.

> I think a protocol is needed, like tracing the – creating one line like a person in charge. If you have a good commander in charge like critical care who is very experienced in the disaster, then you could depend on [them].
>
> (Palliative Care)

> If we ever get to this point we will be in a situation where each of us is working harder than we ever imagined and then some.
>
> (Palliative Care)

Specific changes or additions to the protocol were suggested by participants. Particularly clarifying which patients were encompassed in the protocol, such as chronically vented patients in the hospital and patients at other affiliated hospitals within the growing medical center. Clinicians were concerned about clarifying the interaction between various campuses of this large academic medical center which encompasses several acute care hospitals with separate ICUs.

> We would need to make sure that because it would be [name omitted] medical center and [name omitted] healthcare system, and those aren't the same entity, so it's not clear to me that we necessarily have the right to walk into [affiliated hospital] and take over their resources, but I might be wrong.
>
> (Critical Care)

> I'm saying that if you have a situation…they are already ventilated, right? They've been ventilated for…five months, so I would say that if…they were not offered critical care services in the ICU because we thought their outcome was very poor, and the only thing keeping them alive is a ventilator – otherwise they would die immediately, then that patient when it comes down to the situation would be triaged again.
>
> (Critical Care)

Finally there was contention about how the patient's family would be informed of the triage committee's decision. On one hand, bedside clinicians felt that it would be difficult to pass along a decision that they were not responsible for making, but on the other hand there was recognition that keeping the triage committee from the burden of disclosure could maintain their objectivity.

> I think palliative is more used to having these hard conversations, and critical care is used to sitting down with families and explaining…"Listen, if they stay on a vent they're not going to get any better."
>
> (Respiratory Therapy)

> I wouldn't feel that it is…my role to say, "Well we are going to extubate because this doctor said." I don't think it is fair for any physician who didn't make that call to just say that. It is kind of like saying, "Oh you are not getting chemotherapy but

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> your oncologist didn't tell you. I'm telling you." I just feel like it would be the same and I don't feel like that is fair in any sense.
>
> (Palliative Care)

Quality of Life in Judging Benefit—While the protocol was specifically designed to avoid judgments about the value of individual patients' lives and to maintain focus on immediate survivability, there was a lively debate in the groups about what would be considered an inappropriate value judgment. While all understood that consideration of the patient's social standing (such as profession, socioeconomic status, family composition) in triage decisions is inappropriate, clinicians struggled with whether neurological prognosis and ability to live off of a ventilator were appropriate things to consider or whether they constituted inappropriate clinician-imposed valuation of quality of life.

> So, kind of along those lines…you said we are not going to the [name omitted] nursing home to take vents off the patients. So if we're going to be selectively, for lack of a better term, killing patients in the hospital, why are we not taking people who have been on vents for six months with no mental status and no hope of recovering at this point, why aren't we removing their vents and bringing them in where there is a chance of recovery?
>
> (Critical Care)

> But I thought you were saying that we are not making a quality of life judgment… We are trying to have survivability as sort of the primary criteria.
>
> (Critical Care)

General reactions: For the most part, clinicians in all focus groups were interested in having a protocol in place prior to a disaster occurring, even with the inherent flaws.

> It's not perfect but it's great to do it [creating a protocol]; it needs to be done.
>
> (Critical Care)

Discussion:

While several publications outline potential barriers or challenges to front-line clinicians when implementing crisis standards of care (Satkoske, Kappel, and DeVita 2019, Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster and Institute of 2012, Timbie et al. 2012); this is the first study to our knowledge that uses qualitative methods to explore these barriers with practicing front-line clinicians. Biddison et al. published findings of an extensive community and health care workshop that explored triage decision-making recommendations to inform protocol development (Biddison et al. 2018). Similar themes including the need for advance planning, concerns over clinician bias and the emotional toll of decision-making, transparency, and equity emerged from their study. Our work expands on these themes by taking a completed protocol and addressing specific implementation barriers. Overall, most front-line clinicians were accepting of the crisis standards protocol and indicated that they believed they would be able to carry out such a protocol during disaster conditions. As was found in one cross-sectional survey of clinicians,

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the methods outlined were perceived as fair (Cheung et al. 2017). Several practices were identified as crucial for implementation: officiation of a protocol, dissemination of the protocol to relevant staff, incorporation of the protocol into existing disaster preparedness drills, and planning for post-event staff debriefing.

The best means of addressing the personal and social barriers which clinicians identified are less apparent. For example, some clinicians were concerned about diminished decision-making power, while others valued the triage committee as a mechanism to relieve the burden of unilateral decisions regarding intubation and withdrawal. Allowing a limited appeals process for bedside clinicians may be a feasible compromise.

In order for a protocol to be effective upon deployment, it must be easy to follow. Clinicians agreed that the protocol ought to be streamlined, objective, and followed uniformly by all clinicians regardless of personal beliefs. However, concerns were raised about the accuracy of SOFA scores for identifying patients who are most likely to benefit from life-sustaining treatment. The writers of national guidelines acknowledge this limitation, but alternative objective criteria are lacking. Two other salient questions were raised: whether to include assessments of quality of life in judgments of benefits of ongoing mechanical ventilation and whether to include inpatient long-term ventilated patients under the triage protocol. The lack of consensus in this study is consistent with prior literature (Hick et al. 2007, Timbie et al. 2012). While the examples of quality of life tradeoffs raised by clinicians are understandable, quality of life judgments by clinicians may introduce unconscious bias and penalize poor patients with less healthcare access, a concern mentioned during focus groups. One particularly important area of future research would be to define community and health care provider perspectives on how to consider long-term neurological prognosis in triage protocols. Although the SOFA score is admittedly limited, its objectivity can reduce, but possibly not eliminate, the likelihood of such biases affecting triage.

Clinicians feared being personally penalized after the fact for actions taken during a disaster. It is reasonable to infer from these data that no matter how vetted the protocol is, implementing it will result in moral distress and concerns about consequences. Providing compassionate and comprehensive debriefing after the event may ameliorate these concerns (Biddison et al. 2018). Authorization from state or federal agency to adhere to protocol is required to lessen concerns about legal consequences. Even with such authorization, these concerns may not be completely overcome. More specifically with respect to concerns about consequences, several clinicians observed that having a protocol in place may reduce the burden of liability risk the clinicians are exposed to during disaster conditions. Prior approval by administrators and the public health authority would provide some protection for clinicians. Clinicians recommended clear communication with the public and transparency to reduce the chances of public sanction.

Study limitations included access to bedside clinicians and limited generalizability across contexts and resources other than ventilators. A focus group was conducted with nursing management, whereas responses from bedside nursing staff were not obtained due to logistic constraints. Data acquisition during the respiratory therapy focus group was limited by time, and it is possible that some participants were not able to voice their concerns. In an attempt

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to mitigate this, an individual interview was carried out and the group was encouraged to contact the researchers with any additional thoughts or concerns. A limitation across all focus groups was that minority opinions may have not been voiced or may have been overpowered by majority opinions.

As a single center study in an urban setting, it is possible that these findings may not be directly translatable to other institutions in different settings or with differing means of capacity for augmentation and triage. This study focused on ventilator allocation, which brings ethical issues into sharp relief for these reasons: 1) ventilator supply has sometimes been limited during disasters in the United States; 2) mechanical ventilation is a form of life support; 3) ventilators cannot be shared between patients; and 4) diverting ventilator support from one patient to another requires bedside clinicians to perform a ventilator withdrawal that could result in imminent death of a patient. Strategies may not translate directly to scarcity of other resources such as medications, blood products, or staff.

Conclusion

In conclusion, although clinicians valued having an a priori protocol for allocation of scarce resources in a disaster, significant moral ambiguity remained. This raises concerns about the performance of such a protocol in actual disasters, and highlights the need to include not only triage techniques but to also delineate the values served by protocols in disaster preparedness drills and training.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGMENTS:

The authors would like to thank the clinician participants in this study for sharing their time and insights.

FUNDING: No specific funding was used for this work.

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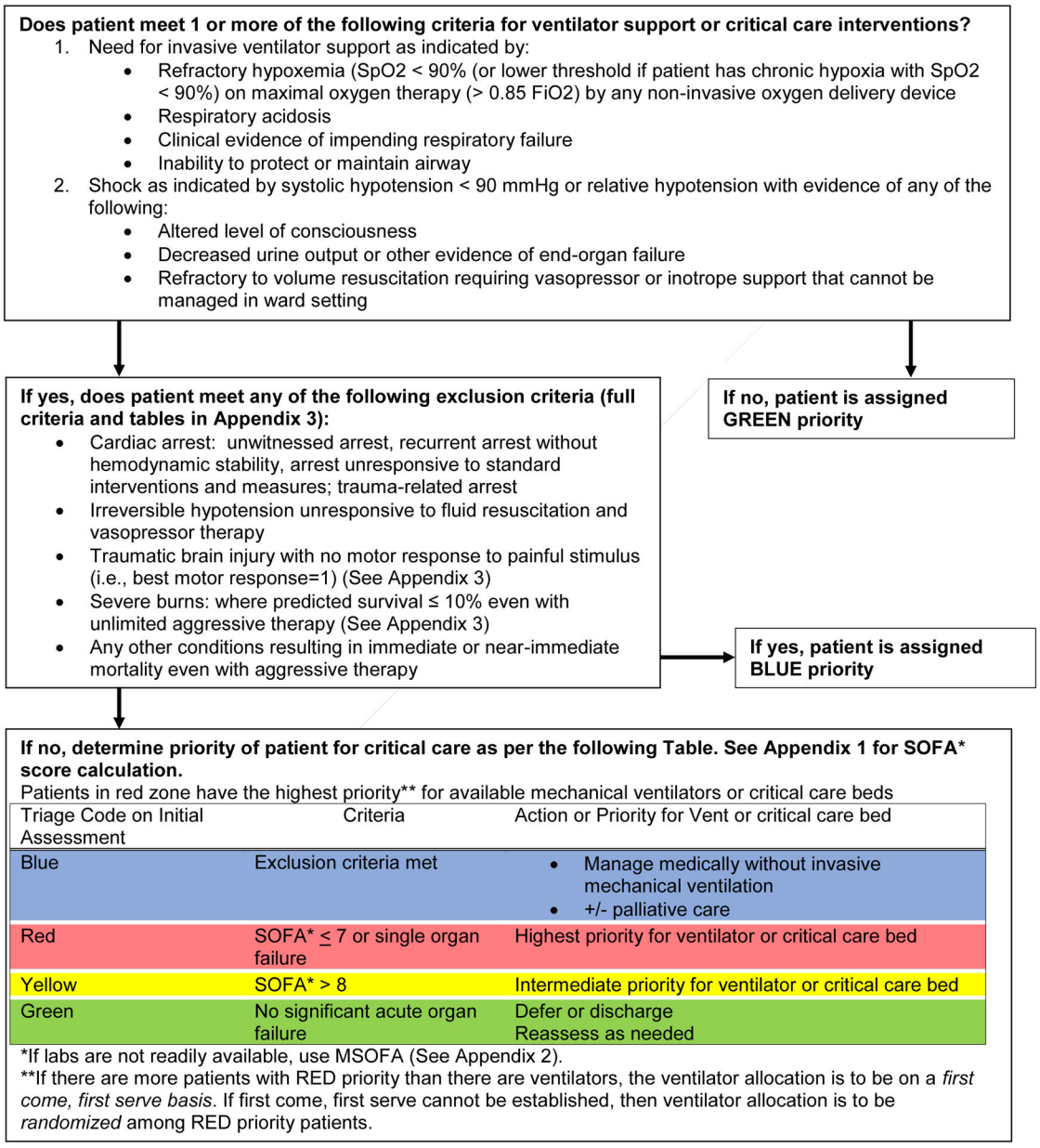

Figure 1:

Triage Prioritization Protocol on Initial Assessment by Triage Officer

Adapted from: Ventilator Allocation Guidelines. New York State Taskforce for Life and The Law. New York State Department of Health, 2015. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf

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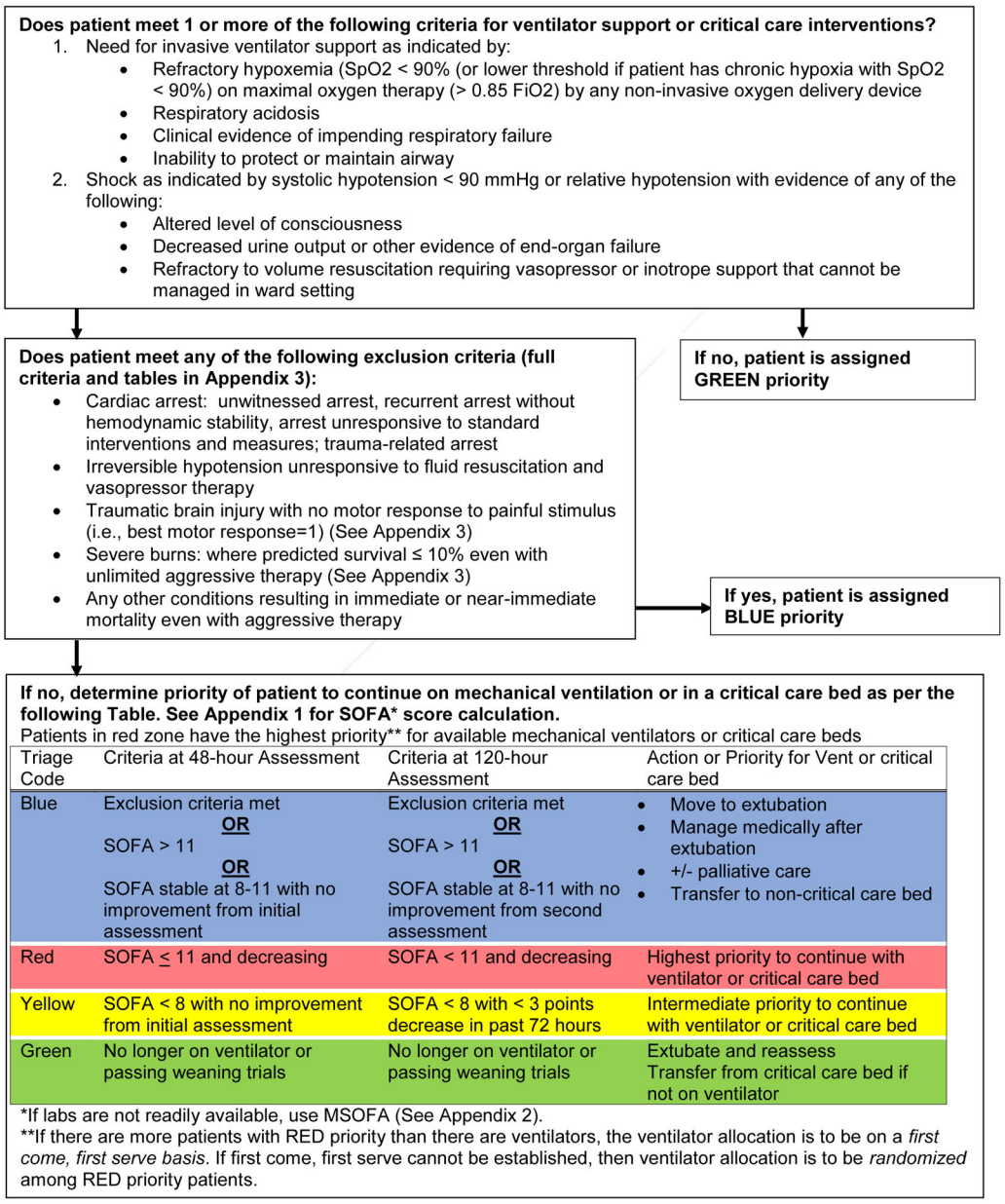

Figure 2:

Triage Prioritization Protocol on 48-hour, 120-hour, and each subsequent 48-hour Assessment beyond 120 hours by Triage Committee.

Adapted from: Ventilator Allocation Guidelines. New York State Taskforce for Life and The Law. New York State Department of Health, 2015. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf

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Table 1:

Summary of Phases I and II

Phase I	• Resources>demand • Ventilators and ability to manage ventilaors still exceed demand • State of emergency may or may not have been declared	• Focus is on augmentation of ventilator availability and ability to manage ventilators to meet demand • Triage officer (CCM consult or ED attending) triages similar to current procedures
Phase II	• Demand>resources • Public Health Emergency declared • Number of patients presenting with acute respiratory failure is or is anticipated to exceed current ability to provide ventilators	• Focus is on triage: i.e. intubation of patients who are likely to benefit from short term mechanical ventilation • Patients unlikely to benefit are not intubated • Trial of critical care and assessment of response critical care to determine benefit of continuing on ventilator