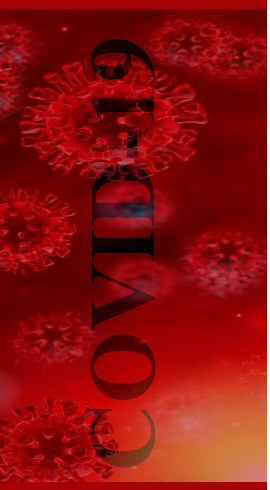
Volume 7
Number 2
April 2021

JOURNAL OF HOSPITAL ETHICS

THE JOHN J. LYNCH, MD CENTER FOR ETHICS



Features

In Practice

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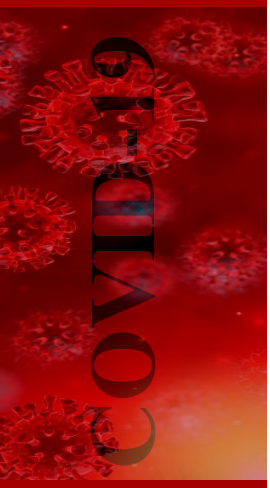

JoHE VOLUME 7, NUMBER 2

Rounding With the Editor

Features

In Practice

Hospital Ethics in an Era of Pandemic

Evan G. DeRenzo, PhD

Dear Readers,

Welcome to the *Journal of Hospital Ethics* (JoHE), Volume 7, Number 2. This is our special issue on COVID-19. For those of you who have been sick with COVID-19 or who have had a loved one who has been sick with COVID-19 (or worse, who have had more than one loved one sick with COVID-19), we hope you are well again. For those of you who have lingering symptoms, we wish you well soon. For those who have lost loved ones since our last JoHE issue, we grieve with you.

With all of the sickness and death this past year has brought, if there is anything we have learned at the Lynch Center for Ethics through this pandemic, it is how important family is for our patients. This is, of course, not a new lesson. But it is a lesson seared indelibly into our hearts and minds as a result of the visitation restrictions that the SARS-CoV-2 virus has required of hospitals and other health care organizations.

One can understand the reasons for these restrictive policies, and families have been tolerant, relatively speaking. Nonetheless, the restrictions have produced emotional burdens on top of unspeakable grief. Especially for our patients who have not been doing well, who have not turned the corner in the right direction, discussions with families about moving toward plans of care focused on comfort only have often been fraught with tensions and conflict.

Mishkin et al make this clear as they state, "…triage decisions are hospital-specific and the reasoning behind recommendations for patient care, and who makes those decisions, may be unclear to surrogates, who find themselves attempting to advocate for patients' wishes despite realistically having few, if any, options." These authors capture the pandemic's acutely heavy burden on surrogates as they note, "…Not only because of the plethora of sources of information, but because of rapidly changing medical knowledge during the pandemic, the sense of uncertainty that surrogates will have in trying to make decisions for their loved ones is heightened." Readers might pay close attention to the recommendations this article makes, especially related to communications with families of African and Afro-Caribbean descent.

At our own hospital, for example, we are acutely aware of the efforts our nurses and physicians make to provide our families with video visits so they can witness for themselves their loved one's decline. Unfortunately, such efforts have too frequently been insufficient to help families, friends and guardians appreciate how poorly a patient is doing and how the decline is not likely reversi-

ble. Death is terrible for everyone. We instinctively avoid, and often overtly fight, its overtaking the lives of our patients. When death comes to isolated hospitalized patients, the distance and separation can be overwhelming for family and friends.

This situation is repeated in hospitals across the country and around the globe. Our case by Cederquist et al makes this reality stark. In their case of Mrs. C, her cardiac arrest is secondary to her COVID-19 infection. For all intents and purposes, Mrs. C is dying, but by the initial interpretation of her hospital's restrictive visitation policy, she is not unstable enough to have her family come in and say their good-byes. The family is caught in the nightmare of not being able to come in and see her, so the process is protracted with added misery for family and medical care team.

Pre-pandemic, family and friends could sit with a dying patient. The closeness of others can bring comfort to the dying if that individual is awake and alert enough to appreciate others' presence. If not for the patient's sake, then at least the nearness is a comfort to the survivors, even when grief is overwhelming. The case of Mrs. C is only resolved because of compassionate communications.

With COVID-19, as with past plagues, protection of the unaffected means dying patients often die alone. My book club recently read Albert Camus's The Plague, copyright 1947. As the only member of the book club who works in a hospital, and who has worked physically in the hospital throughout the past year, the book's plot was eerily similar to present circumstances. The protagonist is a physician. The book follows him during his hospital rounds and watches him come to his scientific hunches much like we have watched the scientific understandings and uncertainties unfurl in COVID-19. Camus writes so beautifully and frightfully one has to frequently remind oneself that he is writing in 1947 not 2021.

Finally, another of the marked similarities between Camus's The Plague and the present are Camus's descriptions of the responses of the public to the pandemic. Such description of sheer panic, sometimes bravado that they will live through it unscathed, results in swings from portrayals of those who virtually barricade themselves in their homes to those who continue to walk the streets in a seemingly devil-may-care mood.

If you haven't read the book, I recommend it. If you read it years ago, reading it again now will amaze you. It is little wonder that Camus was one of the youngest Nobel Prize Winners in Literature.

Several of this issue's articles and one of the cases address organizational considerations presented by the pandemic. Nelson and Lahey raise an interesting thought about how best to support hospital leaders. When this article came in and underwent the initial, internal review, I realized that one never thinks about how to support leadership. It is always the other way around; the discussion is often about how leadership can support the clinicians. The paper's authors take a practical and implementable approach to how to support leadership. So often administration is a thankless task, in no small part because a hospital's clinicians always need more of this or that. Patient care needs rightfully take constant attention. But what are the needs of leadership? How best can they be met? And how may the need for leadership be expanded and strengthened during a pandemic? These are fascinating questions, some of which Nelson and Lahey answer themselves.

In terms of justice and allocation, we have seen many arguments arise in the literature as we gathered more information about the appropriate distribution of resources within hospitals and communities. Dunne et al offer a good deal of experience, which they employ in the development of a moral vaccine allocation algorithm, something well worth contemplating by our readers for their own hospitals. Comer, too, may provide insights our readers may usefully integrate into their own hospital's utilization strategies for Remdesivir.

Our own Christian Carrozzo's case analysis regarding the possible moral challenges in creating a specialized COVID-19 psychiatric unit, is also something many of us wouldn't ordinarily consider. This case illustrates in part the moral tension that can arise between the realization of a possible good for the organization (and thus impacting the services it provides), and the appropriate psychiatric care of an individual. If we are serious about addressing the ethics of mental health in a pandemic, it is important that we pay close attention to the organizational complexities COVID-19 poses for management of a psychiatric unit, where there exists an elevated challenge to keep patients at safe distances from each other and adhere to mask mandates.

Last among our organizationally focused pieces is my article with my colleagues from psychiatry and critical care. With a pandemic that has stretched hospital resources to the breaking point, now that we have learned that COVID-19-related delirium (not merely garden-variety delirium) puts patients at increased risk of intensive care unit admission and death, we suggest a slight addition to routine nursing assessments. It is just possible that delirium assessment performed earlier and more often than is presently standard of care might produce big pay offs for patients and hospitals.

Our last piece is the case about ECMO or extracorporeal mechanical oxygenation. When it needs to be turned off how best can that terrible moment be approached. ECMO is not new technology, although there still are only select medical centers that have the resources, including perhaps first and foremost the specialized and highly trained clinicians capable of competently using this technology. What is new, of course, is the application of ECMO to a patient population of COVID-19 positive patients. At the beginning of SARs-CoV-2, there was a cautiousness about use of ECMO for patient's whose lungs were ravaged by the disease. With experience, outcomes for COVID-19 positive patients has improved. For those COVID-19

positive patients for whom ECMO does not improve survival, however, the period during which the treating team realizes that ECMO should be turned off is an anguish for all involved. Clinicians who work in critical care areas (including clinical ethicists) see much death and know how difficult it is to die in a high tech hospital today. Under COVID-19 conditions, the misery is just unimaginable.

Today, there is an expanding group of clinical bioethicists coming together to attempt to produce a consensus statement on ethics guidelines for ECMO in the era of COVID-19. This group is beginning to congeal, loosely for the moment, within the Clinical Ethics Consultation Affinity Group (CECAG), one of the affinity groups of the American Society of Bioethics and Humanities (ASBH). Nobody is quite sure what processes this project is going to take. Can those who do not belong to ASBH join? Will it only include clinical ethicists and interested others in the United States, or ought the group be international? What sort of research will be required? What will be the range of societies, associations and colleges of various medical, nursing and respiratory therapy that will have to agree to produce a consensus with any authority?

These are just a few of the questions that will have to be hammered out before the substance, i.e., the deep dive, can begin. To be of sufficient merit to warrant the time and effort this project will take means that this will be a long slog. But it holds out the promise of importance and utility for clinical ethics and the application of ECMO technology.

The other promise at the end of Camus' The Plague, also on the horizon in the United States and world-wide, is the end of this scourge with the advent of vaccines. We are so close. And, in the meantime, we hope you find this special COVID-19 issue of JoHE useful, insightful, and challenging. We would love to hear your thoughts.

Sincerely,

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Organizational Ethics Support for Health Care Leaders During the COVID-19 Pandemic and Beyond

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Abstract

Organizational ethics programs can help senior health care leaders align an institution's decision-making to its stated mission and values. The optimal ways organizational ethics can and should support senior leaders, however, are evolving. To inform that conversation, we discuss how organizational ethics has supported senior leaders in two tertiary hospitals during institutional responses to the COVID-19 pandemic. This real-time process of organizational ethics program development has helped characterize the types of support organizational ethics can provide to senior leaders and has identified how organizational ethics can be embedded in leadership processes to ensure the recognition and management of ethical challenges in health care.

Introduction

Organizational ethics can be described as the organization's efforts to define its core values and mission and to embed both into a health care organization decision-making and practices. Organizational ethics programs thus can identify when critical values come into conflict and help resolve those tensions in fair, transparent, and consensus-driven ways. As a result, organizational ethics programs can help address ethical challenges that arise around institutional resource allocation amid scarcity, fair balance between patient needs and other institutional concerns, and thoughtful consideration of all stakeholders, including employees, in making decisions aligned to organizational mission and values. [1-3]

Despite the presence of clinical ethics committees in today's health care institutions, their focus tends to be on the resolution of bedside clinical conflicts and sometimes assistance with prevention of such issues via engagement in quality improvement projects.[4] This important work may not, however, address all institutional ethics needs, leading senior leaders to identify separate and hopefully complementary organization ethics resources.[5] These may arise from the clinical ethics program foundation [6] or arise entirely separately. Whatever the program's origins, the novelty of the role of organizational ethicists may lead to their underutilization or misutilization.

To help clarify the ways organizational ethicists can support leaders of health care organizations, we previously proposed a dashboard for organizational leaders which emphasized the need for effective organizational ethics resources and suggested some metrics that leaders can use to assess the ethical alignment of their organization and various organizational decisions and issues that could benefit.[7] The processes through which organizational ethics – a phrase we use here inclusively to indicate the work of organizational ethicists, organizational ethics programs and clinical ethicists providing organizational ethics support – helps achieve these goals in collaboration with senior leaders have not been fully explored in the ethics literature.

In 2020, health care institutions around the world have scrambled to provide safe, ethical, and financially feasible care amid the epidemic. Stressors have included the specter of few mechanical ventilators, limited hospital capacity and human resources, disrupted personal protective equipment (PPE) supply, testing and pharmaceutical shortages, and the need to balance patient, fami-

ly, and caregiver safety via visitation policies and employee health monitoring.

From crafting Crisis Standard of Care (CSC) guidelines for COVID-19 to providing guidance for the use of scarce personal protective equipment to supporting the formulation of visitation policies and beyond,[8] we show how organizational ethics resources can and have helped institutional leaders deliver on their mission and values during the COVID-19 pandemic. In this way our pandemic response can illuminate how organizational ethics resources can support leaders of health care organizations even in ordinary times.

How COVID-19 pandemic helped demonstrate the value of organizational ethics

As a team of ethicists and senior leaders of two New England tertiary care centers, in this article we illustrate how leaders can harness organizational ethics expertise to align organizational decision-making to mission and values. We summarize how the COVID-19 pandemic influenced our institutions and we depict how organizational ethics helped us make challenging decisions during the pandemic, from fair ventilator allocation, PPE equity, visitation policies, protecting resuscitation team safety in the event of PPE shortages, management of patient refusal of masks and testing, addressing staff moral distress and management of learners. (The contributions of organizational ethics to leadership management of these marquee issues in the COVID-19 epidemic is depicted on the next page in **Figure 1**.)

Central to our institutions' responses to each of these ethically challenging issues was the need to shift from a limited clinical ethics approach centered on individual patients to a broader focus on ethical decision-making across the entire system of health care delivery during a time of crisis. Beyond the specific issues with which organizational ethics supported senior leaders, in this paper the following concrete examples illustrate how organizational ethics supported senior leaders in hopes that enables future implementation of such systems of support even in ordinary times.

Fair, transparent and community response allocation of mechanical ventilators

Many states already had crisis standards of care on file to address shortages of mechanical ventilators and other medical resources during an influenza pandemic, or other public health crises, while others had none. For those that had crisis standards, they were often dusted off and revised during COVID-19, including in Vermont where one of our institutions are located. Key challenges of developing guidelines for insufficient mechanical ventilator supply include need to allocate limited resources fairly and transparently using pragmatic ranking systems that are usable and aligned to existing systems of bed allocation, the duty to insulate staff who are making such heartbreaking decisions from moral distress, and our desire to respond to valid concerns from the disability community as well as advocates for people of color who rightly feared such policies could perpetuate historical health care inequities.

Organizational ethics support for development of these guidelines illustrated key ways organizational ethics can support leaders of health care organizations in general. Examples include synthesizing the ethics literature regarding wise resource allocation, framing the plan-making process around values at play such as moral equity and fairness, solicitation of input from diverse stakeholders, and contributions to public messaging about guidelines including to state officials, reporters, and representatives of interested communities such as advocates for disability rights and people of color.

As an example of how organizational ethics supported senior leaders through the resource allocation policy development process, in both Vermont and New Hampshire, disability advocates were concerned that patients with congenital neurological impairments, cystic fibrosis and other preexisting medical conditions would be disproportionately disadvantaged by the guidelines. We engaged with advocates, incorporated language they suggested in evolving guidelines and reassured them with concrete factual information that their concerns were valid and more fully addressed in updated guidelines. This helped promote not only improvements to our institutional resource allocation guidelines but also, we hope, fostered more trusting relationships between the institution and the communities it serves.

Fair and equitable allocation of personal protective equipment (PPE)

As scientific data regarding optimal health care worker protection from COVID-19 evolved, there was natural variation in PPE usage. Some clinicians used PPE more aggressively without regard to the degree of exposure risk. Others were more targeted in their PPE use, choosing the most protective equipment only for high risk exposures. Nationwide PPE shortages then emerged, forcing the question not only of fair allocation of a scarce medical resource but also regarding how a single complex health care organization can assure fair access across potentially competing departments that typically have complete discretion regarding PPE utilization. This dynamic was complicated by disparate recommendations of national guidelines released by bodies representing different procedural fields. [9, 10] Infection control departments took the lead in such negotiations, providing scientific evidence for a unified approach to PPE utilization and conservation. Senior leadership nonetheless had to balance competing values such as departmental independence and wise network-wide utilization of a shared resource amid evolving

	Frame issues around organizational values	Synthesize ethics literature	Contact and negotiate with reluctant stakeholders	Write and promulgate policies	Support public messaging about organizational decisions making	Support staff wellbeing and resilience	Identify preventive measures for recurrent ethical tensions
Fair allocation of mechanical ventilators	X	X	X	X	X	X	X
Unified utilization of personal protective equipment	X	X	X	X			X
Policy restricting hospital visitation	X		X	X	X		
Balancing staff safety with obligation to provide care	X	X	X	X	X	X	X
Management of patient refusal of infection control measures	X		X	X	X		
Support for staff resilience amid COVID-19 related moral distress	X					X	X

Figure 1. The contribution of organizational ethics to leadership responses to the COVID-19 pandemic.

data. To support senior leadership, organizational ethics contributed by framing the dilemma at hand in terms of shared but potentially conflicting values, conducting outreach to departmental leaders with misgivings, helping frame communications about network-wide decision-making around values such as fairness, teamwork and encouraging the development of accountability systems based on PPE run rates in order to inform next steps in leadership oversight of policy implementation. The organizational ethics perspective thus helped inform conversations about when evidence was sufficient for safe reuse of N95 masks and use of procedure masks for lower risk procedures as part of institutional PPE conservation strategies. Consistent with the observation that organizational ethics thinking can ameliorate costly organizational conflicts,[11] the conversations that allowed implementation of network-wide policies regarding PPE utilization and conservation helped promote enhanced leadership connections across the network at a time in the formation of a relatively young network of hospitals when individual affiliate autonomy and sense of connection to the larger network were still being built.

Visitation policy development

Visitation of hospitalized patients by loved ones is crucial to recovery and to the concept of patient- and family-centered care. Visitation can also risk transmission of SARS-CoV-2 to employees and other patients. It complicates significantly the space engineering challenges inherent to waiting rooms, inpatient rooms with more than one bed, cafeterias and all social distancing and disinfection requirements; and as such visitation restrictions have been a major component of infection control and social distancing in health care institutions during the COVID-19 epidemic. The management of visitation restrictions amid COVID-19 as local epidemiology changed also made consistent communications a challenge, especially as inevitable edge cases arise. Should visitation restrictions be loosened for loved ones wanting to visit a dying patient or children or the birth of a child? Making exceptions on one hospital unit can risk perceptions of unfair application of rules on other units. Are any who call themselves health care workers considered visitors, e.g. interpreters, doulas, and clergy or should the hospital define who does and who does not qualify as a member of the health care team?

Organizational ethics can help define foundational principles that justify visitation restriction policies as well as exceptions to them. It has helped leaders of specific institutional units like labor and delivery and pediatrics develop fair and consistent local rules that can be explained elsewhere by an organizational ethicist conducting shuttlecock diplomacy. Organizational ethics can help reassure staff who feel guilty about denying visitation in a particular instance by helping them understand that such challenging decisions are justified by other potentially more preeminent values in the moment such as the protection of safety of other patients. Inevitably decision-making and institutional communications about visitation can identify breakdowns in the institutional system of accountability and in turn yield system improvements if pointed out by organizational ethics. For instance, if a given department is violating institutional visitation policies without coordination with senior leadership, organizational ethics can catalyze connections between departmental and organizational leadership that yield a shared resolution that in turn can lead to concrete improvements in institutional culture. This aligns to previous findings that organizational ethics involvement can support staff sense of institutional morals and likelihood of retention.[12, 13]

Balancing staff safety from COVID-19 with obligation to provide the standard of care

Health care workers experience elevated risk of COVID-19.[14] Naturally, then, staff safety can come

into tension with other values such as the provision of the standard of care.

There is no single solution to this balancing of values, and after developing generalizable guidelines, institutions can partner with employees to develop individually appropriate plans.[15] For instance, the infection control team can develop expectations of PPE that apply to everyone while human resources may work with older or immunocompromised staff who are at higher risk of developing severe COVID-19 to consider reassignment if desired.

Nowhere is the tension between staff safety and the standard of care as evident as in the moments before cardiopulmonary resuscitation. If adequate PPE are not available when the cardiopulmonary resuscitation team arrives at the door of a COVID-19 patient's room, should they risk their own safety to save a life or risk the patient's wellbeing while awaiting PPE? Grappling with this question – which has innumerable permutations from the conduct of elective procedures on COVID-19 patients to decisions to undertake high risk thoracic procedures on COVID-19 patients amid PPE shortages – can pit individual clinicians' sense of professional obligation against leadership's mandate to assure a safe workplace. If individual clinicians opt to resuscitate, others may feel coerced to do the same, thus making policy development influential on local team culture.

Organizational ethics can help identify the emerging literature regarding deferral of cardiopulmonary resuscitation in COVID-19 patients until adequate PPE are available, can help clinicians with different intuitive resolutions of the tension in values to reach consensus and can identify preventive approaches to avoid the ethical tension in the first place such as avoiding such harrowing decisions via creative investments in adequate PPE for all cardiopulmonary resuscitations.[16, 17] Ultimately, we guided clinicians to ensure adequate PPE were present to assure staff safety before attempting resuscitation in accordance with subsequently published national and international guidance. Fortunately, organizational ethicists were able to reassure clinicians that with adequate PPE available the risk of contracting COVID-19 was extremely low.

Management of patient refusal of masks and asymptomatic testing

Some patients or visitors will refuse to comply with hospital COVID-19 infection control policies, such as screening for symptoms and temperature, mask mandates, physical distancing rules and pre-procedural testing for COVID-19, which in turn can require caregivers to make potentially unaccustomed decisions about whether to discontinue care in order to enforce those rules vs. accept personal risk in order to deliver care.

These decisions involve similar ethical tensions as those regarding cardiopulmonary resuscitation with inadequate PPE but with a new overlay of patient duty to engage productively in their own health care. In addition, to justify mandatory testing, the benefits of mandatory testing must outweigh any downsides in terms of loss of patient autonomy or access to care, with that balance of risks and benefits highly dependent on the pretest probability that the COVID-19 test will be positive.[18] Here organizational ethics can help by framing the problem not only in terms of which institutional values are in tension but also outlining factors that influence this risk-benefit calculus and contributing to communications to community members about the new testing policy. This ultimately has an impact on the patient experience so is of relevance to the institution's chief experience officer as well, bringing the organizational ethicist into collaboration with a wide array of senior leaders.

Addressing staff moral distress

The provision of clinical care in extremely stressful circumstances under conditions of scarce resources can foster moral distress, a major contributor to health care worker burnout, depression, and potentially PTSD related moral injury.[19] The COVID-19 pandemic, therefore, is likely to be followed by a new epidemic of health care worker moral distress.[13, 20, 21, 22]

Organizational ethics can ameliorate the risk of moral distress amid the COVID-19 pandemic in two ways: (1) by ensuring the difficult moral decisions made by health care workers responding to COVID-19 are part of a coherent, transparent, palpable institutional moral culture that includes a defensible organizational ethics decision-making process [13] and (2) by supporting healing conversations with caregivers who have confronted such situations.[23, 24] For example, senior leaders and ethicists met with frontline clinicians responding in Vermont to a nursing home outbreak in part to ensure adequate provision of health care resources, reinforce the need to utilize surge team replacements, and importantly to provide a forum for discussion of emotional reactions to the experience and any moral misgivings that arose during the course of care. In New Hampshire, the group formed to develop crisis standards of care embedded written guidance within the standards regarding the need to address moral distress in the clinician workforce. Using the clinical ethics committee as subject matter experts to articulate the potential roots of moral distress that were anticipated, this group then used the consultative arm of their committee as a mechanism to detect, via rounding on inpatient units, any developing moral distress in the clinicians and intervene when necessary. The clinical ethics committee developed additional resources for the workforce including

information on how to access employee assistance, chaplaincy, and other clinician supports.

Balancing learner safety with their educational interests

The incorporation of learners in the clinical environment during the COVID-19 pandemic has been controversial.[25] In some cases, learners may be dispensable to the provision of clinical care yet have the potential to increase the bandwidth of an already overtaxed clinical workforce. Furthermore, learner safety might be endangered by participation in clinical care, particularly for patients with COVID-19.

In response, some hospitals excluded learners from the clinical environment in order to protect learner safety and conserve scarce PPE. Other institutions felt student participation in COVID-19 and other care were critical to future education regarding the sustainability of the health professions and included them despite downsides. Each institution may need to strike its own balance in collaboration with its educational affiliates in light of local epidemiology. In Vermont and New Hampshire, organizational ethics ameliorated the COVID-19 risk to learners and faculty by converting all large group preclinical learning from in-person to virtual, enforced strict mask-wearing policies for small group in-person learning, and included learners in the clinical environment only once PPE supplies were assured. Neither facility allowed medical students to participate in hands-on care of patients with COVID-19. In both New Hampshire and Vermont, senior leaders appreciated the opportunity to address a surge in COVID-19 cases with expanded clinical bandwidth accomplished in a fashion that was nonetheless safe for learners and appropriate to their level of training.

The issues addressed in relation to balancing learner safety with educational and clinical needs included ensuring that learners such as residents who remained on clinical duty always practiced within the scope of their license, asking medical students who were relieved from ordinary clinical duties to volunteer in other contexts that were appropriate to their level of skill while still educational.

Beyond COVID-19: Toward durable organizational ethics support for senior leaders

Organizational ethics requires adequate institutional support in order to support senior leaders in the fashions outlined above. This institutional support can take many forms depending on the structure of the organizational ethics team and its reporting relationships to senior leaders. Whatever the local approach, key components of adequate organizational ethics support pertain. These have been partly identified and clarified by our organizations during the COVID-19 response.

People working in organizational ethics need adequate protected time to join meetings, draft policy statements, and meet with stakeholders. The amount of protected time required for that work likely varies substantially from organization to organization and may change in response to evolving engagement of organizational ethics expertise. For instance, some organizations may employ a solo organizational ethicist who joins senior leadership meetings, others may form organizational ethics committees that are either integrated with clinical ethics committees or separate from them.[5,6,7] To ensure engagement with senior leadership decisions organizational ethicists should report to specified senior leaders such as the chief medical officer or chief executive officer and have key accountabilities such as policy ownership, committee oversight, or success metrics that are reviewed regularly.

Incorporation into leadership processes is also needed to assure organizational ethics has the opportunity to engage issues with ethical ramifications whether or not senior leaders identify those ramifications up front. People doing organizational ethics work can be consulted on an as needed basis to engage some leadership decisions while other meetings (such as COVID-19 incident command groups) likely benefit from standing ethics expertise. We recently clarified how organizational ethics programs can grow from programs that formerly focused solely on clinical ethics[6, 26] and which organizational issues may benefit from organizational ethics involvement.[7]

In Vermont, we embedded an organizational ethicist in our COVID-19 operational organizational response and in both states clinical and organizational ethicists participated in subgroup meetings focused on Crisis Standards of Care development. In both settings, organizational ethics had a fundamental impact, helping to readily anchor the conversation in explicit discussion of how to balance the good of individual patients with the good of the whole population during a pandemic. Having organizational ethics present to name and reaffirm the balance of fundamental ethical values complemented input from clinicians and operational subject matter experts in conversations about crisis standards of care, PPE use, visitation and testing policies and beyond and helped bring clarity and supported quick, reliable and coherent decision-making. Organizational ethics thus served as our "true north" and helped alleviate staff moral distress about difficult decisions that had to be made very rapidly during the institution's COVID-19 response.

To be effective at supporting senior leaders, people doing organizational ethics work may require training outside of typical clinical ethics expertise including in health care financing, health care delivery science, population-wide communications and familiarity with how

health care is delivered beyond what most clinical ethicists may be familiar with from direct clinical ethics consultation. This training can be obtained with mentorship from senior leaders as well as through complementary roles held by the same individual, such as the practicing clinician leader who is also a health care ethicist. Graduate level training in health care delivery science also can enable the acquisition of such skills. [27]

Conclusion

Organizational ethics can support senior health care leaders in the alignment of institutional decision-making to organizational ethical values. Organizational ethics support for senior leaders during the COVID-19 pandemic has helped encode and integrate the types of support organizational ethics can provide to senior leaders as well as how organizational ethics can be positioned to provide that support most effectively.

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Ethical Distribution of COVID-19 Vaccines to Health Care Workers: One Hospital System's Attempt at a Moral Allocation Algorithm

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Abstract

Early in the coronavirus disease 2019 (COVID-19) pandemic, guidelines providing initial recommendations for ethical distribution of COVID-19 vaccines were released for public use before vaccines were available. Almost all these initial guidelines placed high-risk health workers in the first tier of distributions. But as the COVID-19 vaccines inched closer to distribution, it became increasingly clear that there would not be enough vaccines for all high-risk health workers in the initial distributions – raising the question of how health care systems should tier and distribute scarce vaccines to their high-risk health workers specifically. This article overviews our Health System's efforts to appropriately identify and stage our health care workers at highest risk of COVID-19 in order to provide an ethically justifiable allocation process for vaccines until they were no longer scarce. Our allocation algorithm aimed to capitalize on the data we already possessed, avoid violations of employee privacy or confidentiality, remain objective and unbiased, and be automatable. Moreover, our allocation algorithm importantly reflected Centers for Disease Control and Prevention (CDC) guidelines to include Social Vulnerability Indexing factors by including some personal features of our health care workers – such as gender, race-ethnicity, age, and postal code.

Introduction

Early in the coronavirus disease 2019 (COVID-19) pandemic, the National Academies of Sciences, Engineering, and Mathematics' (NASEM) "Framework for Equitable Allocation of COVID-19 Vaccine" provided initial guidance for distributing COVID-19 vaccines once they were released for public use.[1] Their proposed framework involved a phased distribution hierarchy with high-risk health workers and first responders receiving Phase 1a distributions, and people of all ages with comorbid and underlying conditions that put them at significantly higher risk and older adults living in congregate or overcrowded settings receiving Phase 1b distributions. Our best predictions, however, suggested that initial distributions of COVID-19 vaccines would be so scarce that large health systems would likely be unable to vaccinate all their high-risk health workers and first responders with initial allotments. This short piece addresses our system's efforts to operationalize and further specify the NASEM framework in order to best identify those health care workers at highest risk of COVID-19 infection and provide an ethically justifiable distribution process of vaccines until they are no longer scarce.

Our health system is a six-hospital health care system in the greater Detroit metropolitan areas employing over 33,000 persons and serving a diverse population in inner-city, suburban, and rural areas.

Threats and Vulnerabilities

Our Vaccine Allocation Committee (VAC) was comprised of clinicians, ethicists, operational leaders, epidemiologists, and others from our health care system who met diligently for several weeks in order to carefully develop a vaccine allocation program for our employees. With a focus on safety, quality, and high reliability, we were committed to protecting those at the highest risk for exposure and those who were most vulnerable to the effects of COVID-19. The central aim was to develop an allocation algorithm for ethically distributing scarce COVID-19 vaccines as soon as they were received by our health system. We agreed that the formula should sort individuals in an evidence-based, just, and fair way. Our hope was to create a formula that was automatable, able to capitalize on the data we already had (i.e., avoided surveying), avoided any possible violations of employee privacy or confidentiality (e.g., did not include

sensitive data on employee health comorbidities) and was as objective and unbiased (i.e., removed as many subjective factors) as possible.

Building upon the guidance of NASEM, our VAC decided to create a staged distribution hierarchy for scarce vaccine allocation. To appropriately stage our employees, the proposed algorithm considered the threats that an employee faced - understood as the factors that impacted the likelihood of exposure - in addition to the vulnerabilities that an employee faced - understood as the factors that increased the likelihood of illness due to exposure. While the initial identified threats included location of job and time spent at job, the VAC decided to not to utilize time spent at job because of the difficulties and ambiguities associated with this category. For example, it is not clear how we would unambiguously assign different values to the average number of employee hours worked per week, such data does not tell us anything about whether the employee works from home, is in our buildings, or is bedside with patients, and average number of employee hours does not necessarily increase the likelihood of exposure for employees already working in places of increased likelihood of exposure.

The VAC expanded the location of job category to include those places where the threat of COVID-19 exposure was the highest as well as those procedures that most threatened exposure to COVID-19. These locations and procedures were selected based on CDC data indicating that certain locations and procedures present a greater likelihood of exposure.[2] In particular, the VAC identified those places where aerosol generating procedures (AGP) take place and the personnel who perform AGPs as the most threatened given that COVID spreads primarily through respiratory droplets or small particles, such as those in aerosols, produced when an infected person coughs, sneezes, sings, talks, or breathes.[3] Stage 1 distributions of vaccines, for example, were limited to the pool of inpatient employees belonging to cost centers that captured the places where AGPs take place (e.g., emergency departments and intensive care unit) and the personnel who perform AGPs (e.g., respiratory therapists, physicians, and nurses). These cost centers were vetted and selected by VAC team members from human resources and quality from our corporate suite to ensure that no relevant groups were excluded.

The personal vulnerabilities identified were gender, race-ethnicity, age, and postal code based on CDC documentation. Gender was identified as a factor that increases the likelihood of illness when exposed given CDC data indicating that men who contract COVID are more likely to die than women.[4] Accordingly, the VAC decided that a male gender should be given more weight than a female gender in the algorithm. Similarly, race-ethnicity was also identified as a vulnerability given CDC data indicating that certain race-ethnicity groups faced higher risks of hospitalizations and death when compared to White, non-Hispanic persons.[5] Blacks and Hispanic/Latinos – but not Asians, who were weighted the same as Caucasians – were given more weight than their Caucasian counterparts in the algorithm. Age was also identified as a vulnerability given CDC data indicating that older individuals faced much higher risks of hospitalization and death than younger individuals.[6] Thus, the older the individual, the more corresponding weight they were given in our algorithm as well. The category of age carried the highest numerical weights in our formula since age was determined to be the greatest personal risk indicator for those dying from COVID-19.

The VAC also included postal code as a relevant vulnerability to serve as a proxy for capturing social determinants of health.[7] Food, transportation, and housing insecurities are key examples of social determinants of health that studies have suggested account for some 80% of a person's whole health and wellness.[8] In order to incorporate social determinants of health vulnerabilities into our COVID-19 vaccine allocation algorithm, our VAC looked to the CDC's Social Vulnerability Index (SVI).[9] The SVI, which is updated every year, uses 15 variables from the census to grant a value between 1 and 0 (where 1 signifies the most vulnerable) to four domains of vulnerability: (1) Socioeconomic Status; (2) Housing Composition and Disability; (3) Minority Status and Language; and (4) Housing and Transportation. These rankings are originally applied to census tracts – a unit of geography too discrete for operationalization – which required us to crosswalk and convert into United States Postal Service zip and Canadian postal codes. Employees who live in a zip/postal code in the 95th or higher percentile of social vulnerability were classified as "socially vulnerable," and weighted accordingly, based on a regression model conducted by members from our system's Analytics team. Also, it is also worth noting that the SVI draws on the same data source as Health Resources and Services Administration's Area Deprivation Index, and was tailor-made to discrete census tracts, while the Area Deprivation Index aims at the broader county level. Our system's Analytics and Population Health teams collaborated to incorporate SVI rankings at the zip code level into Population Health's risk stratification and predictive analytics tool.

Because our system employees come from all over southeastern Michigan and Canada, the VAC sought to uncover the most socially vulnerable postal codes in adjacent Canadian locations as well as in Wayne, Jackson, Macomb, Monroe, Washtenaw, and St. Clair counties. Forty-three postal codes in southeastern Michigan

and three in Canada were ultimately demarcated as socially vulnerable postal codes that were given extra weight in the algorithm when compared to other, less socially vulnerable postal codes. Finally, the VAC initially decided that an employee with a confirmed COVID+ test on record would be excluded from the algorithm given the likely presence of relevant COVID-19 antibodies per initial CDC recommendations.[10] The group agreed that it would be morally appropriate to offer them a COVID-19 vaccine once scarcity was no longer an issue.

Risk Points Overview

Our system's Analytics team assigned a stratification of Risk Points per vulnerability category based on the relative weights (coefficients) from the logistic regression model. The model was developed using previous COVID-19 encounter data (patients with COVID-19 tests) gathered during the COVID-19 pandemic, i.e., the age, race-ethnicity, gender, and health outcome for COVID-19+ individuals within our system. Health outcomes were demarcated with a binary flag as either hospitalized/intubated/admitted to an intensive care unit or else deceased. Some categories, such as race-ethnicity, also incorporated national data when our internal data was insufficient, and we added postal codes to help approximate SVI as well. The stratification of Risk Points per vulnerability was as follows (max 22 points.):

Age: 18-29 (0); 30-39 (3); 40-49 (5); 50-64 (9); and 65+ (16) years old

Gender: Female (0) and Male (2)

Race-Ethnicity: Other (0); Non-Hispanic Asian/ Pacific Islander (1); Non-Hispanic White (1); Hispanic/ Latino (2); and Black (3)

Postal Code: Not from 43 Socially Vulnerable United States Zip Codes or 3 Socially Vulnerable Canadian Postal Codes (0); and Yes (1)

Risk Index = RPAge + RPGender + RPRace-Ethnicity + RPPostal Code

Statistical Modeling for Creating Risk Index Formula: *Subjects*

Demographic data from 17,490 patients were included in this study. Data were collected using Epic electronic medical records (Epic Systems Corporation, Verona, WI) in a custom table designed for patients with COVID-19 tests from March 1, 2020 through October 31, 2020. The average age of patients included in this study was 52.76 years old. Patients under 18 years old were excluded from this study. 55% of patients identified as female while 45% identified as male. The race-ethnicity distributions for non-Hispanic White, Black, Hispanic/Latino, non-Hispanic Asian/Pacific Islander, and Other/Unknown were 45%, 38%, 4.2%, 2%, and 11%, respectively.

Outcome

To establish a clear outcome variable, our Analytics team created a binary flag for COVID-19 related health outcomes as noted above where '1' meant the patient had the outcome, while '0' meant the patient did not have the outcome. The COVID-19 outcome was defined as one of the following: ED admission, hospitalization, intensive care unit admission, ventilator use, or death. Their data contained 5155 (29%) records of the COVID-19 outcomes.

Statistical Analysis

To develop the index, our Analytics team split their data into a training and test group. The training data contained 75% of the data while the remaining 25% was left for validation given that validation sets are typically set somewhere between 10% and 33% of the data. The training data were used to develop a logistic regression model with negative COVID-19 outcomes as the dependent variable and all other demographics as the independent variables. After validating the training model, the final points were assigned using all available data. (The stratification of each demographic variable can be found in **Table 1 on page 68.**)

To determine the number of points each level should be assigned, each coefficient was divided by the lowest coefficient in the model and rounded to the nearest integer.[11] For example, a male gender had a coefficient of 0.32 and the lowest coefficient of 0.15 was assigned to a non-Hispanic White race-ethnicity. By dividing 0.32/0.15, we get 2.133, which rounds off to 2, resulting in a final point allocation of 2 for a male gender. (**Table 2 on page 69** shows each coefficient and the resultant points assigned to them.)

Although the analysis performed by our Analytics team did not show statistically significant results for the non-Hispanic Asian/Pacific Islander race-ethnicity, they were nevertheless comfortable referencing CDC data to assign a single point (based on the coefficient 0.17) to this group.

Performance

To assess performance, the model built using training data was assigned to the test set and a confusion matrix was generated. The area under the curve of the model on their test set was 0.7211. The sensitivity was 0.3756 and specificity was 0.8525. The confusion matrix for this model – along with other relevant performance

metrics – can be found in **Table 3 on page 70.)**

Overall, the performance seemed reasonable given the limited data points available and how well it aligned with the values reported by the CDC.

TABLE 1: Descriptive Statistics

Vulnerability Categories	N	N (%) (N = 17,490)
Age Group	17,490	
18-29		2,389 (14%)
30-39		2,403 (14%)
40-49		2,458 (14%)
50-64		4,713 (27%)
> 65		5,527 (32%)
Gender	17,490	
Female		9,682 (55%)
Male		7,808 (45%)
Race/Ethnicity	17,490	
Other/Unknown		1,940 (11%)
Asian/Pacific Islander		352 (2.0%)
Hispanic/Latino		730 (4.2%)
Black		6,563 (38%)
White		7,905 (45%)
Zip hotspot	17,490	5,258 (30%)
COVID-19 outcome: Yes	17,490	5,155 (29%)

Distribution Stages

The four stages of distributions for our system employees were as follows:

Stage 1: Inpatient employees belonging to cost centers that captured both the places where AGPs take place and the personnel who perform them, e.g., critical care attending physicians, ED staff, most fellows and residents, respiratory therapy, intensive care unit staff, catheterization laboratory, etc.

Stage 2: All other inpatient hospital employees not otherwise immunized, e.g., physical and occupational therapy, housekeeping, general medical units' staff, security, hospice, cancer care, ancillary services, etc.

Stage 3: Outpatient employees belonging to cost centers that captured both the places where AGPs take place and the personnel who perform them, e.g., walk-in and urgent care facilities, pulmonary rehabilitation, pediatrics, primary care clinics, etc.
Stage 4: All other inpatient/outpatient/off-site employees not otherwise immunized, e.g., billing, information technology, administrators, clinical documentation, etc.

TABLE 2: Model Coefficients

Characteristic	Coefficient	OR	95% CI	p-value	RP	Points[a]
Age Group						
18-29 (Ref)	—	—	—	—	—	0
30-39	0.51	1.67	1.38-1.99	<0.001	RP_1	3
40-49	0.78	2.18	1.83-2.61	<0.001	RP_2	5
50-64	1.37	3.94	3.35-4.59	<0.001	RP_3	9
> 65	2.4	11.02	9.46-12.87	<0.001	RP_4	16
Gender						
Female (Ref)	—	—	—	—	—	0
Male	0.32	1.38	1.28-1.47	<0.001	RP_5	2
Race-Ethnicity						
Other (Ref)	—	—	—	—	—	0
Asian/Pacific Islander	0.17	1.19	0.89-1.57	0.25	RP_6	1
White	0.15	1.16	1.02-1.33	0.02	RP_7	1
Hispanic/Latino	0.33	1.39	1.12-1.72	<0.001	RP_8	2
Black	0.48	1.62	1.42-1.85	<0.001	RP_9	3
Zip hotspot						
No (Ref)	—	—	—	—	—	0
Yes	0.2	1.22	1.12-1.33	<0.001	RP_{10}	1

The VAC agreed that all the above stages were subject to change and readjustment pending changes in circumstances or relevant facts. Also, in larger departments like environmental services or pharmacy where employees might perform their tasks in different locations, the VAC agreed that managers should be contacted to clarify employee roles and exposure to AGPs in order to more appropriately stratify them among the various stages of distribution. This implies that environmental services health care workers working in the ED, for example, would be boosted into stage 1 as opposed to their colleagues working in corporate office buildings who would remain in stage 2.

Allocation Process
All 33,000+ of our employees were initially de-identified and assigned a number by electronic human resources staff. Those employees with a confirmed COVID-19+ test on record were initially excluded from the pool based

TABLE 3: Confusion Matrix

	Reference/Observed Outcome	0	1
Predictive outcome	0	2647	773
	1	458	465

Accuracy	**0.717**
Sensitivity	0.376
Specificity	0.853
Positive predictive value	0.504
Negative predictive value	0.774
Prevalence	0.285
Area under the curve	0.721

upon expected antibody immunity from past infection. The team of electronic human resources staff then took the list of de-identified employees (already excluded COVID-19+ employees) and assigned each employee a personal risk index score (PRIS). As noted above, this score specifies each person according to their vulnerabilities using the formula, i.e., age, race-ethnicity, gender, and postal code.

The list of de-identified employees with a PRIS was further sorted according to hospital site (i.e., one of our system's six hospitals) and according to their threats (i.e., those cost centers corresponding to where AGPs take place and the personnel who perform them). At this point, every non-COVID-19+ employee had been sorted according to their hospital, properly staged according to their cost center, and ranked within their stage according to their PRIS. Depending on the number of vaccines received, the properly sorted, staged, and scored employees were then offered a vaccine – starting with those employees in stage 1 with the highest PRIS. Once hospital sites received an allotment of vaccines, their non-COVID-19+, stage 1 employees with the highest PRIS scores would be offered vaccines until they ran out. If there were more employees with identical PRIS scores in some stage than available vaccines, the VAC agreed that utilizing a randomizing lottery to determine who was eligible for available vaccines was fair.

For example, if a hospital had enough initial doses to vaccinate their stage 1 employees with a PRIS of 22 down through 11 but had more employees with a PRIS of 10 than available doses, a randomized lottery was recommended to ethically and fairly distribute those remaining doses to the remaining employees with a PRIS of 10. Those employees with a PRIS of 10 in this example who were unselected by the lottery would then be contacted first upon the next delivery of vaccines until the relevant stage was completed. This randomization tool was only expected to be needed, if ever, in the initial stages of the vaccine allocation process given that additional supplies of vaccines and multiple kinds of vaccines were expected in early 2021.

All employees – sorted according to hospital, staged, and given a PRIS – were then re-identified by electronic human resources staff and matched to their employee names. Electronic human resources staff then compiled an ordered list based on the re-identified data to send to Employee Health in order to contact individuals, offer them a vaccine, and begin the vaccine administration process. Importantly, this employee list contained names and contact information only without any further identifying information utilized in the algorithm process to protect employee's private information.

Employee Health then contacted those employees listed to them by HR in order to offer the vaccine, schedule an appointment, or document a declination. Any employee that initially declined but later wished to receive a vaccine had to contact Employee Health at a later date to check for availability and schedule an appointment to be vaccinated. Once Employee Health administered the vaccines to employees, they received a card with the day and time of their next appointment if their vaccine required 2 doses. This card could be used during the daily screening process as well if an employee acutely developed symptoms from vaccination. This card would allow them to continue working given that the development of acute, mild symptoms (e.g., headache, fatigue, low-grade fever, etc.) after vaccination was expected for at least a small portion of employees. Like most health care systems, our system

had health screening protocols that all employees had to pass through, including temperature checks and questions about COVID-19 exposure and symptom history prior to entering the facility.

At first glance, this process may seem quite daunting or complex, but it was surprisingly accomplished rather quickly using the powers of data processing and the ingenuity of our Analytics team. Incidentally, most of our committee time was spent determining the morally relevant sorting features, the appropriate steps in the allocation process, and proper staging. The actual work of sorting employees and obtaining the relevant data was the fastest step of the whole process.

A Major Challenge

One of the most significant challenges we faced was discovering exactly where certain employees work in our attempt to appropriately identify AGP staff for stage 1. Perhaps surprisingly, this was most challenging with respect to providers (physicians, physician assistants, and advance practice providers). As noted above, most cost centers were initially used to quickly and easily identify large groups such as respiratory therapy and nursing. This seemed like the best method for these employees, but we soon found out that this method failed to capture all the relevant AGP staff. The seemingly simple process of identification was complicated, for example, by staff that worked in two different settings, full-time staff in non-clinical settings, and bedside staff that were otherwise part-time or contingent. Moreover, other employee situations presented further sorting difficulties such as an employee from quality (e.g., infection control) who sometimes worked in the ED or a physician who would sometimes round on patients in the ED but was categorized under an administration cost center.

The shortcomings of our initial identification process were most evident with respect to providers. As an alternative, we looked at better capturing them in our algorithm by looking at board certification, privileges, and other cost centers, but these approaches proved similarly problematic. The difficulty in trying to appropriately identify AGP physicians was only present for some physician groups and not others, e.g., identifying anesthesiologists was easy but identifying intensivists proved more challenging. In the end, we had to look at each provider individually within those physician groups that proved difficult to appropriately identify and manually sort them into their proper stage. Thankfully, the medical staff offices ended up sorting through their physician groups over a weekend before we received our first doses of vaccines. To help ameliorate this and related issues in the future, some members of the VAC suggested that, institutionally, we could add a location code to existing position numbers or job descriptions that might help to better define employee placement that may be unclear from their cost center.

Conclusion

Though we faced a few surmountable complications along the way, we believe that our efforts at operationalizing and further specifying the NASEM framework in order to best identify those health care workers at highest risk of COVID-19 infection and provide an ethically justifiable distribution process for vaccines was workable and successful. In general, we believe that this was a positive step forward for seriously considering the social determinants and personal determinates of health in an ethical way. Part of our hope is that this piece will inspire further inclusion of these determinants in future scare resource allocation frameworks.

AUTHORS

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Increased Ethical Burden in Surrogate Decision-Making During COVID-19

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Abstract

Surrogate decision makers are called upon to inform medical teams what unconscious and decisionally incapacitated patients would have wanted for themselves. This task poses significant challenges for surrogates as they struggle to determine what the patient they represent would have wanted, which often takes a physical and emotional toll on the surrogate. Surrogates commonly voice hesitancy regarding withholding or withdrawing treatments, leading to the provision of potentially non-beneficial treatments, driving up costs both to the system and to the family, prolonging the dying process, and increasing distress for the family and the medical team. These ethical issues have been highlighted and exacerbated by the contemporary COVID-19 pandemic. Here we explore the unique manifestations of ethical issues surrounding surrogate decision-making in the COVID-19 context, particularly focusing on how triage, communication, time course and isolation impact the ethics of surrogate decision-making.

Introduction

The 2020 COVID-19 pandemic has introduced, exposed, and exacerbated a variety of individual medical conditions and health care system issues. Medically, the greatest proximate cause of mortality from COVID-19 has been respiratory failure, including adult respiratory distress syndrome (ARDS), but COVID-19 has also contributed to other major health complications such as renal failure in adults and Kawasaki disease in children.[1-3] The pandemic has revealed many gaps in the health care system, including insufficient capacity for testing, ICU beds, ventilators, dialysis machines, and expertly trained staff in key areas such as respiratory therapy.[1, 3, 4] In this analysis we explore how surrogate decision making is not only more difficult and stressful during this time, but in what ways the ethical challenges surrounding surrogate decision making have been heightened.

When patients are unconscious or otherwise decisionally incapacitated, the medical system calls on health care agents to serve as medical decision makers. These health care agents can be identified via health care proxies, health care power of attorneys, by the next of kin available at the hospital, and in some states by an algorithm.[5] For the purpose of this analysis we will refer to all of these decision makers as surrogates. Clinical, practical, and ethical challenges facing surrogates have been well studied. It is known that surrogates experience high psychological distress during decision making, and for some this experience triggers chronic anxiety and depression.[6-10] Studies have found that surrogate decisions often do not reflect the patient's values and preferences, and in situations in which patients later recover capacity, surrogate-patient concordance is low: sometimes no better than chance.[6, 10-15] Possible reasons for this include inadequate communication from the medical team about the range of medical options and insufficient exploration of the patient's values before the patient became incapacitated. Outcomes have included declining treatment the patient would have wanted, overtreatment, prolonging the dying process, and contributing to the high cost of medical care at the end of life, which can in turn negatively affect both the family of the patient and the health care system.[6, 10]

Limited Commodities

Patient choices are limited by the general availability of treatments, what each particular hospital can offer, and insurance coverage. This is not a new issue: transplant organs are a chronically limited commodity, quality acute inpatient physical rehabilitation is often difficult to access,[16] treatments still under study may only be available to those enrolling in research, and health care is limited by cost and insurance coverage.[17]

In the COVID-19 setting, personal protective equipment, medical personnel, medication, and equipment such as ventilators and dialysis machines have been in short supply.[18] This has required government bodies, hospital administrations, and medical staff to navigate optimal distribution of scarce commodities. General emergency triage literature recommends that during a disaster, a triage officer or team with an appropriate range of expertise should be assigned to make resource allocation decisions based on evolving evidence of who would benefit most from the particular intervention.[19] In reality, triage decisions are hospital-specific and the reasoning behind recommendations for patient care, and who makes those decisions, may be unclear to surrogates, who find themselves attempting to advocate for patients' wishes despite realistically having few, if any, options. Resource limitations and subsequent shifting hospital policies mean that in a pandemic, autonomy may not be prioritized (or perceived to be prioritized) in comparison to other goals, such as justice in allocation.[4] This is in significant contrast to the largely autonomy-driven prior experiences had by physicians, patients, and surrogates.

In some cases, rather than desiring greater autonomy, surrogates seek authoritative guidance from physicians during medical care.[20] Physicians should provide a comprehensive informed consent process to the surrogate, as would be expected if they were speaking to the patient themselves. Surrogates often seek advice from, and to share responsibility with, the medical team to reduce the burden and potential trauma of making decisions alone. Surrogates fear the responsibility and the risk of making a moral error if they make the "wrong" decision or if the patient does not survive.[21] Surrogates report appreciating reassurance and validation from clinicians about their decisions, and state that the physician agreeing with their decision helps them continue with their own lives afterwards.[6] Surrogates hoping for greater direction may also experience more stress during the pandemic because of the ambiguity of the information on which to base decisions. In the pandemic, information is particularly uncertain, and rapidly changing. Even the case fatality rate changes frequently.[1, 22] The amplitude of uncertainty and the speed of change of data exacerbate all of the baseline difficulties surrogates face when there is medical uncertainty.

Communication

Communication and Medical Uncertainty

Medical uncertainty always poses a challenge when communicating options and prognosis to patients and surrogates. Studies of physician communication about uncertain outcomes in critical illness have found that physicians fully inform patients about the uncertainty of outcomes only 16-18% of the time.[23] The known percentage risk of a particular procedure or treatment is much easier for physicians to understand and communicate effectively to patients and surrogate decision-makers.[24] Most people, including physicians and even statisticians, have limited ability to mentally turn these percentages into truly meaningful qualitative information.[24, 25] Therefore, both for the patient and for the well-being of the surrogate themselves, it is important for physicians to communicate complete information as efficiently and unambiguously as possible, including information about uncertainty.

A unique aspect of pandemic care is the degree and modality of media coverage of new and unfolding medical data, including incorrect or sensationalized reports.[26, 27] Sources of poor communication and misinformation from the media about the COVID-19 pandemic include genuinely confusing medical information, conspiracy theories, scams and fraud designed to scare citizens into purchasing protective gear or insurance, cyber-scams designed to infiltrate computers, both domestic and international political agendas, celebrities speaking out with opinions outside of their knowledge base, and even mistaken satirical news sites.[28, 29] The United Nations and World Health Organization have actively fought what they are terming an "infodemic," because of misinformation spreading faster than the truth.[29] This is deleterious for everyone watching the news: a meta-analysis of 14 studies and over 5,000 subjects found that short-term trauma-related anxiety predicted long-term psychiatric and medical issues, including decreased life expectancy.[30] We can therefore not rule out the possibility that this type of media information is damaging to viewers chronically. Information overload contributes to the stresses of medical decision-making for patients and surrogates, and incorrect information can obviously lead a patient or surrogate to make a different decision from the one they would otherwise have made. The infodemic may also be eroding trust between the public and physicians, as people often receive information from non-medical sources first, which may contradict what they are later told by medical personnel.

Not only because of the plethora of sources of information, but because of rapidly changing medical knowledge during the pandemic, the sense of uncertainty that surrogates will have in trying to make decisions for their loved ones is heightened. Providers are chal-

llenged to balance providing the known medical data, honestly communicating the degree of uncertainty around that data, and ultimately making a recommendation in spite of these ambiguities. This is in addition to the general challenges of communication, targeting information to the listener's educational level, medical literacy, preferences and goals. This can often lead to providers communicating the most possible number of details and avoiding a clear clinical recommendation. The significant need for clinicians to be prepared to have these difficult conversations also requires that the system allow for time to think, read and process – time many providers cannot set aside during a pandemic without directed administrative support. We recommend that hospitals and clinics support providers in this way and invest in having those who specialize in communication work with high-acuity first-line providers to support them in efficiently reaching a plan of how to communicate uncertainty. Extra resources and time during a pandemic may feel impossible to allocate, but are nevertheless critical.

Communication and Scarce Resources

The narrowing of choices due to scarce or threatened resources and the need to triage is another ethical challenge. Although there are protocols for making triage decisions, what is lacking are evidence-based practices for how to communicate choices to families, or how to engage a surrogate when there is no real choice to make. A non-profit organization called Vital Talk has created a guide for communicating common concepts in the COVID-19, but there is no wide-spread, evidence -based, or formally adopted system of communication for this situation.[31] If the patient is in respiratory failure, and does not meet triage criteria for intubation, implying to a surrogate that there is a choice to be made is unethical. Contacting family to inform them that their loved one is deteriorating is vital, but there may be a tension between complete transparency (that, for example, the patient has such a low possibility of recovery that a ventilator cannot be allocated to them) and avoiding doing harm to the family by informing them of this in excessive detail. The chronic tension between wanting to offer the surrogate options and not being able to offer care that is not available or will not benefit the patient, is significantly heightened in the pandemic by the public health interest of fair and appropriate resource distribution.

These conversations are even harder and more complex when the limited commodity is not concrete, such as an available ventilator, but instead, are resources like limited expert staffing or personal protective equipment. Some hospitals have run out of professional respiratory therapist hours before running out of equipment, and have thus needed to rely on less trained providers to care for patients without informing patients and families of this situation. This is complex in myriad ways, including for the providers themselves.[32] An ethical issue that specifically impacts surrogate decision-making is how and whether to disclose this information, especially if the surrogate specifically asks about the members of the medical team. There is again a need to balance the goal of honesty while avoiding causing excess psychological trauma to the family. This again will necessitate that conversations not be rushed, and that responses are truly thoughtful.

Communication in non-Dominant Languages

A final consideration about communication with surrogate decision-makers during the coronavirus epidemic is to remember the additional practical and ethical burdens on surrogates with Limited English Proficiency (LEP). Communication with patients who are not fluent in the dominant language is a known chronic determinant of inequality across medical settings.[33] In our clinical experience, the current pandemic has further complicated interpretation. Because currently surrogates, and sometimes interpreters, are largely not allowed at bedside, communication between doctors and surrogates is often exclusively by phone. Whether phone interpretation can ever fully replicate an in-person interpretation is unknown. Further, doctors' time to communicate with surrogates during the COVID-19 pandemic is even more limited than at baseline. In our clinical experience, discussions utilizing an interpreter require significant additional time. We are concerned that this combination of factors may result in decreased engagement in the lengthier conversations often required for critically ill patients and their surrogates. These limitations reduce total communication with the LEP population, and further exacerbate inequities in care.

Time Course

Coronavirus can lead to life threatening illness in previously healthy people in a matter of days.[34] Patients who were previously completely healthy - and who had never seriously considered their end-of-life preferences - can quickly become critically ill. One Wuhan study of over 800 patients found a mean of 12 days from first symptom to ICU admission.[35] Decisions about intubation may also happen rapidly, compounding the ethical concerns of surrogate decision-making in a number of ways.

A short time in which to make a decision has previously been cited as a major stressor for surrogates.[36] Although the hospital and legal systems encourage a single representative to act as the main decision-maker, in reality families do - and should - confer at length before making potentially end-of-life decisions. Family

members after a loss.[6] Because of social distancing and travel limitations, families cannot come together at the bedside – or sometimes even elsewhere in person - inhibiting group communication. Combined with often rapid clinical decompensation, ensuring that all involved loved ones have the opportunity to contribute to the plan is further compromised.[36] Decreased quality engagement with the family limits the opportunity to identify additional information about the patient's values and preferences that family members can offer, reducing the probability that the surrogate will have all the relevant data before using substituted judgment.

Surrogates who have had the opportunity to discuss end-of-life preferences with the patient before having to act as a surrogate reported this as a major protective factor for feeling comfortable with the decision.[6] Families are unlikely to have had conventional opportunities to consider the end-of-life preferences of patients who were young and healthy prior to COVID. A meta-analysis of 795,909 people across 150 studies found that only 37% had completed any kind of advance directive. People under 65 years old had only a 32% rate of having an advanced directive.[37] We therefore expect that the need to make a quick decision coupled with a reduced probability of having prepared for the need to do so will increase stress in surrogate decision-makers, and decrease their confidence that they are making the decision the patient would have made. Based on these data, we recommend introducing the topic of advanced care planning upon admission for patients with possible COVID-19, even for otherwise young and healthy patients, because of the possibility of a precipitous decline.

Distance

The need for physical distance between parties in decision-making discussions is one of the most unique and pervasive aspects of the current era. Because of attempts to reduce transmission of coronavirus, physicians are seeing patients less often or via teleconference, and meeting with their own teams by phone and videoconference. Although there are no definitive data about long-term tele-relationships between providers and patients, it is thought to be harder to form an initial therapeutic alliance, but to improve over time.[38] This is not especially helpful for situations of acute critical illness and regardless, all prior data involve providers who opted into using telehealth due to their own preferences, which is unlikely to represent the experiences of those suddenly forced into the use of telehealth to prevent disease transmission (author ADM is also researching the experiences of such providers).

Visitor restrictions in many hospitals have required that surrogates make decisions remotely. Having to make a decision from a distance has been cited as a factor that makes surrogate decision-making more difficult.[6] Via telephone, the surrogate is unable to see for himself how sick the patient looks or whether she appears to be deteriorating or improving. He may not be able to convince himself by phone whether the patient is being well taken care of. And most importantly, he may feel that the distance means he has no possibility of saying goodbye. Not being able to say goodbye when a family member is dying is distressing to relatives, and is associated with long-term depression and post-traumatic stress disorder.[39-41] Many families consider the opportunity to have a parting visit with their loved one to be an essential part of the process. It may be the case that for some surrogates, their strong motivation to visit the patient at least once would prevent them from agreeing to a do-not-resuscitate order, even if they believe it is the right decision, out of a hope that they will be able to have a final visit if they prolong the process.

Use of technology, creativity, and flexibility by providers and systems may mitigate this issue. A willingness of providers to take on the role of assisting with communication between patients and families has been a suggested act of humanity that can allow some families to experience closure.[42] We also suggest that although extreme caution and close preservation of personal protective equipment have been appropriate measures, that we must be careful not to project the necessity of all crisis-phase protocols such as restricting visitors indefinitely into the future. As we learn more about prevention, transmission, and treatment, hospital systems must evolve practices, such as carefully allowing bedside visits of limited family members when patients are unlikely to be discharged alive. It may also at times be appropriate to consider allowing cautious visitation of surrogate decision-makers in order to allow them to have a reasonable view of how the patient is faring prior to asking them to make potentially life and death decisions.

We also must remember that distance plays not only a role in the direct medical setting, but in the entire environment of the family and surrogate to whom a medical team is directing questions. Any social structure that would normally be part of the surrogate's own support system, such as her own work colleagues, church community, or other associations are likely to be less available due to social distancing practices. A known source of comfort to surrogates is the presence of religious support groups, which are now largely avoided to prevent the spread of disease.[6] To what degree such support can be given over the phone has not been determined.

Special Populations

Age and Life Stage

At least some patients affected by COVID-19 are significantly younger than the life expectancy in the United States. As of December 26, 2020, the CDC data show in the United States there have been over 18 million cases and 330,000 deaths. Very few deaths have been in children, and most deaths have been in seniors, but a significant number of deaths have taken place in previously healthy adults of working age.[22] The ethical aspects of considering age, life expectancy, and quality of life in medical decision-making have been thoroughly explored elsewhere.[43, 44] We see surrogate decision-making for young adult patients as also complicated by the current pandemic.

As described above, it is rare for younger healthy patients to have ever documented their end-of-life values or preferences.[37] Younger patients are also significantly more likely to be employed, and to have minor children. Families - including at times the surrogate decision-maker himself - may be financially or practically dependent on the patient. Financial stress has been reported as a barrier to efficient decision-making by surrogates.[6] In some cases, the patient may be the sole source of income and health insurance for the family, creating economic instability for the family in the case of the patient's death. This is especially concerning considering that other household members were likely exposed to the patient prior to their hospitalization, and the surrogate would be rightfully concerned that additional family members could become sick with COVID -19 and require hospitalization themselves. Surrogate decision-makers who are spouses, partners, or co-parents therefore could be motivated to prolong the patient's death from fear that if they lose their spouse's health benefits, they or their children may be left uninsured while ill. Although this is understandable and resources should be committed to help assist families through these situations, it is also concerning that the end result might be to prolong an uncomfortable dying process against what the patient would have wanted and against their interests.

In some of these cases, the surrogate decision-maker is also currently infected with COVID-19, has other medical problems, or has additional sick or dying family members. He or she may be taking on sole care of elderly or minor family members as a result of an identified illness. They may be either newly out of work, or have much increased work, depending on their occupations. Competing responsibilities and personal health problems have both been cited as sources of difficulty for surrogate decision-makers.[6] Given rising unemployment[45] and the high rates of infection of COVID-19, we anticipate these issues to be particularly common during the coronavirus pandemic, and that all of these sources of increased stress on surrogates will at times translate into decreased ability to exercise substituted judgment and best decision-making on behalf of the patient.

Race

In the United States, racially and ethnically based disparities in access to care have been well documented, including in end-of-life care.[46, 47] COVID-19 is known to have overall disproportionately affected people of color, particularly people of Latino and African descent.[48] A single-center Louisiana study found that of 1382 COVID-19+ patients who were hospitalized, 76.9% were black and 23.1% were white.[49] This discrepancy indicates that ethical and psychological issues related to surrogate decision-making during COVID-19 may be even more widespread in patients and surrogates of color.

Surrogate decision-making has been studied in different racial and ethnic groups prior to COVID-19. A study of 1447 surrogates across 22 states found that family members of African American decedents were less likely than those of white decedents to rate the care their loved ones received as excellent (OR 0.4) and were more likely to report that the physician communication was insufficient.[47] African American patients were also less likely to have documented end-of-life wishes.[47] Of patients surveyed about their desire to document end-of-life wishes, significantly fewer African American patients reported intention to document a living will.[50] Another study also found significantly more white patients had a durable power of attorney or a living will than African American patients.[15] African American patients are significantly more likely than white patients to desire life-sustaining or heroic treatments, regardless of whether they report trusting their physicians or the healthcare system.[15, 50] The underlying factors in these differences have not been elucidated, but differences in trust and religious differences have been explored as potential reasons.[50] As some have defined advanced directives as the presence of having a do-not-resuscitate order or other instructions for treatments the patient would not want, it would also make sense that some patients who do wish to be resuscitated would not see any value in completing an advanced directive.[51] This possibility makes it even more difficult to interpret the differences in rates of completing advanced directives, and to determine what racial and ethnic disparities may be linked to these differences.

Because of actual and perceived limitations of life-sustaining and heroic treatments during the COVID-19 pandemic–and because it has been considered to order do-not-resuscitate a standard or even mandatory order for COVID-19+ patients -- although no United States jurisdiction has actually done this to our knowledge – individuals who want all treatments continued indefinitely are less likely to have this value fully honored

than in non-crisis circumstances. Because the African American community has a greater number of people who do want resuscitation, this group is statistically at higher risk for having their end of life values violated.[4, 18] Therefore, surrogates of African American patients may be at further disadvantage in their attempts to extend the patient's autonomy, because of the poor alignment between what our triage system currently is prescribing and the values and preferences of this community. We recommend that physicians keep these stressors and cultural factors in mind when communicating with families of African and Afro-Caribbean descent. **The figure below is a summary of our recommendations:**

Recommendations for Physicians and Medical Teams
Physicians should provide a comprehensive informed consent process to the surrogate, as would be expected if they were speaking to the patient themselves
Physicians should communicate the most total information as efficiently as possible, including information about uncertainty, and ultimately make a recommendation in spite of these ambiguities
Providers should keep stressors and cultural factors in mind especially when communicating with families of African and Afro-Caribbean descent
A willingness of providers to take on the role of assisting with communication between patients and families has been a suggested act of humanity that can allow some families to experience closure
Recommendations for Hospitals and Medical Systems
The topic of advanced care planning should routinely be introduced upon admission for patients with possible COVID-19, even for otherwise young and healthy patients, because of the possibility of a precipitous decline
Professional interpretation should always be used for patients and surrogates with LEP, potentially through the use of remote video-conferencing
Hospitals and clinics should allow providers time to think, read, and process during this time to maximize their ability to provide excellent care
Hospitals and clinics should invest in communication specialists, including in-house palliative care and psychiatry teams, to work with first-line providers to help them efficiently reach a plan of how to communicate uncertainty

Conclusion

Due to precedented but severely exacerbated issues including limited commodities, challenges posed by medical uncertainty and communication, the need for speed, distance and isolation, and competing responsibilities, surrogate decision-making has been extremely difficult. Where we see the need for medical provider caution, and many potential ethical pitfalls, we also see opportunities for creativity, flexibility, and kindness if these issues are considered and included in our mission as thoughtful members of the health care system. By understanding the extra pressures put on surrogate decision-makers during these challenging times, clinicians and hospitals can begin to consider how to mitigate these extra stressors. While encouraging patients to talk to family members about values and preferences has always been important, we must now expand these discussions to all patients regardless of age or health status. We can also consider pandemic-specific factors such as isolation and speed, and how these stressors particularly impact surrogate decision-makers for patients of certain racial and ethnic groups. Finally, we encourage hospitals and clinic systems to provide the necessary time and support to enable clinician sensitivity during this difficult time.

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The Ethical Allocation of Remdesivir Within Hospitals

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Abstract

Recent evidence has shown that remdesivir may shorten length of hospital stay and recovery in COVID-19 patients.[1-3] Many hospitals are experiencing shortages of remdesivir and are being forced to determine systems for the ethical allocation of this drug. Ethical allocation of remdesivir is imperative for upholding principles of justice during public health crisis.[2] Currently, there is no consensus on the ethical distribution of remdesivir to patients within hospitals. This article discusses places of consensus, variance, and limitations of hospital level remdesivir allocation policies throughout the US during the COVID-19 pandemic.

Consensus in Allocating Remdesivir

Hospital policies and ethics literature has reached consensus that remdesivir requires allocation criteria as the potential for drug shortage could create a public health crisis.[4] The overarching structure of these policies includes ethical guiding principles, drug eligibility inclusion and exclusion criteria, and an allocation process. Guiding principles of ethical allocation has found consensus in not excluding patients based on characteristics such as age, disability, gender, race, and immigration status. Allocation criteria have reached consensus on inclusion criteria for patients who should be considered for remdesivir which is derived from the FDA Emergency Use Authorization (EUA) guidelines and includes clinical data such as laboratory confirmed COVID-19 test and oxygen saturation (SpO2) ≤94% on room air, requiring supplemental oxygen.[5]

Consensus in regard to an allocation process is that a first-come-first-serve process of allocation should not to be utilized and that some form of lottery should be used when the number of eligible patients exceeds remdesivir supply.

Variance in Allocating Remdesivir

The greatest variance in ethics policies allocating remdesivir is found in the exclusion criteria for the drug. Some policies did not outright exclude patients, while other policies excluded or reduced the priority of patients who are imminently and irreversibly dying or who are terminally ill with life expectancy under six months.[6-10] Other policies excluded pregnant patients and children as they could receive remdesivir through the compassionate use program.[7] An important variation in allocation policies was the way in which the lottery was structured. Some polices chose to use a weighted lottery, while other polices, such as the Veterans Affairs Hospitals chose to use a random lottery.[6-10] Within weighted lottery policies, variations were found in which patients received greater priority with some lotteries giving patients such as essential workers and disadvantaged populations priority.[7] Most policies chose to implement a random lottery as weighted lotteries which give patients priority based on life style may not be easily implemented and have the propensity to create complex ethical dilemmas which may result in judgements that some people have greater societal value.[6-10]

Limitations in Allocation of Remdesivir Policies

There are several major limitations in remdesivir allocation policies that need to be addressed. First, the EUA guidelines have created a sort of purgatory for pregnant patients.[11] Several hospitals use pregnancy in their exclusion criteria because these women were able to use the compassionate use program; however, under the EUA guidelines, patients are not eligible for compassionate use if their hospital has remdesivir. This issue should be corrected in current hospital policy exclusion criteria. Another limitation is that many of these policies do not include an appeals policy in the event that a patient believes they have had remdesivir withheld unfairly. This may be because many policies have developed binomial exclusion and inclusion criteria which does not lend itself to exceptions. Although this may be the case, patients should have the right to appeal the decision to ensure just treatment.

The fact that each individual hospital is creating their own allocation policy is a limitation in-and-of-itself. Without a community standard for the allocation of remdesivir several problems may arise: 1) patients may qualify for remdesivir at one hospital and be excluded at the hospital across the street; 2) hospitals have varying supplies of remdesivir and hospitals who more conservatively allocate the drug may not be open to sharing their supply with hospitals who run out due to a more liberal allocation policy.

Conclusions

There are varying ethical approaches to the allocation of remdesivir being implemented throughout the country. A community standard for the ethical allocation of remdesivir should be devised in order to ensure just and equal access to this drug for all COVID-19 patients. As a community standard does not yet exist, hospitals should develop a policy for the ethical allocation of remdesivir in order to ensure just treatment of all patients within their institution. Policies should be developed by an interdisciplinary team. Ethical consensus among hospital policies suggests the following policy format: 1) developing patient inclusion and exclusion criteria for remdesivir eligibility that is based on clinical criteria and is blinded to patient characteristics such as age, gender, race, disability, and immigration status; 2) distributing remdesivir to all eligible patients until the number of eligible patients outnumbers the courses of treatment available; 3) at the point in which the supply of remdesivir is lower than eligible patients, entering all eligible patients into a random lottery for distribution; and 4) developing an appeals process for patients who feel they have been unfairly excluded. Once a policy is developed, it should be reevaluated as new evidence emerges.

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Delirium Assessment in COVID-19: What a Difference a Little Change Can Make

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Abstract

As the neurobiology of COVID-19 advances, delirium looms ever larger as a predictor of poor outcome. That is why it is important to identify when delirium is already present and developing. That will require a change in standards of practice which only call presently for daily delirium assessments when patients are in an intensive care unit (ICU). We argue that quick delirium assessments should be added to routine nursing assessments from the time a patient suspected of COVID-19 arrives through the acute care hospital course of all COVID-19 positive patients.

Introduction

Science still has much to learn about how the SARS-CoV-2 virus, or COVID-19, wreaks havoc on the human body. One piece of COVID-19's complexity that is coming into view, however, is the way in which delirium is part of the COVID-19 picture. Although delirium is often seen during critical illness, there appears to be something specific about COVID-19's effects on the central nervous system (CNS) that puts patients at increased risk for delirium.[1]

Even prior to awareness that an individual might be ill with COVID-19, mental status changes may be an early warning signal. For the patient who presents at an acute care hospital's Emergency Department (ED) with altered mental status, this is now an alert that the individual may be infected with COVID-19. Delirium in COVID-19 patients once they have been hospitalized, especially if they have been admitted to an Intensive Care Unit (ICU), is already a predictor of poor outcome.[2]

Now that we have a better appreciation for the neurologic sequelae associated with COVID-19 to include, but not limited to, delirium,[3, 4] it is time to proactively screen, detect, and try to prevent delirium in these patients. Given the morbidity and mortality associated with delirium, it is imperative that we recognize and treat it in an expedited manner. In truth, early detection of delirium and measures to prevent its occurrence are small practice changes that might produce important outcome improvements.

Background

Prior to the advent of COVID-19, delirium has long been known to be common in the hospitalized elderly,[5, 6, 7] although it also has been seen in pediatric populations.[8] The phenomenon of delirium in patients in the acute care hospital setting, especially in the ICU, is well established.[9, 10]

At the beginning of the COVID-19 pandemic, when patients required admission to the hospital for acute hypoxic respiratory failure, particularly to the ICU, altered mental status was often attributed to the most obvious sequelae of COVID-19 infection (i.e. impaired pulmonary function resulting in profound hypoxia and hypoxemia, ultimately resulting in organ damage). What was less clear early on in the pandemic was whether infection with COVID-19 independently contributed to delirium and associated cognitive impairment, regardless of pa-

tients' pulmonary function. Given the degree of hypoxia in these patients' experience, primary efforts have mostly focused on preserving and/or restoring cardiopulmonary function. The more we begin to understand about COVID-19 as a pathogen, however, the more we can begin to see the multifactorial nature by which this virus wreaks havoc on the brain. Even before the COVID-19 pandemic, we've known about coronaviruses and their potential to directly invade neuronal tissue.[11] More recently, we've discovered yet more potential mechanisms by which COVID-19 infection can directly contribute to multi-organ failure, including direct neuronal damage (i.e. COVID-19 infection can trigger widespread systemic inflammatory and immune-mediated responses, as well as increase hypercoagulability and risk for thrombus/embolus formation).[12, 13, 14] The more we understand about COVID -19 and its ability to independently cause neurotoxicity and delirium, the more we are compelled to identify and address this aspect of the infection conscientiously and proactively.

Most cases of delirium are the result of a combination of factors to include patient predisposition (e.g. age, chronic medical comorbidities, presence of pre-existing cognitive impairment), precipitating factors such as acute illness, treatment with certain medications, especially sedative-hypnotic, anxiolytic, and anticholinergic agents, and environmental effects, such as the disorienting processes of an ICU [15] or environmental under-stimulation such as that which patients experience during mandatory isolation.

The *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition,[16] defines delirium as an acute disturbance in a patient's level of attention and awareness, accompanied by other cognitive impairment, that represents a change from baseline and tends to fluctuate throughout the course of the day. There are three (3) major subtypes of delirium, all based upon psychomotor activity: hyperactive, hypoactive, and mixed type. Hyperactive delirium is characterized by restlessness, combative behavior, hypervigilance, and agitation, which is often misdiagnosed as anxiety or acute psychosis. Hypoactive delirium is characterized by lethargy, sluggishness, and decreased responsiveness, which is often misdiagnosed as depression. Hypoactive delirium may be associated with poorest prognosis and is the most prevalent yet is the most likely subtype of delirium to go undiagnosed.[17] Mixed-type delirium includes aspects of both hypoactive and hyperactive delirium.

This information is general knowledge that presages the advent of delirium in the SARS-CoV-2 virus. Now, though, we know that delirium, on top of its generalized probabilities, is highly prevalent and likely a distinct component of the evolving COVID-19 puzzle. That is, it appears that COVID-19 has direct effects on the CNS that increase the probability that COVID-19 patients will develop delirium.[18] This COVID-19-specific information should be setting off flashing lights that early detection of delirium in these patients may have significant influences on outcome.

In summary, in COVID-19, given that the overwhelming focus has been on the obvious manifestations, such as the impact on cardiopulmonary function, the neurologic sequelae of the virus, including its contribution to the development of delirium has yet to garner the attention it deserves. What appears known about delirium in COVID-19, that is consistent with the general delirium literature, is that delirium is an already well-appreciated complication of respiratory illness, such as pneumonia, especially in the elderly. Recent studies have predicted that 20-30% of COVID-19 patients manifest at admission, or develop once hospitalized, frank delirium or altered mental status,[19] with rates as high as 60 – 70% in patients with severe illness.[20] This finding holds up regardless of age. Delirium in COVID-19 patients, as in any hospitalized patients, predicts worse outcomes.

Further, the best management of delirium, whether related to COVID-19 or not, is prevention. Prevention should start with assessment and early identification. Once identified, assessment of delirium should be followed by non-pharmacological, management strategies such as frequent reorienting, which can be accomplished by care team members or contact with family, and environmental strategies. Environmental strategies include, but are not limited to, placing a clock, day of the week and date in a delirious patient's room. There are other, non-pharmacologic strategies but a full discussion of such interventions is beyond the scope of this article. For a review of the pharmacological strategies specific to COVID-19 delirium, which are still little-researched and thus quite variable.[18, 21] The rest of this article will focus on the importance, utility and ease of assessing for identification of delirium through early and daily delirium screening. That is because just mastering this negligibly burdensome improvement in standards of practice can be expected to yield substantial improvements in outcomes for COVID-19 patients. Just this little change can be expected to make a big difference.

How Should This Additional Delirium Assessment Be Done?

Screening assessment for delirium should be done consistently on every hospitalized patient at arrival and throughout the day. This allows the team to quickly identify patients with altered sensorium. Since hypoactive delirium is often missed, screening will be advantageous for early identification. Currently, assessment of delirium or mental status changes in COVID-19 is not

usually part of a routine assessment.[2] This critically important change in routine daily care and management of COVID-19 patients should be initiated everywhere and promptly. This is the singular ethics obligation being recommended in this paper.

As one would expect, when this suggestion is brought up to treatment team members one of, if not the first, response is resistance. Professionals ground this resistance in a perfectly reasonable concern about adding more time to their already exhausting days. The pandemic-specific, crushing exhaustion experienced by treating teams everywhere, teams at their breaking point, means that learning anything new that would add more time seems like too much to ask.

But this resistance may also come from inaccurate assumptions about the extra time and effort such delirium assessment would actually add. The understandable resistance reaction ignores that several delirium screening tools take little time or effort to administer and require no specialized training. The minute one starts talking about doing something that is likely to improve care and that takes less time than what clinicians are presently doing, that is a conversation that receives everyone's attention. For example, one of the most commonly used, validated assessment tools, is the short version of the Confusion Assessment Method (Short CAM).[22] Even though this tool has become commonplace and often used daily in the ICUs that have incorporated a daily delirium screen, it can take quite a bit of time for busy ICU nurses and house staff (usually about 5 minutes, but sometimes longer) to administer. It also requires specialized education and training to produce valid results.[23] Last, and specific to COVID-19, the Short CAM requires that an interview be attempted, which may be irrelevant to assessment of ICU patients and yet the attempt calls on physicians or nurses to stay in the room of a COVID-19 patient longer than need be, an unnecessarily long exposure when risk from exposure is so great.

These reasonable and realistic concerns, however, can be minimized or avoided by using an even easier-to-administer instrument. Of the several that are available, another one that is already internationally used and validated, is the 4A's Test (4AT).[24] This assessment tool takes less than 2 minutes to administer. The 4AT has additional benefits over the Short CAM. They include no interview, no specialized education or training, and it can be used even with patients with hypoactive symptoms. This is especially important in COVID-19, as these patients may only be showing hypoactive symptoms of delirium on arrival to the ED. The 4AT could easily be added to daily nursing assessments, whether the patient is admitted to the floor or to an ICU.

A delirium assessment tool that takes less than 2 minutes should be able to be integrated into a general assessment for patients coming in through the ED. It might be especially important to perform such an assessment in the ED because the results may have material relevance to monitoring progression and resolution of delirium throughout the course of the hospitalization.

The social isolation COVID-19 patients endure is multifactorial and can significantly contribute to the development or worsening of delirium. The need for clinicians to wear protective gear and the fear of contracting and/or spreading the virus, hospital policies restricting or completely prohibiting visitors, along with an inability to freely ambulate creates a "delirium factory," [25] increasing the risks of delirium in these patients. Strategies to mitigate these risks include the use of computers to allow video conferencing between patients with family members and friends in an attempt to keep these patients oriented or reoriented, approximating some of the processes standardly prohibited by the no-visitor/restricted-visitor policies. Or a hospital could create a COVID-19 wing where patients with COVID-19 can commiserate and heal together. Perhaps such changes might reduce the number of delirious COVID-19 patients who end up needing higher levels of care due to worsening mental status changes.

For our readers who may be unfamiliar with such real-time efforts, though, it is important to illuminate the time drains, logistic headaches and risk factors of just having a delirious, COVID-19 patient get to 'face time' with family members or friends. The burden on time expenditures for care team members ought not be minimized. For those of us who are involved in coordination of these 'face time' happenings know well of this activity's complexities. First, it takes just having the numbers of laptops or comparable devices to cover a COVID-19 general medical/surgical floor unit or a specialized COVID intermediate or intensive care unit. These devices regularly breakdown, extras need to be available. When they do break down, team members waste time scrambling to find functional machines. Often nursing and/or social work sets up these remote visits, which take much time on the part of these clinicians just to get a remote visit scheduled. Then, once scheduled, when the exigencies of everyday care in an acute care hospital mix with schedule changes on the part of families and friends, just the seemingly simple actions of 'face timing' delirious COVID-19 patients is often a frequent source of frustration, acting as a natural disincentive to trying it multiple times a day.

Adding a simple, quick, daily delirium screen for COVID-19 inpatients pails against the time required for other care needs for these patients. Surely, when performing a daily delirium screen is so much less burdensome and aggravating than even such seemingly

simple activities such as 'face timing' COVID-19 patients with their family and friends, the prospects for improved outcomes such daily screening could produce surely calls on this small change in present standards of practice.

Conclusion: Next Steps

When dealing with the rapidly evolving science of the SARS-CoV-2 virus, one answer to the question, 'What might be helpful now?' is almost always, 'More research.' For example, it seems odd that there is still equipoise between those who think early identification, monitoring and treatment of delirium have the prospect for improving outcomes for COVID-19 patients and those who think it will not make any difference.[26] Perhaps someone reading this article might want to explore why such equipoise still exists.

At a minimum, one hopes that this little piece provides a kickstart that can begin discussions in hospital ethics committees and in psychiatry, general medicine, intensive care and nursing departments about changing the present standard of practice before more opportunities to improve the care of COVID-19 patients by early delirium detection and regular monitoring are lost.[26] Given the state-of-the science related to the probabilities that hospitalized COVID-19 patients are at such high risk for having delirium either upon hospital arrival or once admitted, and delirium is such a brightly shining arrow pointing to bad outcomes for these patients, that the ethics of what would be such a small practice change seems beyond need for further convincing. What seems needed is spreading the word. Perhaps this little article has given this imperative a good push.

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ACKNOWLEDGEMENT

Thank you to the medical librarians of the William B. Glue Health Sciences Library, MedStar Washington Hospital Center, for their assistance in the preparation of this manuscript.

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Shared Decision Making in the Presence of COVID-19 and the Absence of Families

Lynette Cederquist, MD; Biren Kamdar, MD; Alex Quan; and The Editorial Group of the John J. Lynch, MD Center for Ethics

Case Complexity: 1 2 **3** 4

Abstract

For families and surrogates of patients suffering from COVID-19, the pandemic has made nearly impossible the ability to see their loved ones in the hospital day-to-day. Families and surrogates may now be more hesitant to voice their preferences and concerns, or mistrust of the medical profession on the part of members of the public that may simmer under the surface under ordinary conditions, may be quicker than usual to boil over. Both extremes may compromise the spirit of shared decision-making in medicine.1 Hence, with families absent, providers may find it necessary to adopt a more clinician-directed approach to decision-making. Once a COVID-19 positive patient enters a hospital, and viral spread mitigation policies separate patients and families, it is critically important that physicians be skilled at having end-of-life conversations with families that do not insist that they make decisions to shift to comfort measures only. Skill in these difficult conversations at the highest level is demonstrated when physicians bring families along gradually.

PRESENTATION

Mrs. C was 47 years old. She was brought by ambulance to her community hospital emergency room, where she was diagnosed with hypoxic respiratory failure secondary to COVID-19. After being emergently intubated, she had a pulseless electrical activity (PEA) arrest, requiring 17 minutes of cardiopulmonary resuscitation (CPR). Spontaneous circulation was restored and the patient was stabilized for transport. She was subsequently transferred to the closest tertiary care hospital where brain imaging revealed severe anoxic brain injury.

As had been the case since the beginning of the COVID-19 pandemic, to attempt to prevent the spread of the coronavirus, the hospital – like every hospital around the country - had initiated a restricted visitation policy. Essentially, patients cannot have visitors unless the patient is assessed to be imminently dying. Because Mrs. C was relatively stable, she was not so assessed even though her kidneys were now beginning to decline. The reason for the visitation restriction was explained several times to the patient's husband and adult children. The family was updated regularly by the Intensive Care Unit (ICU) team. Although the team, including the patient's ICU attending physician, regularly described to the family that the patient was not awakening from her arrest and that her kidneys were now failing, nonetheless, the family requested, then insisted, on continued, full life-sustaining treatment, including initiation of dialysis if it became needed.

Over a period of a week or more, multiple goals of care conversations were conducted, including videoconferences to demonstrate the patient's devastating neurologic injury. On hospital day 20, the ICU attending physician, the patient's resident, and nurse practitioner, joined by the hospital's clinical ethics consultant, held a teleconference with the patient's spouse and adult children. Acknowledging the impossible situation facing the family, the physician summarized prior conversations, including comments that continued life sustaining treatment was not producing any improvement in the patient's condition and was therefore not providing the patient any benefit. The team sensed that the patient's husband was moving towards a willingness to shift to comfort measures only, when the resident decided to step in and, unfortunately, made things worse. The resident said that the team didn't want to make the patient suffer.

With that, the most suspicious of the adult children said, "I thought you said our mother's brain was so bad that she wasn't able to communicate or appreciate anything around her," to which the resident responded with, "that's right."

Perhaps because of an apparently deep religious faith, the son then responded with, "I could understand what you mean if you had said that you want to make sure our mother isn't experiencing any pain. She might have pain and not be able to express it. But to suffer, I think, our mother needs to have much more awareness than you have told us she has."

Immediately, the resident recognized his mistake. Suffering is a conscious human phenomenon. A patient who lacks consciousness in light of an anoxic brain injury cannot *suffer.*

Fortunately, this ICU attending was experienced at having residents make this mistake and skilled at getting out of the bind that the inexact usage of the word 'suffer' can produce. He side stepped quickly and replied in a way that honored the son's awareness of the profound difference between suffering and physical pain. He said, "Yes, we don't think the patient can be suffering as you so rightly point out. For that, we are all deeply grateful. Rather, we are concerned that the slower and more drawn-out her death might be is likely to produce more complications that might cause her actual pain or discomfort."

The attending then raised the issue about restrictive visitation policies while also expressing just how difficult the situation had become for the team, as well. He explained that when all could agree that, sadly, the time had come to shift Mrs. C's care to a plan focused exclusively on her comfort and letting nature take its course, two family members at a time would be allowed into the hospital to say their good-byes. Communicating the distressing aspects of Mrs. C's situation as also affecting the team resonated with the family. The next day, the husband called and requested firm recommendations from the ICU team, resulting in a change in status to Do Not Resuscitate (DNR) and a no-escalation order.

The patient continued to deteriorate, and two days later the ICU team called the husband, telling him that he and the patient's children should come in if they felt they needed to do so. The team explained that the patient's blood pressure was becoming unstable and that they believed the patient was now actively dying. The family decided, however, that it would be too much for them. Because the patient had been transferred, the family now lived many hours away. It was unrealistic for them to make the trip.

The attending, with deep compassion, emphatically but gently assured the family that the patient would die comfortably which she did only a few hours later. Thus, by being very careful not to rush the husband or force him to explicitly agree to remove the patient's life-support, these sad conversations were allowed to progress at a pace that carefully brought the family along. By simply explaining to the family – and not asking anything of them – that it would not be in the patient's best interest to pound on her chest and likely break her ribs when her heart stops, the terrible implications could be processed appropriately by the family. By taking an unhurried approach, the attending guided this bereft, physically separated family, through an end-of-life process in which the family could feel that the decision-making had been shared.

Because this husband didn't feel rushed, he was able to trust the ICU team to facilitate a peaceful death for his wife. The hospital chaplain was summoned. The technology was arranged so the hospital chaplain and the family could pray together. With tranquil music playing, the patient died, a nurse holding her hand as she slipped away.

Once a COVID-19 positive patient enters a hospital, and viral spread mitigation policies separate patients and families, it is critically important that physicians be skilled at having end-of-life conversations with families that do not insist that they make decisions to shift to comfort measures only. Skill in these difficult conversations at the highest level is demonstrated when physicians bring families along *gradually.* Only this allows families to feel that their beloved family member died in peace, a feeling of comfort to survivors of this terrible pandemic.

ETHICAL ISSUES

Navigating Shifts in Shared Decision-Making

For families and surrogates of patients suffering from COVID-19, the pandemic has made nearly impossible the ability to see their loved ones in the hospital day-to-day. Combined with media coverage exalting the efforts and expertise of first-line providers donned in PPE, the balance of power that the movement of shared decision-making has sought may be more off-kilter. Families and surrogates may now be more hesitant to voice their preferences and concerns, or mistrust of the medical profession on the part of members of the public that may simmer under the surface under ordinary conditions, may be quicker than usual to boil over. Both extremes may compromise the spirit of shared decision-making in medicine.[1] Hence, with families absent, providers may find it necessary to adopt a more clinician-directed approach to decision-making.

In cases where the family or surrogate do assert decision-making via substituted judgment, without the ability to visually appreciate the severity of their loved one's illness, families may be inclined to request non-beneficial and/or excessive treatments, propagated by unrealistic hopes of recovery. Therefore, a cycle of non-beneficial treatment and unrealistic hope may perpetuate, leaving providers in a quandary and possibly exposing patients to unnecessary pain and/or suffering with the continued use of life-extending technologies that are not providing clinically meaningful benefit.

The family in this case initially adopted a stance of unrealistic hope, requesting aggressive life-sustaining therapy. However, once the family recognized that the physician and nurses were the few people able to see and touch the patient, and because the clinicians updated the family without asking removal of life-extending technology, the family hesitantly but increasingly built

a trusting relationship with the doctor and nurses. This shift in trust empowered the provider to frame decision-making and information sharing in a more clinician-directed manner while at the same time elucidating and honoring the family's wishes and values.

Shared Decision-Making and End-of-Life Discussions via Telephone or Videoconference

Because of the virus mitigation, visitor restriction policies, ICU physicians are experiencing the challenges of shared decision-making via virtual medicine. Mortality in patients requiring mechanical ventilation due to complications from COVID-19 has been reported to be as high as 76% and 97% in patients under and over age 65, respectively, making remote end-of-life discussions an increasingly common occurrence.[2]

Updating families or delivering bad news over virtual communication raises concerns about the situation or environment the recipient is in to engage in critical care discussions. Virtual communication places inherent constraints on a provider's ability to judge family or surrogate's emotional states or reactions regarding the information being conveyed. Monden, Gentry, and Cox outline five phases for effectively delivering bad news: preparation, information acquisition, information sharing, information reception, and response.[3] However, on the virtual platform, ability to manage these communications may be jeopardized. Without knowing the exact situation or environment in which the information will be received, and without being able to anticipate, witness, and respond to emotional responses, the provider can never feel fully prepared for a conversation, or anticipate the outcome. Following-up with a patient's family after end-of-life discussions begin may sometimes require numerous requests to communicate virtually in a short span of time, possibly intruding or infringing on the family's personal space and risking deterioration in clinician rapport with family. Thus, it can be emotionally taxing for both family and the providers to hold conversations about illness, death, and dying on a virtual platform.

In the absence of family at bedside, it is incumbent upon providers to be circumspect about how clinician-directed their actions can and should be.[4] They should be aware of the inherent limitations of communicating virtually and make every effort to engage the patient, family, or surrogate early, just as they should if they were present at the bedside. On the other hand, when the patient, family, or surrogate look to the provider to take on a more unilateral role given family absence, the clinicians should accept that responsibility. Kon and colleagues described a sliding scale of shared decision-making which allows an ethically supportable shift towards a more clinician-directed approach to decision-making when patients and families prefer such an approach.[5] If agreed upon, this approach may prove valuable in guiding providers and families struggling to navigate complicated situations and end-of-life decisions imposed by the COVID-19 pandemic.

RECOMMENDATIONS

1. Before any conversation with the family and the physicians, please give the family time to see and talk to the patient through use of video technology.
2. During the provider/family conversation, rather than asking the family what they know (and put them through the stress of being put on the spot), know ahead of time what the patient's condition was when the team updated the family last and start from there.
3. Ask, "Is there anything that I just said that is different from your understanding?" – and allow enough silent time for more timid family members to speak-up.
4. Then update the family as to the patient's status.
5. When finished, please ask if the family has any questions or concerns so far – again, allowing for enough silence to give family members time to speak-up.
6. Then move – slowly and gently – to a factual, neutral presentation of what is the best expectation of the treating team.
7. Finally, proceed with team recommendations.

REASONING

The recommendations are written as they are to assist clinicians in developing a rapport and trusting relationship with a family whom the team has never met, and whom can only come into the hospital when they have agreed not to contest a shift to a 'no-escalation' or a comfort measures only plan of care. This is an incredibly difficult task. And there is little or no help for scripting busy and exhausted clinicians who are trying to have what, under ordinary circumstances, are among the most difficult conversations to have with families. These difficult conversations have now been made excruciatingly more difficult because they are being conducted remotely.

There is an emerging literature on how COVID-19 is providing the impetus for medical schools to expand their curricula related to telemedicine communication skills.[6, 7] There appears to be a focused and promising effort on the part of a Canadian group of family practice physicians to develop an approach to separating the concepts of physical distancing and social connectedness built on well-established understanding of relationships as the drivers of healing.[8] Scripted assistance for ICU physicians, however, working to come to a shared decision remotely with families about capping or withdrawing life-extending technologies is not yet available.

Like so many in the acute hospital setting, clinical ethicists are learning as this pandemic progresses.

What is certain is that processes for engaging in shared decision-making will look quite different post-pandemic than they did pre-pandemic. The pandemic will almost certainly change how ICU physicians communicate with patients and/or families at the end of life.

AUTHORS

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When Extracorporeal Mechanical Oxygenation Needs to Be Turned-Off

The Editorial Group of the John J. Lynch, MD Center for Ethics

Case Complexity: 1 **2** 3 4

Abstract

Erica Samson was an otherwise healthy 20-year-old college student when she contracted the coronavirus. She was home, taking college classes remotely, when she started not feeling well. Within days, she could hardly breathe and was taken to her closest hospital, where she was quickly put on a ventilator. After several days went by, she was not only not getting better, but she was getting worse. ECMO is designed to give a patient's lungs a rest; essentially taking over for the patient's lungs until they are sufficiently better to be able to resume their natural function. ECMO, however, is the end of the road. There is no other path than comfort measures only when ECMO needs to be turned off because it no longer is providing the 'resting' benefit for which it is designed. Needless to say, although a consent may say turning ECMO off is a strictly medical decision, these decisions are never made in a vacuum.

PRESENTATION

Erica Samson was an otherwise healthy 20-year-old college student when she contracted the coronavirus. She was home, taking college classes remotely, when she started not feeling well. Within days, she could hardly breathe and was taken to her closest hospital, where she was quickly put on a ventilator. After several days went by, she was not only not getting better, but she was getting worse.

Her intensive care unit (ICU) team was puzzled until Erica's mother told them that as a child she had had asthma on and off. It had been so long ago and so mild that her mother, in her upset about how quickly Erica had gotten so sick, had just completely forgotten. Now that they had an answer for why her lungs were not improving, they flew Erica to the regional, tertiary care center with the expectation of putting her on ECMO. ECMO stands for extracorporeal mechanical oxygenation and is the most sophisticated machinery that could help Erica.

ECMO is designed to give a patient's lungs a rest; essentially taking over for the patient's lungs until they are sufficiently better to be able to resume their natural function. ECMO is not a treatment, per se. It is a highly sophisticated life-extending technology designed to take over for a patient's lungs (or if needed, heart, or heart and lungs), until the lungs can again take over the job of breathing for the patient.

After weeks on ECMO, however, Erica was not improving. The hospital's multidisciplinary team was concerned that Erica was not going to make it. She was no longer capacitated as she was becoming increasingly lethargic. The multidisciplinary team agreed it was time to start talking to Erica's mother (her only family member; her father had always been absent and she had no siblings) about turning the ECMO machine off.

As part of the ECMO consenting process, which Erica was a part of and in which her mother was also involved (at Erica's request), the consent includes language that this would be a medical decision, i.e., the decision to turn ECMO off if it is not helping the patient any longer. When that decision is made because a patient has improved enough to breathe on their own, everyone is just happy and ordinarily doesn't question the medical decision. But when things are going badly, so that the ECMO machine is not helping and it is time to allow the patient's care to be shifted to comfort measures only, problems often arise.

That is because unlike most other life-extending technologies, when one option isn't working, there's usually something else to try. ECMO, however, is the end of the road. There is no other path than comfort measures only when ECMO needs to be turned off because it no longer is providing the 'resting' benefit for which it is designed. On a rare occasion, even when it is assessed that the patient will die when ECMO is turned off, an extraordinary patient may be able to sustain themselves, but usually not. Usually, turning the ECMO machine off means certain death for the patient.

Needless to say, although a consent may say turning ECMO off is a strictly medical decision, these decisions are never made in a vacuum. In Erica's case, her

mother has been a loving presence since she arrived. And now, understandably unable to face the prospect that she could lose her only daughter, a child who only 12 weeks ago was a healthy, happy college student, she is beginning to fight with the team as they begin these discussions.

At Erica's hospital, every time a patient goes on ECMO, one of the hospital's clinical ethicists is consulted, so the general ethical issues here are premised in the ECMO assignment. The clinical ethicist participates in the weekly, multidisciplinary ECMO rounds. It is now time for Erica's clinical ethicist to formalize her recommendations to the team.

RECOMMENDATIONS

1. Ethics recommends that the patient's attending and primary nurse begin meeting with the patient's mother every day (rather than once a week) to discuss Erica's clinical status.

2. Ethics recommends that when the attending and primary nurse meets with the patient's mother, the patient's mother be given a particular set of conditions to monitor that would indicate improvement in Erica.

3. Ethics recommends that when the attending and primary nurse meets with the patient's mother, in addition to identifying specifics in Erica's condition to monitor that the mother be given a time trial of how long to be watching for improvement in the specified clinical conditions.

4. Ethics recommends that the hospital's spiritual care department assign someone who already knows the patient's mother to join her for some part of her vigil each day. That is, in addition to the spiritual care support the patient's mother has been receiving from the palliative care team.

REASONING

The tragedy of losing a previously healthy, happy college student is felt well outside the confines of the ICU on which this ECMO patient resides. Because this is a large (900+ bed), Level 1 Trauma, Tertiary Care Center, there are multiple ICUs and the nurses who are trained at the level of practice in these units, along with the comparable physicians, cover multiple units and take Erica with them in their hearts as they practice throughout the hospital. Losing such a previously vital, healthy young person can be among the worst deaths in an adult hospital. Although that might smack of ageism, because most of the deaths are of older adults, it is a natural reaction for which clinicians can not be faulted. Only if decision-making for a young patient is qualitatively different from other, older patients, could one hold such clinicians at fault. Clinicians are humans, too, who have children and aunts and uncles and grandparents of their own.

In Erica's case, there have been no problems, such as leaving her on ECMO past when her clinical status would call for turning the ECMO machine off. The team is doing their best to work with the patient's mother to get her prepared for the time when it should be. But even now, the tug-of-war is brewing.

One of the reasons is that a decision to place a patient on ECMO is often made under emergent or emergency conditions. While true that informed consent is often rushed and those consenting are distracted and frightened so that the complexities of a high-tech rescue intervention are difficult to grasp, ECMO is a particularly complex intervention to explain under high stress conditions, especially because its utility in patients with COVID-19 is scant.[1] Although the Extracorporeal Life Support Organization (ELSO) is tracking all patients with coronavirus who are put on ECMO world-wide, ELSO does not have sufficient data so far to make a recommendation either for or against placing patients with COVID-19 on ECMO. And of the data extant, the findings are grim. Of the published data to date, most report out 100% mortality or close to it.[2-4] Given, however, that data show an improving picture [5] and it represents the last-ditch effort for these patients, clinicians are more likely than not to give it a try if the patient approximates eligibility.

The reason that there is some expectation of success is that ECMO has been shown to be useful in acute respiratory distress syndrome (ARDS) due to other viral infections. They include influenza A (H1N1) and SARS-MERS viruses.[6, 7] So for now, ECMO holds out the last possibility for saving many lives ravaged by COVID-19.

Unfortunately, right from the beginning, preparing patients and families for the worst news starts off by using therapeutic terminology that confuses things, tipping expectations in likely the wrong direction. As previously noted, ECMO is not, technically, a *therapy.* The common sense understanding of a therapy is that it is a medical intervention designed to cure or ameliorate a disease process. ECMO is a rescue technology designed to take over for the lungs, but it won't repair them. It is not an intervention that will in any way treat the underlying disease. But therapeutic language is often applied to ECMO obscuring its actual technical function. Although the clinicians using ECMO understand this distinction, it is ordinarily lost on the non-clinician patient and family members.

Second, ECMO presents another ethical problem, also previously mentioned. That is there is no alternative to ECMO. If ECMO doesn't work, there is nothing more to try.

For example, if a patient is on a ventilator so long that it needs to be removed before it increases the likelihood of complications well beyond the normal complication rate of being critically ill on a ventilator, there are two choices: the patient can be shifted to comfort measures only, with the tube removed, being what is colloquially referred to as 'terminally extubated.' Or, a patient can have a tracheostomy to continue mechanically supported breathing, colloquially referred to as having a trach, and a percutaneous endoscopic gastrostomy, which is a feeding tube, colloquially referred to as a 'peg,' and then be transferred to a lower level facility to see if over time these interventions will help the patient improve. There is no comparable example with ECMO. ECMO is the end of the line.

Thus, when it was becoming clear to Erica's doctors and nurses that she was not improving; that her lungs were just as bad or worse than when she arrived, it was time to start preparing her mother. But how does one prepare a mother for a daughter's death? Such death is out of season. Some say the worst thing that can happen in one's life is to out-live one's children.

Nevertheless, the discussions had to start. Erica could not be supported indefinitely on ECMO. If she were, ultimately one could expect her fingers and toes to necrose because of all the pressors, medications to keep her blood pressure up, that she was required to take. Common complications of ECMO are blood clots, which can occur anywhere in the body, break off and travel to the brain causing a stroke. Little by little, if she wasn't going to get better, she would ultimately die on ECMO, which is not an easy death.

And of course, that's what happened. Each day Erica's mother would negotiate with the team for a little more time, and then just a little more, until Erica suffered a cerebral hemorrhage. Days after that, Erica's mother agreed to turn the ECMO machine off. She was not angry at the team; she appreciated how hard they worked; how hard they tried — COVID-19 is just a terrible disease and ECMO is an imperfect rescue technology. Perhaps when the pandemic is over and the review articles are all written, it will be seen that either criteria for ECMO eligibility will need revision. Perhaps ECMO is more like most innovative technologies in that many of the initial patients for whom it is used end up dying or resulting in unanticipated clinical outcomes. But, as time goes on, and the ethical dimensions of ECMO technology when applied to COVID-19 continue to be assessed, what we can hopefully expect are appropriate regulations being developed and implemented, so as to better condition the outcomes of patients like Erica.

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Inpatient Psychiatry in a Pandemic: The Organization and the Individual

Christian Carrozzo, PhD (c)

Case Complexity: 1 2 3 **4**

Abstract

Carrozzo presents the case of an involuntary admission to the psychiatric inpatient unit at a major urban hospital during the coronavirus pandemic. Mr. King suffers from schizophrenia, is COVID-19 positive, and refuses to maintain his prescription regimen and use of personal protective equipment, creating significant behavioral concerns and an elevated risk for transmission to others. The team is considering transferring to a newly-formed psychiatric unit that is also equipped to care for the complex medical aspects of COVID-19. Mr. King will not go willingly. Do Mr. King's overall circumstances justify that a medication-against-objection panel be convened, in order to medicate Mr. King sufficiently to transfer him to the new unit? This case illustrates the moral tension that can arise between a possible good for the organization, and the appropriate psychiatric care of an individual.

PRESENTATION

Mr. King is a 27-year-old male currently admitted to the psychiatric inpatient unit at a major urban hospital during the coronavirus pandemic. Although typically well-managed, Mr. King suffers from schizophrenia and has often refused to maintain his prescription regimen. A recent incident in which, while not medicated, Mr. King was found about 20 blocks from his apartment loudly and aggressively expressing profanities to both people and statues of a local church at 6 o'clock in the morning, resulted in his arrest by the police who were quick to bring him to the hospital on a legally justified involuntary admission for psychiatric evaluation. After Mr. King's psych evaluation, which determined the need to hospitalize him and begin a medication regimen that would ultimately return Mr. King to a behavioral baseline that merits his safe discharge, he was additionally tested for COVID-19. Mr. King's test returned a positive result for coronavirus infection.

Given his COVID-19 diagnosis, Mr. King has now been involuntarily admitted to a special unit in the hospital separate from the standard psychiatric unit that is equipped to care for the often complex medical aspects of COVID-19 patients, while also with psychiatric support staff and a consult liaison service. Although he is hardly compliant with his medication, the most significant challenge remains for him to consistently attend to his own personal protective equipment (PPE), denying that he is COVID positive, pulling and tugging at his masks, sometimes ripping them off entirely, or simply losing them in the open, common areas of the unit. In terms of immediate safety concerns, although Mr. King is not displaying in any way violent or aggressive behavior, the inpatient unit staff is well aware of the statistics surrounding COVID-19 transmission within the psychiatric patient community when such patients are suffering from functionally debilitating illnesses that create significant barriers to the self-care required for patients and staff to remain protected from transmission.[1, 2]

Often, the standard practice in this type of general circumstance is to consider an emergent intervention (one that would not require Mr. King's consent) given the safety risks he is presenting by being irresponsible with his mask. However, this particular unit has relaxed this protocol in light of so many patients experiencing difficulty with their PPE, making it a difficult standard to maintain. Mr. King would have to be displaying the sort of aggressive behavior that put himself or others in immediate danger, prior to this particular unit likely deciding that emergent medication would be justified.

Several conversations were held with department leadership over the possibility of demarcating a section of the unit that could be devoted to COVID-19 positive patients, exclusively. The idea being, a devoted unit could both relieve the special medical unit from the challenges and concerns about proper care associated with isolating psychiatric patients like Mr. King in special medical units with some psych support but perhaps not best equipped to manage the psychiatric care of COVID-19 patients, safely. Dr. Torrance, the department chief, has been researching about similar efforts,[3] and believes this to be a worthwhile project that could

potentially save lives while creating a therapeutically conducive environment for COVID-19 psychiatric patients experiencing behavioral difficulties similar to Mr. King. It happens to be the case that the hospital system is state-certified for 237 beds, of which only 217 are currently in operation, allowing the department to designate 20 beds for a stand-alone secondary unit for COVID-19 positive patients. Beyond a medical unit focused on COVID-19 that is merely prepared to handle some psychiatric support, the COVID-19 psychiatric unit would be equipped with medical and psychiatric nurses, psychiatric and family-practice attending physicians, a psychiatric nurse practitioner, as well as a social worker.

Next steps would involve the selection of patients who would be transferred to this unit. Those psychiatric patients who are experiencing quite severe symptoms related to COVID-19 would nevertheless remain in the original special medical unit, since management of their COVID-19 disease would be considered a priority over adjustments or compromises to their psychiatric care. Those psychiatric patients with less severe or no symptoms related to their COVID positive status, so as to not require special medical management of their COVID-19 disease, would be moved to the new COVID positive psychiatric unit.

Dr. Torrance decides that Mr. King's symptoms are subtle enough to be considered for the new unit and decides to speak to Mr. King about transferring. When Dr. Torrance explains to Mr. King that the new unit will be further isolated from the special medical unit he was previously in, as well as the medical side of the hospital, Mr. King becomes agitated, expressing that he is not COVID positive and that his freedom has already been violated, therefore he will not be moving to yet another, even more isolated unit, where he "will most definitely get COVID from all those sick people." Mr. King goes on to express that the only place he needs to go is "home," and repeats that he is not COVID positive.

Dr. Torrance is now at a loss – the difficulties being experienced by the special medical unit, including the trouble with Mr. King's psychiatric condition greatly affecting his beliefs as to his infection and thus his commitment and/or ability to appropriately wear a mask, as well as adhere to other safety precautions that are in place given the pandemic, were to be solved by the COVID positive psychiatric unit, so long as the COVID positive patients were able to be transferred. Mr. King's unsafe behavior is simply too great a transmission risk for the other patients in the special medical unit, unless a panel is convened to perhaps consider medication against objection (MAO), sufficient to transfer him to what the department would now consider the most appropriate unit.

Dr. Torrance, in the excitement of developing a new COVID positive psychiatric unit, is now considering whether the entire project should be discarded given situations like that of Mr. King's, or if there is some way to maintain safety, the appropriate psychiatric and COVID-related care of individuals like Mr. King, and continue the project for the long-term good it will bring the hospital. Dr. Torrance contacts the clinical bioethics department for an analysis regarding his next move.

ETHICAL ISSUES

This case presents a variety of factors that could each contribute to distinct ethical considerations. Dr. Torrance's question to the bioethics consultant is whether a move to medicate against objection can be supported, given that partly its motivation is to demonstrate a successful project and thus safeguarding the COVID positive unit as a worthwhile venture. Although an improvement in the general quality of psychiatric care Mr. King would be receiving in the COVID positive unit could be argued as justifying a move for MAO, there are various particular psychiatric considerations that could make the situation worse from the patient's point of view, and, at the end of the day, the transfer is not absolutely necessary, any more than the creation of a COVID positive psych unit is 'necessary,' should the original special medical unit be better prepared to manage patients who require isolation.

RECOMMENDATIONS

1. Consider joint meeting of Mr. King's psychiatric care team to discuss and evaluate Mr. King's condition as one that would indicate a MAO panel be convened. The primary considerations ought to be whether the patient lacks decision-making capacity in relation to an understanding of his mental health and the reasoning behind the prescriptions being recommended, and whether there are legitimate concerns over safety in terms of Mr. King either harming himself or others, not whether a failure to successfully transfer Mr. King to the COVID positive inpatient psychiatric unit (IPU) will affect the project's longevity. The benefits of the unit as understood by the psychiatric department should be presented to leadership with the realistic possibility of having to manage situations similar to this with the potential management of future COVID positive, involuntary patients to the new unit.

2. Consider that newly admitted COVID positive inpatients could be taken directly to the new unit, i.e., the problem of transfer from a special medical unit might be a temporary one. This makes the problem with transferring Mr. King appear more circumstantial and limited, thus perhaps not a concern for future admitted patients, but from this assessment it does not follow

that a circumvention of his autonomy is appropriate as simply a matter of managing the new COVID positive psych unit's 'growing pains.'

3. Consistent with hospital policy, if a MAO panel is suggested by the team given appropriate assessments of capacity and safety, a patient advocate should accompany the team to assess the nature of Mr. King's beliefs and his degree of psychosis as justifiably unsafe in terms of potential harm to himself or others, allowing him one last opportunity to willfully take his medication before moving to an IM drug administered against his will that would permit his physical transfer to the new unit. A bioethicist can serve as patient advocate, however, will retain neutrality in his or her analysis of the reasoning and values at play.

REASONING

An bioethicist should carefully distinguish each factor for its relevance to the question being asked by Dr. Torrance. That question being, in light of the circumstances, should a MAO panel be convened, in order to medicate Mr. King sufficiently to transfer him without issue to the new COVID positive psych unit. One consideration is how this might affect his psychiatric condition should he suddenly realize he has been placed in a unit with nothing but COVID positive patients, while under the false belief that he has not contracted the virus. A capacity assessment in terms of Mr. King's inability to rationally comprehend his circumstances might be straightforward in this case, but the safety component needed in order to thoroughly justify an intervention against objection, let alone an emergent intervention that requires no additional justification, is not entirely clear.

The careful management of this situation also contains an organizational component: how well this new COVID positive psychiatric unit functions will signal to system leadership as to whether the project can continue to be supported, something the psychiatric physicians and staff of the hospital believe, despite an occasional challenge, will be incredibly beneficial to the hospital's psychiatric inpatient community in the short- as well as long-term. Many issues could also be assessed as growing pains for the new unit; issues that will likely systemically dissolve once the unit is in full operation.

Even if the organizational considerations are not sufficient to reasonably suggest MAO on an individual person, it could be that attending to the good of the individual from the perspective of his psychiatric illness and the safety of himself and those around him, in this case will itself also result in support for the project going forward. As listed in the recommendations, the COVID positive psych unit project should be presented transparently for all its potential good as well as its challenges. A sober view of the benefits of any such endeavor will likely include estimations of its more complex features when implemented. Support for the project will likely be stronger when presented as a project-in-development, than if presented as prepared to solve all safety issues while finding itself stumped at the first transfer.

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ACKNOWLEDGEMENT

This case was presented for discussion at the Psychiatric Ethics Conference, MedStar Washington Hospital Center, March 5th, 2021. Special thanks to the Department of Psychiatry for their insightful comments and suggestions on an earlier draft of this article.

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JOURNAL OF HOSPITAL ETHICS **Volume 7, Number 2**

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