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Features

In Practice

MedStar Health

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Rounding With the Editor

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ROUNDING WITH THE EDITOR

Gun Violence, Vulnerability, and Psychiatric Illness

Evan G. DeRenzo, PhD

Dear Readers,

Welcome to the *Journal of Hospital Ethics* (JoHE), Volume 7, Number 3. In this issue we take up a topic that is completely new to JoHE that asks, 'Should physicians screen patients for gun access and counsel about gun safety?' Having spent 22 years in an urban, level 1 Trauma hospital of over 900 beds, to say that we regularly see patients who have gun shot wounds would be an understatement. And this is excluding pediatric patients, as we have a children's hospital a few steps away where children with gun shot wounds would be more likely to go.

Although there are those who would say that it is not anyone's business who has access to guns, many of us in health care think such an argument is not compelling, especially when looking at the facts. Given that in the United States (US), as of 2015,[1] there were over 350 million guns in private hands, and with the run on gun purchases that has occurred during the pandemic, that number is likely much greater now than it was in 2015. Given that the United States is one of very few countries in the developed world with gun ownership ensconced in our constitution, has the least restrictions on such ownership, and with the most lives lost to gun violence, it seems that the time has come for action. We just must be careful that focusing only on health care doesn't cause us to focus in the wrong direction. We don't want to grab onto simplistic – and probably wrong-headed – solutions and right now it seems as though our mentally ill have been targeted.

It's easy to seek blame when terrible things happen. And there can be little doubt that terrible things happen in this country because of gun violence. Unfortunately, many are swayed by the media's seemingly singular attention to the mentally ill.[2] This is, however, looking in the wrong direction and only exacerbates harmful outcomes. The way the media reports on the gun violence problem creates or underscores misguided and myopic understandings of the social complexities of the problem and increases stigma of the mentally ill.

One need not dig deeply into the problem of gun violence for one to find that there are social contributors to the causes of such violence that reduce the influence of diagnosed mental illness.[3] Rather than looking to the mentally ill, we need to be looking at causes of socially embedded racism, domestic violence, poverty, housing, drug abuse, and a lack of educational opportunities for just a few places to seek responsibility. One is concerned

that an inappropriate spotlight is shown on the mentally ill when discussing solutions to gun violence. But all one has to do is look around in areas where urban, tertiary care hospitals are located to know that community -based gun violence is covered by the media only superficially and in this way diverts policy makers from focusing on what issues related to gun violence really need attention.

That the Dickey Amendment, if not repealed, at least has had its more pernicious effects dampened is important progress. For the past 25 years, thanks to the National Rifle Association's strangle hold on members of the US Congress, virtually all research into gun violence and health outcomes has stopped as a result of the Dickey Amendment cutting off Federal funds for gun violence research. Finally, however, that strangle hold is weakening and the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) now have (albeit paltry) funding for gun violence research. For an excellent article on the facts and misperceptions about gag orders on physicians speaking to patients about gun access and safety, see Wintemute et al.[4] as cited in the article by Baghel and Singer in this issue.

It is important that soundly designed and executed research be done. A strong argument can be made for robustly funding demonstrably successful existing community programs such as Cure Violence or the Operation Peacekeeper Gang Outreach. Cure Violence (formerly known as CeaseFire-Chicago) focuses on interrupting a small number of members of a community who are at high risk for shooting someone or being shot. Operation Peacekeeper is a program that mentors youth who might otherwise join a gang. The weakness in the argument that rather than fund research on the problem but rather give the money to such programs is, however, that funding is usually not fungible. If funding is marked for one purpose it is usually not anticipatable that it can just as easily fund another purpose.

Nor is looking to the existing literature likely to be a big help in truly elucidating the multiple influences on the problem or the best solutions. If Roszko et al. are right, most of the medical literature on screening and counseling is weak.[5] More well designed and executed studies are needed. But the research itself must change. Traditional research studies call for designs that narrow questions and the selection of participants so that there is the least possibility that unidentified variables will confound conclusions. But research methods will need to broaden. For example, in a paper mainly on mass shootings, a new and potentially more revealing approach has been elucidated.[6] This work calls for an interdisciplinary approach in which the study is situated in a much larger context that includes enlarged social and cultural structures. Metzl et al. make note that everything about the research should be reviewed through a lens that takes account of racial bias in systems that, "define, measure, and record psychiatric diagnoses, as well as those that enforce laws and impose criminal justice sanctions."[6] Stating further that, "…research should be guided by an overarching framework that incorporates social, cultural, legal," as well as political and psychological variables.[6] This is a vision for psychiatric research into gun violence. But it is a vision that should guide a framework that ought to be applied to new approaches to research, in general, about sources and solutions to gun violence in this country.

It seems patently obvious that asking appropriate questions about access to guns is reasonable information to obtain, routinely, at hospital admissions. Making a fuss about physicians and other providers asking questions about access to firearms should be similar. The politics of the gun lobby and the passion that some Americans have for gun ownership should no longer be barriers to physicians asking questions about access to guns. Having guns around increases the prospects for guns being used and, as a result, having persons come into our hospitals with gunshot wounds. Having gun access conversations routinized in hospital settings should become as ordinary as any other conversation that could be considered particularly sensitive between provider and patient. There is nothing new or complicated about that.

Looking at the rest of our summer issue one sees a focus from different ethical perspectives on matters related to particularly vulnerable patients in a hospital. Our first feature presents an algorithmic approach to hospital discharge. Certainly, we could use one. Anyone who has worked in a hospital knows that discharge is fraught with challenges to that hospital's ability to be fair. Since I started with my concerns for psychiatrically ill patients being scapegoated in discussions of causes and solutions to the problems of gun violence in this country, I'll just focus here for a moment on the problems of finding not only safe but therapeutic discharge possibilities for our psychiatrically ill patients. Let's just think for a moment about patients with psychiatric disease who also have health problems that cause them to need placement in a rehabilitation facility. These patients may have the worst possibilities for safe and therapeutic discharge. Many existing facilities will not accept such patients for fear of disruptive behavior. The promise of a community network of psychiatric care facilities never materialized so for the most part, those don't exist. A more systematic approach to hospital discharge of this patient population is likely to be an improvement over today's rather chaotic approach to their discharge. And although my piece with Norine McGrath also includes considerations of discharge,

by responding to questions addressed during the Lasker Forum on Ethics Challenges in Biomedical Research and Practice, I'll leave it to the reader to explore our position.

Our first two case analyses in our In Practice section also present important ethical complexities in totally different patients but both of whom have psychiatric illness layered on top of somatic medical needs. I have found both cases highly thought provoking; I hope you do as well. Our third case brings the issue full circle; it seems to consider the very notion of balance as a virtue, as does our first feature. When one thinks of balance, many different thoughts may arise. One might remember the balancing we tried as children on a teeter-totter. One may think of balance as the homeostasis in animal creatures that allow us to live healthy lives; having one's metabolism off balance is usually an unpleasant experience. One might think of balance as fairness, with each side having the same access to opportunity so that there is an equality to how things are divvied up. All these thoughts and many others may be raised by our last case and our first feature. Perhaps you will find this beginning and end both thought provoking and satisfying. We surely hope so.

Sincerely,

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Ethical Hospital Discharge: A Balanced Algorithmic Approach

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Abstract

Hospital discharge decisions are often complex and multifaceted, bringing fundamental bioethics principles of beneficence, non-maleficence, wise resource allocation and autonomy into tension. Balancing these principles effectively in complex clinical contexts can be a challenge for multiple reasons, including clinician tendency to overemphasize beneficence toward individual patients, intrinsic lack of clarity of the commonly used concept of a "safe discharge" and complex social determinants of post-discharge options for patients. To alleviate these challenges, and thus provide clinicians with more workable ethical framework to use when considering hospital discharge, we discuss ethical tensions in hospital discharge decisions and propose a pragmatic hospital discharge decision-making algorithm which can help resolve moments of tension between competing ethical principles. This algorithm and regular multidisciplinary care meetings can ease caregiver conflict around discharge decision making and optimize discharge decisions for individual patients while supporting wise use of finite hospital resources.

Introduction

Hospitalized patients are increasingly sick and medically complex with patient needs frequently exceeding hospital bed availability.[1, 2] The inpatient bed crunch now fuels frequent emergency room boarding of patients who would otherwise have been admitted, which in turn leads to worsened patient outcomes.[2, 3] Medical complexity is not the only driver of prolonged hospitalizations, however. Prolonged hospitalization can also stem from challenges finding post-discharge care options for patients who have been medically stabilized.

Hospital discharge is a high stakes decision that can bring core principles in bioethics into conflict, beneficence, non-maleficence, and wise resource allocation. Multidisciplinary teams responsible for discharge decisions are frequently comprised of members who also prioritize these ethical principles differently from one another. Respect for patient autonomy, which is of course another foundational ethical principle, plays a more secondary role in hospital decision-making, as discussed below.

The ethics of hospital discharge have been discussed previously. Swidler et al.[4] explored difficult hospital discharge decisions, such as patients who refuse to accept a physician's decision to discharge them from the hospital or who, conversely, demand discharge against medical advice. In each case they considered preeminent ethical principles such as respect for patient autonomy and wise resource allocation but the authors did not develop an overall process for resolving moments of tension between these principles. Jankowski et al.[5] conceived of person-focused, system-focused, and mixed discharge decisions, propose an ethical framework to address each scenario. In each case they discussed how competing ethical principles such as respect for patient autonomy and wise resource allocation may come into tension. Yet, despite this excellent prior work, we have seen no pragmatic guidance on the real-time resolution of such ethical tensions, however, likely allowing for clinical confusion when difficult decisions arise.

Given the increasing scarcity of hospital resources and thus the growing frequency of challenging hospital discharge decisions, we propose and justify an ethical hospital discharge decision-making algorithm which can be used to resolve challenging hospital discharge decisions.

Defining "A Safe Discharge" Leads to Confusion

When hospital discharge is being considered, it is common for clinicians to consider whether the plan under consideration represents "a safe discharge." Is the patient sufficiently medically stable and independent of hospital-level care to have a reasonable chance to thrive outside of the hospital?

One obstacle to the balanced resolution of moments when ethical principles involved in hospital discharge decision-making come into tension in routine clinical practice is that the definition of a "safe discharge" is unclear. Some clinicians define safety as the absence of specific negative outcomes, implementing metrics to quantify the likelihood of morbidity, mortality, and readmission for specific patient populations and, in some cases, such metrics have led to shorter stays following specific surgical procedures.[6,7] It is difficult however to apply such metrics to all medically complex, frail patients, with numerous hospital problems and social challenges. The enormous complexity of the group of patients being discharged from the hospital defies easy rubrics to define "a safe discharge." Some, such as Goodacre, have argued that attempting to define a simple biomedical metric for discharge decision making is irrational due to the limitations of our ability to prognosticate accurately and to weigh-in any useful quantitative way the risks of continued hospitalization vs the risks of discharge.[8] Our anecdotal experience is that some clinicians understand "safe" to mean free from almost any imaginable clinical harm, which is an unworkably broad and paternalistic definition. Given the inevitable disputes that will arise around such an inherently subjective outcome of medical care, it is not surprising that disputes can arise over timing of discharge and that hospitalization can be prolonged until those conflicts are resolved.

More Achievable And Specific Goals of Hospital Discharge

Instead of focusing on the intrinsically unclear definition of "a safe discharge," we propose that discharge decisions focus on what medical goals which can and cannot be realistically achieved by hospitalization, and a balanced resolution of any foundational ethical principles raised by this thought process.

It may be most reasonable to center the discussion around whether residual clinical indications for hospitalization remain, or whether concerns around discharge are arising from sources which are non-medical in nature.

For patients whose medical indication for hospitalization has been resolved, discharge may be held up by social factors such as the unavailability of an ideal home context for healing. This is when foundational ethical principles can come into conflict.

For instance, if clinicians fear a patient may not do well after hospital discharge despite resolution of the medical issue that led to hospital admission, the ethical principles of beneficence and wise resource allocation may come into conflict. Focusing on beneficence, clinicians may fear that further patient recovery from the medical condition that led to hospital admission may be undermined by, for instance, a chaotic home environment. If clinicians focus solely on beneficence, they will opt to keep the patient in the hospital, perhaps indefinitely, and conflict may arise about whether indefinite hospitalization is advisable for a patient whose indication for hospital admission has resolved. Incorporation of the also-important foundational ethical principle of wise resource allocation, however, may bring clinicians to the conclusion that hospitalization as a scarce community resource cannot and should not be used to redress chaotic home environments. Indefinite hospitalization due to chaotic home environment is likely impractical, whereas other community based resources such as nursing homes, respite care and homeless shelters may be more appropriate and cost effective. This more balanced ethical perspective can lead to concrete improvements in the hospital discharge plan.

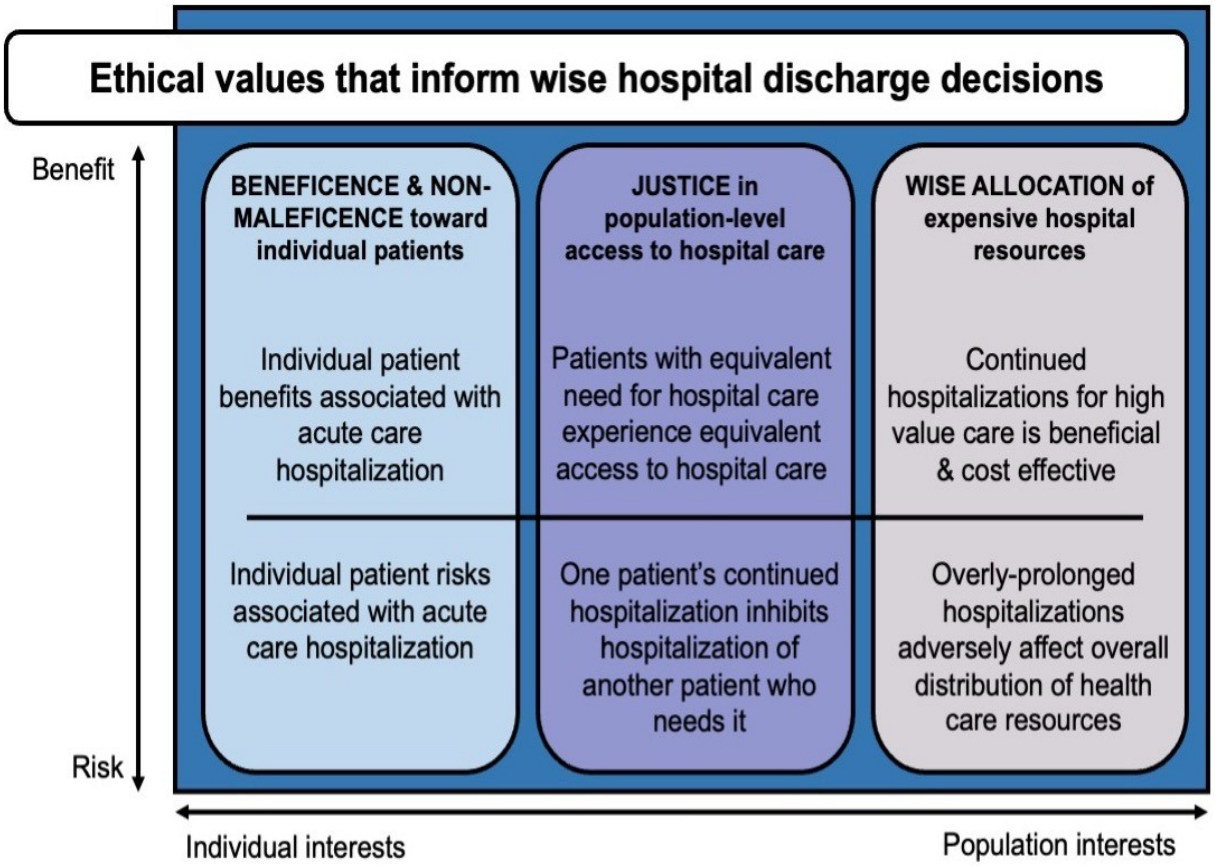
How Ethical Principles Can Come Into Competition During Hospital Discharge Decision-Making

To support the forthcoming discussion of ways to balance times when foundational ethical principles conflict during hospital discharge decision-making, **Figure 1 (page 106)** depicts how the foundational ethical principles of beneficence, nonmaleficence and wise resource allocation can relate to hospital discharge decisions.

Beneficence. Hospital care should lead to clinical benefit, meaning that patients discharged prematurely may experience adverse outcomes as a result of inadequate access to necessary care. Hospitals motivated primarily by financial concerns may aim to fill hospital beds with patient who can pay more for health care services, and this practice can lead to premature discharge of some patients who require continued monitoring. This practice of "dumping" has drawn national media attention as well as regulatory attention in the form of readmission disincentives. [9, 10]

Nonmaleficence. Obligations to non-maleficence are also critical to consider, as hospitalization is associated with myriad risks including exacerbation of frailty, hospital acquired infections, and deep vein thrombosis. Patients hospitalized for excessively long durations thus may incur increased medical risks along with substantial costs. Ideally, hospitals would discharge patients as soon as the benefits of hospitalization cease to outweigh their risks.

Figure 1: Ethical Principles Relevant to Hospital Discharge Decisions



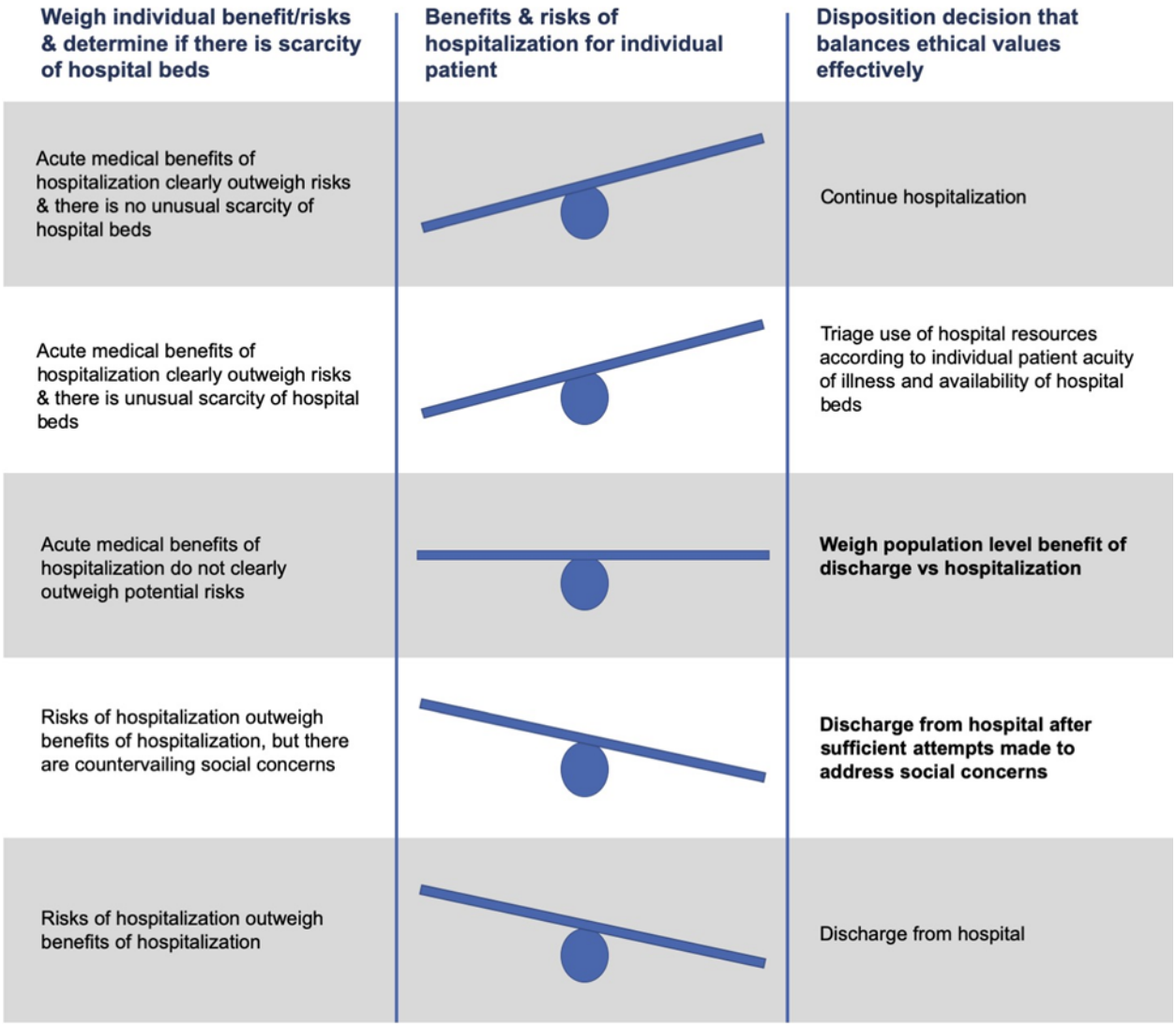
Justice. Fair allocation of the community pool of lifesaving health care resources dictates that patients with equivalent need for hospitalization experience equivalent access to hospitalization without regard to race, insurance status, zip code, personal social connections, the presence of stigmatized diagnoses such as addiction, or other social factors unrelated to clinical need.

Wise Resource Allocation. One patient's unnecessarily prolonged hospitalization can reduce hospital bed availability for another patient who presents to the emergency department with a life-threatening illness, which likely contributes to increased emergency room patient mortality during times of hospital crowding.[3] This is a potent reminder that hospitalization is a finite community resource that be used to maximize total population level health and wellbeing. The tension between beneficence and nonmaleficence priorities thus must be managed amid complex incentives for individual clinicians and the institutions that employ them.[11, 12] The concept of high value care inherently requires clinicians to consider the potential financial and human costs associated with the services that they offer, which is sometimes attempted via enacting financial incentives that influence discharge decision-making such as readmission disincentives.[13, 14] Binary financial disincentives such as this seem a clumsy instrument to resolve the competing ethical tensions inherent in complex hospital discharge decisions.

Toward a Balanced Ethical Approach to Discharge Decision-Making

To support clinician resolution of instances when foundational bioethical principles may conflict in hospital discharge decision-making, in **Figure 2 (page 107)** we present several categories of instances in which foundational ethical principles conflict in different ways in a fashion that requires a distinctive solution. The distinctive solution to each type of conflict between foundational ethical principles is driven by both pragmatic and ethical considerations. To aid clinicians attempting to identify and balance competing ethical principles in a pragmatic fashion in the care of individual patients, we depict an algorithm to guide discharge decision-making in **Figure 3 (page 108)**.

Figure 2: Five Common Ethical Discernments Made by Clinicians Making Hospital Discharge Decisions

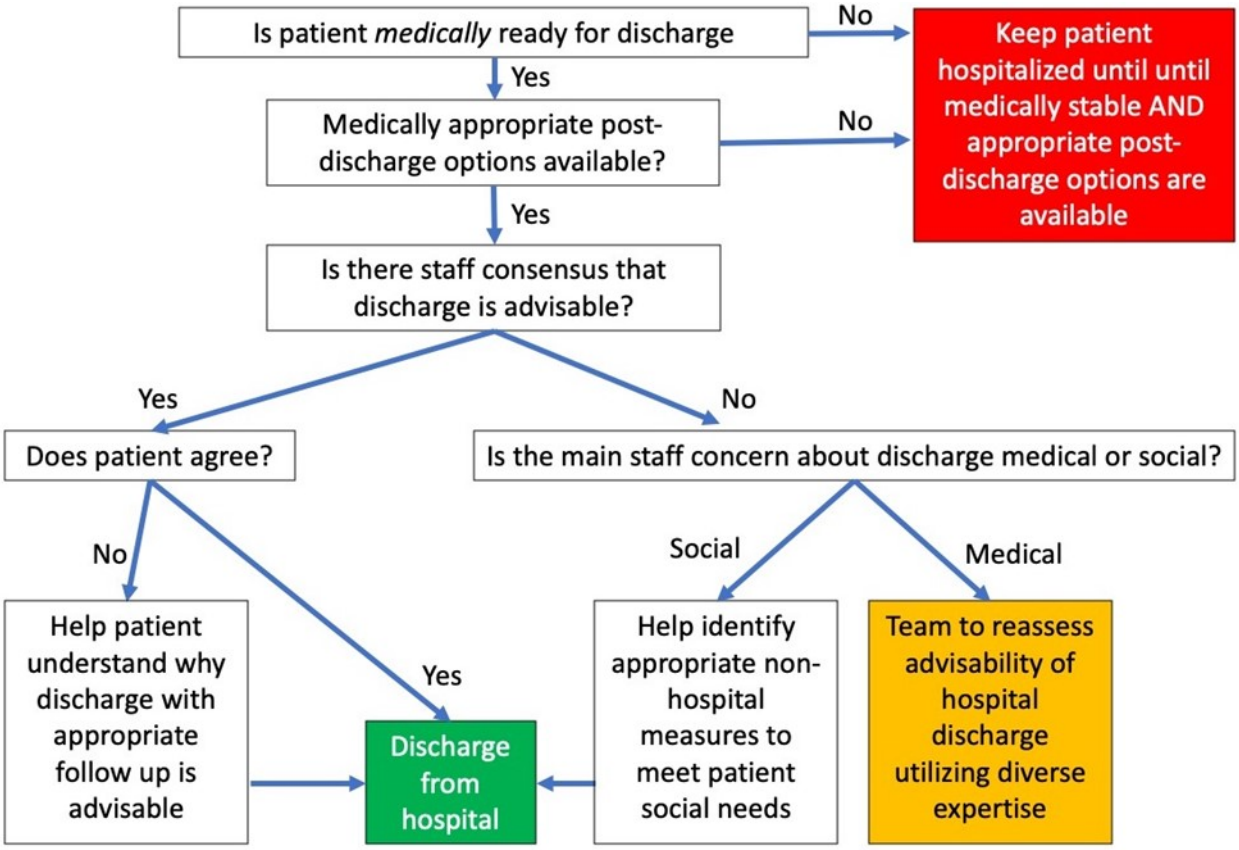


The algorithm begins with medical indications for hospitalization vs discharge, as these factors should be preeminent in the use of such medical interventions. Other factors including patient preferences and the availability of social supports after discharge are important to consider but are subordinate to whether the medical intervention of hospitalization remains medically indicated.

Each bedside clinician should prioritize the provision of high-quality care. Beneficence-based care that promotes the health-related interests of the patient and aligns with individual patient goals includes the provision of effective treatment that promotes readiness for discharge. While patient interests should remain primary, it is also incumbent upon clinicians to have an awareness of resource constraints that may exist within the hospital or health system. This does not imply that those clinicians engage in bedside rationing but instead remain open to communication from leadership regarding resource allocation decisions that are happening at a systemic level. This allows clinicians to properly advocate for individual patient needs while not being ignorant of or resistant to steps taken to allocate resources wisely. In such situations, resource allocation decisions should be made by a separate entity, either a unit leader or chief medical officer, in order to free bedside clinicians to advocate for their patient alone, albeit in collaboration with leadership.

Once it is determined that the patient is medically ready for discharge, next steps depend on the availability of an appropriate discharge option. If a consensus option is available, discharge may occur. If not, clinicians can focus on alleviating any obstacle such as insurance coverage for a given outpatient setting or advocacy for placement

Figure 3: Algorithm to Guide Ethical Discharge Decision-Making



once such a setting is available.

The Role of Patient Autonomy in Hospital Discharge Decision-Making

Beneficence, non-maleficence, and wise resource allocation often supersede respect for patient autonomy in hospital discharge decisions, but autonomy considerations can predominate when there are conflicts between the treating team and the patient or his or her surrogate about discharge decisions. Health care professionals have an obligation to respect the autonomy of patients and their surrogates, which includes a duty to partner with them on hospital discharge decisions. This commitment to partnership should not be mistaken for full capitulation to all patient preferences. Ultimately the clinician is the expert regarding medical indications for hospital discharge while the patient is expert about goals of care, meaning sometimes the clinician must sometimes discharge a patient from the hospital for medical reasons even over patient (or surrogate) objections. While all patients have a right to medical care, they do not have a right to services which are not medically indicated.[5] In these situations, it is important that clinicians explore the reluctance for discharge, but ultimately there is no ethical obligation to house patients in hospitals once their medical needs are resolved.

Disagreements can also arise when a patient asks to be discharged from the hospital earlier or to a different context than recommended by his or her medical team. For instance, patients may wish to be discharged home at the end of their hospital stay, while clinicians fear that they are no longer able to safely live alone. Prolonging hospital stays due to these concerns or discharging patients to living situations that they deem intolerable in the name of safety is another form of flawed, beneficence-above-all decision making. That approach can easily become excessively paternalistic because it positions the clinician as the final arbiter of what the patient's quality of life should be.

Even when patients and clinicians agree about discharge decisions, external factors such as the availability of mental health care, nutrition services, and housing, may affect the viability of a consensus discharge decision. The patient may not have access to a care facility that is ideally convenient to family visitation, or they may have be-

havioral needs that exceed available facility capabilities. Clinicians must weigh whether such social obstacles to ideal discharge can exert a truly deleterious effect on patient medical wellbeing. Utilizing extended inpatient hospitalization as a "one-size-fits-all" approach in an effort to solve outpatient resource dilemmas can worsen the shortage of scarce hospital resources.

Caregiver Team Conflict

The issue of team disputes about whether it is advisable to discharge a patient presents another decision point reflected in **Figure 3 (Page 108)** Such disputes arise regularly—particularly for patients who face complex medical and social challenges. We encourage caregiver team collaboration in advance of discharge decisions whenever possible. While physicians may be best positioned to characterize patient safety from a medical standpoint, it is equally important to learn from nurses and occupational therapy, for instance, regarding how functional and independent a patient would be upon discharge from the hospital. Metrics that predict readmission rates can inform some decisions, recognizing that such metrics do not exist for every diagnosis or patient situation and as above metric-based discussions can devolve into misdirected efforts to assure "safety."[15, 16] Some patients find it difficult to manage diseases for which indefinite hospitalization is not always the right answer despite a sizeable chance of relapse. In consensus building conversations, it is important to differentiate between medical vs social factors that drive impressions of advisability of patient discharge from the hospital. Hospitalization is a reasonable intervention for patients with unstable medical conditions whereas different social interventions may well be superior for patients whose social situations are the source of instability.

Ways of Addressing Difficult Choices About Discharge Decision-Making

Recognizing that team conflict may arise even when making ethically balanced decision-making about hospital discharge, it can be helpful to consider how to conduct such team conversations about hospital decision making in order to maximize the chances of generating consensus and preventing team member moral distress.[17] Much as with other ethical challenges encountered in clinical practice it can be helpful to air all viewpoints and engage the team in a shared process of reconciliation of differences and identification of balancing solutions. For instance ensuring that both physician and nursing perspectives are considered and harmonized can be important to developing solutions acceptable to each type of clinician. At the University of Vermont Medical Center (UVMMC), complex care rounds are regularly recurring meetings of caregivers from multiple professions (physicians, nurses, care managers, specialists, ethicists and more) with the mandate to balance competing principles and develop consensus solutions. Individual caregivers are included in these sessions when challenges or conflicts arise for patients under their care. We believe these conversations have helped instruct multiple participants in the general mechanics of ethical resolution of hospital discharge decision-making even when competing ethical principles initially made the resolution unclear to some participants. Such meetings can also drive institutional advocacy in the community for better patient care resources outside of the hospital. For example, in response to the recurring challenge of finding adequate skilled nursing facility beds in patients ready for discharge, UVMMC is partnering with a skilled nursing facility which will give preferential admission to recently hospitalized patients in return for staff training opportunities available within the hospital.

It is all too common that the largest barrier to safe discharge is the paucity or absence of appropriate community resources. Lack of housing and lack of long-term care facilities, particularly those equipped to serve people with mental health diagnoses, are an increasing concern across the nation. While it is reasonable to briefly extend a hospital stay until a suitable discharge placement is found, maintaining patients in hospital for extended periods of time due to the absence of such facilities is not a sustainable practice or an appropriate use of health care resources. Using hospitals as housing may alleviate concerns about individual patients but prevents scarce hospital resources from being used by others who need acute medical care, risks complications of hospitalization for the patient housed there, and may mask the true breadth of community resource scarcity.[18]

When faced with less-than-ideal disposition options, clinicians should work with case managers and social workers to facilitate patient access to all existing community resources.[18] When repeatedly faced with inadequate post-hospital resources, it should serve as a signal that more advocacy within the health care institution and potentially to local and state governments is needed in order to address that scarcity. Clinicians are uniquely equipped to provide first-hand accounts of the toll that the absence of these community resources takes on acutely ill patients, and hospital administrators should facilitate the communication of these perspectives to lawmakers. While housing instability and inadequate mental healthcare are both major risk factors for poor health outcomes, indefinite hospitalization is an inappropriate tool to address these social shortcomings. There have been notable successes in communities where hospitals have worked to spearhead development

of low cost and transitional housing,[19] and in the absence of initiatives from local and state government, hospitals should consider whether developing housing and mental health programs would serve their patients more broadly and allow for higher value care.

Challenges Encountered During Patient Decision-Making: Surrogate Decision-Makers

While not specifically addressed in **Figure 3 (Page 108)**, patients who are medically ready for discharge but lack decisional capacity are more vulnerable and present unique disposition challenges. Beneficence-based obligations and respect for persons become the predominant ethical considerations for patients who lack capacity necessitating the involvement of an appropriate surrogate decision-maker (i.e., health care agent, medical guardian, or informal surrogate) to participate in discharge decisions. Previously appointed health care agents and medical guardians (and in some states even informal surrogates) have the authority to make medical decisions and advocate on behalf of incapacitated patients consistent with the patient's goals and values and/or best interests. If the patient's appropriate surrogate decision-maker objects to the proposed discharge plan, attempts to resolve the disagreement (as previously described) and achieve consensus should be pursued. If agreement cannot be reached, it is ethically permissible to proceed with discharging the patient so long as appropriate and reasonable options have been offered, the risks of refusing have been discussed with the surrogate, and all other legal and regulatory requirements for discharge have been met and documented.

Incapacitated patients who do not have a previously named health care agent or medical guardian but are medically appropriate for discharge may require a prolonged stay in the hospital while efforts are directed at identifying an appropriate surrogate to assist with discharge planning. Some facilities may not accept a patient who lacks capacity without a legal decision-maker in place. If no surrogate can be identified or is willing to serve, a petition for guardianship (with appropriate permissions for determining the patient's residency) will likely be required. As a result, patients in this situation would remain hospitalized until a medical guardian is appointed and appropriate discharge planning options are completed.

Conclusion

Ethically balanced hospital discharge decision-making can be facilitated by the use of a simple algorithm along with multidisciplinary team conflict resolution, thereby leading to higher value care and reduced caregiver conflict.

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Should Physicians Address Firearm Violence? A Clinical Response to a Public Health Crisis

Geetika Baghel, MD and Eric A. Singer MD, MA, MS, FACS, FASCO

Abstract

The information gleaned from the standard history and physical exam guides medical professionals--physicians, physician assistants, and nurses--in their attempt to alleviate the burden of acute and chronic conditions. Yet, there are questions that they are not prepared to address. These questions specifically relate to firearm possession and violence. We define firearm (gun) violence as interpersonal or self-inflicted harm using firearms. Current and future medical professionals are underprepared to handle this topic tactfully.[12] Furthermore, ambiguous and divided ethical positions on firearms threaten the foundational tenet of medicine: *primum non nocere.*[21] Due to the cultural and political complexity of addressing this issue in the United States, we will focus our discussion on three salient points. First, medical professionals are morally obligated to address firearm violence. Second, firearm violence is a public health issue and addressing it has pervasive value. Third, firearm counseling and education should begin at the medical trainee level. These points are illustrated with examples, data, and propositions for reform. While the manners in which training curricula are developed and implemented may vary by institution and setting, their importance should not be underestimated.

Ethics And The Moral Code For Addressing Firearms

Why do physicians have a moral obligation to address firearm violence from a preventative lens? The answer to this question rests in the exploration of Hippocratic tradition and contemporary medical ethics. Hippocratic tradition relies on the assumption that medical graduates possess all necessary knowledge for translating therapeutic intent into clinical benefit.[21] Tradition uses a black-and-white approach to treatment that is biased by one's judgment of what is best for the patient. In this paternalistic model, medical professionals determine clinical benefit over patient and community goals, values, and ideals.

Contemporary medicine has intentionally moved away from this notion, introducing a code of ethics that fosters cooperation of patient-physician values and goals.[17-22] Simultaneously, its tenets have introduced ethical grey areas in practice. For example, the World Medical Association's International Code of Ethics states that a "physician shall strive to use health care resources in the best way to benefit patients and their community." [22] By this principle, medical professionals are morally obligated to address the harms of firearm possession and violence. Another line of the Code states, "a physician shall respect the rights and preferences of patients, colleagues, and other health professionals." Together, the statements introduce a bioethical paradox in the United States: how can clinicians prevent firearm violence while respecting their patients' and colleagues' Constitutional rights? Yet, another way to consider this issue is: in upholding individual autonomy, are clinicians bystanders to the violation of benevolence, nonmaleficence, and justice in the event of gun-related public health catastrophes?

We argue that medical professionals are obligated to address firearm violence as a public health issue. Although contemporary medicine has evolved to reject the paternalism of Hippocratic tradition, the fundamental responsibility of medical professionals persists: "help or do no harm to the patient." [21] This statement is a moral ultimatum. Additionally, it highlights the function and core values of medicine while establishing a foundation of trust for the public. Patients who see medical providers do so with the understanding that every exchange is an informational and educational transaction. Unlike conditions such as diabetes or hypertension, which physicians can elicit with specific tests, firearm safety counseling can only be achieved through patient testimony and trust. This trust can only be established if medical

professionals act on the force of a patient-centered moral obligation to prevent firearm violence, by asking patients directly about possession and storage.

Historically, physicians have faced obstacles to advocate against firearm violence outside of medical practice. The Dickey Amendment of 1997 reduced firearm research funding by 96%, nearly silencing firearm research up to 2015.[15, 20] But in 2018, an omnibus spending bill increased NIH funding for firearm research by nearly $25 million.[20] The action presented a unique opportunity in public health. Increased funding further supports the notion that medical professionals have an important role in addressing our nation's crisis. In fact, it is such a pressing issue that multiple medical societies have taken a stance on how to address firearm violence **(Table 1)**. Clinicians influence patient attitudes where such opportunities are available, and this in turn affects the probability of preventing firearm violence in a community.

Table 1: Professional Society Positions on Firearm Violence

Professional Society	Statements
American College of Surgeons (ACS) [23]	1. Support legislation banning civilian access to assault weapons, large ammunition clips, and munitions designed for military and law enforcement agencies 2. Support enhancing mandatory background checks for purchase of firearms to include gun shows and auctions 3**. Support ensuring that healthcare professionals can fulfill their role in preventing firearm injuries by health screening, patient counseling, and referral to mental health services for those with behavioral medical conditions** 4. Support developing and promoting proactive programs directed at improving safe gun storage and teaching non-violent conflict resolution for a culture that often glorifies guns and violence in media and gaming 5. Support evidence-based research on firearm injury and creation of national firearm injury database to inform federal health policy
American College of Emergency Physicians (ACEP)[24]	1. Support private and public funding into firearm safety and injury prevention research 2. **Protect the duty of physicians to discuss firearm safety with patients** 3. Support universal background checks for all firearm transactions including private sales and transfers 4. Support adequate enforcement of existing laws and support new legislation that prevents high-risk and prohibited individuals from obtaining firearms 5. Restrict sale and ownership of weapons, munitions and large-capacity magazines that are designed for military or law enforcement use, and prohibit sale of after-market modifications that increase lethality of legal firearms 6. Support prohibitions on 3-D printing of firearms and their components 7. Investigate social determinants of health and other cultural risk factors on patterns of firearm injury (poverty, intimate partner violence, etc.) 8. Support confidential national firearm injury research registry while encouraging states to establish uniform approach to tracking and recording firearm-related injuries (homicide, suicide, unintentional, self-defense, intimate-partner violence, officer-involved, etc.)

American College of Emergency Physicians (ACEP)[24]	9. Promote access to effective, affordable and sustainable mental health services for emergency department patients with acute mental illness for whom access to firearm possesses real risk to life for themselves or others 10. **Provide healthcare providers with information on most effective ways to counsel patients and families on proper firearm safety, emphasizing evidence-based methods that are shown to reduce intentional and unintentional injuries** 11. Support research into public policies that may reduce the risk of all types of firearm-related injuries Support community-based and hospital-based programs that would allow early intervention to prevent firearm-related injuries and long-term consequences
American College of Physicians (ACP)[25]	1. Support strengthening and enforcing state and federal laws to prohibit domestic violence offenders from purchasing or possessing firearms to reduce firearm-related injuries and death 2. Oppose concealed carry reciprocity; states permitting concealed carry require training in handling and storage of firearms to reduce risk of deaths and injuries 3. Support child access prevention laws that hold firearm owners accountable for safe storage of firearms by imposing criminal liability on individuals who store firearms where minors could gain access to them 4. Limit and regulate manufacture, sale, transfer and possession of firearms designed to increase rapid killing capacity, including large-capacity magazine and devices such as bump stocks; increase minimum age to purchase semiautomatic weapons and large-capacity weapons to 21, only as interim step toward a complete ban 5. Enactment of extreme risk protection order laws which allow family members and law enforcement to petition a court to temporarily remove firearms from individuals who are at risk of harming themselves or others while due process protections
American Academy of Family Physicians (AAFP)[26]	1. Fund appropriate gun violence research and public health surveillance for prevention strategies 2. **Allow physicians to counsel patients about injury prevention, including safe storage practices; oppose "gag rule" bills that aim to discourage doctor-patient communication** 3. Background checks should ensure that those have been convicted of a violent criminal offense and those who have been involuntarily committed to a mental institution or otherwise adjudicated to be suffering a severe mental condition posing danger to others or themselves are not able to purchase firearms 4. Support stronger gun trafficking and straw purchase laws, reinstate ban on sale of assault weapons and high-capacity magazines

Many physicians (66-84%) believe they have the right and responsibility to inquire about firearm possession and counsel patients on preventative measures.[10] However, the actual practice of screening measures varies. A study of veterans who screened for suicidal ideation reported only 15% of physician-documented inquiries about firearm possession.[10] Internal strife about whose responsibility it is to counsel patients is also an issue. A physician attitude

survey found that 65% of 222 respondents disagreed or strongly disagreed that a primary care provider is responsible for assessing a patient's mental soundness with firearm possession.[10] These conflicting attitudes may be the result of legislative actions that often lead physicians to bioethical crossroads. In 2010, the Affordable Care Act restricted the collection of firearm information by physicians. Select states, such as Florida, Missouri, and Minnesota have enacted restrictions on physicians to inquire about firearms.[10] Although none of this legislation applies to good-faith practices or extreme risk laws,[14] they are powerful enough to deter physicians from engaging in counseling.

Public Health Harms And Steps For Prevention

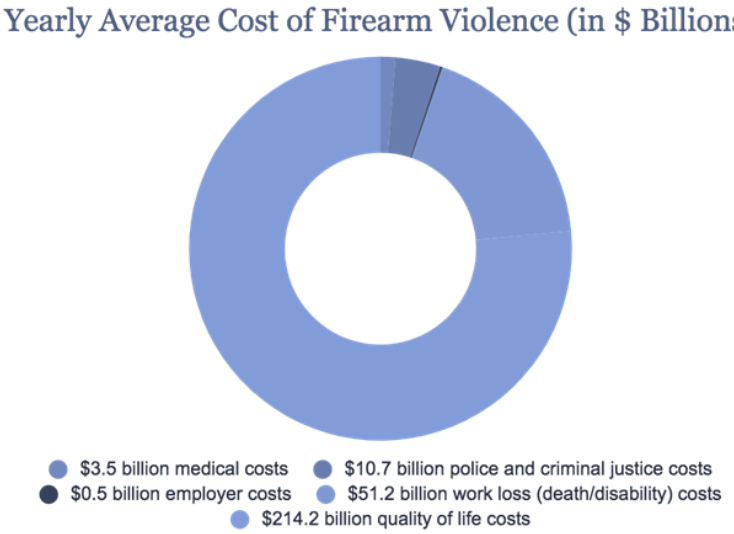
Gun violence is the twelfth most common cause of death in the nation and the third most common cause of injury and death in children.[1] The United States has the highest rate of firearm violence among developed nations. With nearly 40,000 deaths and over 80,000 disabling injuries each year, the gun epidemic remains an enduring public health crisis.[1] As **Table 2** illustrates, firearm violence is a public health issue in women's health, pediatrics, mental health, and systemic racism.

Table 2: The Public Health Toll of Firearm Possession

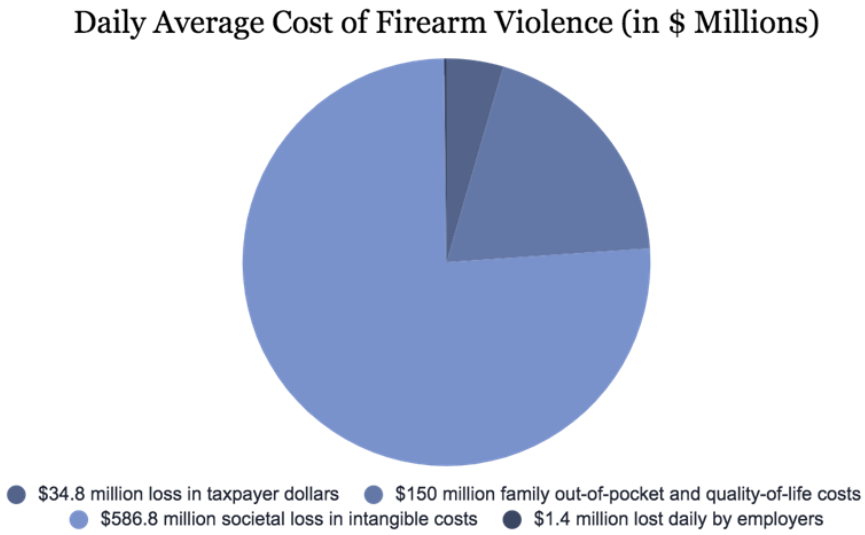
Public Health Domain	Morbidity And Mortality Risk in Home With Firearm
Women/LGBTQ[2]	5x increased risk of death by gun-related homicide after domestic violence incident
Pediatrics[3, 4, 5]	50% of estimated households with children have access to loaded gun 30% increase in gun-related deaths in children ≤18 years old since 2019 70% of accidental interpersonal or self-inflicted shootings 80% of gun-related suicides in children ≤18 years old
Mental Health[6, 8, 14]	10x higher rate of gun-related suicide than other developed countries 25x higher rate of gun-related homicide than other developed countries 3x increased risk of death by suicide with access to firearms
Systemic Racism[18, 19]	Black Americans are 10x more likely to die by gun homicide than white Americans

The ongoing coronavirus pandemic has only exacerbated this issue. Firearm purchases surged at an estimated 2.6 million sales in 2020 alone, far greater than during the Great Depression.[14] This surge placed a strain on the country's background check system and spilled over into public health consequences. It is estimated that, without intervention, the United States will see an additional 5,000 to 7,000 firearm-related deaths from 2020 onward.[14] Thus, medical professionals have a unique opportunity to tackle this crisis through education and advocacy.

The economic burden of firearm violence highlights the depth and breadth of this crisis. In an average year, the United States loses $280 billion to firearm disasters, more than the US Department of Veterans Affairs' annual budget: [4, 9]



On an average day, American taxpayers lose $34.8 million for medical care and criminal justice services related to gun violence: [4, 9]



The most sobering takeaway from this breakdown is that similar to hypertension, diabetes, and sexually transmitted infections, firearm violence is entirely preventable. The difference is that, unlike the aforementioned morbidities, physicians do not regularly or actively address gun violence. Besides curbing mortality and morbidity, tack-

ling firearm possession from a preventative stance has significant financial benefits for the American healthcare system.

Educating And Empowering Tomorrow's Healthcare Professionals

The question of when and how clinicians should intervene remains at large. On whom does the task of counseling fall and what should be the standard of care? Are nurses, physician assistants, and trainees (fellows/residents/students) included in legislative limitations? According to the Code of Federal Regulations, all legislative limitations are null when a patient is at risk of imminent harm.[10] In this case, medical personnel are legally mandated to report potential firearm violence. Simultaneously, the omnibus bill of 2018 no longer prohibits the collection of information for research purposes.

Although a standardized format for mitigating firearm violence in the United States has not yet been established, numerous medical professional societies have published guidelines for clinicians to address the public health issue. All of them agree that physicians have a duty to discuss firearm safety with patients (**Table 1**). However, firearm violence as a preventable issue is still infantile and unfamiliar for many academic institutions. Therefore, creating a standard set of guidelines that would teach medical, physician assistant, and nursing students and residents how to inquire and counsel about firearms is imperative. Programs can redesign curricula to address this epidemic at the institutional level. National societies must agree upon a protocol that clinicians in all stages of training can use in patient histories. State-level societies may then adapt this protocol based on legislative permissions to ask and counsel patients on firearm safety. By proactively teaching trainees, medical professionals may more easily anticipate warning signs and mitigate potential gun violence.

The conversation between patient and physician is difficult but necessary. Studies of high-risk patient perspectives regarding firearm counseling show that most are open to non-judgmental conversations on gun safety.[10, 13] If clinicians can be trained to systematically approach firearm safety counseling in the clinic, they may develop the confidence to effectively reduce gun-related morbidity and mortality.

Combining research with standards of care has powerful effects in prevention, as demonstrated by other preventable causes of morbidity and mortality. Due to increased federal funding of research efforts and safety education practices, American deaths from motor vehicle crashes, fires, and drowning have been reduced by 31%, 38%, and 52%, respectively over the last 20 years.[16] These results are promising for the normalization of research in firearm safety and counseling. The benefits of patient counseling on firearm safety are indisputable. The few studies on implemented firearm counseling demonstrate significant benefits. A cluster-randomized controlled trial to screen, briefly intervene, and refer to treatment (SBIRT) found a significant increase in safe firearm storage.[10] A study estimated that if half of the households with children and at least one unlocked gun switched to locking all guns, 30% of youth gun suicides and unintentional deaths could be prevented.[7] Another demonstrated that collaborations with community non-profits in Philadelphia and Massachusetts increased the amount of providers counseling on gun safety.[1] These studies demonstrate the potential impact physician and provider interventions can have in tackling the firearm epidemic.

Discussion

Medical professionals are at a crossroads for addressing firearm violence in patient settings. The epidemic of gun violence continues to plague American healthcare as a major public health issue. Although many professional societies have released statements on the issue, there is no standard protocol for addressing firearm storage, safety, or mitigating violence. Clinicians are morally obligated to address firearms in patient settings by the shared values of Hippocratic tradition and contemporary medical ethics. While historically, physicians have been limited due to legislation and lack of research funding, recent changes have shifted in favor of addressing firearm injuries and gun violence. As prior studies have established, preventative measures and interventions effectively mitigate preventable causes of morbidity and mortality. Clinicians can thus be involved in the conversation of firearm safety as trainees. The practice of medicine must change to better reflect the educational goals of patient-centered care. Teaching medical students and trainees early in their careers on how to have conversations regarding firearm possession can reduce the risk of firearm violence. Early introductions to addressing gun storage and safety in social histories can shift the paradigm of medical practice to one that both collaborates with patients and works to prevent unnecessary injury and death.[11, 13] The ways training curricula are developed and implemented may vary by institution and setting, but their importance should not be underestimated.

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Ethical Considerations When Using Complex Rescue Technologies in Innovative Ways: The Example of ECMO and COVID-19

Evan G. DeRenzo, PhD and Norine McGrath, MD

Abstract

In this article, questions addressed during the Lasker Forum on Ethics Challenges in Biomedical Research and Practice are applied to a population of critically ill patients with the novel coronavirus who are using the technology of extracorporeal membrane oxygenation (ECMO). ECMO is a rescue technology used for almost 50 years for patients with respiratory, cardiac, or combined cardiopulmonary failure refractory to conventional supportive and therapeutic modalities.[2] It is central to ethics considerations that ECMO is a life-sustaining, but not a curative, technology. We argue that hospital leadership responsibilities include supporting the explicit ethics training of house staff and data collection assistance for their individual, treating clinicians. In order for the call to be heeded to change the culture of modern medicine, from one that relies most heavily on the individual physician into a systems approach that sees hospital administration and its individual treating clinicians as parts of systems within systems, more attention will be needed by all involved.

Introduction

On May 15 and 16, 2003, the Lasker Forum on Ethics Challenges in Biomedical Research and Practice was held in Washington, DC at the American Association for the Advancement of Science (AAAS). Much time was spent attempting to identify a bright line between medical research and innovative practice in clinical medicine. No bright line could be found. Out of that forum came a book by Eaton and Kennedy,[1] encapsulating the forum's discussions and conclusions, including the main ethical concerns about how such technologies might best be introduced into the clinical care setting.

In this article, questions addressed during the forum are applied to a population of critically ill patients with the novel coronavirus who are using the technology of extracorporeal membrane oxygenation (ECMO). These questions are:

1. What are a physician's ethical obligations, when seeking consent for ECMO from a COVID-19 positive patient or the patient's surrogate, to overcome barriers to understanding the limits of this technology?
2. What are a physician's obligations to protect a COVID -19 patient, once on ECMO, from the harm of extended ECMO use until death?
3. What is a hospital's/ hospital organization's/ hospital system's obligation to support physicians and other care providers in the discerning use of ECMO for COVID-19 patients? (Hereafter, the author shall use the terms "hospital," "hospital organization," "organization/ organizational," and "hospital system," interchangeably).

In other words, our moral considerations are specified to the context of exploring the innovative, critical care rescue technology known as ECMO during the SARS-CoV-2 pandemic.

History And Current Use of ECMO

ECMO is a rescue technology used for almost 50 years for patients with respiratory, cardiac, or combined cardiopulmonary failure refractory to conventional supportive and therapeutic modalities.[2] In 1972, J. Donald Hill published the report of the first successful use of extracorporeal oxygenation in an adult.[3] The pioneering pediatric surgeon, Robert H. Bartlett went on to stabilize and mature the young field with the establishment of the Extracorporeal Life Support Organization (ELSO) in 1989.

Bartlett and his group reported the first successful use of ECMO in a neonate, born with meconium aspiration, in 1976.[4, 5] ECMO was also used in adults, but because of poor outcomes in adults, its early use was mostly in pediatrics. Nonetheless, with advances producing improved outcomes, ECMO is again being used for adults.[6-9]

ECMO provides prolonged cardiac and respiratory support to patients whose heart or lungs or both are unable to sustain an adequate gas exchange or perfusion to maintain life through an artificial, and mainly external, device. During this process, blood is taken from the venous system and is oxygenated outside the body. Blood is then returned to the body through the arterial or venous system depending on the support provided.

It is central to ethics considerations that ECMO is a life-sustaining, but not a curative, technology. ECMO offers assisted circulation of oxygenated blood in patients whose lungs and/or hearts are severely compromised by either injury or illness. In some patients, ECMO works optimally so that the patient's lungs and/or heart recover sufficient function. Other patients require permanent assistive circulatory devises, such as a ventricular assist device (VAD) or transplantation. Other patients will neither recover the function of native organs nor meet criteria for VADs or transplantation, leading to ethical challenges regarding the continuation and withdrawal of treatment.

Given that the SARS-CoV-2 virus is a novel disease process, there have been no clear pathways to figuring out individual or organizational obligations with the use of ECMO in these patients. "As in the early days of other organ support systems a major problem has been to define which overwhelming (and usually rapidly fatal) lung conditions are reversible with time and which are not." [10]

With no previous knowledge of the coronavirus COVID-19's behavior, there could be no certainties about patients' prognosis on ECMO. Although the past is usually the best predictor of the future, and, "Previous viral illnesses in recent times such as MERS and H1N1 have shown to present good results from ECMO." [11] Thus it is appropriate to attempt ECMO in advanced cases of COVID respiratory failure. However, where there has been no time to collect much data, prudence called for clear and explicit acknowledgment of such uncertainty in the informed consenting process.

When knowledge and experience are scarce, and the level of crisis creates urgency, it is the clinical hunch of physicians, what may be best thought of as the art of medicine, that drives decision-making. This is especially true in the intensive care unit (ICU) for critically ill patients with COVID-19 where patients can decompensate quickly. Many ECMO centers created criteria independently for placing adult patients on ECMO, ELSO has provided guidance, and there is a recently published consensus guidance document.[12] Nonetheless, particularly early in a new disease process, there is always space for clinical judgment. That is what makes clinical medicine an art, not a science. But it is this that is often the hardest for physicians to make clear and understood while engaging patients or their surrogates in considerations of using such a complex technology with an untested condition such as COVID-19. Explaining uncertainty is one of the most difficult aspects of high technology and unproven interventions. Physicians do not like to feel, or show, uncertainty, and uncertainty is equally or more uncomfortable for patients and surrogates to digest. In the discussion of ECMO, the stakes are much greater than the possible use of an untested medication or vaccine.

In an ideal circumstance, the use of a rescue technology with patients presenting with disease of unknowable safety and effectiveness profiles would be studied under research protocols prior to widespread implementation in the relatively unregulated environment of clinical care. In the United States (US) as is the case with off-label drug use, once the US Food and Drug Administration (FDA), has approved use of a surgical device, that device does not require FDA reapproval for a surgeon to use that device in an innovative way. So, with desperation rampant and minimal, but some data in possibly similar viruses as drivers for the application of unresearched technology in patients presenting with critical illness, there would be little to act as a barrier to application of ECMO in COVID-19 patients.

With many atrocities in clinical research having come into public view since WWII, however, in part producing the advent of contemporary bioethics, and bringing greater scrutiny and regulation of clinical research and clinical medicine, a debate in surgery took shape about 20 years ago that is far from settled. This debate is about whether and when an innovative surgical intervention should be subjected to rigorous clinical trials rather than simply allowed to become part of clinical surgery's standards of practice. Subjecting a surgical innovation to rigorous clinical research evaluation means wide and rapid usage will be slowed. If not, and a surgical innovation is allowed to work its way into practice through traditional clinical care routes, it may eventually become a standard of practice without receiving the research attention needed to know whether it is safe and more beneficial than harmful. Rather, surgical advances have taken place by trial and error, based on clinical judgment. Unlike the introduction of new pharmaceuticals that have long been highly regulated, innovations in surgical practice have not. Therefore, the inclination to apply ECMO technology to the

rescue therapy of critically ill patients with COVID-19 seems like a relatively easy leap of faith.

But while the application of ECMO technology to critically ill patients is understandable from an individual as well as organizational perspective, what obligations exist to prevent harm to the likely critically ill patient using the unproven technology? One way is to work hard to have patients and/or surrogates giving their permission for a patient's use of the unproven technology, to understand the known potential risks of harm, potential for benefit, and alternatives, including shifting to comfort measures only, as best as can be known. Only as the experience of clinicians mounts in articulating these aspects of informed consent, and the uncertainties become clearer, can the obligations of the clinicians come into focus and the organizational obligations, if any, begin to take form.

What are a physician's ethical obligations, when seeking consent for ECMO from a COVID-19 patient or the patient's surrogate, to understand the limits of this technology?

There has long existed the belief that a physician can convince a patient or a surrogate, particularly under life-threatening conditions, to consent to almost anything. Although disasters have followed poorly conducted research consenting, for the most part, in the clinical research setting, informed consent is conducted punctiliously. Potential for risks, benefits, and alternatives, including no research participation, are ordinarily well-articulated, as required by regulation and professionalism.

In clinical medicine, however, especially in an emergency or imminently life-threatening situation, it lacks prudence to be so sanguine. Although this might be an ethically acceptable reason for a bias towards accepting a physician's recommendation in the clinical setting, where the inherent conflict of interest that exists in clinical research ought to be absent, what is being recommended is expected to be in the patient's best interest. In the informed consenting process to initiate ECMO, it is necessary to spend a substantive amount of time explaining that deciding to discontinue ECMO is a medical decision, which means that the physicians (along with the full interdisciplinary team) will make the call and tell the patient or surrogate. That is, at the point that the team believes ECMO is no longer providing a clinically meaningful benefit, the physicians will tell the patient or surrogate that it is time to discontinue ECMO. In the era of pandemic visitation restrictions, surrogates and families cannot be present at the bedside until the patient is expected to live merely hours to days. In practice, things rarely go as the policy anticipates; patients and/or surrogates ordinarily contest the physician's plan to discontinue ECMO.

What are a physician's obligations to protect a COVID-19 patient, once on ECMO, from the harm of extended ECMO use until death?

Before reaching the point where the conversation must turn to taking a patient off life-extending technologies, clinicians have their standard obligations to protect any patient from harm. This ethics norm is no different for ECMO. For example, there is the problem of when to shift a patient who is likely to need prolonged mechanical ventilation (PMV) to a tracheostomy, a surgical procedure. This problem has been well-studied, but no clear answers have emerged. Unfortunately, it is still a complex, technical problem, where clinical trials data remain uncertain and indefinite.[13]

If after years of studying this issue central to guiding how to improve outcomes determining what timing might be better for which COVID-19 patients is going to be an uphill battle. With the data so new and treatment decisions for these patients changing so quickly, it is difficult to imagine that the informed consenting process about when to attempt to shift a ventilated patient to ECMO will be any less riddled with uncertainties than transition to a tracheostomy.

There are aspects of COVID-19 that set a collision course with the demands of the ECMO machinery. For example, a common adverse event in ECMO is bleeding. When the bleeding affects the brain, it is often particularly devastating.[14, 15] With neurologic injury such as intracerebral hemorrhage, subarachnoid hemorrhage, or ischemic infarcts, a COVID-19 ECMO patient whose prognosis had been promising at one moment, may turn grim the next.

Infectious complications are also among the common side effects of ECMO.[16, 17] What is worth noting here is that infections may be especially difficult to manage in COVID-19 patients. The multiple invasive devices that ECMO patients require sets them up for infection. Because the diagnosis of infection is difficult to make in a patient on ECMO,[18] given that the standard signs and symptoms of infection, such as fever and leukocytosis, may be absent, the patient with COVID-19 simply adds additional complexity for physicians and other team members trying to protect that patient from the harm of additional infections that could further impede his or her prospects for clearing a COVID-19 infection and surviving to decannulation. (Decannulation is the term used for discontinuing ECMO.)

Further, when a patient is on a ventilator and close to death, the patient is usually not capacitated, mobile, or able to communicate very easily with those in the patient's own environment. This is sometimes true for the ECMO patient, but sometimes not. Some ECMO patients, including COVID-19 ECMO patients, are awake, capacitated, and mobile.

Stopping ECMO, for a patient who is decisionally capacitated and communicating, referred to as the "awake" ECMO patient,[19, 20] is unlike turning off a ventilator or stopping other life-extending technologies for patients who are sedated. That is, for most other life-extending technologies, particularly ventilators, patients are significantly sedated in order to be comfortable, such that they no longer can communicate with the world around them.

Discussion of why this distinction between the greater ease in end-of-life decision making for the sedated versus the awake patient exists is beyond the scope of this article. Suffice it here to simply note the difference. But even when the COVID-19 patient is on a ventilator, close to death, not capacitated, mobile, or able to communicate with the patient's own environment, the decision to discontinue life-extending technologies is, most often than not, a difficult one. Discontinuation of ECMO is, again, no different. What is different is that for ECMO, the decision is explicitly stated to be a *medical* decision within the informed consent process. Patient- and family-centered values are suspended, or at least that is the intention. Nonetheless, deciding when to stop ECMO usually turns out not to be a medical decision in a vacuum. It is going to at least be a decision in which surrogates will be involved. And deciding when and how to turn the ECMO machine off will be difficult indeed. When should ECMO be turned off? What can be the moral justification for turning it off one day versus another? With COVID-19, this decision making is even more wrenching since the viral mitigation policies of none or minimal family visitation. The nurses and physicians scramble to find mobile phones and tablets that allow the surrogate and other family members to see the patient. But for those who have taken part in these remote 'family meetings' it is clear how inadequate they are in communicating much of the important information that surrogates and families need to truly be clinically involved. Although public expectations are high that surrogates and other family members are equal partners in the decision-making process, usually the facts fall short.

Perhaps the best for now is to remember the seminal work of Wendler and Rid.[21] They found that a substantial percentage of surrogates who had to make end-of-life decisions for patients suffered emotional and psychological harms for months and years after the associated death. But it is never really either the clinicians or the family members who decide when a technology is doing more harm than good. It is, usually, the patient's body, i.e., the disease process, that makes harm to the patient clear. That is the true limit of any rescue technology, but especially for an unproven technology such as ECMO when used for patients with such a new disease as COVID-19.

The Responsibility of Hospitals as Organizations

Hospitals in the United States have long been places to care for the sick as well as centers of medical innovation and discovery. Here, we accept DeGeorge's elucidation of this responsibility:

"A hospital, as an organization, chooses alternatives and acts rationally; therefore, like an individual, it is seen as having moral responsibility. This responsibility is primarily administrative, with duties owed to its patients, health professionals, and the community served. The hospital's primary obligations are to develop norms to which the hospital and staff must conform, to serve patients by providing the best care possible, to allocate resources so as most effectively to respond to the needs of the community and to create policies which allow staff members to refrain from performing acts which they consider immoral." [22]

Identifying these hospital obligations, organizationally, brings us back to considering how these obligations apply to the use of ECMO in a hospital and particularly to ECMO with COVID-19 patients. Here we focus on hospital responsibilities for establishing and reinforcing norms related to resource utilization, creating necessary policies, and an organization's obligations for assisting individual clinicians in providing the best care to patients and families possible.

Physicians and nurses are highly and specifically trained professionals, and ECMO patients are some of the most intensely monitored patients in a hospital. Care of COVID-19 patients on ECMO can last weeks, with many dying nonetheless, and given pressures to avoid excessive lengths of stay, it is not surprising that as death inches closer, clinicians begin to think about resource utilization.

Ethically, however, it should never be the individual treating clinician's responsibility to consider resource utilization, even if harboring such thoughts may be occasionally unavoidable. Training physicians and nurses to banish such thoughts when they occur ought to be a central component of a hospital's ethics program. Learning to banish such thoughts ought to be part of the skill set of a self-controlled and composed clinician.

This is one of the most ethically challenging problems of working in a high-technology clinical setting. Clinical ethicists ought to be consistently attempting to help clinicians learn not to think about resource utilization in relation to any specific patient. One of the most ancient ethical norms in medicine is that once a physician or nurse is in a relationship with a patient, that clinician's obligations are to that patient.

That is why it is the obligation of the administrative arm of a hospital to lift resource utilization pressures off the shoulders of individual physicians and nurses. In considering such an expensive resource as ECMO, expensive in dollars and cents as well as in the technical skills of the professionals and their psychological wellbeing, resource utilization decisions must be the responsibility of hospital leadership.

This responsibility of leadership is not only because it is they who have the hospital's resource utilization big picture understanding of the effects of ECMO utilization on the various other parts of the hospital. It is hospital leadership who should be setting the tone and ethical norms for the hospital. It is leadership who ought to rigorously broadcast to all clinicians that they will not be pressured about such resource utilization issues as length of stay or whether to place a COVID-19 patient on ECMO if the clinical indications for that patient are that they have a reasonably good chance of benefiting from the technology.

Responsibility for hospital resource utilization belongs to those at levels above the individual treating provider. Committees should be organized to oversee and set policy for the management of complex rescue technology. Ethically, by lifting resource utilization decisions to levels above the treating clinician, the moral climate of the hospital can be immeasurably strengthened. This way, the ethically appropriate relationship between treating clinicians and patients can be set and maintained.

Policy Development

Next, we turn to a hospital's obligations for policy development, specifically around the informed consenting process for ECMO. This article began discussing the individual clinician's obligations for conducting informed consenting processes that not only include all the potential benefits of ECMO for the selected COVID -19 patient but also clarity about ECMO's limitations such as high complication rates. In the event that ECMO is no longer beneficial or has become actually harmful, turning off the ECMO machine will be the physician's judgment. Now we focus on the organizations, and the justifications for such obligations, to both make clear in policy, as well as to support the mechanisms and time needed to fully enact such policy.

Here we consider the specificities of managing a COVID-19 patient on ECMO, especially at end of life, along with the convergence of the 'patient-centered' movement and contemporary expectations by patients and surrogates for partnered decision making. Informed consent policies have had to clarify that a decision to turn ECMO off will be a medical decision, i.e., medically justified.

But simply passing such policy through a hospital's committees for policy development and approval will not be enough to assure that informed consenting processes will be enacted. Attending physicians and physician trainees are so swamped with the science of medicine that the ethical aspects of how to perform "soft" skills such as informed consent may not receive appropriate focus

Administration needs to set a norm, with leadership adherence, that taking the time to have complex conversations with patients and families is as important as any other ICU function. Without explicitly teaching physician trainees the ethical nuances of what they do and who they should be as they do it, the ethical foundations of properly informing can easily be missed in the rush to obtain a consent document signature. Administration must play their supporting role. This is especially true in hospitals providing innovative, high technology, rescue interventions such as ECMO.

This calls on administration, including budgeting, risk management, and human resource professionals, to learn what excellence in informed consent includes and to understand that inadequate informed consent processes contribute negatively to outcomes for patients, families, provider teams, and the bottom line.

It has been important, for example, to constrain resident hours to humanly manageable time frames.[23, 24] The complexity of critical care hospital medicine has evolved towards a team structure, as has been the case in virtually all other therapeutic areas.[25] These changes, however, have produced their own challenges.[26-28] Report after report issued by the National Academy of Medicine and its sister organization have emphasized that expecting the work of health care today to be the responsibility of individual physicians is an impossibility. A systems approach is what is required.

Intangibles related to ethics excellence account for much of the moral climate of a hospital which is brought into sight by, for example, the paper by Jeff Berger. Berger suggests that moral distress – a marker for problems with the moral climate of a hospital – are, as he states, "…common, but under-recognized in medical education and training, and this relative inattention may undermine educators' efforts to promote empathy, ethics practice, and professionalism. Moral distress should be recognized as a feature of the clinical landscape…" [30] To expect individual attending physicians to find the time and energy to address this problem without additional resources is unrealistic.

In a program described by Vertrees et al.[31] a trainee ethics program is described as including small group classes taught by experienced clinicians over the course of residency. This program is a prime example of the extent of additional resources that are likely needed in today's hospital, at least in institutions with patients as sick as those needing ECMO, to help physician trainees

grasp the ethical nuances of their work. Because of this program's national stature, it is likely, also, that the group is much respected and well-funded by its hospital's leaders and human resource professionals. Clearly, conducting this kind of program, on an annual basis for all medicine and surgical residents, is well beyond the capabilities of the treating physicians without substantial time and resources devoted to such an effort by administration.

Patient Safety

Real, sustained attention to the potential for harm to hospitalized patients did not fully register with the medical community or the public until the publication of the Institute of Medicine (IOM) report, To Err is Human: Building a Safer Health System.[32]

The report jolted everyone with its eye-popping statistic that approximately 44,000 to 90,000 hospitalized patients are injured or die from preventable events every year in the US. These numbers launched the patient safety movement in clinical medicine, a movement that is strong and still evolving.

Patient safety efforts take many forms. With the publication of the IOM's second report from the Committee on the Quality of Health Care in America, Crossing the Quality Chasm,[33] published on the heels of the 'To Err' report, the American health care community was called to appreciate the need for, and then implementation of, necessary and sweeping culture changes in patient safety, improvements developed from a systems perspective. Two of the most important and fundamental concepts to understand coming out of this second report and the continuing work is that 1) the exponential growth of contemporary medical science that delivers new studies, medications, and devices at such a prodigious rate as to overwhelm physicians' ability to stay on top of the knowledge base and 2) acute care hospitals have had to shift from caring for patients with primarily or strictly acute care needs to patients with acute care needs layered on top of chronic disease. One of the most important organizational implications of these findings is that it must be an organizational goal to assist individual clinicians to make sense of this mass of information, which is even more true in the rapidly changing treatment recommendations for COVID-19 critical care.

Evidence for the appropriateness and effectiveness of ECMO for COVID-19 patients is not yet well tested and therefore not so convincing. For example, in an in-depth Canadian technology assessment of safety, efficacy, and cost-effectiveness of ECMO in adults with cardiac arrest or cardiogenic shock, they found that although ECMO may reduce brain damage and deaths, the quality of the existing studies is so poor that these findings are questionable. So poor, in fact, that they graded the quality of ECMO research evidence as low or very low on most of the indices they examined.[34]

Relatedly, an organizational obligation that blurs the research/clinical care line but stands to assist clinical care is to free the attending physicians and trainees (i.e., interns, residents, and fellows), to participate in research projects and/or practice committees to learn from others' COVID/ECMO experiences. For example, the state of Maryland has long been a leader in healthcare legislation. Producing such legislation takes skill and persistence in building state-wide coalitions. Thus, when COVID-19 hit, the stage had already been set to build collaborative relationships across systems to work through the complexities that were going to arise. In Maryland, this became the regional practice committee formed by Johns Hopkins University, Lifebridge Health, Luminis Health, MedStar Health, and the University of Maryland. This group developed an "(a)llocation schema for mechanical ventilators, intensive care unit resources, blood components, novel therapeutics, extracorporeal membrane oxygenation, and renal replacement therapies," "(t)he goal of this partnership was to develop operational SRA," (scarce resource allocation), "processes which could engender community trust by assuring that allocation decisions were fair, consistent, legally permissible, and non-discriminatory across all participating hospitals." [35] The group has held conference calls to which others within the partnership can listen. These have been important learning sessions and are the kind of state and regional coalitions in which hospital leadership should encourage their clinicians to participate.

Conclusion: Implications For Introducing The Next Novel, Critical Care Rescue Technologies

ECMO is only the latest novel rescue therapy to be applied to critically ill patients. As the science of medicine progresses, new rescue technologies in critical care medicine will arise. Once a given technology is FDA approved for one indication, physicians and surgeons will figure out innovative uses for them in our human efforts to defeat death. One can only hope that lessons learned by a hospital's leadership, budgeting, risk management and human resources professionals with the application of ECMO technology in the age of COVID-19 translate into an appreciation of their increasing responsibilities. These include supporting the explicit ethics training of house staff and data collection assistance for their individual, treating clinicians. For the call to be heeded to change the culture of modern medicine from one that relies most heavily on the individual physician into a systems approach that sees hospital administration and its individual treating clinicians as parts of systems within systems, more attention will be needed by all involved.

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Balancing the Risks and Benefits of Interventions for Pregnant Patients With Acute Psychosis

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Case Complexity: 1 2 3 **4**

Abstract

A 25-year-old woman who is 8 months pregnant is brought to the emergency department with altered mental status. The medical team was concerned about next steps in management should the fetus continue to show signs of distress, since Ms. J was unable to provide informed consent for cesarean delivery. Some physicians and nurses on the obstetrics team worried that performing cesarean section without consent would be tantamount to assault and battery. However, other team members feared that a lack of intervention could lead to fetal demise, an outcome that they felt was ethically worse and unacceptable.

PRESENTATION

Ms. J is a 25-year-old pregnant woman who was brought to the emergency department by paramedics after being found wandering in a residential neighborhood appearing unkempt and having altered mentation. She had no identifying documentation or belongings on her person and was presumed to be homeless. During her exam she was able to state her name and reported that she was "8 months pregnant," but otherwise demonstrated disorganized thoughts and provided tangential or nonverbal responses. She was not able to provide any emergency contact information and her past medical, psychiatric, and social history were similarly unknown. After unremarkable laboratory testing including a complete blood count, comprehensive metabolic panel, thyroid markers, and urine toxicology, she was admitted to the inpatient psychiatric unit for acute psychosis.

While in the psychiatric ward, a fetal nonstress test (NST) was performed to obtain information on fetal wellbeing. Her initial NST was nonreactive with decelerations, which raised a possibility of fetal distress. Without stating why, she physically refused to cooperate with further fetal monitoring and repeatedly removed the external monitors from her abdomen. Ms. J appeared uncomfortable and paranoid, becoming increasingly agitated. She appeared to respond to internal stimuli and was not able to participate in discussions regarding her own care or that of her fetus. The psychiatrist performed a capacity assessment and determined that Ms. J did not have decision-making capacity. The psychiatrist then ordered emergent intramuscular injections of haloperidol and she was transferred to Labor & Delivery.

Upon arrival, the obstetricians resumed fetal monitoring and discussed whether Ms. J should be physically restrained if she became agitated again in order to prevent her from removing her external monitors. They were concerned about the next step in management should the fetus continue to show signs of distress because Ms. J was unable to provide informed consent for cesarean delivery. Some physicians and nurses on the obstetrics team worried that performing cesarean section without consent would be tantamount to assault and battery. However, other team members feared that a lack of intervention could lead to fetal demise, an outcome that they felt was ethically worse and unacceptable.

A social worker was consulted to help identify and locate any family members to serve as Ms. J's surrogate decision-maker; however, it was uncertain whether family members could be contacted in time if an emergent indication for cesarean delivery arose. Even if a surrogate could provide informed consent for a cesarean section on Ms. J's behalf, the obstetrics team had concerns about the safety of performing surgery on a physically agitated patient and discussed whether she should be restrained in this situation. The hospital bioethics committee was urgently consulted.

ETHICAL ISSUES

There are many unique ethical challenges involved in the care of pregnant women with acute psychosis due to illnesses such as schizophrenia, bipolar disorder, and substance use disorders. Decision-making capacity may be limited or completely impaired in these patients. Physicians are therefore faced with the dilemma of determining if a patient is able to give informed consent, and whether certain interventions for maternal and/or fetal benefit in the absence of informed consent are ethically justified.

Here, the primary ethical challenges are 1) does this patient have the capacity to make her own medical decisions and decisions regarding her fetus, 2) how should a surrogate decision-maker be identified when family members are unknown or unavailable, and 3) are interventions which follow the typical obstetric standard of care ethically justified in a pregnant patient who lacks decisional capacity due to psychiatric illness?

RECOMMENDATIONS

1. Perform regular capacity assessments and clearly document the results of the evaluation.
2. Obtain psychiatric consultation to assist with impairing psychotic symptoms. In many cases, antipsychotics may provide benefit to both mother and fetus.
3. If involuntary fetal monitoring is being considered, a prior determination should be made if interventions without maternal consent, including cesarean delivery, would be undertaken in response to an abnormal monitoring result. If interventions in response to abnormal fetal heart tracings (FHTs) would not be justified or undertaken without maternal consent, involuntary fetal monitoring should be avoided.
4. Avoid use of restraints unless all other means of maintaining patient and staff safety have been exhausted. Use of restraints is likely to be traumatizing and worsen physical and mental health outcomes for both mother and fetus.

In this case, the bioethics committee recommendation agreed with the psychiatrist's assessment that the patient did not have decision-making capacity. Despite the patient's inability to provide consent, the bioethics committee also recommended she continue to receive antipsychotic medication in order to avoid restraints and possibly hasten recovery of her decisional capacity. The committee also asserted that if the patient demonstrated no change in decisional capacity upon reassessment after treatment with haloperidol, and if all efforts to identify a family member or close friend are exhausted, then her treating physicians may serve as a surrogate of last resort for medical decision-making.

REASONING

Providing care when decision-making capacity is compromised by acute psychiatric illness is further complicated in pregnancy by the additional pressures of time constraints and fetal considerations. This case reviews ethical calculations for the risks and benefits of interventions for pregnant women who are impaired by psychotic symptoms and may be unable to provide consent for routine or emergency obstetric treatment. Evaluation of decisional capacity is a fundamental initial step in determining the treatment course for a pregnant patient whose ability to provide consent is suspected of being impaired by psychosis, with a framework for this process previously established and reviewed.[1-3]

A thorough psychiatric evaluation may provide valuable information regarding the severity and nature of the psychotic illness and any possible interference in decision-making. A thorough understanding of the patient's disease course will aid the determination of next steps for clinical care, as decision-making capacity of a psychotic patient may not be permanently impaired, but instead fluctuate over time. Symptoms stemming from a recent drug ingestion may resolve after a short course of supportive treatment, while symptoms that are severe and chronic in nature may not be expected to meaningfully improve in time for a woman to participate in time-sensitive decisions. Collaboration with a psychiatric consultant may be required to gather requisite data needed for informed ethical decisions.

Decision-Making About Intrapartum Management For a Patient Without Decision-Making Capacity

The ethics and law of decision making for patients who lack decision-making capacity have become very well established.[4-5] When a clinically appropriate assessment of lost decision-making capacity has been made and documented in the patent's record, the team should seek authorization of recommended clinical management from the legally designated surrogate. Typically, applicable law provides a list, starting with a court-appointed guardian, then spouse and other family members, close friend, and surrogate of last resort, usually one or two physicians. The team should consult organizational policy. Uncertainties should be addressed to organizational legal counsel.

Two consensus ethical and legal standards should guide surrogate decision-making. The first is the substituted judgment standard, a decision based on a reliable identification of the patient's relevant values, beliefs, and preferences. When the surrogate is not able to meet this standard, the best interests standard applies. This standard is a function of clinical judgment about medically reasonable clinical management, which the surrogate should authorize. In cases such as this, it is not uncommon that no family member or other legally des-

ignated surrogate such as a close friend can be identified. Applicable law usually provides for a surrogate of last resort, often two physicians. These surrogates may not be able to meet the substituted judgment standard. The best interests standard will then apply: when cesarean delivery should be recommended in rigorous clinical judgment, it should be authorized.

Organizational leaders should assure that decision-making policies are complete and clear. The ethics and law of surrogate decision-making are so well understood that policy should stipulate that seeking a court order is not required.

Intervention Considerations

Pharmacologic Intervention

Antipsychotics may be useful agents in restoring the decisional capacity of psychotic patients, and their use towards these aims fulfills the ethical obligations to autonomy and both maternal and fetal beneficence. Antipsychotic treatment may promote the mother's ability to adequately care for herself and appropriately care for her developing fetus before and after birth. Additionally, reduction in symptoms and improvement in reality testing may increase the mother's ability to participate in the delivery process, which respects her agency and reduces the risk of a traumatic birth experience. Left untreated, maternal psychiatric illness increases infant mortality and morbidity through numerous avenues.[6] Thus, administration of antipsychotic agents may improve both maternal and fetal outcomes.

Concerns with psychotropic medications may center on the mother's inability or refusal to consent to treatment and any potential teratogenic effects on the fetus. While involuntary medication administration may infringe on the autonomy of the mother, antipsychotics may concurrently promote autonomy by restoring capacity and competence.[7-8] When possible, medication should be offered voluntarily in an oral formulation before involuntary administration. Regularly scheduled medication is preferred over a pattern of continuous emergent dosing, as it is likely to be more effective and less traumatic.

Notably, numerous recent studies have not found an increased risk of congenital malformations with exposure to antipsychotics, and a single dose is generally considered low risk.[9-10] Risks of other side effects in the mother and fetus are typically dose-dependent, so the minimal effective dosage should be pursued. Haloperidol is often preferred for first-line treatment of acute psychosis in pregnancy because of its longer record of established safety data and lower side effect burden.[8, 11] As psychosis in pregnancy often represents a psychiatric and obstetric emergency, a psychiatric consultation is warranted to assist with medication recommendations and need for further psychiatric treatment.

Fetal Monitoring

Fetal monitoring is a relatively benign, low-risk assessment tool that imposes no harm to the pregnant woman or the fetus. Nonstress testing (NST) is a form of antepartum fetal monitoring that can provide clinically useful information about fetal oxygenation and acid-base status. Ethical dilemmas surrounding involuntary fetal monitoring do not typically stem from NST itself, but from the lower positive predictive value of nonreactive NSTs (with or without variable decelerations) and the potential harms associated with aggressive or invasive interventions which may be performed in response to these results. Outcomes of fetal heart tracing (FHT) abnormalities vary widely, and the overall clinical efficacy of fetal monitoring in predicting and preventing adverse fetal outcomes, whether it is performed in the context of an antepartum NSTs or continuous fetal monitoring for a laboring patient, remains controversial.[12-14]

If involuntary fetal monitoring is being considered, a prior determination should be made if interventions without maternal consent, including cesarean delivery, would be undertaken in response to an abnormal monitoring result. Beneficence-based obligations to perform fetal monitoring may vary depending on the presence of preexisting comorbidities or obstetric conditions associated with a higher risk of neonatal morbidity or mortality (e.g., poorly controlled diabetes, hypertensive disease, fetal growth restriction, or oligohydramnios). If interventions in response to abnormal FHTs would not be justified or undertaken without maternal consent, involuntary fetal monitoring should be avoided.

Physical Restraints

Risks of restraints are higher for pregnant patients than the general population. The American College of Obstetricians and Gynecologists (ACOG) recommends against physical restraints because of the increased risk of maternal venous thrombosis, interference with the physician's ability to evaluate complaints (such as abdominal pain or vaginal bleeding), interference with the physician's ability to respond to emergencies (such as eclamptic seizures, shoulder dystocia, and hemorrhage), and interference with normal labor and delivery.[15] Use of restraints is also associated with marginalized social groups, is experienced as dehumanizing, and may inject coercion into the physician-patient relationship.[16] Thus, for most cases of psychosis in pregnancy, physical restraints do not promote maternal or fetal beneficence and are contraindicated unless all other means of maintaining patient and staff safety have been exhausted.

Patients with a history of mental illness may have become pregnant as a result of unwanted or even forced sexual intercourse. To prevent physical resistance and

the use of physical restraints, in the event of indicated cesarean delivery, sedation should be administered. The patient in our case did not physically resist intramuscular injections of haloperidol. Being touched, much less having surgery performed, may trigger a strong reaction. Psychiatric consultation can help to manage such sequelae.

Conclusion

Pregnant women with acute psychosis pose ethical challenges to physicians that are well understood in the ethics and law of surrogate decision making. Organizational policy should guide care teams, with the sustained support of organizational leadership. For these patients, treatment of psychotic symptoms can provide substantial maternal and fetal benefit, and psychiatric consultation may not only assist with symptom management, but also provide information useful for ethical decision making.

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Palliative Care and Chronic Psychiatric Disorder

Paul Noufi, MD

Case Complexity: 1 **2** 3 4

Abstract

A 28-year-old male patient is recently diagnosed with colon adenocarcinoma with metastases to the liver. The patient is homeless and found to be at very high risk of opiate use disorder relapse and of opiate diversion. The palliative care provider agrees to continue the prescription with the condition that the patient follow-up concomitantly with a substance use disorder (SUD) specialist. Is the palliative care provider coercing the patient to a treatment for the sake of getting appropriate pain management? The patient did not show any evidence of loss of capacity to make the decision to get SUD treatment on his own; is the clinician infringing on the autonomy of this patient?

PRESENTATION

Mr. X is a 28-year-old male patient with a medical history of recently diagnosed colon adenocarcinoma with metastases to the liver. His past psychiatric history is significant for stimulant and opiate use disorder and a questionable history of bipolar disorder or of a personality disorder.

Mr. X is homeless, with a very low socioeconomic status and a difficulty with acquiring basic needs and over-the-counter medications. He is a freelance musician and most of his income comes from occasional musical performances. His social support is minimal with mainly one sister who provides long-distance support and one friend who "helps out sometimes." There is a pervasive history of interpersonal difficulties leading to frequent challenges and estrangements. Early on in his medical follow-up, the patient expressed deep fears of being abandoned during this escalating and serious illness.

When the patient is admitted for the first time to the hospital for evaluation of his adenocarcinoma and for deliberation on his treatment plan, the palliative care team is consulted for management of his neoplasm -related abdominal pain. During the first encounter with the palliative care provider, the patient is immediately triggered and becomes verbally aggressive and closed-off to any intervention or verbal de-escalation, leading to an early interruption of the assessment. However, in an attempt to break the patient's cycle of self-fulfilled prophecies of persistent abandonment, the provider continues and eventually succeeds in establishing rapport with the patient, enough to persuade him to subsequently continue follow-up in the outpatient palliative care clinic.

The patient is found to be at very high risk of opiate use disorder relapse and of opiate diversion. However, his severe neoplasm-related pain requires a prescription of opiates for improvement of quality of life. A plan is established with the patient to increase the safety of the prescription. This includes a weekly prescription of a limited number of opiate doses, a weekly urine drug screen (UDS) with the agreement that substances other than cannabinoids are not expected to be detected, and a bimonthly in-person evaluation in the palliative care as well as oncology clinics.

For a while, the patient is maintained on opiate treatment with a good response of his pain and is regularly following up with his oncologist and receiving chemotherapy. His UDS is persistently negative for stimulants and non-prescribed opiates. Mr. X is expressing deep gratitude for the care he is receiving and is hopeful about his treatment.

Six weeks into his follow-up, a UDS is positive for amphetamines. Mr. X explains that this is a "one-time-only" relapse in the context of severe fatigue secondary to his chemotherapy regimen. The palliative care provider agrees to continue the prescription with the condition that the patient follow-up concomitantly with a substance use disorder (SUD) specialist, for which a referral is provided.

Unfortunately, after this incident, Mr. X starts skipping appointments and demanding unreasonable or non-feasible changes to his appointment timings. The referral to the SUD specialist is never completed. During one of his outpatient appointments, a code BERT (behavioral response team) is called because of staff safety concerns due to verbal and physical escalation while attempting to schedule his next appointment. The UDS results are inconsistently provided with an occurrence of detection of stimulants.

The palliative care team is at a loss as to how to best manage Mr. X. His chronic psychiatric condition is affecting his ability to adhere to the outpatient clinic prescription and to other safety precautions implemented in the clinic. His behavior poses a risk not only to himself, but also to staff members and to other clinic patients. At the same time, his neoplasm-related pain continues to require opiate treatment to be controlled. The providers are faced with Mr. X's clear distress and deeply rooted fears of abandonment but, unfortunately, he is starting to "break" an agreed-upon prescription contract that guarantees his safety and that of his environment. The agreement also guarantees the professional safety of the prescriber.

ETHICAL ISSUES

Is the palliative care provider coercing the patient to a treatment that he is not interested in for the sake of getting appropriate pain management? The patient did not show any evidence of loss of capacity to make the decision to get SUD treatment on his own; is the clinician infringing on the autonomy of this patient?

In addition, the provider is also considering his own motivations to recommend SUD treatment. Does he have a right to coerce this patient in order to maintain his own professional interests and the safety of his clinic and of the staff he works with?

What is the right of this patient to appropriate palliative management and quality end-of-life care and where does that right end?

RECOMMENDATIONS

Consider a multidisciplinary meeting involving bioethics, palliative care, and consultation- liaison (CL) psychiatry where the provider can express his concerns and discuss his motivations with other team members. The CL psychiatrist and the palliative care provider can discuss the challenges encountered in the treatment of this patient and complement each other's expertise to look beyond matters of simple capacity to make decisions and address the real underlying distress.

Consider continuing regular follow-up in the palliative care clinic with the agreement to discontinue opiate treatment and only provide alternative pain management methods until re- evaluation. This might help alleviate the fear of abandonment that the patient is experiencing, and ensures that the patient continues to receive appropriate medical follow-up and treatment. If follow-up will occur in the clinic, the teams ought to make sure that they have a safe plan with clear boundaries and conditions.

Alternatively, if the decision is to discharge the patient from the clinic, the palliative care provider ought to make sure that abandonment does not occur by providing the patient with outside options to continue receiving treatment. This might include continuing the prescription with the primary oncologist if they feel comfortable providing it or referring the patient to other palliative care clinics that have a different setting, conditions for follow-up, or an embedded SUD specialist among their team members.

REASONING

It is evident in the medical literature that there exists a clear disparity in the provision of end-of- life care for patients with severe and chronic mental illness as compared to the general population.[1] This is particularly true in patients with a past or current history of SUD.[2] These disparities stem from multiple factors, including but not limited to stigma, socioeconomic factors, and a lack of clear guidelines or resources for the management of these complicated cases. With these patients in general, as in the specific case presented here, the provider wants to make sure that he offers quality care with no involuntary bias, while still ensuring safety for both the patient and the medical staff.

The first thought in this case is that the autonomy of the patient ought to be respected, especially given the patient is displaying decision-making capacity on his SUD treatment at the time of the assessment. However, the autonomy of the patient is not unlimited. The issue here stems more from the safety risk than from the mental illness itself. This case could be framed as a conflict between the two ethical principles of autonomy (for Mr. X) and justice (safety and safe options for all persons involved). While healthcare providers strive to support their patients' autonomy, clear boundaries should continue to be strictly implemented to prevent risk of violence in the healthcare setting.[3] In the absence of these boundaries and safety insurances, one also wonders if and how the provider can continue to provide high quality care when he himself feels threatened or coerced into a treatment plan that becomes driven by the patient's dynamics.

While compassion is a powerful skill that clinicians should foster, it is also important to keep in mind that it remains very different from empathy. Providers ought to be mindful and self-aware of this difference and of their own biases as they try to provide the best care that is suited to the needs of the patient. These

considerations should always be thought of alongside a necessary requirement to protect the staff. On a systemic level, more studies are needed to further understand the challenges faced in the provision of end-of-life care to patients with mental illness, and to address them in a more evidence-based fashion.

AUTHOR

Paul Noufi, MD attended college and medical school in a French university in Beirut. After medical school, he completed a residency in psychiatry at the American University of Beirut Medical Center. In the hope of providing a holistic management for patients suffering with advanced medical or psychiatric illnesses, Dr. Noufi completed a fellowship in Consultation-Liaison psychiatry at the MedStar Georgetown University Hospital-National Institutes of Health and a palliative medicine fellowship at MedStar Washington Hospital Center. He is currently working as a palliative care attending physician at the MedStar Harbor Hospital. Dr. Noufi's professional interests include the management of mental health disorders in patients with chronic pain, meaning-centered therapy/counseling, and medical humanities.

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The Unbefriended Patient: An Ethical Balancing Act

Alexander Zhang, MD and Zahava Nilly Brodt-Ciner, MD

Case Complexity: 1 2 **3** 4

Abstract

A 44-year-old man with untreated schizoaffective disorder is diagnosed with diffusely metastatic colon cancer. Inpatient psychiatry consultants confirmed that he lacked capacity for medical decision-making, and advised against initiating anti-psychotic medications due to concerns about intolerable adverse effects. He is unbefriended and neither a candidate for home hospice (lacking support at home), nor placement at a hospice-capable facility (being uninsured). Beauchamp and Childress' four principles have been widely applied in medical ethics. Though this model proves effective when patients or their proxies have the capacity to communicate their wishes, it is a more limited framework when patients are incapacitated and lack a proxy. The Four Box Model otherwise known as the Four Quadrant Model or Four Topics Approach, may aid physicians in the decision-making process when they are faced with these difficult situations.

PRESENTATION

K.N. was a 44-year-old man with untreated schizoaffective disorder who presented to the hospital with severe abdominal pain and was diagnosed with diffusely metastatic colon cancer. Despite education about his diagnosis, he demonstrated paranoid thinking about all offered treatments, including cancer-directed therapy and symptom management. He stated he expected to be cured and wished to go home. He was admitted to the internal medicine service and was seen by multiple specialists given the complexity of his case. Inpatient psychiatry consultants confirmed that he lacked capacity for medical decision-making, and advised against initiating anti-psychotic medications due to concerns about intolerable adverse effects.

K.N. had two sisters living out-of-state who initially agreed to serve as medical proxies and requested his code status be DNR/DNI. However, the sisters ultimately stopped answering or returning calls from the medical team, making him an unbefriended patient. While the primary team explored the option of applying for guardianship, his condition worsened. Due to the extent of his disease, the inpatient oncologists recommended a focus on comfort care. A palliative medicine consult was obtained, and hospice was recommended. However, he was neither a candidate for home hospice (lacking support at home), nor placement at a hospice-capable facility (being uninsured). He did not meet our institution's criteria for inpatient hospice, since he was refusing medications. Thus, he remained on the medical ward of our hospital.

As his condition deteriorated, he continued to refuse treatment. He developed signs of a bowel obstruction and frequently refused pain medication and antiemetics. The medicine team felt moral distress caring for him without adequate symptom control. A medical ethics consultation recommended respecting his refusal of medications and advised keeping the DNR/DNI in place. He passed away in the hospital after a 79-day stay.

ETHICAL ISSUES

Physician as The Decision Maker And Alternatives

Much of the difficulty in providing care for K.N. stemmed from the perceived conflict between the principles of autonomy, beneficence, non-maleficence, and justice.[1] Patient autonomy is the principle in which an individual has the right to make decisions regarding medical treatment regardless of its impact on their health. Beneficence states that every proposed intervention and decision should be performed with doing good in mind. The practice of non-maleficence requires that minimal harm should come about when attempting to achieve the desired medical outcome. And justice is achieved by ensuring that all decisions and treatment be offered to individuals regardless of the differences in their background. Limited evidence exists about how best to balance these principles in unbefriended patients, a uniquely vulnerable population.[1] Further, studies have shown that, while patients await guardianship, critical decisions often fall on the shoulders of physi-

cians.[2]

Of particular difficulty in the case above were the decisions surrounding palliative treatment. For example, consider the act of administering an intravenous pain medication in an alert patient against their wishes. Would the medical team have to restrain the patient to do so? Such methods could cause the patient to have feelings of distrust, isolation, and psychological distress. Forced treatment could erode the relationship between the patient and medical team. And if no palliative care was provided, how would the medical team navigate caring for someone who was visibly suffering? In the case above, K.N. suffered from an untreated mental illness and was inconsistent in his decisions about symptomatic treatment and diagnostic testing. Unbefriended patients are often from vulnerable populations, such as the elderly, homeless, or mentally ill.[2] Primary mental illness or substance use disorders can impair decision-making capacity. These vulnerable populations have received increasing attention, yet there has been no national standardization of care for unbefriended patients.

The first line of defense is preventing a scenario in which a vulnerable patient becomes unbefriended. This can be accomplished by helping patients complete advanced directives or establish reliable surrogates ahead of time. The pitfall of this approach is that it won't protect some of the most vulnerable individuals, for example patients who rarely seek medical care, who are lost to follow-up, or who have poor health literacy. Survey estimates have shown that advance directives (AD) completion in the USA is between 2-30%.[3] Without ADs or reliable surrogates, decision-making for patients falls to the provider team. In these scenarios, providers must rely on their experience with the patient during their care. Unfortunately, this approach can lead to false interpretation of a patient's goals of care - time spent together may be short, and patients may be unable to articulate their wishes due to physical or psychological illness.

Coppola's study on the accuracy of surrogate predictions for this patient population show that primary care physicians and hospitalists had an accuracy of 0.66 and 0.64 respectively in terms of treatment decisions (compared to what the patient would have chosen).[3] Examples included treatment for Alzheimer's disease, emphysema, coma or stroke with poor prognosis, or cancer. Family surrogates were more accurate overall compared to physicians in most treatment decisions (this finding was statistically significant with a $p<0.05$). Family surrogates were typically found to make overtreatment errors (prediction that the patient would want treatment that the patient did not want), while primary care physicians consistently made undertreatment errors (prediction that the patient would not want a treatment that the patient did want). Hospitalists made both type of errors, however slightly favored overtreatment (overall difference in decision making was found to be statistically significant, with a $p<0.01$).[3] Coppola's team also studied the effect of advanced directives on prediction accuracy. Only hospitalists' accuracy was improved with Health Care Directives (HCD) compared to no ADs, greatly decreasing overtreatment errors without increasing undertreatment errors. In the absence of ADs and family surrogates, physicians often have difficulty accurately choosing treatment options for patients without capacity. As Dr. Connor stated, "providers live within the culture of medicine, a culture distinct from that of many patients. Studies comparing physician preferences, particularly around end-of-life issues, with those of the public demonstrate that doctors' values frequently differ from those of their patients." [2] This study highlights some of the many difficulties when taking care of unbefriended patients with regards to respecting beneficence and nonmaleficence.

To help in difficult situations such as this, resources such as ethics committees and court- appointed guardians can be utilized. Unfortunately, there is considerable variability in the expertise and availability of court-appointed guardians and the exact process of having one appointed will vary by legal jurisdiction. Additionally, non-patient-appointed surrogates can be even further removed in terms of awareness of patient preferences, potentially limiting their ability or comfort with making certain types of decisions.[4]

Four Box Model vs Four Moral Principles

Physicians sometimes find themselves the primary decision makers for acute or chronically ill patients who lack decision-making capacity. Though it is a moral and professional responsibility to uphold ethical medical care, the "right" decision can often be unclear. Beauchamp and Childress' four principles have been widely applied in medical ethics. This framework focuses primarily on the patient's perspective. Though this model proves effective when patients or their proxies have the capacity to communicate their wishes, it is a more limited framework when patients are incapacitated and lack a proxy. The Four Box Model otherwise known as the Four Quadrant Model or Four Topics Approach, may aid physicians in the decision-making process when they are faced with these difficult situations. [5-8]

The Four Box Model, though distinct from the four principles, incorporates much of the ideology of the latter into its tenets. **(See Table 1 on page 137)**

Table 1: The Four Box Model

1. Medical Indication	2. Patient Preference
3. Quality of Life	4. Contextual Features

In considering Medical Indication, one utilizes the expertise of medical professionals to analyze the current clinical condition of the patient and advise the patient of the best course of action. This incorporates the tenets of beneficence and nonmaleficence by providing valuable information that allows patients and their families to make informed decisions about their care. The tenet of Patient Preference allows patients (with capacity) and surrogates to guide the course of care, thereby preserving their autonomy. With any illness, the goal of treatment is to improve a patient's perceived Quality of Life as much as possible. As this parameter can be very subjective in nature, care teams should be mindful of when to give and withhold treatment based on the patient's prognosis. Providing proper counseling to patients and their families in this regard naturally incorporates beneficence, nonmaleficence, and patient autonomy into practice. Lastly, each case must be considered based on the Contextual Features of the individual patient. While administering care, one should be cognizant of how the cost of care or the endpoints of management will impact their personal lives, cultural identity, and financial stability.

Dr. Teven and his team applied the Four Box Model in the setting of caring for burn patients.[7] These patients ranged from having minor injuries with good prognosis to being critically ill with uncertain prognosis. For patients who were incapacitated and unbefriended, Dr. Teven and his team found great utility in using this model when making decisions on the patients' behalf. Though eliciting patient preference was often difficult in these settings, Dr. Teven and his team were able to substantiate their decisions based on Medical Indications, predicted changes in Quality of Life, and Contextual Features. This enabled them to make the most ethically sound decision for their patients. Medical professionals intuitively use their experience and knowledge to guide care for incapacitated patients, but having an established framework that lends credence to their decisions may give many the confidence to take action during difficult situations. It can be difficult to contextualize Beauchamp and Childress' four principles, whereas the Four Box Model creates a readily applicable analysis process. As Dr. Sokol describes, "the four quadrants operate very close to the action, asking questions of immediate relevance to the case at hand," which may allow physicians to grasp the next best step more easily during an ethical dilemma.[6]

The Four Box Model is not without limitations. Despite being more grounded in the decision-making process, it does not offer any specific recommendations or guidelines. Especially in the care of complex medical patients at the end of life, as many unbefriended patients are, opinions on prognosis and the best course of action (in other words, the Medical Indications) can vary drastically between practitioners. As described in a qualitative study written by a clinical ethics committee in Singapore, many referrals to their team related to the "uncertainty about when to continue repeated treatment and when to put a stop to such treatment," as well as difficulty "in predicting the reversibility of the acute medical condition and the exact prognosis." [8] Since Patient Preference becomes uncertain once patients become incapacitated, it is important for primary care teams to begin goals of care conversations early, hopefully preventing difficult ethical situations.

Quality of Life (QOL) as a tenet becomes a complex risk/benefit analysis when treating severely ill patients or those believed to be at the end of life. As previously described, the subjective nature of this tenet becomes a severely limiting factor with critically ill and incapacitated patients as several studies have highlighted important differences in patients' and clinicians' perception of patients' QOL.[9-11] Considering a patient's Contextual Features in medically complex patients, often the factors under deliberation are related to the loved ones' understanding and thus decision-making. Elements like cost of care, caregiver burden, and guilt/grief lead to difficult ethical decisions that can run contrary to other tenets. A commonly encountered situation is when surrogate decision makers have difficulty coming to terms with the poor prognosis of their loved one and thus wish to "do everything" for them leading to overtreatment (with the false hope that this might change prognosis).

Though rare, physicians can find themselves in situations where they must make difficult medical and ethical decisions on behalf of an unbefriended patient who has not yet been appointed legal guardianship. We therefore believe that the utility and efficacy of the Four Box Model is a reasonable and easily applicable model for care teams to adopt.

(A Four Box Model for K.N. is provided in Table 2 on page 138)

Table 2: Four Box Model Analysis For patient K.N.

Medical Indication	Patient Preference
- Newly diagnosed, diffusely metastatic colon cancer with poor prognosis. - Chronic schizoaffective disorder with symptoms of psychosis. - Treatment options included chemotherapy with palliative intent vs. symptomatic control alone.	- Patient lacks capacity to make his own medical decisions. - No existing advanced directive. - Patient believes his health will spontaneously improve and wishes to go home. - Patient inconsistently requested or refused symptomatic treatment, such as analgesics and antiemetics.
Quality of Life	**Contextual Features**
- Without chemotherapy, patient expected to survive up to a few months. - With chemotherapy, patient would have a small chance of prolonging survival but would likely suffer side effects. - Symptomatic treatment could improve the quality of life and may prolong life as a result. - Due to the patient's poor understanding of his condition, the goals of care could only be judged by the medical team's reasoning. - Thus, the decision was made to forgo chemotherapy.	- Patient's family included a cognitively impaired father and 2 sisters. - The sisters resided out of state and had initially been in regular contact with the team. Later in his care, they stopped answering or returning calls. - Patient had been lost to follow up multiple times and did not regularly see a physician. - Patient lacked insurance, limiting outpatient treatment and discharge options. - Patient did not meet requirements for hospice either in the hospital or upon discharge.

As demonstrated, many of the decisions that were made by K.N.'s medical team can be organized into the four categories. Additionally, this framework helps shift the ethical focus to objective measures of the patient's situation. Since one difficulty in caring for unbefriended patients can be the lack of information about subjective preferences, this objective analysis can be instrumental in caring for this population.

RECOMMENDATIONS

1. Prepare advance directives, discuss goals of care, and attempt to establish a surrogate as early as possible in order to prevent patients from becoming unbefriended. The process for guardianship should be started or researched early if the medical team realizes that a patient is at risk for becoming unbefriended.

2. If a patient is already unbefriended, acquiring insight into their preferences from any available source may be invaluable to future decision making. The responsibility of making medical decisions in the interim between loss of capacity and acquisition of a proxy/guardian often falls upon the care team.

3. A collaborative and multidisciplinary approach is often needed to provide unbefriended patients with the most effective and ethical treatment. Palliative Care and Medical Ethics teams are often able to provide an objective and expert opinion on situations unfamiliar to the primary care team.

4. Physicians should familiarize themselves with the resources available to them in their geographical region and medical system. Knowing the qualifying criteria and time required to become established in different programs are important variables in planning ahead.

5. The Four Box Model incorporates the widely accepted Four Moral Principles in a way that enables providers to feel more confident they are the doing the best for their patients, especially when their patients are incapacitated. By incorporating the four principles into a framework capable of integrating the medical professionals' knowledge and experience, the decision-making process in ethically fraught situations can become less mystifying.

REASONING

Vulnerable populations face many barriers to receiving the care they need; the unbefriended patient population exemplifying some of the most difficult situations clinicians and patients can face. Often, care teams lack information about patient preferences and may have had little contact with the patient and their proxies prior to patients becoming unbefriended. Many of these patients have limited care histories outside of their current admission and there is often little to no contact with individuals who know the patient well.

Prevention methods such as advance directives and official medical proxies established in the outpatient setting can significantly reduce the incidence of unbefriended patients. This will be most effective in patients who receive regular medical care, however is difficult to implement for those who have poor health literacy or rarely seek healthcare. For patients who only receive care in the acute setting, care teams should do their best to educate patients and to develop these directives as they can be instrumental in the patient's future treatment. The process can be time consuming and should be started early. When encountering unbefriended patients, medical professionals who have more frequent contact with these patients throughout the day, such as nurses, technicians, physical or occupational therapists, and social workers, often gather important insight into patients' preferences and should be regularly consulted in these situations. Medical Ethics committees and Palliative Care teams are also resources that should be included in an unbefriended patient's multidisciplinary care.

Frameworks such as the Four Box Model and the Four Moral Principles can be very useful while care teams are the acting surrogates. Unfortunately, at this time, there are few standardized resources to help navigate these difficult ethical situations; the care unbefriended patients receive can vary drastically between area codes and healthcare systems. As of now, the healthcare system in place makes it difficult for systemic changes to occur quickly, thus much of the responsibility then falls to multidisciplinary care teams to prevent or develop treatment plans for these patients. Applying the strategies above can help medical providers rise to this challenge in a fashion that is both ethically appropriate and medically indicated.

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